DOCTOR OF PHILOSOPHY

Theory applied to social healthcare systems to gain a better understanding of implementation of evidence A multi-method research project using Qualitative Comparative Analysis to explore complex causality when assuming the implementation of evidence context is a social complex adaptive system

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Using Qualitative Comparative Analysis to operationalise Complexity Theory applied to social healthcare systems to gain a better understanding of implementation of evidence

A multi-method research project using Qualitative Comparative Analysis to explore complex causality when assuming the implementation of evidence context is a social complex adaptive system

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“I think the next [21st] century will be the century of complexity.”

Stephen Hawking

(quote from an interview in San Jose Mercury News (23rd Jan 2000))

Yr wyf drwy hyn yn datgan mai canlyniad fy ymchwil fy hun yw'r thesis hwn, ac eithrio lle nodir yn wahanol. Caiff ffynonellau eraill eu cydnabod gan droednodiadau yn rhoi cyfeiriadau eglur. Nid yw sylwedd y gwaith hwn wedi cael ei dderbyn o'r blaen ar gyfer unrhyw radd, ac nid yw'n cael ei gyflwyno ar yr un pryd mewn ymgeisiaeth am unrhyw radd oni bai ei fod, fel y cytunwyd gan y Brifysgol, am gymwysterau deuol cymeradwy.

I hereby declare that this thesis is the results of my own investigations, except where otherwise stated. All other sources are acknowledged by bibliographic references. This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree unless, as agreed by the University, for approved dual awards.

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Abstract

Background: Successful implementation of evidence is challenging and commonly not sustained overtime. RCT methods are often unable to provide conclusive evidence of effective implementation strategies because of individual case context heterogeneity. Complimentary process evaluations provide information to explain trial results. Complexity Theory applied to the social context of healthcare may provide better explanations of the implementation context when viewed as a complex adaptive system. Qualitative Comparative Analysis (QCA) methodology offers a different approach to synthesising process evaluation findings with their trial outcome. This case-based method can evaluate common patterns of implicating implementation factors that arise across individual cases e.g. NHS organisations. Different configurations of factors provide greater explanatory power when assessing complex system behaviour in healthcare contexts. The methodological structure of QCA provides an opportunity to systematically connect theory with data to account for the heterogenous implementation context in individual cases. This is demonstrated by using the output of high-quality trial and process evaluation that evaluated implementation strategies to implement a guideline in NHS organisations.

Aim: To operationalise Complexity Theory concepts using QCA methodology to explain the context of implementation of evidence (fasting before surgery guidance).

Methods: Three empirical studies, included:

I. Building a novel conceptual framework with concepts drawn from *social* Complexity Theory texts and systematically identified implementation theories and frameworks.
II. Conducting a systematic review of QCA studies in healthcare.
III. Evaluating QCA methods with a complexity lens, first by process tracing outcome and process data from an implementation trial to differentiate the different causal pathways for each NHS organisation.

Findings:

I. Five simplified social Complex Adaptive Systems (CAS) concepts include: 'Interaction', 'Self-organisation', 'Emergence', 'History' and 'Temporality'. The novel conceptual framework for implementation research includes three additional concepts: '<u>Individual agent</u>', 'Interaction', 'Self organisation', 'Emergence', 'History', 'Temporality', '<u>System Organising Principle</u>', and '<u>Innovation</u>'.

II. Nineteen QCA studies (1987-2015) showed variable quality with authors selecting QCA to explain data complexity. A further 32 QCA studies (2015-2019) indicate increasing use and improvements in application.

III. Final QCA models covering 16 NHS organisations suggest fasting practice improvements were a function of *all* five of the final social CAS informed conditions. This required engagement of leading individuals, micro-systems, policy dissemination, targeted activities and the ability to override the system imperative to manage the operating list.

Conclusion: QCA methods using a Complexity Theory informed conceptual framework indicates the potential for systematic exploration of trial and process data to explain inconclusive findings and heterogeneity of the individual NHS organisation contexts. QCA can expose condition and outcome patterns that vary across NHS organisations by operationalising social Complex Adaptive Systems concepts. Adopting this systems approach to implementation research aids explanation of the implementation context. This thesis presents a novel conceptual framework for implementation research facilitated by a synthesis method of increasing interest in health, and illustrates an exemplar to systematically assess trial outcome and process findings.

Recommendations

When adopting a complex adaptive systems perspective to understand implementation processes and events within social healthcare systems, Qualitative Comparative Analysis (QCA) methods provide a methodological device to expose causally complex process steps. As an addition, to the healthcare methods toolbox alongside other more typical evidence-based methods QCA counterbalances the over-simplification of trial designs. QCA explanatory models use the logic of sets based on necessity and sufficiency of causal conditions to derive complex causal associations between them. This approach manages factor complexity and case context sensitivity. Direct engagement with theory to provide explanations of what happened and why to inform future implementation projects was enabled by this method. Future development requires standards for both conduct and reporting of QCA. These standards should also focus on application in the health and implementation research context. This is to take account of the demand for rigour and validation in evidence-based research in health sciences.

Outputs

Published articles

Chandler, J. (2018). The paradox of intervening in complex adaptive systems comment on ‘Using Complexity and Network Concepts to Inform Healthcare Knowledge Translation’. *International Journal of Health Policy and Management*, *7*(6), 569–571. https://doi.org/10.15171/ijhpm.2018.05

Chandler, J., Rycroft-Malone, J., Hawkes, C., & Noyes, J. (2016). Application of simplified Complexity Theory concepts for healthcare social systems to explain the implementation of evidence into practice. *Journal of Advanced Nursing*, *72*(2), 461–480. https://doi.org/10.1111/jan.12815

Presentations

Chandler J. Rycroft Malone R, Hawkes C. Noyes J. *Application of simplified Complexity Theory concepts for healthcare social systems to explain the implementation of evidence into practice* 2018, Nursing Science, London.

Chandler J. *Complex causality*, 2017, Global Evidence Summit, Cape town, South Africa.

Chandler J, Kahwati L, Sutcliffe K, Kneale D, Thomas J. *Applying current philosophical insights on causality using Qualitative Comparative Analysis as an additional synthesis in systematic reviews to address complex interventions* 2017, Global Evidence Summit, Cape town, South Africa.

Chandler J. Rycroft Malone R, Noyes J. *A methodological review of Qualitative Comparative Analysis application within health research*. MMIRA Conference 2016, Durham, UK.

Chandler J. *The Cochrane Review moving beyond RCT’s: philosophical notions of causality and its implications*: Cochrane Colloquium, 2014, Hyderabad, India.

Foreword

I began my career in nursing both general and psychiatric, making a change to undertake two degrees (undergraduate and postgraduate) in environmental studies and public health (environmental epidemiology). This led to positions in nursing research and later undertaking this PhD. My interest in Complexity Theory arose in these natural and health system degrees. My ideas for utilising Qualitative Comparative Analysis formed early prompted by a complexity in health services conference in 2003. This long path from 2003 to 2019 is a significant personal achievement with false starts and a challenging family and personal life. I have worked full time throughout, except part time for six months. I also stopped work for 10 months in 2018 to complete analysis and write up. Throughout these challenges I have remained motivated. Also, interest has expanded in applications of Complexity Theory concepts to healthcare and the use of Qualitative Comparative Analysis methods in health research during the lifetime of my PhD. This has affirmed my thesis starting point and shows the continuing currency of my work.

My thinking throughout my career has focussed on the dynamic connections and relations between agents and entities, a whole person or a whole system. From holistic approaches to nursing care, a psychological view of the whole person and dynamics of personality influencing mental health to ecology and understanding natural systems and the self-regulation of the biosphere. I continue this connectionist thinking into the field of implementation research with an emphasis on understanding the influence of the case context. I am now employed by the National Health Service (NHS) to conduct evaluations on implementation projects in NHS organisations of new models of care, digital technologies and other innovative products. These evaluations funded by NHS England and the Office for Life Sciences seek to understand how to transform healthcare. The transformation focus is the provision of better integrated systems between primary and secondary care, and encouragement of people to manage their own care, a more personalised approach. My thesis outputs remain relevant to the persistent themes that emerge within this health context to understand innovation implementation, spread and adoption, for example, why does it work here but not there?

Chapter 1: Implementation in Complex Adaptive Systems

1.1 Introduction

Formed seventy-one years ago, the NHS, the National Health Service, the United Kingdom's publicly funded healthcare system, has grown exponentially in size and organisational complexity. Perpetual re-structuring, political and patient expectations, increasing use of technology, new treatments and demands for high quality evidence-based care put constant pressure on the healthcare system to adapt and respond to these challenges.

Due to this multi-layered system complexity, I start my thesis with the premise that healthcare is a social system and better understood as a Complex Adaptive System (CAS). My longstanding interest in applying CAS concepts to healthcare systems arose from an introduction to Complexity Theory, a broader theoretical framework, through an environmental studies degree and a public health masters' degree specialising in environmental epidemiology. I wanted to discover *how* to apply Complex Adaptive Systems theory to healthcare settings, specifically the implementation of evidence-based guidance. Although routine implementation of evidence-based guidance is a key expectation of a high-quality health system, turning this expectation into reality has failed to gain momentum (Brennan et al 2018).

First, I developed a novel implementation framework using social CAS concepts to try to explain why implementation of evidence is more difficult than anticipated in implementation projects. To test this framework, I used Qualitative Comparative Analysis (QCA), a specific method that explores complex causality in social systems.

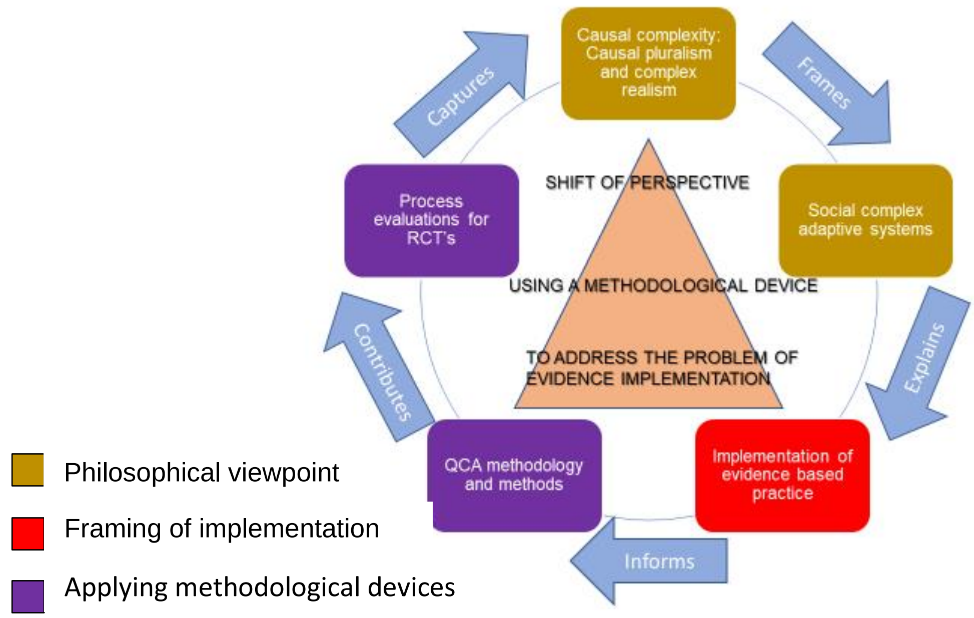
I tested the operationalisation of my novel implementation framework using QCA as a methodological device. QCA methods are relatively new to healthcare research and, specifically, to implementation research. QCA synthesises data across a set of well-defined cases to expose causally relevant factors that configure in different arrangements across the case set to obtain a common outcome of interest. This allows the identification of complex causal patterns of multiple factors to achieve this outcome rather than provide the probability of a single factor. Although atypical to health research, QCA makes an important addition to the implementation methodological toolbox. The last five years have witnessed a notable increase in interest and application of QCA in health research (Chapter 5).

Successful implementation of guidelines and other evidenced-based products (systematic reviews, health technology appraisals) is a challenge (Wiltsey Stirman et al 2012, Boaz et al

2011). In addition, implementation of new treatments, practices and innovations may result in time lags of up to 17 years (Hull et al 2019). There are limitations with typical evaluation methods, such as randomised controlled trials (RCT), when assessing implementation processes and activities to support knowledge-based dissemination through guidelines within a specific context (Cartwright 2017). Implementation is context specific (Braithwaite et al 2017, May 2016, 2013,), and methods that aggregate data across populations lose the opportunity to consider the complexities of the individual case context. I expose this problem in an implementation trial that involved NHS surgical departments in the UK implementing guideline recommendations on fasting before surgery.

This chapter introduces the thesis questions and objectives. I discuss my philosophical and methodological positions further in Chapter 2. Below in Fig.1.1, I illustrate the flow of my thesis and provide further detail in the following sections on key topics that I cover: causal complexity and pluralism, complex realism, social Complex Adaptive Systems (from Complexity Theory), and QCA methodology and methods.

Fig. 1.1. Thesis flow diagram



In this thesis, I ask two primary questions:

> Can Complexity Theory (specifically CAS) provide a better understanding and explanation of implementation of evidence in healthcare systems?
>
> How can Qualitative Comparative Analysis methods be used to operationalise Complexity Theory (specifically CAS) concepts?

Five secondary questions clarify further these primary questions:

How should Complexity Theory (specifically CAS) be adapted to the field of implementation research in healthcare systems?

How has QCA been used in the field of healthcare?

How can QCA be adapted to implementation research?

What contribution do QCA methods make in enabling a Complexity Theory (specifically CAS) perspective?

How can the QCA approach to causal complexity benefit implementation research?

1.1.1 Thesis contribution to implementation research

The following outlines the original contribution to implementation and healthcare research of work I undertook for this thesis. This thesis presents an additional example of using *complexity thinking* from the Complexity Theory paradigm moving forward in implementation research and healthcare (Braithwaite et al 2018, Greenhalgh and Papoutsi 2018, Greenhalgh et al 2017, Thompson et al 2016, May 2016). My key thesis contributions are:

- A novel framework for social CAS for implementation projects.
- The first methodological review of QCA methods used in health studies and a QCA study appraisal checklist, based on quality advice from the wider QCA methods community.
- An empirical study exploring QCA methods to expose social CAS behaviour in implementation processes as a better explanation of what happened in an implementation trial.

The following sections briefly define the principle thesis elements of philosophy, theory and methodology. These address the ongoing problem of how to determine, define, or model successful implementation, a key objective of the evidence-based heuristic (Rycroft-Malone and Bucknell 2010). First, I briefly outline the problem of implementation and typical methodological approaches.

1.2 The implementation problem

Quality of care, evidence-based practice and better performance are key milestones for both NHS Trusts and other Health Boards in the UK, as well as elsewhere. International health research organisations such as Cochrane, national guideline developers in the UK and worldwide (Guidelines International Network) and the National Institute of Health and Care Excellence have formally established effectiveness of care through evidence-based practice.

These is a continual expectation for healthcare professionals and organisations to implement evidence-based practice.

In addition, there are demands for dedicated resources to support the sheer volume of guidance (Lowson, 2015). Also, the development of behaviour changing models that characterise interventions and their implementation needs aimed at specific barriers and enablers to facilitate successful implementation (Michie et al, 2011, Ramsey et al 2010). Other work focuses on individual and organisational behaviour within the context (the system or setting) of the intervention (May et al 2016, Squires et al 2015, Rycroft-Malone et al 2013, Meijers 2006, McCormack et al 2002,). However, given the effort and resources employed, successful implementation of the prolific publication of healthcare evidence and guidance remains a challenge. An academic industry manifested by the journal *Implementation Science* evolved to address these many challenges to changing healthcare practice and to improve uptake of research findings into healthcare policy and practice (Michie 2017). Evaluation of implementation strategies to address implementation barriers has shown that finding solutions is challenging at microsystem level, the point of delivery of care to the patient (Flodgren et al 2019, Reed and Card 2016, Ivers et al 2012) and the macrosystem (Pantoja et al 2017) level of health system organisation.

However, regular use of RCT methods to evaluate the effectiveness of implementation strategies often result in inconclusive evidence of effectiveness because of individual case context heterogeneity (Seers et al 2018, Rycroft-Malone et al 2013). Therefore, such evaluations need other mixed method approaches (Flodgren et al 2019). One key component of complementary trial process evaluations is to explain implementation processes and trial results by providing contextual information (Moore et al 2015).

I selected a specific theoretical perspective (Complex Adaptive Systems) aided by a specific methodological device (Qualitative Comparative Analysis) to provide further explanations of what happens in individual healthcare contexts during implementation research processes. The aim was to provide transferable evidence to inform future implementation trials. To illustrate the problem, in the following section I describe two implementation trials that implement complex interventions into complex health systems with inconclusive results.

1.2.1 Inconclusive implementation trials

These two large cluster randomised trials tested implementation strategies to enable better implementation of evidence. They had embedded high quality process evaluations underpinned by the well-established Promoting Action Research in Health Services (PARIHS) conceptual framework (Rycroft-Malone et al 2013, Kitson et al 2008, Rycroft-Malone et al 2004, Rycroft-Malone 2002). However, both raised several barriers and facilitators that hampered the trial design due to the impact of the individual health organisation context.

The PARIHS framework assumes successful implementation (SI) is a function (*f*) of credible evidence (E), receptive context (C) and active facilitation (F). It was recently updated to i-PARIHS (Harvey and Kitson 2015) in response to critique and use of the framework (Helfrich et al 2009) to create a more dynamic version that moves from SI= f (E, C, F) to SI = Fac^n (I + R + C) (Harvey and Kitson 2015 p. 4). Where Fac^n refers to multiple facilitation elements that align with the innovation (I), recipients of the innovation (R), in a specific context (C). This renewed version puts facilitation as key to enabling the innovation (guidance, intervention), context (inner (proximal) and outer (distal)) and recipients of the intervention as individuals (patients and healthcare professionals) and as groups of individuals. However, despite the strengths of these trials, where both included well-conceived process evaluations underpinned by a conceptual framework, they were in the end, inconclusive. These trials illustrated two problematic assumptions that did not follow through. First the use of trial methodology, and second the PARIHS conceptual framework assumptions did not play out. Process evaluations offer an opportunity to explore implementation processes but, as I will demonstrate, they are limited by their theoretical perspectives and methods.

These two trials, the national Peri-operative Implementation Study Evaluation (POISE) trial (Rycroft-Malone 2013, Rycroft-Malone et al 2012), study data re-synthesised and analysed in this thesis, and the international Facilitating Implementation of Research Evidence (FIRE) trial (Seers et al 2018, Rycroft-Malone et al 2018, Harvey et al 2018) indicate that neither proposed implementation strategies nor trial objectives functioned as framed by the trialists. Therefore, the studies could not determine whether these strategies worked or not. The POISE trial concluded implementation of fasting guidance to reduce prolonged fasting before surgery needed strategic priority, dedicated resources with leadership and clear lines of responsibility, effective teamwork and communication with implementation activity ring-fenced. The FIRE trial tested two different facilitation approaches to implement an incontinence guideline recommendation in nursing homes. Harvey and colleagues (2018) discussed the issues raised by this study to manage fidelity and adaptation to the intended intervention (two types of facilitation, one providing intensive support and input to facilitators and the other more standard facilitation) and concluded that there is a need for experienced facilitators properly supported and mentored by managers. But what was also needed, according to the study results, was “a theoretical approach to fidelity, with a focus on mechanisms, informed by prospective use of process evaluation data and more detailed investigation of the context-facilitation dynamic.” Both these trials indicated a complex dynamic occurring within the real-world context of NHS organisations, where the trial often fails to deliver a meaningful result and the process evaluation compensates with a description of what happened. Other implementation trials also have shown a similar pattern (Neyens et al 2011). I have used the POISE trial outcome and process evaluation data to unpick the issues raised and proceeded to transform the data using a different theoretical and methodological approach.

1.3 Using Complexity Theory to frame the problem

Complexity Theory is employed by diverse researchers, working in many areas of research in physical, biological, information and social fields (Johnson 2011, Mitchell 2011, Castellani and Hafferty 2010, Gribben 2004, Byrne 1998, Gell Mann 1994). This emerging paradigm, increasing in healthcare (Braithwaite et al 2018, Greenhalgh and Papoutsi 2018, Strumberg et al 2016), seeks to elucidate how different structures come to exist based on sets of rules, or recursive behaviour, that creates greater organisation and complexity. Complex macrostructures arise from microstructures that evolved from interaction between individual agents (human agents) and have their own properties not separately identifiable at the lower order microsystem or individual level. The processes of learning and adapting to the local environment are key to understanding CAS behaviour. Although CAS is now persistent within the language of healthcare Braithwaite 2018, Braithwaite et al 2017, Thompson 2016, Moore 2015, Strumberg and Martin 2009, Kernick 2004), there is a lack of consistency with its application and language (Thompson 2016). CAS is often used as an interpretative lens (Matheson 2017, Hannighan 2013, Trenholm and Ferlie 2013) rather than operationalised through methods to evaluate or test its application. This is the focus of my thesis. Emergence of social order within the CAS perspective (Sawyer 2005) explains collective behaviour of human agents (through conversations, meaning, symbols, etc.) and the social structures they create. Due to system feedback these higher order social structures impact on individuals in a complex web of back and forth interactions producing both stable and de-stabling structures.

From this perspective, healthcare systems, as complex social systems, deliver healthcare to individual patients via complex organisation and interaction of hard structures (buildings, equipment and technology) and soft systems such as the organisation of care by healthcare professionals to provide diagnosis, treatment and other care approaches and support structures. Social systems need to consider human agency and decision making. These human-based systems in healthcare need to respond to improvement expectations and the evidence-base for changes to practice etc. Effective care and treatments and understanding what works for patients is central to the function of delivering healthcare. Thus, I assume healthcare is delivered through social systems of socially organised structures and practices.

I disentangle the use of the term *complexity* that is often used to refer to something that is *complicated*. I refer to complexity as a phenomenon with its own specific characteristics as indicated above.

Based on this perspective, healthcare and implementation of evidence-based recommendations and practice and other healthcare interventions are not discrete from the system they enter but are disrupters (Noyes et al 2019, Petticrew et al 2019, Thomas et al 2019, Hawe et al 2009, Shiell et al 2008). Therefore, I suggest when designing implementation activities that seek to change these social structures and practices, they need to consider the learning and adaptive behaviour of social Complex Adaptive Systems (social CAS). I explore key aspects of this CAS behaviour, such as the rationale for system existence, its history and how this history explains the current system status. CAS behaviour change is not expected to be linear: change transitions can be both disappointing (due to expectations) and lead to unexpected events. Fasting practice (POISE trial) is longstanding, fundamental and highly integrated into the surgical system, and therefore provides an ideal example to explore social CAS.

The Medical Research Council (MRC) guidance on process evaluations to evaluate complex interventions concluded that “contributions of complexity science to evaluation remain on a theoretical level, and there are few empirical examples for it to inform guidance. Process evaluation may offer a means of providing some of these empirical examples by, for example, using qualitative data to capture feedback loops and investigate complex causal pathways”. (Moore et al 2014, p. 44).

Randomised trial process evaluations evolved to capture context, mechanisms and participant perspectives to explain trial findings and enable transfer of the intervention to other settings beyond the trial participants (Bonell et al 2006, Oakley et al 2006). Ramsey and colleagues (2010) illustrate how theory-based process evaluations may capture causal mechanisms at play. The MRC strongly recommends the collection and use of both outcome and process data with a focus on the development of the multi-method process evaluation and its synthesis with the outcome data (Moore et al 2015, 2014). QCA methods can synthesise both process factors and outcome data by case, maintaining the specific case context, illustrated in my thesis. First, I link CAS and QCA methodology.

1.4 Thesis assumptions

I considered the epistemological basis of social CAS as a theoretical lens and QCA methodology as a method to expose complex patterns of behaviour in social systems. I examined perspectives on reality and causality that counterbalance the experimenter’s worldview. Debates address the limits of RCT experiments to provide the necessary information for policymakers (Deaton and Cartwright 2018), in particular for complex interventions that are very reliant on social systems to function (Ioannidis 2018). This is because they are reductive and cannot take account of or engage with the surrounding system (Cilliers 2013). In addition, I assume the social world is not a single social CAS but involves multi-layered and multi-nested social CASs interconnected in complex ways of influence and cause and effect. Therefore, I aim to explore methods that address complex causal influences. These causal influences are assumed to work up through the different levels within a given system under investigation and will bring about effects elsewhere in the social CAS structure.

I explain my adoption of a complex realist position (Byrne and Callaghan 2014, Harvey 2002) in Chapter 2, which draws upon critical realist philosophy. This position considers an external reality that exists beyond our minds. We might infer its existence from our observations and in time our knowledge and understanding of the world beyond our minds will accommodate further insights. Both complex and critical realist philosophy assumes that the existence of reality is overlaid by human interpretation. Complex realism engages more explicitly (but not exclusively, see Chapter 2) with a social reality of Complex Adaptive Systems. When engaging with social CAS we seek to understand how social relations and in turn social practices come about and move beyond the experimenter's reductive perspective that seeks to identify a direct relationship between a cause and its subsequent effect. Increasing attention paid by philosophers on causality in science takes account of the multiplicity of causal theories and how they might collectively provide explanations for what is happening in the world, that is, how one thing leads to another and then another, etc. This is referred to as causal pluralism (Cartwright 2007) or a causal mosaic (Illari and Russo 2014). I explain further in Chapter 2 the utility of this philosophical position to address intricate, interrelated and causally dependent pathways to an effect or outcome of interest. I discuss how QCA methodology enables explanatory inference (Lipton 2004) for complex behaviour in complex social systems (Illari and Russo 2014, Ragin 2010, Cartwright 2007).

1.5 Methods to manage complexity in healthcare social systems

Case study designs and realistic evaluation are two approaches that can be used to manage case complexity. However, these designs do not typically go beyond five to six cases for in-depth study. QCA is a case-based methodology that evaluates patterns of *implicating* factors across a common set of cases (e.g. NHS organisations) that engages and exploits heterogeneity between these cases, unlike RCT's reliance on homogeneous populations (Olsen 2019, Cartwright 2010). QCA can retain individual case contexts in analysis from a medium number of 10+ cases at the lower end to 50+ at the other end, and is also used in much larger N studies (Rhioux and Ragin 2009), although a degree of case context sensitivity is then lost (Thomann and Maggetti 2017). QCA provides an opportunity to systematically connect theory with data to account for this heterogeneity across individual cases. By identifying different configurations of implicating (causal) factors, QCA has potential to assess complex system behaviour in healthcare contexts. I demonstrate this potential by using the output of a high-quality trial (Flodgren et al 2019) and its process evaluation that evaluated implementation strategies to facilitate guideline implementation in NHS organisations (Rycroft-Malone et al 2012). I use an additional method, process tracing (Beach and Pederson 2013), a within-case method, to extract the evidence from the data of each NHS organisation in the POISE trial to create the individual case narratives for assessment in the QCA study.

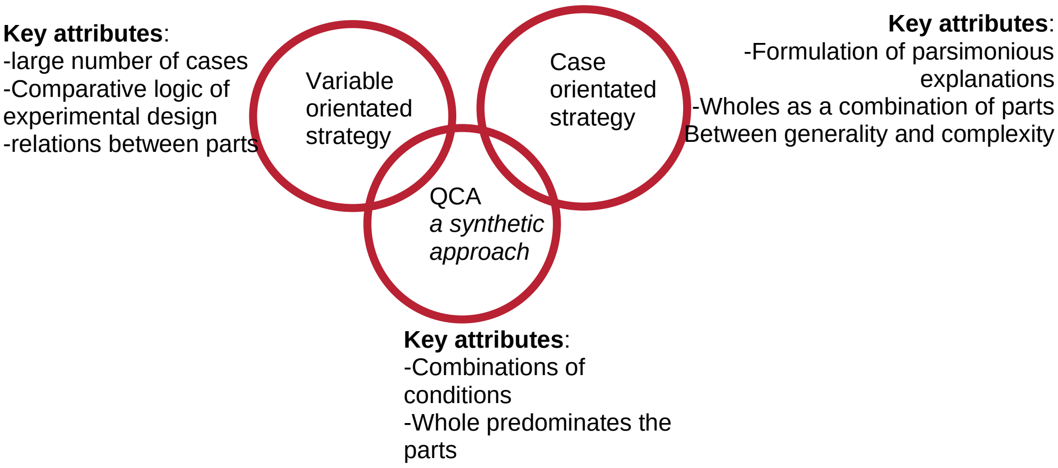
Before undertaking the QCA study I conducted a methodological review of current examples of QCA undertaken in a health context, to examine transferability and utility of the method to the implementation of evidence in health settings. Currently, this is the first review of QCA methodology migrating from social and political science to the healthcare and evidence-based methods context. The review undertaken includes quality assessment of the studies, the authors' rationale and their epistemological assumptions using framework synthesis, which indicates the need to manage complexity (complicated data and complex healthcare interventions). I report a range of both quality and methodological issues undertaken by the studies and note developments that have occurred over time as applications of the method have increased since the start of this PhD. I developed a new tool for assessment of such studies with a view to establishing good practice standards in future applications of QCA, along with the work of others advising on quality standards for conducting and reporting QCA. I cover a range of issues with QCA methods and indicate some of the critiques and developments.

1.5.1 Using Qualitative Comparative Analysis methods

QCA is distinctly different from the average net effect approach (outcome) and qualitative research thematic approach (process), the methods conducted in the original study. The QCA study will use a new conceptual framework to evaluate the POISE trial process evaluation data from a fresh perspective to see whether both the framework and QCA methods can better explain poor implementation of guideline recommendations from the original data.

Ragin (1987) first described the method and methodology in *The Comparative Method: Moving Beyond Qualitative and Quantitative Strategies*. The purpose of this comparative method is to take the best attributes of case orientated (small N, e.g. case study(s)) and variable orientated (large N, e.g. survey, RCT) research strategies with the notion of comparing wholes (cases) as configurations of parts as a bridge between complexity and generality (Figure 1.5.1). Traditional statistics use linear algebra, but Ragin proposes Boolean algebra (Ragin 1987, p. 86-102) or fuzzy set analysis (Ragin 2000), also referred to as the algebra of logic and sets. The technique examines causal complexity by exploring the possible ‘conditions’ that might lead to an outcome and whether the ‘cases’ identified with the outcome exhibit a range of conditions. The likelihood is that some cases may exhibit some but not all possible identified conditions when the outcome is present. In other words, several different configurations of conditions lead to a given outcome. The conception of causality is multiple conjunctural causation (Rihoux and Ragin 2009). A combination of causally relevant conditions generates an outcome, and several different combinations of those conditions may produce the same outcome. This is defined as the diversity orientated approach (Ragin 2000, p. 119). QCA takes data from a variety of sources and transforms it for the purpose of synthesis to enable pattern seeking in the data. Fig. 1.5.1. elaborates on the key attributes of QCA as a bridge between the two ends of the methodological spectrum of case study (complexity) and population (generality) based designs.

Fig. 1.5.1 QCA methods – a methodological bridge



Since the beginning of this PhD in 2010, increasing examples of QCA application in health studies to address causal complexity appear to support my initial choice of methodology (Chapter 5).

1.5.2 Dataset used in Qualitative Comparative Analysis study

The point I seek to illustrate is that well-established guidance underpinned by credible and robust evidence leading to an uncomplicated and unambiguous recommendation, ultimately, when tested in the real-world, struggled to gain traction to improve patient care. Also, the conceptual and methodological design of the POISE trial was unable to reveal which strategy would improve implementation of the simple recommendation to reduce prolonged pre-operative fasting to two hours for individual patients. Fasting practice, based on the Royal College of Nursing (RCN) guideline (Westby 2005) endorsed by the Royal College of Anaesthetists used in the implementation trial during 2006-2009, continues to present a problem (Hamid 2014). Resistance to change was illustrated by a single audit of one UK based District General Hospital with a mean fluid fast of 8.6 hours dropping to 7.1 hours with a mean difference of 1.5 (0.1 to 2.8, P value 0.035) (Kyritotos 2014). This showed a drop in keeping with the results in the POISE trial but remains illusively far from the 2-hour RCN guideline target for individual patients. A systematic review undertaken more recently indicates that practice of prolonged fasting remains entrenched (Lambert and Carey 2016). Operations in the UK increased by 40% between 2005 and 2016 (https://www.nhsconfed.org/resources/key-statistics-on-the-nhs) and, therefore, potentially more patients suffer prolonged fasts and there is increased pressure on surgical teams limiting their ability to reduce fasting times. I make a key point at this juncture which is elaborated further in Chapter 7. The guideline implies that establishing a shorter pre-operative fasting time involves monitoring the patient based on likely circumstances, such as delays and cancellations. I will re-phrase this monitoring to clarify that we expect the patient's fast to be *regulated* based on hour to hour circumstances. This was the recommendation goal, otherwise how else might it be implemented? However, two other organisational fasting tactics predominate, *blanket fasting* (everyone fasts from the same time regardless of operation time) and *fasting as if first on the list,* where the patients are fasted appropriately in relation to the operating list start time. Therefore, patients high on the list will lean more to a recommended fast time. I disentangle and explore these complexities that arise with this guidance and implementation strategies used in the POISE trial to leverage implementation.

1.6 Thesis structure and output

In summary, to address the thesis questions I built a novel conceptual framework from social CAS concepts integrated with implementation theories and models. This novel conceptual framework was operationalised using QCA methodology and methods to present an empirical example of reinterpreting a trial's outcome and process evaluation (POISE). This example indicates, on the one hand, the limits of randomised controlled trials for complicated implementation projects and, on the other hand, suggests that expectations of evidence-based guidance are perhaps unrealistic and do not engage properly with real world contexts. The data provided by the POISE trial process evaluation to promote the implementation of simple, credible and acceptable evidence-based recommendations to reduce prolonged fasting for fluids before routine surgery challenged the guidance's assumptions. The importance of proper conduct and reporting remains as relevant for QCA methods as with RCT's (Chapter 5), and I discuss several issues when considering the application of this method to health research. Further studies are needed, although the research reported here shows potential for implementation.

Table 1.5 summarises chapter structure and contribution to implementation research.

Table 1.5 Thesis questions, structure and contribution

Chapter	Content summary	Contribution
Q. 1 Can Complexity Theory provide a better understanding and explanation of implementation of evidence in healthcare systems?		
2. Methodology	Established an epistemological frame of reference to underpin the study: **EXPLAINED COMPLEX REALISM & COMPLEX CAUSALITY**	Employed a *complex* realist perspective with a causal pluralist stance to engage with methods for social CAS
3. Complexity Theory for social systems	Developed simplified concepts from social complexity theories: **DEVELOPED SOCIAL CAS CONCEPTS**	Developed a novel interpretation and conceptualisation of Complexity Theory concepts
4. Conceptual framework development	Identified and synthesised implementation theories, models and frameworks and built a conceptual framework for social CAS: **INTEGRATED SOCIAL CAS CONCEPTS WITH CORE IMPLEMENTATION CONCEPTS**	Formed a novel conceptual framework integrating social CAS concepts with a synthesis of implementation theories, models and frameworks
Q. 2 Can Qualitative Comparative Analysis methods operationalise Complexity Theory concepts?		
5. A methodological review of QCA use in healthcare research	Conducted a methodological review of QCA use in health studies and discussed issues in QCA within the review and beyond, as well as key developments within health research: **GAINED UNDERSTANDING OF QCA METHODS AND UTILITY IN HEALTH STUDIES**	Produced first review of health studies employing QCA methods
6. Methods of the Qualitative Comparative analysis study	Data were retrospectively extracted from a cluster randomised implementation trial with an embedded process	Undertook an exemplar QCA study in health, specifically explaining implementation in health

	evaluation. Data extracted using process tracing methods to create individual case narratives. **DATA INPUTTED**	research tying concepts from the conceptual tightly with methods
7. Findings of the Qualitative Comparative analysis study	Tests framework using QCA methodology and methods, developing explanatory models: **PRESENTS QCA MODELS**	Show how QCA analysis approaches are specifically relevant to implementation research
8. Discussion	Discusses findings based on the QCA models and implementation change patterns. Evaluation of conceptual framework and QCA methods and thesis limitations presented. Discussed active areas of QCA methods development. **MAKE RECOMMENDATIONS FOR FUTURE RESEARCH AND PRACTICE**	Elaborate on thesis contribution.
9. Conclusions		Thesis conclusion and final statement

Chapter 2: Methodology

2.1 Introduction

Following recent developments in philosophy on both causation (Illari and Russo 2014, Cartwright 2007, Russo and Williamson 2007) and realism (Bhaskar 2015, Byrne and Callaghan 2014), I will focus on how both perspectives fit with a Complex Adaptive System (CAS) viewpoint. I will also discuss whether methods selected for my research fit within these epistemological standpoints and the evolving frameworks in implementation research.

This chapter elaborates on the premise and assumptions underlying my thesis of complex realism and explores the current philosophical context on causation in science to expand on the notion of complex causality. The latter part of the chapter discusses methods for implementation within complex contexts assumed to operate as a social Complex Adaptive Systems (CAS). I start with the problem in implementation research.

2.2 Implementation research

Implementation research seeks to understand why implementation fails to get evidence-based guidance adopted into practice (Eccles and Mittman 2006) and assumes that the implementation context involves processes that influence and inhibit implementation of evidence (Eccles et al 2009). This field of research investigates theories and methods to promote the uptake of research findings into healthcare in clinical, organisational or policy contexts, from the stance that the implementation context is multi-layered (Chapter 1). The social healthcare implementation context involves several layers, including individuals (multiple healthcare professionals, non-clinical staff, patients) and organisations (hospital infrastructure, technology, computerised information systems, delivery of treatments to patients, culture and working practices). Beyond the individual NHS organisation this involves the wider contextual influence of national, regulatory, policy and guidance instruments that target the individual NHS organisation.

2.2.1 Theory and concepts for use in implementation research

In the last twenty years or so there has been an evolution of theories and conceptual models to better understand individual behaviour and implementation contextual factors (e.g. Pfadenhauer et al 2017, Rycroft-Malone and Bucknell 2010, May et al 2007, May 2006, Michie and West 2004). Calls for appropriate application of theory to address the implementation of interventions (Davidoff et al 2019, Eccles et al 2009, Grimshaw and

Eccles 2004) are ongoing but, with only 26% of process evaluations up to 2017 making specific use of theory (McIntyre et al 2018), it remains an area of weakness (Graham and Tetroe 2010, Damschroeder et al 2009, May et al 2006). The role of theory in science describes both what happens (cause) and why it happens (explanation: processes and mechanisms) (Vandebrouke 2008). Of course, we also need opinions and perspectives of those who experience giving and receiving healthcare. Finding a difference between intervention and control in a trial only provides a test of prior knowledge, more available for pharmacological interventions (Ioannidis 2018). For the purpose of implementation and replication we require an explanatory framework that incorporates both the mechanisms of the intervention and, more specifically, the context in which the intervention is deployed (Davidoff 2019).

The slow emergence of Complexity Theory (Kernick 2004, Pslek 2003, Sweeney and Griffiths 2002, Pslek and Greenhalgh 2001, Wilson et al 2001) to explain the multi-layered reality of healthcare, that is, the relationship between macrostructures (organisational) and micro-level behaviour (individuals) has also now impacted implementation research (Braithwaite 2018, May et al 2016). This theory seeks to explain the dynamic co-existence of the multiple interactions, processes and outcomes that occur within health systems and accounts for the unexpected consequences and events that arise over time (Rycroft-Malone 2007, Chapter 3). Complexity Theory characterises physical, biological and social systems as evolving, and emergent, from the co-operative interaction of agents creating higher order structures and systems that have separate properties from the agents from which they were derived. However, finding methods or approaches on how best to utilise this theory in implementation research requires examples (Brainard and Hunter 2016, Moore et al 2014). My thesis provides an example of Complexity Theory tied tightly to method to foster interpretation and thus explanation of data by individual case and context. By doing so, it answers the question:

> Can Complexity Theory provide a better understanding and explanation of implementation of evidence in healthcare systems?

2.2.2 Introduction of novel methods to implementation research

There are strong viewpoints on the confirmatory basis of randomised controlled trials (RCTs) to provide the best and most reliable evidence and that other evaluative methods cannot protect against bias which makes them underdetermined (Vandebrouke 2008). Therefore, due care and attention should be paid to the introduction of novel methods to fields of science, such as implementation. I set out with the specific purpose of evaluating a method (Qualitative Comparative Analysis, QCA) from political sociology as a vehicle for Complexity Theory to better explain the implementation context. The introduction of this method into implementation research allows the assessment of causal complex relationships in social structures that maintains case context sensitivity whilst permitting across case comparison. QCA does not aggregate data either quantitatively or qualitatively (themes) but synthesises multiple forms of data (maintained by case) to identify patterns of *causal* factors across the cases. These factors are expected to configure in different arrangements, indicating an informative pattern across those cases. This complex arrangement of causal factors has potential to capture the dynamic of complex systems on specific aspects that a researcher is interested in (Byrne and Callaghan 2014, Cartwright 2007, Byrne 2002). The presence or absence of these factors across the cases derives the complex factor patterns (configurations). I sought to illustrate how this method aids implementation research by maintaining case specificity that provides a different approach to addressing complex phenomena within healthcare contexts. My assumption and focus in my exploratory study were that in implementation research we are trying to expose and understand complex causal relations and processes that occur differently across individual case contexts.

Therefore, the second question I addressed was:

> How can Qualitative Comparative Analysis methods be used to operationalise Complexity Theory (specifically CAS) concepts?

To address both these questions, I outline different perspectives of reality, causality and explanation to provide an epistemological frame for my research. I take a standpoint that reality exists, but it is inevitably beyond our capacity to capture it entirely within our methods and observations. I draw attention to the development of a complex realist perspective that accounts for a reality that assumes social CAS are functioning. I elaborate on typical methods used in both healthcare and implementation evidence-based research to illustrate the main point: explaining complex phenomena in social healthcare systems requires a different approach and set of methods, in particular when there is a need to address the influence of the implementation context at an individual case level.

2.3 Cause and reality

Diverse philosophical accounts of reality and causality are moving towards pluralistic positions (Illari and Russo 2014, Cartwright 2007, Godfrey Smith 2003). I focus on those interested in accounting for causality in evidence-based medicine and practice. Particular attention is paid to the type of causality underpinning RCTs and its limits to ascertain the information policy stakeholders and healthcare practitioners need to implement changes to care within the healthcare context (Deaton and Cartwright 2018), explicitly context-sensitive non-pharmacological interventions (Ioannidis 2018). First, I describe my approach to the development of this chapter.

2.3.1 Literature identification

I identified relevant literature using snowballing techniques starting with citations from key works and summaries provided by the online Stanford Encyclopaedia of Philosophy (https://plato.stanford.edu/), cross-citation between articles and key works, and journal article series providing debates indicating active areas of thought. Also, I reviewed textbooks summarising the current field of causation for the sciences to assist in signposting and summarising the literature. Due to rapid expansion of this literature, what follows represents my individual journey to knit theoretical concepts for CAS with methods (Qualitative Comparative Analysis) that address complex causality in social healthcare systems.

2.3.2 Perspectives on reality

Different perspectives on what constitutes reality and permits our study of it have evolved over time. These different perspectives fall into the following very broad categories:

- A *logical positivist* (empiricism) perspective – reality is only determined by observation and therefore we can only know 'it' exists through our observations (and experiments).
- A *realist* (realism) perspective – reality can be determined through the composition of information from our observations, and its actual existence can be inferred.
- A *socially constructed* (naturalism) perspective – reality exists through the interpretations of the observer, in other words, reality is mind-dependent.

These perspectives tend to operate as opposing forces (Godfrey Smith 2003). Within these broad perspectives on reality there are multiple nuanced stances. However, combining these perspectives suggests we access the independent world through our minds and our senses using language to communicate our understandings of the world, and this world is only partly accessible to our methods, thus knowledge is under constant revision (Godfrey Smith 2003). Consequently, greater knowledge will continue to shift our understanding of the external reality as more of it becomes known to us. A realist position is the middle path on which I now focus.

There are multiple interpretations of realist ontologies: critical, scientific, naïve (Barnet-Page and Thomas 2009), structural (Worrell 2011), subtle (Hammersley 1992) naturalised (Godfrey Smith 2003) and many others (Pawson 2018, Searle 1995). Pawson (2018, p. 207), in his realist family tree, includes recent evidenced-based medicine interested philosophers along with other disciplines (e.g. sociology), such as Howick (2011) and Russo and Williamson (2007), because of their interest in mechanisms. I discuss this later in this chapter.

The adoption of different realist positions, such as ‘scientific realism’, suggests that structures exist in the world beyond our knowledge, and either we know what we know at any given moment confirmed through experimentation (empiricist) or we can theorise and build on these theories over time as more of the structure is revealed. This is referred to as a process of continuity (Chakravartty 2014). ‘Structural realism’ perceives an underlying structure that is held across theories overtime even when theory A is superseded by theory B and therefore the explanation is one of a cumulative process of a current theory being only partially correct and therefore replaced by an updated theory (Worrell 1989). However, the nature of the structure does not itself change and can be determined by mathematics and its physical properties, so we are constrained by the limits of our knowledge about the structure (Ladyman 2016).

More recently in healthcare, a strong interest has developed in ‘critical realism’ as a lens through which to understand ‘complexities’ within healthcare (Emmel et al 2018, Wong et al 2013, Pawson 2006), and specifically implementation research (Rycroft-Malone et al, 2018, Rycroft-Malone et al 2015, McCormack et al 2013, Rycroft-Malone et al 2012,). ‘Critical realism’, evolved from Roy Bhaskar’s original concept of ‘transcendental realism’ (Gerrits and Verwij 2013) and ‘critical naturalism’ whereby he transcended positivism (empiricism) and hermeneutics (idealism/interpretation) to provide explanatory accounts of social reality (Hartwig 2014). Important notions that link to understanding causation from this critical realist perspective are *power* and *capacity* that indicate a potential causal mechanism can exist but requires an additional component or condition to enable an effect to occur. Likewise, the cause and effect relationship can be blocked (disabled). The identification of what works or enables something to happen in social reality is key to the concept of ‘generative mechanism’ in the critical realist context. In addition, an individual contributes to the social evolution of the ‘generative structures’, which in turn shapes the individual (Reed and Harvey 1992).

Inevitably, there is a wide school of thought evolving within the critical realist tradition that includes metarealism (Williams et al 2017) and Bhaskar’s subsequent dialectical critical realism (Hartwig 2014, Harvey 2010), amongst others. Although the dynamic, inter-connected and multi-layered social world is accounted for in critical realism philosophy, further developments engage directly with Complexity Theory, a logical home for my research. I, therefore, focus on the nuance of a *complex* realist position which expresses more directly the realist position engaging with a Complexity Theory perspective.

2.3.2.1 Defining a complex realist perspective

A complex realist stance ascribes to the existence of an external reality composed of structures that are constantly organising into nested systems that have emerged iteratively over time and are not decomposable to the principle components from which they have evolved. Such systems are contingent on their context and temporally irreversible. This perspective (Byrne and Callaghan 2014, Byrne 2002, Reed and Harvey 1992) assumes the prior existence of an emergent order in the world to which we have limited access. Also, the observer's view of the emergent Complex Adaptive System will involve an interpretation of their observations.

Reed and Harvey (1992) introduced the concept of complex realism by combining Bhaskar's philosophical ontology for social realism (Bhaskar 2015) with Prigogine's scientific ontology of dissipative structures (Prigogine 1997). They argue for the compatibility between these two ontologies and present a social ontology, which ascribes that although operating differently, the natural and social worlds cannot be viewed as separate levels but as the progression of the natural evolving into the social.

This ongoing progression appears in Karl Popper's *Objective Knowledge* (Magee 1973, p. 65) where he offers a simple formulism to illustrate continuous natural to social adaption. This sets a temporal unidirectional process that is expected to repeat, but at each step creates something different from its initial starting point. Here, I reproduce this formula with my own interpretations to fit it into context here:

$$P_1 \rightarrow TS \rightarrow EE \rightarrow P_2$$

Karl Popper	**Problem**	**Trial solution**	**Error elimination**	**Result**
Thesis author interpretation	*Current state*	*Intervention/ innovation or contextual consequence*	*Adaptation*	*New emergent state*

Adapted from Magee 1973, p. 35

The pattern is the process of continuity, feedback, learning and adaption moving continuously to a new emergent state. The current state of P_1 is always superseded by the state P_2 (Magee 1973) after states TS and EE have occurred. EE represents an adjustment with continued adjustments occurring over time that build an increasing 'complex structure' tied to its evolutionary path. This simplicity lies under all complexity (Gribbin 2004) but it is important to understand historically where the observer is along the trajectory of the system structure. Popper did not directly engage with Complexity Theory, which began emerging in the 1950's with systems science and cybernetics (Chandler et al 2016). This continual process of adaption creates complex linkages and arrangements to construct the different multi-layered systems.

Both Bhaskar and Prigogine take this perspective further and adopt a view that systems operate under certain conditions, that is, they self-organise and emerge into higher order structures that are non-decomposable to original components or entities. Systems are open and typically large-scale and do not operate in states of equilibrium. These changed system states are not predictable or reversible. Thus, temporality and historicity are important aspects needed to understand and explain these systems (Reed and Harvey 1992). Harvey (2010) qualifies the definition of the complex realist paradigm that was a "compression of complexity theory and critical realism" (Harvey 2010, p. 24) as underpinned by concepts that state:

- reality exists beyond our "attempts to understand and manipulate" the world;
- natural sciences have a role to play in social systems but must allow for the role of human agency;
- the world is constructed in a series of hierarchically organised and evolving nested systems;
- these systems are "contingently structured and temporally staggered" and cannot be confined to controlled experiments and causal regularity (Harvey 2010, p. 24).

Byrne (2002) described complex realism as an ontology for social systems. He defined it briefly as:

- social measurements as process;
- changes in kind and transformation rather than variables removed from their context,
- allows description of relationships between system levels and system aspects without resorting to aggregation;
- "Complex realism allows us……to explore interaction as a guide to the character of systems understood as complex products of parts, wholes, part-part interactions, part-whole interactions and part-part-whole interactions" etc. (Byrne 2002, p. 9).

Complex realism for social CAS

As complex realists, Byrne and Callaghan (2014) develop further the notions that underpin this ontological position. They used Morin's (2006) concepts of 'restricted complexity' and 'general complexity', advocating for clarity between greater complexity evolving from multiple interactions based on 'simple' rules that create complex structures overtime – restricted complexity – whereby one establishes the rules that create the structures. However, in contrast, 'general complexity' can only define the whole system, and Byrne and Callaghan (2014) make the important point that the emergent structures that occur at multiple levels of higher ordered organisation in social systems are not solely dependent on 'micro-determined' emergence. In other words, large complex social systems (e.g. NHS organisations) have properties that enable changes and adaptations to occur that do not directly incur micro-system emergence of interacting individuals. The complex realist perspective provides a complexity frame for the social world that is both a way of knowing how things can be known and what the world is *really* like (Byrne and Callaghan 2014).

The complex realist position requires greater refinement and clarity on the measurement and modelling of social CAS (Holland 2014). The appropriate blending of different perspectives remains a topic of discussion in the literature (Holland 2014, Bonell et al 2013, Marchal et al 2012). Therefore, we need an ontologically sound basis to engage with social CAS as a framework for understanding the function and development of social systems and how we can study these systems.

2.3.3 Perspectives on causation

Interest to understand the nature of causation, particularly in the field of health sciences and evidence-based medicine, has increased significantly amongst philosophers in the last 20 years (Cartwright 2007). This has led to a view that the interpretation of causality in the health sciences requires closer philosophical attention as it "infers causal relations from mixed evidence: on the one hand, mechanisms and theoretical knowledge, and on the other, statistics and probabilities. Statistics are used to show that the cause makes a difference to the effect, and mechanism allows causal relationships to explain the occurrence of an effect". (Russo and Williamson 2007, p. 158). The multiplicity of systems from the physical to the biological, and finally the social, all connect and interact at some level in some place, challenging our methods to abstract enough system information and knowledge on which we might seek to intervene or observe.

"Our causal models are correct, if and only if, they approximate well enough to the causal laws that govern the operation of the system in question. The claim is that there are a great variety of kinds of causal relations embedded in a great variety of kinds of causal systems as well as a variety of causal questions that can be asked." (Cartwright 2007, p. 250-1)

2.3.3.1 Defining a pluralist causal philosophy

From a complex realist standpoint, a broader notion is needed of how we understand the way the world works. A view of causality requires greater clarity on what is meant by cause and how to determine whether there is a causal connection between multiple interacting entities and their activities. Again, current multiple perspectives on causality exist (e.g. Misangyi et al 2017, Reiss 2009, Cartwright 2007, Russo and Williamson 2007, Pearl 2000, Mackie 1974) with nuancing of different notions of causal relationships. However, this is now leading to pluralist positions (Illari and Russo 2014, Cartwright 2007) that blend or incorporate multiple dimensions of causality to explain real world causal relations. It is this multiplicity of causality that provides a rational argument for a complex reality in which complex causal relations reside which can explain the behaviour of the implementation context and intervention.

Defining causation has a long history that starts as far back as Aristotle. Cause as a concept has been inconsistent, in that exceptions always exist in various causal models and theories, which resists unification of concepts (Reiss 2009). Debates will centre on both metaphysical and epistemological levels, as well as application for use via research methods. Causal concepts can include what and when something triggers an event or accelerates it, or delays or prevents it (Godfrey Smith 2010). It can also mean the causal relationship will always occur, based on an underlying regularity (lawlike), as espoused by the philosopher David Hume (Morris et al 2017). Furthermore, philosophical discussions will address language and our conceptualisation of cause as a relation and what it means in a specific account, what accounts for truth and how truth can be verified, typically by empirical methods (Illari and Russo 2014, p. 202). Although conceptions of cause remain ambiguous, science requires a basis on which it can make statements of ‘truth’ or ‘fact’ or ‘evidence’ through claims and proof, reasoning and logic etc. Some of these causal concepts are listed in Table 2.6.2.a. Fire and wound infection are used to articulate these concepts to illustrate broadly the nature of the causal question that might be asked. An example of looking for a simple cause and effect relationship is to ask, “what caused the fire in the litter basket?” This may start with identifying a trigger (a lit cigarette) in the presence of dry paper. However, in a tower block fire resulting in multiple deaths and injuries the causal trajectory starts with a trigger (faulty fridge in one flat), an open window, the presence of cladding on the building, the presence of air space in the cladding creating a draught that accelerates the fire across the whole building, lack of escape routes and water sprinkler systems, etc. Medical errors often have this trajectory, when a series of causal steps occur to lead to a serious adverse event (Reason 2000). These error events are often considered preventable. I suggest that the lack of success in implementation of guidance and changes to practice or treatment plans in healthcare follow a similar but reverse trajectory of cause and effect between initiation and successful achievement of objectives. The trajectory to success needs several enabling steps or processes within the healthcare context.

Table 2.3.3.a Causal concepts explained

Type of causal concept	**Explanatory examples**	**Health example: Transmission of infection to wound post-surgery**
Causation by absence or prevention	Something that intercepts a possible causal sequence, thus interventions to prevent fire in fire risk situations.	Strategies such as the use of masks, gowns and gloves during surgery act as barriers to prevent transfer of bacteria to the wound site.
Cause as identified by the difference (effect) it makes	Whether protective clothing to prevent a fireperson from harm in their job is effective or not (makes a difference) from non-protective clothing.	Evaluating between antiseptic skin preparation formulations: which to use or not to use, based on their effectiveness in preventing post-operative wound infection.
Cause as identified by its production, process or mechanism	Where we can identify the actual mechanism or process leading to a fire, a spark near flammable material. Mechanisms afford explanation, whereas difference making does not.	Swabbing routinely patients' nasal cavity for MRSA (methicillin-resistant Staph. aureus) before surgery because microbiological studies show this is a key mechanism of infection transfer.
Cause as regular instances (lawlike)	Refers to natural laws, e.g. that fire requires oxygen, therefore fire always occurs in the presence of oxygen. Furthermore, although oxygen is a necessary cause for fire to occur, it is not sufficient, as other agents are also required for fire to occur.	Surgical site infection is caused by the transmission of bacteria, a process that is well understood. Immune systems, unbroken skin and other preventative strategies block transmission of bacteria to the wrong place.

Cause as capacity, power or tendency (propensity)	Many items are flammable, others are not. However, for the fire to occur it requires another causal agent to ignite the flammable material.	Bacteria can be airborne or move from its origin or source to the wound through physical contact or exchange of fluids transmission, etc. If the patient is immune-compromised or vulnerable, the bacteria in the wound can to lead sepsis. Therefore, some patients are vulnerable and will be more prone towards infection.
Counterfactual dependence	Establishing causal relations by eliminating other explanations. It may have not been the spark from an electrical fault in the fridge that caused the fire but overheating due to material placed at the rear of the fridge. However, counterfactual dependence is not always the case as several potential causes might compete to bring about an effect (Reiss, 2009).	Identifying the transmission route and the source of bacteria may be more complex and the failure of one or more prevention strategies may create the causal pathway to a post-operative surgical site infection.
Probabilistic theories of causation	Causal relations can be defined in terms of probabilistic dependence: when A causes B, A raises or lowers the probability of B. Therefore, the risk that a fire will occur is either increased or decreased by access to flammable material and a trigger, e.g. a lit match or electrical fault. There is a given probability that a fire will occur, so a lit match may not always ignite flammable material should it not remain alight long enough.	Likewise, with bacteria entering a wound, certain types of surgery may have a greater probability or risk of infection warranting additional preventative measures. High-risk surgery includes trauma or surgery that involves entering the gastro-intestinal system where there is a risk of faecal contamination.

Cause as a cluster of concepts, family resemblance, pluralist or mosaic accounts	These accounts suggest links between a variety of causal concepts, although these differ in emphasis and definition. Exponents of these accounts are attempting to manage the many concepts of causation into a single account. Debates centre on the semantics of terms and how they are then applied and also whether there is a unifying or universal concept or whether a concept overarches and links concepts. A major fire resulting in multiple fatalities and injuries (fire causes death/injury) can incur many causal claims: what started the fire, what caused the fire to spread, what did not prevent the fire from spreading, what facilities (fire escapes, sprinklers) were available to prevent loss of life etc. Who is responsible (does this constitute cause?), due to either neglect of their duties or ignorance and so on.	Investigations into outbreaks of infections in hospital caused by the transmission of bacteria may have complex pathways of initiation, transfer and breakdown in prevention strategies, such as handwashing between patients.
Cause through CAS and notions of trajectories	A certain causal event occurs through a pathway of events whereby multiple triggers occur. An example is the cause of death in tragic circumstances, whereby multiple events led to death, but the death may not have occurred at multiple opportunities following the initial trigger (or cause).	The death of a patient following surgery as a result of bacterial infection in the wound may have a complex pathway between contamination and death, starting with the health of the patient and other complicating diagnoses, e.g. age (elderly or neonatal).

Moving towards pluralism

Williamson (2010) reviews multiple theories of probability and argues that any one theory that provides for a kind of claim to the exclusion of others provides only a partial account of the totality of possible causal relations. He puts forward an epistemological theory of causation to attend to problems he identifies between probability and mechanisms and probability and counterexamples. Both probability and mechanistic knowledge are needed. Again, like Illari and Russo (2014), he does not suggest a unification of all concepts but “it is the uses to which causal claims are put that determines the nature of causality” (Williamson 2010, p. 18). Specifically, as illustrated with the fire example, it is the nature of the causal question and the likely causal trajectory determining causality.

Illari and Russo provide an overview of causality for the sciences and simplify the key causal questions to: Is there a causal relation between X and Y? Does X cause Y? What are the causes of Y? What are the effects of X? How much of X causes Y? (Illari and Russo 2014, p. 4). Illari and Russo (2014) examine multiple notions of causality and indicate that causality forms models that are either monistic, pluralistic, integrated or unified. They frame five scientific problems:

- Inference: what causes the effect and by how much?
- Prediction: what happens next?
- Explanation: how and why did the effect happen?
- Control: when we manipulate parameters, what happens?
- Reasoning: what conceptualisation of causation and methods used supports assumptions and interpretation of findings?

So, we:

- need *prediction* to test hypotheses based on a theory to predict future events of C and E. This allows us to determine whether it might occur again, but we do not know how C causes E;
- might seek an *explanation* of how C causes E, by identifying what enables C to cause E (by which mechanism or process);
- may *control* parameters, alter and create new situations to observe whether the relations between C and E change in response to these manipulations;
- can use *reason* based on our assumptions, prior knowledge, theories and the models we create to *infer* a causal relationship when we cannot directly observe it.

These different scientific problems address the multiplicity of scientific endeavours to advance knowledge. Implementation research involves all five problems and therefore causal assessment cannot rely upon a single causal concept. Multiple forms of evidence are needed to evaluate causal relationships (Illari and Russo 2014). We need “an independent concept of cause that, nevertheless, bears some systematic relationship with different evidential methods”, so we need one hypothesis supported by more than one source of evidence (Russo and Williamson 2011, Reiss 2009, p. 28). Causal monism cannot explain all aspects of evidence needed, and pluralism does not unify the different causal explanations (Russo and Williamson 2011). Therefore, causation seems to involve a variety of causal relations which suggests greater transparency is needed on the nature of the causal assumptions made by researchers.

Multi-sided view of causation

A pluralistic multi-sided view of causation embracing multiple causal concepts is more able to address the complex realist stance that assumes the world is created in an evolutionary, historically contingent, temporally located direction. In other words, Complex Adaptive Systems (CAS). Table 2.6.2.b summarises the substantive work in causal philosophy undertaken by Illari and Russo (2014). This process of disaggregating and qualifying different concepts for the purpose of how researchers might use or interpret their activities lends itself to a view of multiplicity rather than attempting to unify causal notions into a singularity, hence pluralism. The argument then lies with the view that triangulation of multiple forms of evidence that converge on a causal relationship is stronger that reliance on a single point of evidence (Illari and Russo 2014). Combining different forms of evidence (Bazeley 2018) is not new or unusual. However, establishing a strong philosophical basis for doing so enables a coherent argument for interpretation. Within the field of implementation research when RCTs are used alongside process evaluations to assess whether there is a difference (outcome), and why and how (process), different causal relations are being integrated. Given the push to explain implementation in terms of mechanisms, processes and outcomes that are contingent on the context of implementation (Damschroder 2009, May 2016), I consider there is a defence to assuming a concept of causal complexity, as discussed here.

Furthermore, causation typically assumes that cause precedes effect. However, from a Complex Adaptive System perspective it is not straightforwardly unidirectional because anticipation can lead to prevention or changes to an unexpected future causal relation (Heylighen 2010). CAS (biological and social) show the ability to anticipate, learn and adapt to their environment or circumstances (Holland 2000, Chapter 3). Emergent higher order structures (CAS), can create “downward causation” effects on sub-systems (attributed to Donald Campbell 1974, Magee 1974). Cause, from this perspective, is not a static linear relation, but an evolutionary, adaptive and dynamic one based on feedback between local agents within the system.

Table. 2.3.3.b A multi-sided view of causality (drawn from the work of Illari and Russo 2014)

Causal concept	What does it do?	Elaboration
A regular instance	Determines that A is necessary for B to occur.	According to Hume, if we observe cause that is regularly followed by an effect, we can determine that the relationship is causal. The question arises as to whether that must occur in every instance, otherwise the factor is then considered not causal. Other accounts permit regularity but allow for occasion when C does not always follow E in every circumstance. Mackie's (1974) INUS* account uses the basis for necessity but in a causally complex arrangement. *An **I**nsufficient, but **N**on-redundant part of an **U**nnecessary but **S**ufficient condition
Variation and manipulation	Determines A when modified changes to B is a causal factor for B if no other factors are correlated.	Manipulation is the basis for RCTs where the manipulation of factor can show an effect in controlled conditions protecting from other explanations. We can also follow effects from causes overtime e.g. cohort studies. Variance in cause observed by a proportional variance in effect indicates cause if no other explanation is provided.
Probabilistic dependence	Determines there is a difference between A and B based on probabilities.	Causality based on probabilistic dependence assumes causality is not deterministic and that other factors may also lead to the effect. Thus, 100% probability indicates a necessity relationship. However, lower probability indicates that other causal factors are also relevant, which important for risk factor analysis. A low probability indicates that something is less likely to cause E. Therefore, a strength of relationship is indicated based on the likelihood of occurrence.
Production: Process and mechanism	Identifies the mechanism or steps that occur to enable A to cause B.	Process and mechanism are focussed on links, connections and process steps between C and E. Mechanisms are devices to explain phenomena of how C enables E. This needs to involve descriptions of the phenomenon, the entities, the activities and the organisation that connects the links to confer the mechanisms.

Capacity propensity and power	A set of conditions are required for C to enable E.	Capacities-Powers-Dispositions (CPDs) explains what it is that permits C to enable E. It specifies both the conditions to enable C to invoke E and also those that might prevent C from involving E, or their absence.
Counterfactual argument	Addresses ‘what if’ questions. If A occurred or did not occur, then would B occur or not occur?	This concept describes a situation when we have current knowledge or evidence, we can *reason* other possible causal relationships or explanations. However, these may not be valid because they have yet to be tested or evaluated. This is the basis for hypothesis testing.
Multi-component (pluralist and mosaic)	Drawing together multiple aspects of causality into a general framework for use by researchers, applied as relevant for their purposes.	A range of causal concepts can be used to infer a causal relation that accommodates diverse aspects of reality that are needed to provide evidence. This entails joining *how we know* causal relations with the different ways in which we *can know* these causal relations. Based on the question we can ask whether something works and how and why it works or does not work.

2.4 Defining complex causation in Complex Adaptive Systems

A description of complex causation entails a relational approach to causality that moves away from reductionism (observing the parts that make up the whole) to a synthetic view of interactions and relations between the parts, which eventually derive the outcome or effect from a varied combination of factors (Ragin 2010, Byrne 2005).

2.4.1 Complex causality in complex healthcare systems

The development of pluralist accounts of causation (Illari and Russo 2014, Cartwright 2011, 2007, Russo and Williamson 2007) may offer a suitable fit with the CAS perspective and methods needed to capture and explain 'what happened'. I assume that certain key system functions of healthcare social systems (e.g. healthcare organisations, systems of practice and complex treatment programmes) and their human agents (healthcare professionals and patients) operate under various parameters of 'control'. However, these systems also *self-organise* (Braithwaite et al 2018, Kernick et al 2004, Kauffman 1995), which means no single healthcare professional has absolute overall control of the system.

Based on the level of abstraction within the system of interest, the causal relation may be relatively simple or increasingly complex as more of the system is involved in the research activity. When applying the social CAS lens, specific outcomes cannot be guaranteed, and future trajectories may follow a range of possibilities. Therefore, when implementing change into real world scenarios assumed to be CAS, how do we account for complex causal relations? Finding methods that engage with the perspective of multiple interacting complex adaptive healthcare systems is a challenge (Braithwaite et al 2018). The key point is that complex systems are not decomposable into their constituent parts and thus complex causation (in social systems here) needs to explain the 'messy reality' of the system (Byrne et al 2010).

2.4.2 Causal relations and complex causality

Complex causality is dynamic, interactive and non-linear. Of course, direct linear relationships can exist at lower levels of the system under observation, but these do not describe the behaviour or effect that occurs at higher levels of the system. Non-linearity is a key concept when considering the causal links between the cause of 'interest' and the 'effect' of interest and therefore its proximity or/and macro/micro impact on the causal pathway(s) of 'interest'. The scientific process extracts a part of the whole system, however that might be defined, and should note the wider system of influence. For the purposes of what methods do and do not do in addressing complex causality, the RCT is a clear situation whereby for its *premises* to equate to their *conclusions* (for the conclusions to be true), the study parameters need to be very narrowly determined. The experimental method focuses on a single factor in isolation from the wider context of that factor (or complex system in which it operates) to *confirm* that a relationship exists between the causal factor and its effect. Therefore, generalisability, has limits beyond the trial context (Cartwright 2013, 2007). Causal relations, other than causal difference, become more relevant to address the specifics of context. I expand further in the next sections on those pertinent to the focus in the research undertaken for this thesis: 'mechanisms', 'necessity" and 'sufficiency'.

2.4.2.1 Mechanisms

Mechanisms are important when dealing with complex systems (Glennan 2002, in Illari and Russo 2014, p. 125) because they track the 'how' from cause to effect, to connect the cause to its effect. Thus, mechanisms provide causal explanation (Illari and Russo 2014). However, not all explanations are mechanisms. Illari and Russo (2014) define mechanism as something that:

- does not describe phenomena alone, that is, observing behaviour without explaining the aspects of the causal pathway that bring about that behaviour;
- connects activities with their entities;
- has an underlying organisation, therefore no organisation equates to no mechanism.

In addition, observations might identify a signal that indicates the presence of a causal relationship, but it does not define the mechanisms needed to establish or confirm that cause and effect relationship (Illari and Russo 2014).

Gerring (2008) identifies nine definitions for mechanism in the social sciences and argues that a singular concept – the pathway or process by which an effect is produced – covers all others as they either elaborate or debate this definition. In reference to social mechanisms, Dalkin and colleagues (2015) refer to differentiating between mechanistic activities, reason and resources in programme evaluations. This concurs with a view that mechanism can explain why something happened or not, but a mechanism needs to have the capacity or resources to enable its activation. To establish mechanistic pathways to successful implementation in social CAS requires tracing these nonlinear mechanisms that generate the effect. In Chapter 6, I will utilise the social science method 'process tracing' (Beach and Pederson 2013) to further illustrate this point.

Social system structures can be created by a variety of mechanisms, and the same mechanisms may result in a variety of structures. In this social system context, 'generative causation' (Pawson 2006) looks for these capacities or resources (causal powers) within the objects or agents or structures under investigation. Mechanisms "are the engines of explanation in realist analysis" and they operate when "a sequence of events or a pattern of behaviour are explained as being part of a system and the mechanism tells us what it is about that system that generates uniformity," and therefore explains causal connections (Pawson 2006, p. 23). Bhaskar (2015) provides an account for a multi-layered social reality that involves multiple structures that brings about social events (Williams et al 2017) and illustrates a pluralist and complex causal position.

"…. just as the same type of event may be determined by a (disjunctive) plurality of mechanisms ...., so (i) the same kind of mechanism may sustain alternative structures and (ii) the same structure may be reproduced by a variety of different types of mechanism." Bhaskar (2015 p. 170).

Cartwright (2007) goes further to elaborate how mechanisms allow us to generalise a causal relation beyond the sample population. Consequently, while an appropriate dependence in the sample data can warrant a causal claim 'C causes E' in the sample population, a plausible mechanism or theoretical connection is required to warrant the more general claim 'C causes E' beyond the sample population. Furthermore, mechanisms also impose negative constraints: if there is not a plausible mechanism from C to E, then any correlation is likely to be spurious. Thus, mechanisms can be pursued to differentiate between causal models that are underdetermined by probabilistic evidence alone (significance tests, effect measures) (Cartwright 2007). Likewise, as mechanistic reasoning can be overturned by clinical comparative studies, hypotheses constructed by combining both comparative studies and mechanistic reasoning are less likely to be spurious than hypotheses supported by one type of evidence (Howick 2011). Knowledge of mechanisms can therefore support inference made in trials, for example.

"High quality mechanistic reasoning involving inferences from "not incomplete" mechanisms that take into account complexity can and should be allowed to bolster the strength of evidence in favour of claims that treatments are effective." (Howick 2011, p. 136)

The overriding point about mechanism within causal philosophy is that it explains how A is connected to B and that there are a variety of ways this can be understood. Connecting A to B can require a trigger, some additional quantity or factor, a series of necessary steps or the capacity to transmit from A to B (not blocked by interference of some kind), and these intermediate processes (parts) may each be described at different levels within the cause and effect relationship, when adopting a complex systems perspective. Byrne and Callaghan (2014) qualify mechanisms within a social complexity frame as taking:

"the state of the social system at a point in time and explain the trajectory of that system through past times by referring to a constellation both of internal control parameters and of the state(s) of systems with which the system of interest intersects." (Byrne and Callaghan 2014, p. 48)

The identification of the constellation of control parameters may suggest a pattern by which similar systems might follow a similar trajectory (Byrne and Callaghan 2014). This constellation of control parameters or conditions are central to the notion of complex causality in the context of this thesis. I elaborate on a specific set of causal conditions central to QCA methodology in identifying configurations of causal conditions across a set of cases (see section 2.4.4).

2.4.2.2 Necessary and sufficient conditions

Illari and Russo (2014) summarise necessary and sufficient conditions as an approach that assumes these concepts build a complex set of causes or mechanisms that are sufficient for the outcome. First, I specify sufficient and necessary conditions and then the INUS concept (**I**nsufficient, but **N**on-redundant (necessary) part of an **U**nnecessary but **S**ufficient condition), that explains causes as parts that can configure in different ways in different circumstances, permitting more than one pathway of conditions towards an outcome. This is central to QCA methodology.

Sufficient condition

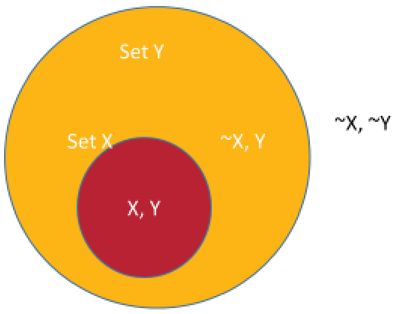
A condition or causal factor whenever present so is the outcome, however, the outcome may occur by other conditions. This is illustrated in Fig. 2.4.2.2.a below. The Venn diagram shows the subset relation X $\rightarrow$ Y in red, where both are present. Set X does not explain all cases of set Y. Therefore, other conditions or factors explain Y. Outside set Y, the universal set, neither Y nor X are present. Note ~ means 'not'. The two by two table (Schneider and Wagemann 2012, p. 59) explains set relations further. 1 = present, 0 = absent, therefore the subset X, Y tallies with cell b in figure 2, ~X, Y with cell a, ~X, ~Y with cell c. Cell d refers to X, ~Y and should not present any observable cases in this cell because X is sufficient for Y. This would constitute a contradiction.

Fig. 2.4.2.2.a Sufficient conditions

Set relations: Patterns of sufficient conditions

Sufficient conditions

X=condition, Y=outcome



Two by two table - sufficiency			
Y	1	allowed (but not relevant) a	allowed b
	0	c allowed (but not relevant)	d not allowed
		0	1
		X	

Adapted from Schneider & Wagemann, (2012) *Set-Theoretic Methods: A guide to Qualitative Comparative Analysis*. Cambridge University Press, Cambridge, UK p.59-60.

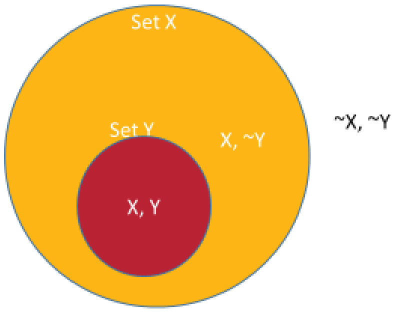
Necessary condition

A necessary condition is a condition or factor, if whenever the outcome is present the condition is also present. Therefore, whenever X is present, Y is also present. However, X may be present when Y is not present. This means condition X may also result in another outcome not just this outcome. To illustrate this point table 2.4.2.2.b shows that you cannot have any observed cases in cell *a* where outcome Y is present but condition X not to fulfil necessity. Cell *b* satisfies necessity, where observed cases are present for Y and X. Cells c and d are not relevant.

Fig. 2.4.2.2.b Necessary conditions

Set relations: Patterns of necessary conditions

Necessary conditions X=condition, Y=outcome



Two by two table - necessity

Y			
	1	Not allowed a	allowed b
	0	c allowed (but not relevant)	d allowed (but not relevant)
		0	1
		X	

Adapted from Schneider & Wagemann, (2012) *Set-Theoretic Methods: A guide to Qualitative Comparative Analysis*. Cambridge University Press, Cambridge, UK p.71-72.

Complexity of the real world is such that set relations do not operate so neatly, and we are often more likely to identify more partial and inconsistent findings that require further assessment using parameters of fit (Schneider & Wagemann 2012).

Complex causal arrangements

The complexity of social relations is further elaborated by Mackie's (1974) INUS condition. which is a ***N**on-**r**edundant* (necessary) part of a condition which is itself ***U**nnecessary but **S**ufficient for the result. I elaborate below:

Cause A is an INUS condition of effect P, only if, for some condition X and for some condition Y, (AX or Y) is a necessary (Y always present when P occurs, therefore P cannot occur without Y) and sufficient (P always occurs when Y is present) condition of P, but A is not a sufficient (not always present) condition of P, and X is not a sufficient condition of P.

This articulates that a cause is often part of multiple separate causes for the outcome (Cartwright 2007), which are difficult to manage in quantitative designs (Schneider and Wagemann 2012). Another is the SUIN condition, a condition that is ***S***ufficient, but ***U***nnecessary part of a condition that is ***I***nsufficient but ***N***ecessary for the outcome (Mahoney et al 2009). Cartwright (2007) considers in causal terms that unlike RCTs, a QCA study cannot clinch a result (section 2.5.1.2). However, it moves beyond simplistic notions of 'yes' or ‘no’ causality to the ‘functional form of the causes’ and may provide better explanations of how the cause and effect relationship is obtained (Cartwright 2007).

In addition, Mackie introduces the notion of a *causal field*, this aligns with notions of context. Thus, causal relations occur within a background, for which we could replace ‘field’ with the term ‘system’. Mackie acknowledges the multi-layered reality of real-world systems but also notes that our causal relations are potentially limited by the scale at which we define the causal relation. This is because we cannot engage the whole of the real. Therefore, finding a genuinely sufficient condition, one which is “by itself, adequate to secure the effect”, is unlikely. However, some general causal statements do pick out necessary conditions – e.g., “the yellow fever virus is the cause of yellow fever.” It has no other cause. Mackie also reminds us that for almost any particular effect there will be numerous causes, not just *the* cause. Mackie also addresses temporality in causal relations with the notion that ‘causal priority’ is not temporal because of the possibility of backwards and simultaneous causation. Backwards and simultaneous causation refer to an anticipated future effect, so the future affects the present. Holland (1992) suggests that CAS based on learning and prior information can ‘anticipate’, and so arguably the future anticipated event influences the nature of the current causal condition that may bring that effect into a real event.

2.5 Methods to address social Complex Adaptive Systems

In this chapter, I argue for the adoption of broader, pluralist rather than monist perspectives of reality and causal philosophy to better address the assumption that we are, and co-exist in, social CAS, which have specific characteristics. I expand on social CAS in the next chapter. The tool kit of methods in implementation research needs to expand to enable the capture of social complex causal relations to allow a better understanding of the variance between individual cases and their unique contexts. I comment first on trial methodology and its causal structure which are widely regarded as confirmatory when testing for a cause and effect relationship. Second, I propose for implementation research methods that allow for case sensitivity and include the context within which an implementation event occurs. I evaluate one solution with potential, QCA. I use QCA to operationalisation the social CAS concepts (Chapter 3) to explain the POISE dataset.

2.5.1 Evidence-based methodology

Evidence-based medicine and subsequent evidence-based fields rely upon experimental randomised study designs to determine whether a given treatment or policy is efficacious and effective in comparison to standard treatment, placebo or another similar treatment. This deductive method is based upon the causal logic and assumptions of the experiment. RCTs determine whether a difference occurred in the controlled comparison which was not a chance difference but an actual difference within specific limits (confidence interval, see Table 2.3.3.a). Two key methodological features establish the right of RCTs to make causal claims. First, the internal logic is that all factors are controlled ensuring that only the parameters of interest undergo the test and that bias (contamination) does not occur (e.g. blinding of observer and treatment recipient). Second, concealed random allocation ensures baseline similarity between treatment and control group, such that selection of participants at baseline does not influence the results leading to a misinterpretation of a true effect. RCTs are based on probabilistic dependence between the cause and its effect. When using RCTs, variables under evaluation should meet prescribed control parameters and have close proximity between the causal agent and its effect, be reproducible (regular) and account for other interactions in the analysis (Byrne 2002). However, the 'control' of a set of parameters cannot safely assume that all 'system' or contextual factors are under control within the experiment and beyond within the wider target treatment population (Cartwright 2007), especially for social systems and interventions (Ioannidis 2018). Thus, RCTs work best with highly specified and contained interventions, in that the randomised case is not affected by variation in the treatment or the case's subsequent trajectory whilst undergoing the specified treatment (Byrne 2002). RCTs, therefore, are the litmus test sought to ascertain whether an intervention is effective and produces a change in the outcome. This 'descriptive causation', however, does not explain the causal relationship (Johnson and Schoonenboom 2015). Whether using RCT or non-RCT evidence, further information is often required to establish the potential causal relationship (Howick et al 2009), and the causal relationship does not cover all cases with either the presence of an effect or a known causal agent of interest (Rothman 2005). In addition, I address probability theory to differentiate it from set theory that underpins QCA.

2.5.1.1 Probability

The causal relationship in RCTs relies upon showing the probability of an effect at the population level, and we are left to infer whether the effect (outcome) will occur in any single case. Probability theory contends that when A causes B, A raises or lowers the probability of B (Williamson 2010). Statistical procedures using probability theory defined as "the probability of the occurrence of a particular event equals the proportion of times that the event would (or does) occur in a large number of similar repeated trials. It has a value between 0 and 1, equalling 0 if the event can never occur and 1 if it is certain to occur" (Kirkwood 1997 p. 73). A probability may also be expressed as a percentage, taking a value between 0% and 100% (Kirkwood 1997). Generally, probability does not reach 100%, suggesting other factors are relevant in the cases whereby 1 or 100% was not reached. By treating Diabetes Type 1 with insulin we expect the probability of treatment of successful effect in this instance to be close to, if not, 100%. Effectiveness of insulin will be concerned with titration of dose and management by the individual of their sugar intake etc. However, most treatments do not reach this level of probability providing absolute certainty about the treatment for the population of interest, and not for all cases. Hence the recent impetus for personalised medicine and individual genome mapping (Annual Report of the Chief Medical Officer, 2016), which promises to target and titrate treatment to the individual rather a population of individuals, of which many may not benefit from the treatment.

2.5.1.2 Internal and external validity of trials

In addition, there is a tension between ensuring internal methodological integrity to make causal claims and the applicability of the results to the wider target population, the rationale for conducting the RCT (Cartwright 2007). To further clarify this problem between internal and external validity, fig. 2.5.1.2 summarises Cartwright’s (2007) core argument on the problem of causal claims using different methods:

Fig. 2.5.1.2 Cartwright’s ‘clincher’ and ‘voucher’ concepts (2007, Chapter 3)

Study design characteristics	**The Clincher (e.g. Randomised designs)**	**The Voucher (other non-experimental designs e.g. QCA (Ragin 1987))**
Topic focus	Narrow focus	Broad focus
Outcome focus	Identifies effect and its magnitude	Process and mechanisms
Task	Provides a degree of certainty or confidence in the result	Offers the best explanation
Generalisability (external validity	Restricted extrapolation	Generalise to wider populations and contexts

Cartwright (2017, 2013, 2010) suggests that the applicability of RCTs to the real world is confined by ensuring internal validity, although RCTs’ causal claims are true, if internal validity is maintained. Therefore, the RCT methodological structure provides confirmatory evidence to support the causal claim, when conducted well in ideal circumstances. Use of other methods although not structurally able to ‘clinch’ the causal claim, can nevertheless ‘vouch’ for it (Cartwright 2007; Cartwright includes QCA). Pharmacological interventions undergo a long development pathway from the laboratory to the clinical environment and so are underpinned by substantial knowledge prior to testing in RCTs of efficacy or effectiveness. This is not typical of other social type interventions (Ioannidus 2018), including guidelines to change practices such as implementing fasting regimes. Evaluations in healthcare settings are not controllable, hence the strong focus on context in implementation research. Delivery of interventions need contextual information to explain how they functioned in specific settings (Pfadenhauer et al 2017, May et al 2016). This type of knowledge would have greater external validity beyond the trial context.

2.5.2 Implementation research methods: case, context and outcome

By accepting RCTs provide confirmatory information of a causal relationship we can nevertheless consider other methods that vouch for that causal relationship. In other words, methods that go beyond description. RCTs are outcome focused. In implementation research we need to know not only whether an intervention works but also how, where, when, in which circumstances etc. an intervention works or does not work. RCTs are unable to capture the causal complexity of real systems that are inter-connected at multiple levels based on the assumption of higher order emergence. This is because they isolate causal factors from the wider system in which they are conducted (Cilliers 2013). Implementation research needs to take account of differences that occur in individual case contexts (Pfadenhauer et al 2017, May et al 2016) both within a case, such as conducting a case study, and across similar cases in order to ascertain any common patterns of response to the implementation process. Implementation research needs to connect causal factors to the outcome through process evaluations and the identification of mechanisms.

Application of a complex realist perspective to methods within healthcare directs the researcher towards explaining events that occur within their context, how interventions are deployed and why they work or do not work, or work but not as intended. In addition, connecting levels between different layers of the humancentric real world such as biology, sociology and psychology (Galea et al 2010, Clark et al 2008) is within the realist realm as envisaged by Bhaskar's multi-layered social reality and Prigogine's dissipative structures. Therefore, CAS, whether they are human biological systems or social systems, a hospital, a department or clinical area within a hospital, a field of research such as implementation, or a care pathway, all function in the social sphere. Given the inter-connectivity between these different system levels (Cilliers 2001), researchers need to clarify their observational boundary because it is not possible to view the whole or universal system (Cilliers 2005). For research purposes the system becomes the unit of interest and comprises a bounded object referred to as the 'case' for the research activity. Maintaining the case structure is key to observing the system's function. Such a research investigation needs to identify system components and how they come together to function collectively (Castellani and Hafferty 2010).

Examples of methods identified as fitting within a complex realist position for social systems are agent-based modelling, action-based research (Gerrits and Verwiji 2013), qualitative narratives using grounded theory, process tracing and sequencing, case study, ethnographic approaches (Byrne and Callaghan 2014), quantitative approaches such as equation-based modelling (Byrne and Callaghan 2014) and realistic evaluation and realist synthesis (Pawson 2006). These methods are mostly explanatory (some also exploratory) and seek to gain a view of how and why something occurs or does not occur. Complexity consistent methodology can establish what happened, or is happening, at given point in time, in each context, to establish evidence of system behaviour. This information might inform future system behaviour.

An additional method recommended for managing causal complexity in social systems is QCA (Cartwright 2007, Byrne 2005, 2002, Ragin 1987) (origin political sociology), which integrates and transforms systematically qualitative and quantitative data. Data are disaggregated, compared and re-synthesised across a set of common cases (Ragin 2008) that best fit the data. QCA uses set theory to manage these causal conditions, allowing the simultaneous comparison of multiple conditions to seek causally complex patterns.

Set theory, a form of mathematical logic, classifies types of objects or factors by their belonging to a category (set). It is not counting or describing frequencies of the objects or factors present in the cases. Statistical approaches may be applied when large datasets are available (Thomman and Maggetti 2017, Olsen et al 2018). Numerical tests are undertaken to assess the robustness of the final configurations as to their *coverage* and *consistency* of the causal relationship, across cases for individual factors, or configurations of factors. However, there is a fundamental difference between probability and set relation logic.

A simple illustration of the difference between probability and set relation logic, for example, is made by posing a choice between drinking water from a bottle based on the addition of a poison. Two bottles of poisoned water are presented. Bottle A is presented as choice based on the probability than 1 in 10 bottles selected contains a fatal dose. Bottle B is presented as belonging to the set of poisoned water bottles with a fuzzy set membership of 0.1. Given the desperate need to drink water and presented with this choice, which is the safest choice to make? Answer is described in Box 2.5.2.

2.5.3 Set relation logic

The QCA research strategy and methods assume that social relations are set-theoretic in nature, that is, we categorise reality into whether something belongs to one category or another. In addition, categories may inter-relate and members of a category can be members of other categories based on the field of relations under study. Sets are a collection of objects that relate to each other in some way that would constitute the rules for membership of that set. Crisp sets determine whether cases are members of a set or not (1, 0). Fuzzy sets allow partial membership, membership by degree neither fully in nor fully out of the set (Schneider and Wagemann 2012, Ragin 2008, 2000, 1987). Numerical descriptors between 1 and 0 are used, e.g. 0.67, 0.5, 0.33, for a set with five assignment options. 0.5 is the point of greatest ambiguity between whether the object is in or out of the set, so this assignment is neither in nor out. This means we are not sure whether the object is in or out of the set. In set theory membership is determined by data, observation, common knowledge or other forms of evidence using a variety of research methods appropriate to the research question and the cases under study. These set relations describe the causal condition or factor of interest using the causal terms sufficiency and necessity and combinations of these.

Box 2.5.2 Answer to the bottled water choice

Bottle B – because although you may have a 9 out of 10 chance of drinking clear water, there remains a 1 in 10 chance that you will die with Bottle A. However, with Bottle B you will drink water that is only containing a small amount of poison based on only just being in the set (0.1) of poisoned bottles and thus, although you may become unwell you will survive.

2.5.4 Selecting Qualitative Comparative Analysis to operationalise social Complex Adaptive System concepts

QCA is a complexity-informed method (Byrne and Ragin 2010) that fits within the complex realist framework (Byrne and Callaghan 2014, Gerrits and Verwiji 2013). Furthermore, this cross-case comparison of variables was designed as a "*comparison of wholes as configurations of parts*" (Ragin 1987, p. 84). QCA explicitly seeks causal relations in the social world (Ragin 2008, 2000, 1987). It goes beyond description and seeks to determine the factors, conditions or attributes that may configure differently across different cases, maintaining context specificity, to a common outcome of interest. This method supports the retention of the individual case complex system narrative (Byrne and Callaghan 2014). It permits the comparison of multiple cases from 10 to 100+ and therefore goes beyond other qualitative case study and evaluation approaches. QCA's methodological architecture is based on set theoretic relationships, not counts or events (frequency). QCA examines whether these factors individually or in combination are necessary or sufficient (Box, 2.4.2.2) to obtain the outcome.

QCA synthesises data to explain *what configuration of factors are most relevant in obtaining the outcome.* Cartwright (2007) suggests utilising the INUS formula (section 2.4.2.2.), that allows us to identify the functional form of the causes. In addition, can determine that a cause is a cause for some cases and not for others although there is no way of dealing with unknown or omitted factors, that is, factors not included in the QCA synthesis. The identification, selection, reduction and exclusion of causally relevant conditions is an important research task that may involve multiple methods. Relevant examples in this context are Befani et al 2007 (with realistic evaluation), and Castellani et al 2019 (with agent-based modelling). With CAS we need to understand that causal relations are not static and do not exist under all circumstances, all the time (Susuki 2018). Therefore, QCA is an iterative approach that needs review over time as social systems evolve and change.

For implementation research, the utility of applying a social CAS perspective to either intervention design or its evaluation has yet to be shown, and examples are needed (Brainard and Hunter 2016, Moore et al 2014). Research undertaken for this thesis presents a structured approach to implementing a CAS perspective using QCA methods that:

- Retains case structure and identity throughout synthesis.
- Examines more than 5-6 cases, the limit in other potential approaches.
- Permits examination of multiple factors of interest.
- Shows systematically links between causal factors of interest and an outcome.
- Exposes patterns of differently configured factors across cases, potentially identifying common causal factors of interest across cases.
- Enables the evaluation of theory.

QCA methodology and methods are elaborated further in the next section of this chapter.

2.6 Qualitative Comparative Analysis

Ragin (1987) first describes his methodology and method in '*The Comparative Method: Moving beyond Qualitative and Quantitative Strategies'.* QCA methodology starts with the assumption of across case heterogeneity with the same outcome. QCA is both a research strategy and a data analysis technique for causal analysis based on set relationships (Schneider and Wageman 2012, p. 13) which can produce modest generalisations (Rihoux and Ragin 2009, Ragin 1987). Linear cause and effect relationships are unable to take account of complex causal mechanisms in social systems. Therefore, Ragin's assessment of *multiple conjunctural causation* (Rihoux and Ragin 2009) assumes that a combination of causally relevant conditions generates an outcome and several different combinations of conditions may produce the same outcome in different cases. It challenges the assumption that an outcome can result from a single cause or a single combination of causes in the social world. These set relationships are characterised by *asymmetry* (Ragin 2008), the conditions that obtain the outcome do not mirror those that do not obtain the outcome. Also, *equifinality* describes a state whereby alternative factors combine to produce the same outcome (Schneider and Wagemann 2012). Core causal concepts underpinning set relations are the arrangements of sufficient and necessary conditions (section 2.3.2.2).

The method sets out procedures to specify cases both with and without the outcome and their relevant causal conditions to identify the configurational patterns. The method has expanded into a set of different methods: the already mentioned crisp set and fuzzy set, and the multiple variable set and the temporal set (Rihoux and Ragin 2009). The truth table is the key methodological device:

> "The task of truth table refinement is demanding, for it requires in-depth knowledge of cases and many iterations between theory, cases, and truth table construction. In effect, the truth table disciplines the research process, providing a framework for comparing cases as configurations of similarities and differences while exploring patterns of consistency and inconsistency with respect to case outcomes" (Ragin 2008, p. 25).

Proponents of QCA describe this research strategy as one that bridges the divide between quantitative and qualitative approaches (Cooper et al 2012). Ragin (1987) describes this as a difference between case orientated and variable orientated approaches with the purpose identifying commonality amongst diversity (Ragin 2000 p. 34-35). He further defines his view of diversity in relation to phenomena: "Diversity is best understood as a synthesis that transcends these two opposing principles of generality and complexity. To study diversity is to take a broad view of social phenomena, without imposing homogenising assumptions at the outset of the research, as in much variable-orientated work, for example, the assumption that all cases are drawn from the same "population". (Ragin 2000, p. 35).

2.6.1 The rationale for Qualitative Comparative Analysis

QCA allows exploration of causal complexity rather than assuming that a net effect is enough information in complex social systems (Chapters 3 and 4). The net effects assumption is that each variable, by itself, can influence the magnitude or probability of the outcome (Ragin 2008, p.177). The method is gathering interest in several quarters as quantification techniques reach their limits (Befani 2016, Thomas 2014). QCA shifts thinking to a configurational approach of causally relevant conditions permitting exploration of the combined factors that may result, or not, in an outcome (Fiss 2007), and allows for variability as expected in real situations. Byrne (2011, 2013) makes links between Complexity Theory within the social sphere and QCA. Bhaskar (2015) argues “the epistemological fact that social structures only ever manifest themselves in open systems means that criteria for the rational assessment of theories must be *explanatory* and non-predictive; while the relational consideration that social science is internal to its subject-matter lays the ground for a kind of *critique* in which, without the addition of any extraneous value judgements, one can pass immediately from facts to values, or more precisely from explanatory theories to practical imperatives.” (Bhaskar 2015, p. 160).

Theories need methods that permit practical application in real world populations (Cartwright 2018, 2007, Grant et al 2013, Ramsey et al 2010). By identifying combinations of factors that result or do not result in the outcome of interest, allowing for variance in contexts (the individual cases) has practical advantage over methods that provide themes or description (qualitative research, process evaluations) or a summary statistic (RCTs, systematic reviews). My rationale for selecting this method was that it accommodates contextual differences between individual cases, whilst simultaneously finding common patterns that either lead or not to an outcome, such as successful implementation as defined.

Case based methods that use set theory and set relations are becoming increasingly common across disciplines (Wageman and Schneider 2010), suggesting adaptability. This development brings critique and examination of the method (Lucas and Szatrowski 2014). This has resulted in further development of these methods beyond Ragin’s original work (Schneider and Wagemann 2012, Cooper et al 2012). Examples are also increasing across disciplines (Rihoux et al 2011) and include engagement with Complexity Theory (Haynes 2019, 2018).

Applications of QCA are explored through a review of applications of QCA in healthcare in Chapter 5. Critique and limitations of QCA are discussed in Chapters 5, 7 and 8. The following section presents QCA methods.

2.6.2 Principle Qualitative Comparative Analysis procedures

QCA is constructed by the identification and specification of a set of cases that share a degree of commonality on the outcome and the hypothesised factors of interest. However, the cases are also heterogeneous enough to ensure exposure of the system’s complexity. The following define the core attributes of QCA: the case, the outcome and the condition/factor etc. theorised to result in the outcome. Definitions of these three constructs are in Box 2.6.2.

Box 2.6.2 Definitions of QCA constructs

QCA concept	Definition
Case	A bounded object (Rihoux and Lobe 2009) or construct specified for across case comparison with a set of comparable attributes that relate to the outcome of interest. Both negative and positive cases are sought in relation to outcome status. Case-orientated approaches should illustrate familiarity with cases throughout the study steps.
Outcome	The variable or variant of interest to address the question in the study that we wish to explain. Whether it is present or not is of interest.
Condition (causal factors of interest)	A *causal* factor (mechanism) that explains an effect on the outcome. It is not an independent variable in the statistical sense. QCA considers multiple *causal* (mechanisms) in configurational patterns. The condition should vary across cases. The case to condition ratio should be managed and decisions and judgements made.

2.6.2.1 Defining cases

Case as a construct needs to be a well-defined and self-sufficient entity, contain a set of minimally integrated, nested constellations which are historically open evolving systems, and should, as a social construct, include human intentionality (Harvey 2009, p. 30). The interpretation following Ragin's strategy to compare the 'parts' of whole cases is that each individual case provides an individual implementation context and social CAS for the purposes of the study reported in Chapters 6 and 7. From the outset, I note that the cases in the POISE study dataset are a subset of a total set of cases of the universal set of all UK NHS organisation surgical departments, and so different sets of similar cases could affect the results. It is the generalisability of the cases to the universal set that permits limited generalisability or explanation of phenomena to cases beyond the case set examined. I discuss in Chapter 5 how I managed this subset of cases.

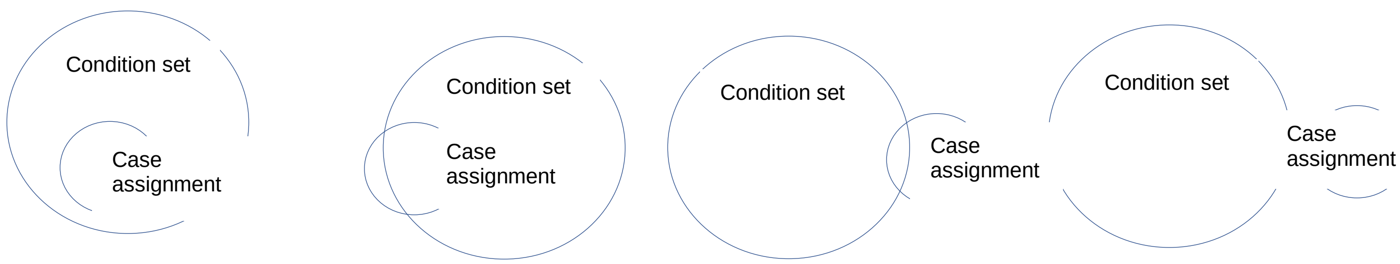
2.6.2.2 Defining conditions and outcome

QCA methods examine causal complexity by exploring the possible conditions (mechanisms) that might lead to an outcome and whether the 'cases' identified with the outcome exhibit any of these conditions, the likelihood being that some cases may exhibit some but not all possible identified conditions when the outcome is present. In other words, several different configurations of conditions lead to a given outcome. The conception of causality is multiple conjunctural causation (Rihoux and Ragin 2009). This assumes that often a combination of causally relevant conditions generates an outcome, and several different combinations of conditions may produce the same outcome. This is defined as the diversity orientated approach (Ragin 2000, p. 119).

2.6.2.3 Transformation of data into set membership assignment

The set membership assignment value is based on the degree to which a condition or factor is a subset of another set and is not a ranking or an ordinal scale; it defines one type of thing in relation to another, based on its subset relationship. This calibration procedure of assigning membership values is neither a measurement nor a quantity. Crisp set will allocate values 0/1, fuzzy set can assign any set of values between 0 and 1. Fig. 2.6.2.3. provides an example for a four-value set. This will transform the raw data table to a ‘truth table’ of assigned set membership values. The truth table will present all cases assigned to a logical combination of conditions (truth table row), this may result in some logical combinations of conditions without observed cases and these are referred to as logical remainders. Their treatment along with contradictions, rows that are logically incompatible, need to be handled within the analysis. Thus, this is a key transformation moment and requires a high degree of transparency and explanation of steps undertaken. Further explanation is provided in chapters 6 and 7.

Fig. 2.6.2.3 Illustration of set membership assignments



Fully in (1) Partially out but more in than out (0.66) Partially in but more out than in (0.33) Fully out (0)

Individual NHS organisation case membership assignments are conducted for both the outcome and the condition sets. Once assignment is allocated, QCA analysis is undertaken using software that will explore the individual case configurations for patterns of necessary and sufficient conditions using Boolean algebra or fuzzy set algorithms. Following initial single condition analysis, the process of minimisation is undertaken to reduce complex formula into a minimal formula that is sufficient for the outcome. Three types of solution formula are presented by the software. The complex solution where no logical remainders are used. An intermediate solution where plausible logical remainders are selectively used to derive the solution formula. Last, the parsimonious solution formula that includes automatically are logical remainders. The method provides checks that determine case coverage and the consistency of the empirical data within the sets and subset relationships. Appendix 2.1. outlines a typical QCA procedure step by step.

Applications of QCA are explored through a review of applications of QCA in healthcare in Chapter 5. Critique and limitations of QCA are discussed in Chapters 5, 7 and 8.

Chapter 3: Complexity Theory for social systems

"In a complex universe, intervention A does not predictably lead to outcome B. Stuff happens. Things get in the way. Something we could not have predicted pops up—and gives an initiative a boost. A key person leaves the organisation—and a crucial project grinds to a halt. A new government is voted in—and fiscal incentives are soon re-jigged in a way that renders a carefully-crafted strategic plan obsolete. Two people meet in a training course—and a collaboration is born."

(Greenhalgh et al 2017, p. V)

3.1 Introduction

Complexity Theory developed from systems science for both natural and social sciences and involves biological systems, large ecosystems, artificial intelligence (cybernetics) and information and communication systems, economics and organisational systems, and other social systems and structures. This theory evolved from developments in the fields of systems science and cybernetics from the 1950's (Chandler et al 2016, see appendix 3.1). It seeks to explain complex phenomena (spread of infectious diseases, climate and weather patterns) by understanding the nature and function of the 'whole' system. Complexity Theory seeks to explain large-scale phenomena as emergent from micro phenomena. A longstanding interest in this theory has led me to consider its use within healthcare, specifically within the area of implementation research.

Since seminal papers in the *British Medical Journal* (*BMJ*) in 2001 (Pslek and Greenhalgh 2001, Pslek and Wilson 2001, Wilson and Holt 2001, Fraser and Greenhalgh 2001), many authors have applied Complexity Theory within their healthcare domains of interest (e.g. Westhorp 2012, Kernick and Mitchell 2010, Leykum 2007, Litaker et al 2006). Thompson and colleagues (2016) concluded in their review of Complexity Theory use in health services research that conceptual confusion arises because authors define their own terms for use within their context although certain characteristics, such as emergence, are consistent. Therefore, the health research discipline needs greater consistency when applying Complexity Theory. This includes the need for more Complexity Theory consistent approaches that systematically address research design, data collection and analysis (Thompson 2016, Westhorp 2012). Therefore, my first step was to systematically derive Complexity Theory concepts for application within the health implementation research context. I undertook this by developing a conceptual framework that draws on simplified Complex Adaptive System concepts for social systems.

Given the scale and breadth of Complexity Theory, this chapter will drill down to its application for implementation research and social healthcare systems and practice change. It will address the first thesis question:

Can Complexity Theory provide a better understanding and explanation of implementation of evidence in healthcare systems?

3.2 Complexity Theory

This emergent paradigm (Braithwaite et al 2018) covers all disciplines in science. The term 'complexity' is often used to describe something that is messy, complicated or difficult to disentangle. However, Complexity Theory describes phenomena particularised around a set of core characteristics. A key characterisation of Complexity Theory for all systems is the capacity for *self-organising* which, as Kaufman (1995) argues, enabled life to emerge from earlier spontaneous emergence of chemicals reacting together. From the earliest form of life to the other end of human-created organisation, no single entity or individual has sole control, that is, no external designer. No one controls the internet, for example, which has emerged from technological advancement and human need to communicate. Tim Berner-Lees initiated the World Wide Web now evolved beyond this originator in unforeseen ways. Perpetual interaction of individual agents leads to greater system complexity and emergent phenomena (Johnson 2009). This is often cited as the system becoming 'greater than the sum of *its* parts'. Complexity Theory explains whole system behaviour, not the individual constituent parts, and is defined simply as '*the study of the phenomena which emerge from a collection of interacting objects*' (Johnson 2009, p. 1).

'Emergence', another core concept (Holland 2014), was described by Goldstein as "*the arising of novel and coherent structures, patterns and properties of self-organization in complex systems*" (Goldstein 1999, p. 49). It explains the evolutionary phenomenon that takes us from sub-atomic particles to human society (Gell-Man 1994). It is the dynamic and progressive evolution of structures that underpins concepts for applying Complexity Theory to physical structures (the snowflake, quantum mechanics), biological structures (plant and animal evolution, and termite behaviour, bird migrations, the biosphere) and social structures (economics, societies, traffic flows). Put at its simplest, *emergence* is when certain elements combine to create something else that is not present within the individual parts that created the combined structure, systems or behaviour. Therefore, disassembly and reassembly like a car is not possible. Interconnectivity between structures and systems is fundamental to making sense of Complexity Theory. Complexity Theory continues to evolve and develop to explain complex phenomena across multiple types of systems: physical, biological and social.

3.2.1 Types of complex systems

Definitions need to be specific to the context of the system (Mitchell 2011). However, there are general characterisations. Shared concepts across disciplines are self-organisation and emergence with adaptation leading to increased system complexity of structures that continually evolve (Mitchell 2011) into higher order structures or organisation. I address the appropriation of this theory to social systems because Complexity Theory and Chaos Theory (Gleick 1998) span different system types. Holland (2014) separates complex systems into two broad kinds of complexity: Complex Physical Systems (CPS) and Complex Adaptative Systems (CAS). Both types of systems display certain general properties of self-organising, forming collective patterns of behaviour and structure. Behaviour is not predictable and can either display large changes in response to small changes or 'fat-tailed' behaviour. This is where rare events (e.g. mass extinctions and market crashes) occur much more often than predicted by a normal (bell curve) distribution (Holland 2014). Collections of interacting agents result in diverse adaptive behaviour through learning. Non-linear and dynamic is a frequent complex system behaviour and development description. This is when feedback to a response is not in proportion, so 1:1, 2:2 (linear), but could be twice as much (or greater) or half as much (or less) (Hilborn 2000).

3.2.1.1 Complex physical systems (CPS)

CPS are the *sum of their parts* characterised by laws and simple rules that evolve complex phenomena. They are deterministic systems which can be fully described (Aron 2004). Fractal structures are formed by recurring patterns following 'simple rules'. These complex structures evolve patterns of 'self-similarity' at different scales (Gleick 1998). An example in health is the anatomical fractal, like structure of the blood circulatory system, which branches into further branches at smaller scales, like trees. Also, non-linear dynamics of deterministic systems applied to these physiological processes involve heart rate regulation with feedback to allow the heart to respond to changing conditions (Aron 2004). Heart rate responds to feedback as a system but does not adapt to something different or into a higher order structure. Non-linear dynamics of blood glucose and insulin regulation is another example of a complex physical system (Holt 2004). However, evolution of the heart is part of complex adaptive behaviour. Artificial intelligence and game theory exploit the 'simple' rules concept of CPS.

Some complexity theorists use the concept of ‘simple rules’ (CPS) by producing new rules to bring about change in health systems (Reed et al 2018, Kitson et al 2017). I see two problems with this idea. First, identifying or designing simple rules as one does in a game can lead to changes in behaviour, is a problem because higher order emergence and therefore complexity over time cannot be decomposed to its original rules (Chandler 2018). The second problem is the assumption that by defining these rules, it ensures the desired outcome occurs in an advanced complex structure. This is contradictory to the conceptual basis of emergent structures (Chandler 2018). However, Braithwaite and colleagues describe local complex health systems and individuals within them, who behave based on sets of internalised rules as;

> “...trying to improve health services and offering better care will usually be better achieved by working with rather than against the localised rules produced by, and which guide, the front lines of care. Running human systems like healthcare, on this analysis, should be more like tending to a forest than prescribing detailed software code.” (Braithwaite et al 2017, p. 25-26)

But they also suggest that for implementation to occur, the context “must be re-etched or re-inscribed such that its culture, politics, and characteristics are altered”, (Braithwaite et al 2018). This does suggest a conundrum for implementation practice and the wish to bring about change.

Discussions on appropriating Complexity Theory (both CPS and CAS) suggest that describing, managing and bringing about change in social systems, including healthcare systems, is problematic (Paley 2010, Pslek and Greenhalgh 2001). This is partly due to the conceptual misappropriation to health systems of CPS concepts, such as ‘strange attractor’ and ‘sensitivity to initial conditions’, which are attributed to the behaviour of CPS (Paley 2010). These concepts respectively describe system features that pull systems into certain recursive patterns, and *small* changes in original parameters that can result in disproportionate large system effects because the pathway is non-linear. Re-conceptualisation of these CPS characteristics for social systems uses positive attractors as features that could influence, for example, the trajectories of people with chronic conditions such as diabetes to improve their chronic disease management pathway (Byrne and Callaghan 2014).

3.2.1.2 Complex Adaptive Systems (CAS)

CAS agents learn and adapt when interacting with other agents (Holland 2014) and produce *something greater than the sum of their parts*. Further description defines a key aspect of

CAS as agents that organise a structure at one level which then become the agents for the next level: from chromosomes to organs, to organisms, to populations of organisms, for example. Holland (2014) refers to this layered emergent organisation as ‘hierarchical generative processes’, which are akin to generative mechanisms and structures described by others (Chapter 2, section 2.3.2). Similarly, social systems also mirror this organisation of complex structures in the behaviour of societies, cultures and human organisation. Thus, human-created structures and systems, such as economic and technological information systems, adapt through self-organisation and emerge into higher order structures (Mitchell 2011, Gell-Mann 1994). This includes the organisation of societies (Sawyer 2005) and social practices within societies (Castellani and Hafferty 2010).

Within social CAS, Byrne and Callaghan (2014) qualify the difference between ‘restricted complexity’ in CPS and ‘general complexity’ in CAS. Restricted complexity describes rule-based systems, whose complex structures are confined to a limited set of possible outcomes where the rules are identifiable and modifiable, although the eventual outcome is not a given (Holland 2000). General complexity refers to descriptions of the overall structure and behaviour of the CAS. This explains the adaptive evolution of the biological system (mammals, humans) that have a heart (CAS) rather than the self-regulatory behaviour of the heart (CPS).

Human-based healthcare systems organise and deliver care to patients through leaders, managers, clinicians, etc. However, we can also recognise that no individual leader or clinician has complete control of practice within their sphere of influence (Braithwaite et al 2017). Therefore, CAS needs specific application to social systems rather than biological Complex Adaptive Systems.

3.2.1.3 Social CAS

In social systems, human agency influences adaptive behaviour in social organisations on the one hand, but also follows collective emergent and adaptive behaviour ascribed to Complexity Theory on the other. I will now refer to *social* CAS throughout, specifically to distinguish between common patterns of behaviour across all types of systems and those that specifically characterise social systems. Importantly, although human intention is key to social system behaviour, individuals do not intend the overall design that eventually emerges (Sawyer 2005). Nevertheless, intentionality (goals, motivation and strategy) of human agents is crucial in applying Complexity Theory to social systems (Cilliers 1998). Social CASs comprise social agents that interact and communicate through conversations that organise social practices (Stacey 2003). These in turn form social structures and include discourse, codes and symbols, social institutions and nation states (Castellani and Hafferty 2010, Stacey 2003). From the initial interaction between human agents, emergent social activity and social structure creates a separate entity with its own powers beyond individual agents (Sawyer 2005). Sawyer's 'Emergence Paradigm' states that his meta-theory does not preclude other lower level theories (Sawyer 2005) to explain specific behaviours at lower theoretical levels (Noyes et al 2016). However, social CAS theory can provide an overarching explanation that can encompass more specific and middle-range theories (Greenhalgh et al 2010). In other words, it is a general theory that does not predict the actual emergent pattern of a specific social behaviour (Cilliers 1998). Multiple system levels need a layering of theories to provide appropriate explanations (Westhorp 2012).

To explain success or failure of implementation activity, we need theory to address the self-organising, adaptive and emergent properties of health systems. This involves human agency of healthcare professionals responsible for deciding on healthcare organisation and delivery.

3.3 Complexity Theory and implementation research

Medical Research Council (UK) (2014) guidance on process evaluation of complex interventions suggests Complexity Theory's potential for application. Process data capture of feedback loops can allow investigation of complex causal pathways within the context of implementation of the intervention. However, this requires examples (Moore et al 2014). The intention of my research is to help fill this gap by providing a practical example of conceptualising social CAS for implementation research. Authors use different forms of Complexity Theory interchangeably to describe social healthcare systems. I explicitly differentiate between CPS, CAS and social CAS. I use the collective term Complexity Theory where relevant. Further differentiation is provided in the following sections between appropriation to healthcare generally and to implementation research; the focus of the thesis.

3.3.1 Complexity Theory usage in healthcare

There are many studies that highlight the complexity of healthcare systems, including multiple agents and contexts (Vos 2011, Evenson et al 2010, Dobbins et al 2009, Flanaghan et al 2009, Kontos et a 2009, Chenot et al 2008, Kirsch et al 2008, Stetler et al 2008), and how these are navigated in implementation research (Garliardi et al 2012, Kennedy et al 2012, Van Dijk et al 2011, Bowman et al 2008, Kilborne et al 2007). Complexity Theory has been used as an interpretative lens in implementation studies (Mowles 2014, Simpson et al 2013, Trenholm and Ferlie 2013) and to build frameworks for knowledge utilisation (Kitson et al 2017). In healthcare generally, Complexity Theory also applies to human anatomy and physiology, for example as it explains the self-regulation of glycaemic control in diabetes (Cooper and Geyer 2009, Holt 2004).

Some examples employ specific complexity-orientated approaches to evaluate Complex Adaptive Systems. Braithwaite et al (2017) and Vandenbroucke et al (2007) develop causal loop diagrams to illustrate both complexity and non-linearity of system behaviour. These diagrams expose causally complex relationships and interconnections between different aspects of the system influencing a problem or issue. Causal loop diagrams describe *post hoc* causal interconnections between different variables to create an overarching narrative (Kim 1992). Further examples have presented patient flows in a whole health system in primary, secondary and emergency care (Braithwaite et al 2017) and tackling obesity (Vandenbroucke et al 2007). Although Vandenbroucke and colleagues adopt a simplistic view of a system rather than a CAS perspective, the causal loop diagram tool, nevertheless, illustrates the complexity described by many in healthcare.

A recent scoping review (Thompson et al 2016) exploring the use of Complexity Theory in health from database inception to January 2015 identified 44 studies – 27 qualitative, 14 quantitative and three mixed methods – and found that “conceptual confusion and inconsistent application hinders the operationalisation of this potentially important perspective” (Thompson et al 2016 p.14). In addition, there is a need for applications of social CAS that move from using Complexity Theory concepts as an interpretative lens or metaphor (Thompson 2016, Chandler et al 2016, Westhorp 2012) towards research designed to explain complex system behaviour. Development in the field needs conceptual consistency and more examples of application (Brainard and Hunter 2016).

I have contributed to this gap by undertaking a systematic synthesis of complexity concepts for social systems, from which, I created a simplified set for integration with a synthesis of implementation concepts. Application as an explanatory framework operationalised through Qualitative Comparative Analysis (QCA) methodology follows in Chapters 6 and 7.

3.3.2 Complexity Theory use in implementation research

As implementation models, theories and frameworks have developed over time (see Chapter 4), there has emerged an increasing focus on the influence of individual behaviour (Atkins et al 2017), importance of micro-system management (May et al 2007, 2006) and the influence of the implementation context or system (Pfadenhauer et al 2017, Rohwer et al 2017, May et al 2016). Several examples of explicit application of Complexity Theory to the implementation field have been developed recently, for example, Braithwaite et al 2018 and Reed et al 2018. Braithwaite and colleagues (2018) align with key complexity concepts of self-organisation, adaption, feedback, path dependence, agency, perturbation and tipping points (phase transition) applied to two case studies. Authors draw from a body of work that underpins “Complexity Science for health systems” (Braithwaite et al 2017). This comprehensive work builds on Braithwaite’s previous work on health systems. My approach to social CAS conceptual development explicitly focused on seminal works within the social science application of Complexity Theory, which builds on the work of original complexity theorists e.g. Gell-Mann (1994). I describe my systematic approach to concept development in the following section.

3.4 Simplified Complexity Theory concepts for social systems in healthcare

Social Complexity has developed in different directions with explanations from different sociological standpoints. Although multiple examples of Complexity Theory use in healthcare are available, there is a need for more consistent description and better reporting of theory operationalisation (Thompson 2016). I present only a summary of my own work on simplified Complexity Theory conceptual development in the following sections because it is published in the *Journal of Advanced Nursing* (Chandler et al 2016, https://doi.org/10.1111/jan.12815), and therefore I do not fully reproduce this work here.

3.4.1 Forming simplified social Complex Adaptive System concepts

I examined the work of key social Complexity Theorists to derive simplified concepts that could account for the social world and human agency within a Complexity Theory informed framework for implementation.

3.4.2 Aim

To construct a set of simplified social CAS concepts to build a conceptual framework to explain processes that do or do not lead to successful implementation of evidence-based guidance to change clinical practice (fasting before surgery).

3.4.3 Methods

I had a degree of familiarity with the evolving Complexity Theory literature from attendance at conferences and an email list of primary healthcare researchers. From this starting point I purposively selected texts that spanned theoretical development and application from the late 1990’s to 2013, covering fields of sociology, management studies and healthcare. These texts adopt different conceptual stances. However, the purpose was to abstract common concepts both relevant to social systems as well as fit within the ‘background’ of Complexity Theory. The authors of these selected texts have a common base of citations to well-established Complexity Theorists such as I Prigogine, M Reed and D L Harvey, S Kaufman, J Holland, N Luhmann, M Waldrop, R Lewin, R Axelrod and M Gell-Mann. Therefore, to adopt a practical approach, I identified a representative selection of works that covered social and health complexity theory perspectives.

I undertook across-text comparison using annotation of these purposively selected texts and extracted core concepts and developed themes to arrive at the final simplified concepts. Appendices 3.2 and 3.3 provide details on extraction, simplification and development of final concepts.

To test the applicability of these high-level concepts they were applied post hoc to the POISE implementation trial process evaluation findings as an interpretative theoretical lens (Chandler et al 2016). This original study (Rycroft-Malone et al 2013) evaluated three implementation strategies in 19 NHS organisations (Chapter 1, section 1.5.2). Study process evaluation findings were grouped into summaries (Chandler et al 2016). Three overarching macrosystem topic areas were identified through a thematic analysis and categorisation of the process findings from the study report (Rycroft-Malone et al 2010). These were then viewed through the lens of the simplified constructed concepts.

3.4.4 Findings

Five simplified social CAS concepts were constructed from the reduction of each theorist's perspective which, although seemingly different, nevertheless referred collectively to the conceptual phenomena: *Interaction, Self-organisation, Emergence, History* and *Temporality* (Chandler et al 2016). These five concepts are elaborated in Table 3.4.4., Appendix 3.4. provides the fuller summary.

Table 3.4.4. Summary of the five simplified concepts for Complexity Theory as applied to social systems (adapted from Chandler et al 2016)

CT simplified concept	Abbreviated elaboration
Self-organisation	Self-organisation describes how systems evolve without an 'external controller' and organises from within itself in response to its external environment, making decisions that lead to adaptation. Smaller complex systems nest in larger systems in which they interact and respond to the influence of the behaviour of either the larger or smaller system.
Interaction	Interaction in a complex system is the bidirectional transfer (feedback) of information from one decision-making agent (individual human) to another and represents the inter-play of micro-agency at varying levels within a social system. This interplay of information transfer is either enhanced, suppressed or

	altered leading to effects on the system. These interactions will be non-linear (asymmetric) and, paradoxically, large changes can have a small effect, whereas small changes can have a large effect. In human systems communication through language and behaviour of human individuals is the principle structure of social interactions and organisation of social systems. However, human systems have broadened this to include technological and automated interfaces.
Emergence	Through interaction and self-organisation of the system in response to environmental stimuli and internal requirements to maintain the system, constant adaptation results through the characteristic of emergence. The phenomenon of emergence leads to greater system complexity that is not equal to the systems' constituent parts. Also, organisation such as social structures and systems result in multiple hierarchical structures. Individuals do not have a complete schema of the 'whole' system of which they are a part because system information is 'distributed' among the individuals. It is not possible to dismantle the emergent property into its constituent parts.
System history	System history maintains that although the system continually transforms overtime, its origins suggest a 'boundary' within which the system responds, maintaining an adherence to trace 'behaviours'' (Cilliers 1998), such as 'habits'. This could involve in social systems' organisational culture as an evolving history that presents a boundary in which the system will behave.
Temporality	Complex systems are always in a constant state of flux between stable and unstable system states. With emergence and transformation of the system comes increasing complexity and reactivity through feedback processes over time, hence the importance of temporality. Systems also have periods of 'stability' and create stable structures. This is logically obvious within social structures. Social systems could follow certain trajectories based on decisions made and are not pre-determined.

Application of the five social CAS concepts were applied following a sift of the process evaluation findings to a core set of process evaluation themes (Box 3.4.4).

Box 3.4.4 Process evaluation themes

1. The impact of system factors to limit (inhibit) the evaluation and implementation of the proposed guideline recommendations.
2. The impact of communication and interaction between individuals, teams, departments and professions on the evaluation and implementation of the proposed guideline recommendations.
3. The impact of the longevity of the history of traditional fasting practice in the face of accepted credible evidence to change the practice. (Chandler et al, 2016)

The conclusion from this initial interpretative exercise suggested that a move to an individualised fasting regime was reliant on the role of decision-making individuals and system 'habits' to adhere to the current practice of blanket fasting. Blanket fasting refers to the practice where all patients were fasted from the same time irrespective of where they were on the operating list.

It is noted that David Byrne, a key exponent of Complexity Theory for the social sciences, in his earlier work in 1998, did not refer to either of the five other sources I identified in 2013. However, in subsequent work (Byrne and Callaghan 2014), he has provided critique and cites all sources I have used. This coalescence suggests a core body of work building within the field of Complexity Theory for social systems.

3.4.4.1 Interpretation

My interpretation from this initial work of developing simplified social CAS concepts for the implementation context indicates the need to understand the practice context, its history and its rationale for initial development, as well as the multiple influences between the local actors and their environment (May 2016). Similarly, it is important to understand the limits on successful change management within the individual NHS organisations. There is an inherent paradox when making changes to social systems (Chandler 2018). On the one hand, we know that we can change systems and 'make things happen' but on the other hand, it is problematic to consider we have complete control. This is especially an issue for implementation research, which implies bringing about change in health systems.

3.5 Two additional concepts

Following the development of these social CAS concepts, I introduce two further concepts. I utilised these in the development of the social CAS for implementation research conceptual framework (Chapter 4) and in the QCA study (Chapters 6 and 7). The first is my conceptualisation of an ‘organising principle’ which drives the care practice system and presents the rationale for its origin and continuation. Second, complexity theorists use the term ‘phase transition’ to describe system response to changes in system parameters. I explain my rationale for introducing these additional concepts following this first conceptual development and their utility to implementation research.

After making my conceptualisation of an ‘organising principle’, I later noted its use elsewhere by complexity theorist, Strumberg (Strumberg et al 2016). To clarify and reduce confusion, he uses the same term to explain that the health system should place the health of the individual at the centre of how it *should* organise. In other words, he argues for a patient-centric healthcare organisation as opposed to the current dominant disease model. Although this suggests shifting the system driver, my adoption of the term is markedly different in emphasis and use.

3.5.1 The organising principle hypothesis

In drawing on the Complexity Theory concepts for social systems, a basic starting point is to assume that if all states of both living and nonliving systems are perpetually changing their system state (over short to medium and very long timescales), and that if, over time, they retain parts of their original state, parts of a changed emergent state and parts of the current state under observation, they are liable to change to a new state in time. Therefore, this observation suggests an underlying principle that considers that all system states continually *organise* as they move from one state to another. Self-organisation specifically attends to the notion of the system organising from within itself without external control. The *organising principle* focuses on trying to define the system’s organising patterns, rules, key determinants or rationale. The social CAS are both dynamic and stable with aspects of structural stability reproducible over time (Byrne and Callaghan 2014), although also liable to change over variable time spans. The purpose is to ascertain the organising components of the system at a point in time and describe how the systems parameters lead to stable structures, such as social healthcare practices. For example, a simple healthcare intervention, hand hygiene to prevent infection, commenced when Semmelweis identified the aetiology of puerperal sepsis in 1847. This was cause by doctors not washing their hands between visiting the morgue and performing examinations on pregnant women. This was before the role of bacteria was proved and before the later pursuit of antisepsis was pushed in hospitals by Joseph Lister (Loudon 2013). Major developments over the years include producing guidelines in the 1980’s and introducing antiseptic alcohol-based hand rubs (ABHR) in the early 2000’s (WHO 2009). However, ensuring absolute compliance amongst health workers remains a concern (Gould et al 2017, Chatfield et al 2017). So, what compelling and over-riding factors in the clinical environment interfere with habituating compliance? What aspects of practice are resistant to change? Is this resistance caused by other systems of practice and care overriding hand hygiene? Is it just laziness? I suggest that healthcare workers operate in complex contexts managing multiple tasks simultaneously across multiple systems of care and other practice imperatives, which can interfere with basic practices, such as handwashing.

There are, of course, imperatives to change practice (Sarkies et al 2017). However, the problem arises when the current system imperative is either not obvious or it is misunderstood. This then presents problems with changes to practice or acceptance of new practices (May 2007). Perspectives on change include the challenge to tackle habitual behaviour (Nilsen, 2012) and the 'normalisation' of new behaviour or practice change into practice (May 2009, 2006).

I am suggesting the *organising principle* of different healthcare practice systems occurs to meet certain imperatives, and therefore change is difficult if it undermines the imperative. Whilst clinicians in 1847 were ignorant of the impact of their behaviour, lack of education on hygiene can no longer be the case.

3.5.1.1 Implementation and the 'organising principle'

The POISE implementation trial identified barriers and facilitators to changing practice. These included unclear professional authority for fasting practice and lack of resources to make the necessary changes to both policy and practice (Rycroft-Malone et al 2013). However, further thematic analysis suggested that the management of the operating list was a key aspect in maintaining the current prolonged fasting duration status quo (Chandler et al 2016). Assessments of the context or setting before implementation of an intervention are well established within implementation research (Greenhalgh et al 2017, May 2016, Rycroft-Malone et al 2013, 2009, Damschroeder 2009, Kitson et al 2008, Greenhalgh et al 2004, Kitson et al 1998). This includes assessment of multiple factors (e.g. culture, leadership, individual belief and behaviour, resources and capacity) to fit the intervention into the healthcare context. This inevitably mediates the intervention on its implementation (May 2016). A diagnostic exercise of the context was part of an implementation strategy evaluated in the POISE study. This strategy, a Plan Do Study Act (PDSA) quality improvement cycle, included a pre-intervention process mapping activity to identify improvement points modelled on the quality improvement practice at the time (NHS Institute for Innovation and Improvement 2005). I suggest a primary imperative can ensure maintenance of current practice, it is not just simply maintained due to habit.

To illustrate this point, I applied the *lens* of the simplified social CAS concepts (Table 3.4.4) to a systematic review (Gould et al 2017) and qualitative meta-summary (Chatfield et al 2017) on the effectiveness of handwashing, published separately in 2017. Both studies indicated ongoing problems with good hand hygiene behaviour to prevent hospital acquired infections. These two reviews provided quantitative outcome data and process information. I raise the following key methodological and interpretative points (see Appendix 3.5 for the case report):

- The studies indicate the ongoing struggle to achieve evidence that the system has changed or responded to a specific intervention.
- There is a continuous struggle for those reviewing primary studies of their methodological limitations and the inevitable limits to aggregating heterogeneous data.
- Both studies raised the issue of the need for theory to underpin the interventions and expected mechanisms, which is missing in many primary studies.
- The re-interpretation indicated other imperatives that overrode good practice in hand hygiene. Availability of alcohol hand rubs may provide some effect to ensure good hand hygiene. However, the reviews were uncertain in establishing a strategy that ensures hand hygiene compliance.

The assumption here is to recognise the ongoing state of a system's *organising principle* (a necessity or imperative) or rationale, and subsequently its reaction to intervention or perturbation impacts. The *organising principle* assumes that systems will seek energy efficiencies (short cuts) (Johnson 2011) to meet the imperatives that drive the system's behaviour. Therefore, logically, 'intervenors' or 'implementers' need to understand these imperatives and how to interact with them. The *organising principle* suggests that the outcome of interest and its influences (factors that affect it – to occur or not to occur) are part of a system. This system has an '*organising principle*' that defines its behaviour, development, adaption and likely response to any intervention. Although this might be a gross simplification, current implementation models and theories suggest an *organising principle* for healthcare systems by referring to drivers and incentives. This is discussed in detail in Chapter 4.

3.5.2 Phase transition (tipping points)

In the Complex Adaptive System literature, references to 'phase transition' explain changes to systems where some seemingly small change leads to a radical system change to a new state. Typically, a gradual build up occurs where the degree of change is not widespread, but then flips in a widespread non-linear and accelerated manner. Understanding this 'system change behaviour' would benefit implementation research.

In the physical sciences, phase transitions occur at a point when a small change made to a parameter (condition) leads to a rapid transition to an altered state. The classical example is the transition between the states, gas, solid and fluid, most notably water. The changing parameter is temperature, and between 99.9^{o}C and 100^{o}C water turns into steam (a gas) and below 0^{0}C into solid ice. This notion of phase transition is also applied to social system behaviour such as stock market crashes (Levy 2015). This behaviour occurs at a collective macroscopic level (whole system), not with single agents in the system (Prigogone 1997). Linear dose-response relationships are not observed at this macroscopic level (Hawe 2015). The term is popularised both in Complexity Theory (Gribben 2004, Prigogone 1997, Kaufman 1995) and Complexity Theory for social systems (Hawe 2015, Byrne and Callaghan 2014, Levy 2005, Johnson 2002). Both natural phase transitions and social phase transitions describe a rapid transition between a pre and post state, based on a small change in a parameter value. The input parameter is not proportional to the observed output. For example, one degree more heat from 99^{0}C to 100^{0}C turns liquid water to a gas (steam). However, we can see that the heat input has incrementally built up overtime. Methods for capturing these transitions in health or social systems are:

- Systematic reviews of interventions to conduct separate meta-analyses at different timepoints (Higgins et al 2019) to show change. Also, syntheses of qualitative studies of factors that enable or inhibit implementation of interventions or conduct of long-term longitudinal studies (Petticrew et al 2019).
- Mathematical modelling (Levy 2016), for a deterministic framework to model whether a social system has a propensity for phase transition. This assumes there is low heterogeneity amongst the agents involved in the system.
- INUS analysis in QCA to identify which "dynamical systems "tip" from one to another" (Befani 2016, p.141).

In order to find examples identifying 'phase transition' in implementation research, I undertook a simple search in databases MEDLINE (n=91), ASSIA (n=16) and Psychinfo (20) and only found chemical, molecular or biological examples. However, Befani (2016) suggests using QCA to identify retrospectively whether configurational patterns of causal factors change across cases to signal a transition to widespread implementation. I considered whether this phase transition behaviour was observable in the structure of the findings of the QCA study I conducted (Chapter 7).

3.6 Summary

I have set out to legitimise application of Complexity Theory to social systems and structures. These dynamic systems are punctuated with moments of stability, de-stability and phase transitions. This results in key changes and adaptations in the system (consider revolutions and major social changes that include the beginning of the NHS). Organisation is continuous but not linear. In explaining an underlying system *organising principle,* observations will consider how things interconnect within systems, why change occurs or does not occur and what are the motivators for doing so, given the overriding imperatives present. Braithwaite and colleagues provide a summary comparison between Complexity Theory and implementation science by making a fundamental point that interventions are entering into a system, “already teeming with activity and relationships, knowledge uptake is rarely simple or straight forward, and has to find a place in an intricate, pre-existing milieu.” (Braithwaite et al 2018, p. 7).

Chapter 4: Conceptual framework development

4.1 Introduction

In this chapter, I present a novel conceptual framework that integrates the simplified concepts for social Complex Adaptive Systems (CAS) (Chapter 3) with a synthesis of concepts extracted from implementation theories, models and frameworks. I reduce the multiplicity of the implementation theories, concepts and frameworks to their essential parts. From which led conceptual advancement (Ca mpbell et al 2011) and the production of a new framework providing a novel view of implementation theory through the lens of social CAS. Such systems are contingent on their context and temporally irreversible. Therefore, to address the thesis question – can Complexity Theory provide a better understanding and explanation of implementation of evidence in healthcare systems? – I used my novel conceptual framework to re-structure the extracted POISE implementation trial data in preparation for application in the Qualitative Comparative Analysis (QCA) study described (Chapters 6 and 7). It both provides an interpretative framework and forms concepts for utilisation in QCA methodology.

Box 4.1.1. Definitions for theory, model and framework

Theory: Analytical principles or statements designed to structure observation, understanding and explanation of the world (Nilsen 2015) are theories. They are made up of concepts that characterise a particular phenomenon and these concepts are mental images of phenomena and propositions which are statements about the concepts (Rycroft-Malone and Bucknall 2010). In addition, theories can be descriptive, explanatory or predictive. They describe or guide process and understand or explain influences or they evaluate at multiple levels of description (Noyes 2016, fig.1).

Model: A deliberate simplification of a phenomenon or a specific aspect of a phenomenon – models describe, theories explain (Nilsen 2015). The concepts within a model should be well-defined, and the relationships between them specific. Models are representations of the real thing; they attempt to objectify the concept they represent (Rycroft-Malone and Bucknall 2010). In summary, they are narrower in scope and more precise than a conceptual framework.

Framework: Denotes a structure, overview, outline, system or plan consisting of various descriptive categories, e.g. concepts, constructs, or variables and the relations between them (Nilsen, 2015). A conceptual framework is made up of sets of concepts and the propositions that integrate them into meaningful structure (Rycroft-Malone and Bucknall 2010). Moulin (2015) describes implementation and knowledge translation frameworks as covering concepts: the process (stages and steps), domains (groups or levels of influence) and factors: barriers, enablers and determinants of practice, strategies (approaches to address the factors and implement innovation) and evaluations.

4.1.1 Defining a framework

Given the evolution of implementation research, in order to provide a comprehensive base to the proposed conceptual framework, the search inclusion criteria covered ‘models’, ‘frameworks’ and ‘theories’. Box 4.1.1. elaborates the differences between model, theory and framework. Classification categories of implementation theories and frameworks are descriptive, explanatory or predictive (Nilsen 2015). Theories, models and frameworks can specify causal relationships and mechanisms of a phenomenon, as well as relations with other phenomenon (Rycroft- Malone and Bucknall 2010). Given the specific task of integration with the social CAS concepts, which specifically adopts micro to macro emergence, the proposed conceptual framework will fit the description for ‘framework’ outlined in Box 4.1.1. and seeks to be explanatory. However, further discussion in operationalising the framework through QCA methods may suggest predictive concepts.

4.2 Methods

Fig.4.2 provides an overview of the process undertaken to achieve the final conceptual framework. First, I undertook a systematic, yet pragmatic identification of examples of models, theories and frameworks for implementation. A took two-pronged approach and utilised work by key authors in implementation research (Nilsen 2015, Rycroft-Malone and Bucknall 2010) pre-2015, and a systematic search post-2015. I de-duplicated titles before selecting relevant works between the pre-2015 search and the post-2015 search results. I stopped selection of works when saturation reached the level of diversification of implementation concepts and single concepts. I undertook concept extraction in a final set of included studies. Second, I followed concept extraction with a theory synthesis that integrated these implementation concepts with the previous chapter’s simplified social Complex Adaptive System (CAS) concepts to construct the final conceptual framework for use in the QCA study.

Fig. 4.2. Overview of conceptual framework development

Search to identify implementation models, frameworks and theories

↓

Data extraction of key concepts from included implementation models, frameworks and theories

↓

Synthesis abstraction, combining and refinement of implementation concepts

↓

Juxtaposition of implementation concepts with social CAS concepts

↓

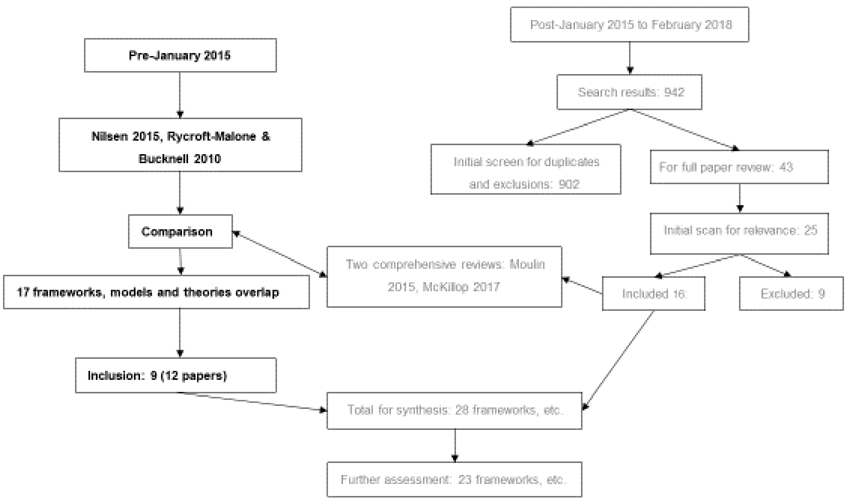
Development of a final integrated conceptual framework

4.2.1 Search approach

For the pre-2015 search I used Nilsen's (2015) work that categorised implementation theories and models etc. and used substantive summaries by others, e.g. Rycroft-Malone and Bucknall's book (2010) to create a list of works to review. Nilsen's (2015) review scope was broad and pragmatically inclusive, although not typically systematic or comprehensive. Works included were dated between 1975 and 2015. Nilsen's inclusion criteria looked for 'model', 'theory' and 'framework' within implementation science and evidence-based practice. He proposes five categories to classify models, theories and frameworks for implementation: process models, determinant frameworks, classic theories, implementation theories and evaluation frameworks. Those underlined fit the purpose of this conceptual development (Nilsen 2015, fig. 1, p. 4). Although I selected frameworks from Nilsen's other categories, those underlined described frameworks that provided understanding and explanation of implementation outcomes. These categories enable users to utilise the models, frameworks, etc., appropriately describing processes (how to), provide explanation (what is happening and why) and structures to evaluate implementation (Nilsen 2015). I used other sources, such as the work of Rycroft-Malone and Bucknall (2010). Their selection criteria included examples of models and frameworks used internationally, which were subjected to independent evaluation and worked across settings and disciplines.

Fig. 4.2.1 Pre-2015 search results and initially included implementation models and frameworks

*Post-January 2015 (greyed out)



4.2.1.1 Sources searched

I undertook searches in Medline, CINHAL (or Social Sciences Citation Index (Carroll 2013) and did a targeted search in the journal *Implementation Science.* PsycINFO was not available for me at the time of the search, although retrieval of records from CINHAL suggests duplicate record or retrieval from the PsycINFO database. Also, access to Embase was not available.

4.2.1.2 Search dates

The current search captured recent developments from January 2015 to February 2018.

4.2.1.3 Search strategy and terms

I used Booth and Carroll's (2015) method for developing a search strategy because it provided a systematic approach to searching for published frameworks, models or theories. Booth and Carroll's (2015) BeHEMoTh (Behaviour of interest, Health context, Exclusions, Models or Theories) search strategy is designed to identify multiple theories etc. These theories, models and frameworks explain how a complex intervention expects to work on implementation and following interpretation (Booth and Carroll 2015). This systematic approach ensures identification of most possible frameworks, models and theories to foster a comprehensive conceptualisation of new concepts or theories for testing.

Table 4.2.1.1 Search strategy terms

Strategy	Terms
Be-behaviour of Interest	Implementation of evidence based [practice, medicine, knowledge]
H- Health context	All clinical settings
E- Exclusions	-
MoTh – Models or theories	Model or theory or theories or framework or concept or conceptual

4.2.2 Data extraction

After screening of titles and reviewing of full reports, I extracted key implementation concepts. This extracted text was reduced to key elements or variables to form the core concepts for the proposed conceptual framework following Pound and Campbell's (2015) theory synthesis approach (see below for elaboration). It was premature to undertake the other option, a metatheory which compares, and weaves related theories of interest to form a whole theory (Pound and Campbell 2015). Theory synthesis evaluates concepts, propositions and models for similarity, convergence or divergence across different examples in order to form synthesised concepts for integration. Therefore, data extraction of included models and frameworks covered the following:

- Author & year (plus related articles viewed)
- Title of model, framework or theory
- Key objective and coverage – parts relevant to implementation and synthesis
- Development/evaluation (empirical, conceptual analysis, construct development, formal evaluations, extensive usage)
- Purpose or function: predictive, explanatory or descriptive (Nilsen/Rycroft-Malone and Bucknall)
- Abstraction of key theoretical assumptions, propositions or underlying theory used (e.g. classical) (how is the underlying function of the concept expected to operate – its causal assumption)
- Key domains, concepts, constructs etc.

4.2.3 Abstraction and synthesis of concepts

I followed Pound and Campbell's (2015), three-stage theory synthesis method based on the work of Turner's (1991) meta-theorising for sociological theories. Pound and Campbell's (2015) theory synthesis approach allows across theory comparison and breakdown of theoretical and conceptual abstracts for reformation and transformation from their original context, while keeping the essential conceptual meaning. This occurs where there is conceptual convergence and potential for combining concepts. Concepts can both link and cluster. Abstraction of concepts is selective for the new purpose or theoretical question. The researcher should transparently determine the balance between diverse and common aspects across all theories and models included. Also, one should note that abstraction removes the constructs from their context (Pound and Campbell 2015). This process involves several stages.

Stage 1: Synthesis preparation

Following identification of suitable theories, extraction of what is useful, plausible and relevant to the purpose of the current synthesis was undertaken. Section 4.2.2 sets out the material extracted from each article reporting an implementation theory, model or framework in healthcare.

Stage 2: Synthesis

The synthesis step enables theories to become comparable by breaking them down into "simple propositions and rendering them abstract" (Pound and Campbell 2015, p. 61). The synthesis compared these abstractions for divergence and convergence with the social CAS concepts.

Stage 3: Synthesis refinement

The process of synthesis refinement is to create an applicable novel theory appropriate to the context of the secondary purpose. In this case, the purpose is to examine and refine the implementation concepts for integration with the simplified concepts for social CAS.

Following the synthesis of implementation models and frameworks, abstracted core elements were integrated (matched), where appropriate, with the social CAS concepts in a mapping of concepts in a tabular format. This involved identifying which theories covered social CAS concepts and mapping of the individual concept elements from the different implementation theories, etc. to the social CAS concepts.

4.2.4 Juxtaposing concepts of implementation and social Complex Adaptive Systems

Finally, drawing from the integration of the concepts, I conceptualised how they fitted together in a framework, and undertook further refinement. I juxtaposed implementation concepts with the social CAS concepts (Chapter 3). This involved interrogating and sense testing my abstraction and inclusion of concepts. Concepts were examined for convergence or whether they diverged to a degree to be incompatible, but also whether ‘both and’ was more appropriate than ‘either or’ decisions leading to discarding concepts.

4.3 Search results

A flow diagram at Fig. 4.3.2 shows results by source and final numbers following removal of duplicates. Initial screening included any paper providing a conceptual development, whether covering the whole process of implementation or presenting singular concepts, such as leadership and fidelity. I also retrieved and screened a set of conference abstracts from the Proceedings of the 9th Annual Conference on the Science of Dissemination and Implementation (2017) from *Implementation Science.* This was the latest available set of abstract proceedings available to check for subsequent publications. I identified seven relevant conference reports. Search for relevant papers retrieved one published paper and two slide sets. I also retrieved two related papers cited by conference authors. 43 full paper reviews resulted in further exclusions, leaving 25 papers in total. Of these 25, two were protocols, nine research articles, eight descriptive papers and five reviews, which included references to work prior to January 2015. The five reviews of implementation models and theories had multiple overlapping citations. I reviewed these 25 papers and reduced them to16 papers and provide rationales for their inclusion (N=16) and exclusion (N=9) (see Appendices 4.1 and 4.2). Those excluded were either beyond the scope of this review or they significantly overlapped with an included article (Schoville 2015) or were specific to a certain sector (Hojberg 2018).

4.3.1 Exclusions post-January 2015

Many articles excluded at abstract and title screening were multiple examples of application of popular frameworks: Knowledge to Action (n=10), Promoting Action in Research Implementation in Health Services (PARIHS) (n=24), Consolidated Framework for Implementation Research (CFIR) (n=26), CFIR for chronic care model (n=22) and Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) (n=71). Therefore, selection included only articles reporting the original framework (or latest version).

Regarding other exclusions, six articles were developments for implementation measurement. 50 articles were examples of implementation frameworks or models for specific areas of care or disease, and therefore not relevant. Other exclusions included those not covering healthcare and healthcare settings, and those that were evaluating implementation strategies or implementation generally.

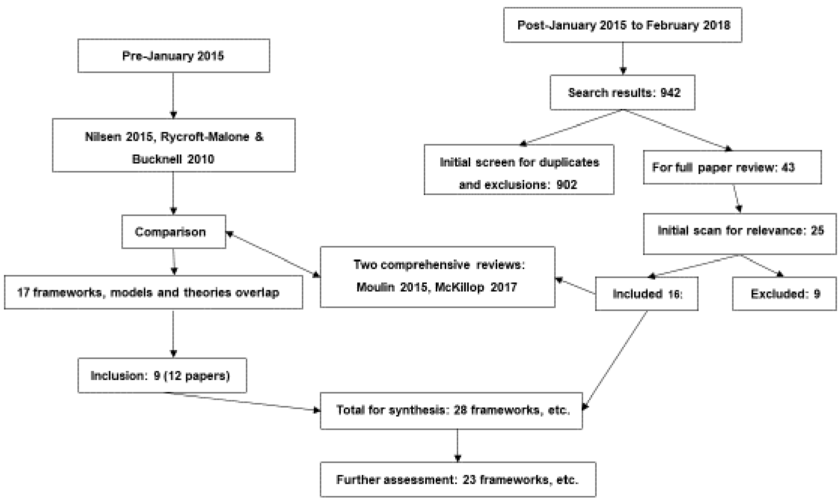
4.3.2 Selection of included studies

The selection of studies included the 16 included in the post-January 2015 search with those from the pre-2015 work of Nilsen (2015), and Rycroft-Malone and Bucknall (2010). Nilsen identified 44 different theories, models and frameworks (including a range of classical theories not specific to implementation). Two reviews from the current search conducted extensive literature searches, McKillop 2017 and Moullin 2015. I undertook a comparison across these four works to identify relevant works possibly missing from the current search from January 2015. These initial four references are summarised at Appendix 4.3. Seventeen conceptual model/framework/theory overlaps occurred between Nilsen (2015), Rycroft-Malone and Bucknall (2010), Moullin (2015) and articles found in the current post-January 2015 search. Six of the 35 reviews identified by McKillop also overlap with these other key summaries. Therefore, those selected were important works identified before 2015 and they overlapped with reviews that retain currency and remain active, e.g. PARIHS. Therefore, 16 papers identified in the post-January 2015 search were added to 12 additional papers obtained to cover nine frameworks identified in the pre-2015 review. These 28 papers reported 23 implementation frameworks and models etc. These are listed below. Subsequently, I identified additional primary papers reporting the model, framework or theory.

1. Normalisation Process Theory in common use (key papers: May 2009, Murray 2010).
2. General Theory of Implementation (May 2013 – first theory of implementation)
3. Implementation, Context and Complexity (May 2016 – relevant conceptualisation to current conceptual framework)
4. PARIHS in common use (key papers: Kitson 2008, Rycroft-Malone 2004, 2002)
5. RE-AIM in common use (Glasgow 1999)
6. CFIR in common use (Damschroder 2009)
7. Knowledge to Action in common use (Graham and Tetroe 2010)
8. Diffusion model (Greenhalgh, 2004 seminal work)
9. COM-B and Behaviour Wheel with the Theoretical Domains Framework in common use (Michie 2011).

I undertook a final sift of these 28 papers selected for data extraction. On further reading I gained a better understanding of the framing of key concepts and their underlying theoretical premise (explicit or implicit). Also, those best articulated in a short-abstracted paragraph were often later developments or connected to a body of work. This further sift resulted in 23 relevant separate models, theories or frameworks for full data extraction. This final selection of theories, models and frameworks for inclusion provided novel or specific concepts, overarching broad frameworks or models that encapsulated multiple aspects and provided extractable theoretical premises for the concepts. Fig. 4.3.2. summarises the flow of articles identified and selected for inclusion in the synthesis.

Fig. 4.3.2. Flow chart of search results and final included implementation theories, frameworks and models for synthesis



A summary list of the 23 separate frameworks and theories etc. covered by 35 articles are listed in Table 4.3.3. Appendix 4.4. contains full details of these 23 frameworks. Additional articles are cited and obtained as necessary to provide further detail and clarification of the authors' work.

Table 4.3.2. List of included frameworks

Model, framework or theory title or brief description	Author and year
1. Context and Implementation of Complex Interventions (CICI) framework	Pfadenhauer 2017 Rohwer 2017
2. Knowledge translation framework on aging and health	Ellen 2017
3. Model for understanding success in quality	Kaplan 2018
4. $R=MC^2$	Scaccia 2015
5. Informal advice seeking relationships	Dearing 2017
6. Model of implementation strategy design	Sarkies 2017
7. Definition of sustainability	Moore 2017
8. Conceptual model for considering the determinants of diffusion, dissemination and sustainability of innovations in health service delivery and organisation	Greenhalgh 2004
9. Non-adoption, Abandonment, and Challenges to the Scale up, Spread and Sustainability of Health and Care technologies (NASSS)	Greenhalgh 2017
10. iLead-transformational leadership intervention for implementation leadership training of healthcare managers	Richter 2016
11. Leadership and Organisational Change for Implementation (LOCI)	Aarons 2017
12. Exploration, Adoption/Preparation, Implementation, Sustainment (EPIS)	Aarons 2011

13. Leadership-climate relationship as a mechanism of the implementation of cultural competence	Guerrero 2017
14. Refinement to the National Implementation Research Network frameworks for application in diverse endeavours	Bertram 2015
15. Reach, Efficacy, Adoption, Implementation, Maintenance, RE-AIM	Glasgow 1999
16. Prompting Action on Research Implementation in Health Services PARIHS	Rycroft-Malone 2010, 2013 Kitson 1998, 2008 Harvey and KLitson 2015 (i-PARIHS)
17. Consolidated Framework for Implementation Research (CFIR)	Damschroeder 2009
18. A Generic Implementation Framework	Moullin 2015
19. Understanding the attributes of implementation frameworks	McKillop 2017
20. Normalisation Process Model (NPM)	May 2006 (2007)
21. A general theory of implementation	May 2013
22. Implementation, context and complexity	May 2016
23. Large programme of work to promote the influence of psychological theories to understand human behaviour change in the implementation of evidence-based practice	Atkins 2017 Michie 2017 Michie 2011 Michie 2005

Rapid development in the last 10 years has produced a degree of duplication across these theories, models and frameworks. The synthesis aimed to abstract a broad range of concepts and theories to cover all aspects of implementation. This task was needed to best represent the evolving implementation field. It needed to balance manageable synthesis whilst ensuring a breadth of conceptual thinking before further refinement moved the concepts from their origins. Inevitably, some work was not included in this process. I used a guiding heuristic to cover different levels of conceptual abstraction from Nilsen (2015) to ensure all levels of abstraction were covered as shown in Table 4.3.3. below.

Table 4.3.3. Implementation frameworks and theories conceptual levels

Level	Elaboration	Examples
High level	General, broadly across interventions and innovations or knowledge utilisation with a high-level abstraction.	Generic Implementation Framework, (Moullin 2015) General Theory of Implementation (May 2013) McKillop (2017) meta-narrative review, Diffusion model (Greenhalgh 2004), Normalisation Process theory (May 2009)
Medium level	Overarching multi-component frameworks and models.	CFIR（Damschroder 2009), RE-AIM (Glasgow 1999), COM-B and Behaviour Wheel and theoretical Domains Framework (Michie 2017, 2011, 2005).
Low level	Addressing specific aspects of implementation, e.g. fidelity, sustainability and leadership.	CICI (Pfadenhauer 2017)

4.3.3 Description of included studies

The 23 models, frameworks and theories provided a range of descriptive, explanatory and predictive theories. Six were identified as predictive and 14 as descriptive. Explanatory overlapped with both descriptive and predictive frameworks etc. with only one identified as explanatory alone. Approaches undertaken to develop these models and theories included:

- literature searches (systematic, selective, snowballing or purposively working from previous work);
- personal experience and;
- conduct of empirical studies.

Methods for development included:

- surveys;
- expert panels and consensus techniques;
- comparison with other well-known frameworks or theories;
- development from originators experience in the field; or used
- meta-narrative mapping techniques, narrative and framework synthesis, concept development and grounded theory development.

Following initial extraction, I removed two papers as a degree of saturation was reached and they did not provide further explication. These were Moore (2015) and McWilliam (2016). However, McWilliam's Triple P Implementation Framework for positive parenting programme has some key concepts that fit with the social CAS framework, 'minimal sufficiency' and 'self-regulation' and will be used in discussion of the framework.

Quality of reporting and development are not examined. However, multiple citations and applications show a degree of current credibility. Various updates do not seem to undo any original conceptualisations and often seek to broaden scope or include missing elements rather than subtract from the original concepts, e.g. PARIHS (Rycroft-Malone et al 2013, Harvey et al 2015).

I provide a brief summation as to what implementation involves:

- an event, action or system disruptor;
- the medium in which it occurs, such as climate, environment, context and setting, that in turn includes the wider context of political, legal or administrative systems;
- the object of implementation, e.g. innovation, intervention, programme;
- occurring through mechanisms, processes or steps, or strategies used.

Descriptions also involve defining the system state at the time of implementation (readiness, capacity, culture, resources) and the interaction between human agents: facilitators, leaders, champions and implementation recipients. Human behaviour and the complexities of changing human behaviour concepts are prominent at both delivery and receipt of the intervention.

Overall, implementation requires understanding of multiple factors that influence its execution and its realisation. Context was a persistent theme, fundamental to influence implementation and its success, which requires collaborative adaptation among individuals within the system to sustain innovation or practice change over time.

4.4 Theory synthesis findings

Appendix 4.5 presents a synthesis of the 23 included theories, models and frameworks and their core concepts. These implementation concepts were then mapped to the simplifying social CAS concepts in section 4.4.5. towards building the final framework. Due to saturation, 17 frameworks (Appendix 4.6) were retained throughout the following synthesis reduction.

4.4.1 Overview of key features across models, frameworks and theories

I summarised the key features of these 17 retained (Appendix 4.6) implementation models and frameworks, and the one retained theory (May 2013). Key areas, such as the importance of context, intervention or innovation attributes and behaviour of individuals, overlapped in multiple frameworks. Other key aspects conveyed were complex recursive processes operating within dynamic environments with multiple complex influences that inevitably moderate or hinder implementation as intended. Implementation strategies were key through proactive facilitation or leadership, for example. The state of the context or system prior to implementation was highlighted as an important implementation factor, as was its capacity and readiness to respond. Integration of the innovation, knowledge or intervention (implementation object) involves the task of normalising and making adaptions to local circumstances taking account of the continuity needed to embed it to ensure its sustainability. Similarly, it is important to take account of both benefits and potential harms or unintended consequences that may occur in implementation projects. Resources, creating the climate for change and providing clarity on expectations are key to success. The following themes highlight key aspects observed across this large body of work.

4.4.1.1 Linear vs non-linear

Comprehensive, wide ranging and overarching general frameworks, models and theories take a mechanistic, linear step-by-step approach which may require some iterative backwards and forwards through the process stages (e.g. Bertram 2015, Aarons 2011,) or they address the dynamic, non-linear impacts of the implementation context, environment or setting (e.g. Greenhalgh 2017). More sophisticated models are built up over time based on wide-ranging syntheses of theories and models etc. These move to a systems-based approach (e.g. Pfadenhauer 2017, Rohwer 2017, Moullin 2015, Damschroeder 2009) whereby one is interacting and causing an event that is disruptive to the system that has stable habitual embedded practices in place. The complexity and expectations of change needed for innovation implementation, includes its response to the context and the wider organisation, and individuals (deliverers and recipients). These elements will determine implementation success of the innovation (research evidence, guideline, technology, programme etc.) (Rycroft-Malone 2013, 2010, May 2013) and whether it is sustained over the longer term (Moore 2017, Greenhalgh 2004).

4.4.1.2 Complex vs complexity

The frequent use of the term complexity throughout these articles often describes complicatedness of implementation (as a multi-component requirement). Those specifically taking a Complexity Theory stance (e.g. Greenhalgh et al 2017) defined explicitly their understanding of complexity. Descriptions included level of difficulty, involvement of multiple factors and the act of implementation as complex (Kaplan 2018, Pfadenhauer 2017, Rycroft-Malone 2013, 2010 Damschroeder 2009). Others describe more the dynamic nature of systems that are not easily unpicked or manipulated to embed a new element within the system (Greenhalgh 2017, May 2013). System-influencing factors are well-described across the frameworks, although *context*, *setting* and *environment* is the same thing for some and distinctly different for others (Damschroeder 2009). Also, many give greater attention to innovation/intervention attributes, its complexity and whether it is implementable (Greenhalgh 2017, Pfadenhauer 2017). The included theories, models and frameworks cover individual human behaviour with varying degrees: their ability to communicate, interact, negotiate and exchange information and knowledge during implementation in each setting. This is specifically addressed by the work of Atkins and colleagues (2017) and Michie and colleagues (2017, 2011).

4.4.1.3 Capacity and resources

A strong, overarching emergent theme from the synthesis describes implementation as a set of social, interactive, multiplicative, dynamic and recursive processes needing transformational leadership (e.g. Aarons 2017, Richter 2016), resources and individual and organisational capacity (e.g. May 2007, 2006) clearly placed within both the multiple local and wider contextual influences (Ellen 2017, May 2016, Damschroeder 2009). Implementation climate, context, actors or agents, object of implementation, implementation leadership, process, steps and strategies are the central components needed to support implementation.

4.4.1.4 History and time

Authors articulate perspectives and components that involve interactive feedback loops, evolution and adaption over time (e.g. Kaplan 2018, Ellen 2017, Moore 2017, Scaccia 2015). The historical context of systems and current system status is interrupted and potentially disrupted by the implementation object.

4.4.1.5 Innovation assessment

Models and frameworks etc. articulate the need to assess the intervention, its characteristics, desirability or tension for change, its ability to intersect with different parts of the system and its evaluation in terms of workability and fidelity (e.g. Greenhalgh 2017, 2004). Purposeful facilitation of change or intervention introduction is viewed as key to successful implementation (Harvey et al 2018, Rycroft-Malone et al 2013, 2010). Also stressed was establishing the imperative and the willingness, capability and capacity of individuals and organisations to adopt the new practice or technology. This leads to the need to assess and manage behaviour change of both deliverers and recipients of the intervention and the behaviour change it hopes to achieve (e.g. Atkins 2017, Michie and Johnson 2017, 2011).

4.4.1.6 Managing whole systems

There are several models and frameworks with their respective lists of domains and diagrams which attempt to map the whole system of influences identified (e.g. Pfadenhauer 2017, Greenhalgh 2017, 2004, May 2016). This also includes notions of instability and system fluctuation. A key point is to understand and assess which complex intervention components work based on interactions and co-dependence between the individual components and the context. The individual healthcare professional, their cognitive and psychological behaviour and interactions and relationships with others, as well as their capacity, motivation and the opportunity to act, are central to the implementation process in healthcare systems (e.g. Atkins 2017, Michie and Johnson 2017). The status and capacity of organisations to respond and, more importantly, to continue to embed, normalise and sustain practice or technology (May 2007, 2006) needs continuing adaptation and evolution (Moore 2017). Many authors list the wider geopolitical and social forces that might impact and more specific mandated factors, e.g. regulation and policy instruments.

In sum, the breadth and ambition of implementation projects is to transform healthcare systems, practice and the behaviour of individual agents, both professionals and patients. This can include the whole health system from the macro-level of geopolitical and regulatory frameworks to the microsystem structures that deliver care directly to patients. The purpose here is to illustrate the application of Complexity Theory concepts (social Complex Adaptive System) to provide a better understanding and explanation of how implementation of evidence in healthcare systems functions.

4.4.1.7 Diagrammatic representations of implementation models and frameworks

One notable observation of the different frameworks is the overall visual structure of the diagrammatic representations of the framework or model. They can be very simple or quite complex, trying to convey all potential aspects of reality and inter-relationships within the implementation context. These diagrams show unidirectional, multidirectional, cyclic, layered or spiral designs. Substantive frameworks cover multiple attributes or concepts creating multi-layered structures. These show relationships between multiple different concepts that represent multiple agents and organisational levels, as well as the multiple influences for consideration within each context.

The rationale for making this point aids consideration of the diagrammatic representation of the final conceptual framework developed here. Greenhalgh et al (2017) use a spiral in their framework to represent non-static dynamic systems of continuous progress and change in adopting new technologies over time that inevitably require intended or unintended adaption. Similarly, Chandler et al (2016) tried to show 3D dynamics in 2D representation, the attributes of real systems that continuously feedback in progressive shifts of change and emergent structures over time. Although recursive and dynamic, with time added into the model, it is important to convey a forward motion of the system.

When considering cause and effect relationships, some of these models and frameworks attempt to diagrammatically convey multiple causal relations in complex arrangements occurring over time (Greenhalgh et al 2017, Greenhalgh et al 2004). Many authors attempt to convey all conceivable influences within implementation programmes such as Pfadenhauer et al's (2017) CICI framework diagrammatic representation and Moullin's (2015) Generic Implementation Framework diagram. Damschroeder et al's (2009) diagram tries to present a simplified diagram to convey inner and outer context and processes of continuous change throughout. Many models present lists or tables of elements of context/setting and structures, implementation procedures and the involvement of human agency. Tension between simplifying to essential elements while also incorporating all known influences for consideration is highlighted by authors' diagrams. Images of CAS per se present web or network structures with multiple directional connections between inter-acting agents, which leads to hierarchical structures to illustrate emergent behaviour evolving into macrostructures (Braithwaite et al 2017, Chandler et al 2016).

4.4.2 Harmonisation of concepts

Overall, given both sets of concepts (social CAS and implementation) related to individuals, structures and organisation from large scale macro-system levels to microsystem levels, the correspondence between concepts was close. I undertook the following steps to reach a final framework.

First, I conducted an initial comparison to identify common elements in the implementation models and frameworks etc. that harmonised with the social CAS concepts (Table 4.4.2.). This comparison involved 17 of the original 23 models and frameworks due to overlap and saturation. The original five conceptual social CAS concepts (Chandler et al 2016) are briefly defined (Chapter 3, Table 3.4.4.). Appendix 3.4 provides full definitions for concepts *interaction*, *self-organisation*, *emergence*, *history* and *temporality* with the addition of the System Organising Principle (Chapter 3, section 3.5.1). Convergence is strong with interaction and system history and modest with emergence, self-organisation and temporality. The concept that the system operates under an imperative was not identified in key implementation models, theories and frameworks, although referred to by Dearing et al 2017. Further detail drawn from seven models, frameworks and theory (Atkins 2017, McKillop 2017, Pfadenhauer 2017, Rohwer 2017,Greenhalgh 2017, 2004, May 2016, 2013, 2007, 2006, Harvey and Kitson 2015, Damschroeder 2009, , Rycroft-Malone 2013, 2010, Michie et al 2011, 2005, Kitson 2008, 1998, ,) comprehensively covered implementation rather than singular concepts. Appendix 4.7. provides an illustration of convergence for each social Complex Adaptive System concept using these examples. There is a degree of interpretation given the overview provided by the authors that their conceptualisation or assumption were translatable for the purpose of theory synthesis. For example, simply referring to interaction between agents is insufficient within the context of implementation healthcare. I re-defined the concept *interaction* to separate interaction (collective interaction between agents) and individual agent (behaviour within individual agent). Interaction is key to how humans organise and construct their world through language and other forms of organising communication. Equally, individual agents can have a powerful impact within systems.

Table 4.4.2. Selected implementation frameworks and models social CAS juxtaposed with abstracted implementation concepts

SELECTED EXAMPLES (N=16) Implementation framework, model, theory	SOCIAL CAS: INTERACTION Interplay of agents, actors, structures, levels, context, settings	SOCIAL CAS: SELF-ORGANISAT-ION How things evolve or change takes place, autonomous decision making, adaption	SOCIAL CAS: EMERGENCE Processes of change, action, causality	SOCIAL CAS: HISTORY Importance of prior context and behaviour, structure, beliefs, attitudes of agents/actors	SOCIAL CAS: TEMPO-RALITY Consequences and change with time as a core element, trajectories, expectations, outcomes (process, summative, modelling)	SOCIAL CAS: SYSTEM ORGANISING PRINCIPLE To identify the system's central organising rule, key determinant or pattern that is imperative for its existence, drivers, imperatives
1. Pfadenhauer 2017, 2015, Rohwer 2017	√	√		√	√	
2. Ellen 2017	√			√	√	

3. Kaplan 2018	√					
4. Scaccia 2015				√		
5. Dearing 2017	√	√				
6. Sarkies 2017				√		√
7. Moore 2017		√	√		√	
8. Greenhalgh 2017 and 2004	√		√	√	√	
9. Aarons 2017, Guerrero 2017, Richter 2016	√					
10. Bertram 2015 (includes Fixsen 2005)	√		√			
11. Glasgow 1999	√		√			
12. Harvey 2015, Rycroft-Malone 2013, 2010, Kitson 2008, 1998	√			√		
13. Damschroder 2009	√					
14. Moullin 2015	√				√	
15. McKillop 2017	√	√		√		
16. May 2016, 2013, 2007, 2006	√	√	√	√	√	
17. Atkins 2017, Michie 2011, 2005	√					

Taking account of the contribution made by the implementation frameworks and models, it was clear there were two additional domains of simplified social CAS concepts that were missing from those presented in Table 4.4.2. These were ‘individual’ separated from ‘interaction’ and ‘innovation or intervention’ referring to the implementation object or event. Appendix 4.8 maps key elements of the above 17 key frameworks to these seven social CAS domains. Key implementation elements are organised by individual agents or actors, implementation processes, context, drivers and the implementation object or event.

4.5 Final conceptual framework

The final framework starts from the thesis assumption that the implementation context for using evidence-based guidance involves human agency, their social processes and structures. These function under certain principles common to all human social systems. So, by extension, this includes the delivery of healthcare treatments and the function of health systems, either within a ‘unit’ (microsystem) or wider health system of multiple units and structures (macrosystem). The central idea is that microsystems evolve into macrosystems through processes of interaction, self-organisation and emergence. Therefore, delivery of care is interconnected between multiple activities dispersed throughout the system. Complex activities distributed throughout systems with multiple dependencies within a system, adapted over time, are difficult to change or disassemble and reassemble. Implementation models and frameworks are themselves becoming increasingly complex with multiple components and factors that need consideration for implementation practice. In summary, these include:

- The need for implementation theory to explain the implementation processes and mechanisms for successful implementation.
- The need for theory to explain the mechanisms of how the implementation object —- intervention, innovation guidance, knowledge etc. — is expected to perform in its target setting.
- Detailing the intervention characteristics and features and noting their complexity and if and how its multi-components are interdependent.
- The use of implementation strategies to facilitate the implementation process and implementation of the intervention etc.

- The importance of assessing the implications or impact of multiple confounding factors or extraneous factors on which successful implementation is dependent – the implementation context, setting and wider environmental, socio-economic and socio-political factors.
- The importance of understanding human behaviour for the individual and individuals working together and the specific factors within healthcare of professional boundaries, responsibilities and power (hierarchical) structures.
- Key themes are capacity, capability, motivation (drivers, imperatives etc.), resources, sustainability and the importance of leadership in implementation efforts.

4.5.1 Integration of social Complex Adaptive System and implementation concepts

The domains for the framework comprise five social CAS concepts (Chapter 3) plus additional domains (‘individual’ and ‘innovation’) for application to implementation research. The implementation concepts and factors are drawn from the works listed above and re-constituted here. The framework operates as an interconnected system, while allowing identification of aspects of the system.

4.5.1.1 Framework domains, concepts and factors

Each social CAS domain was assigned and matched with key implementation concepts and implementation factors.

Social CAS – Individual agent

Describes and explains individual human agency behaviour at the microsystem level.

Implementation concepts	Implementation factors
Leaders, champions, opinion leaders, change agents, targeted individuals (e.g. healthcare professionals, patients).	Individual skills, memory and attention Professional role and identity Beliefs Incentives Response to consequents, stresses Individual intentions and motivations Response to barriers, facilitators Response to social influences, norms, pressure Emotion reactions: anxiety, stress

	Ability to self-regulate behaviour

Social CAS – Interaction

Describes and explains the interactions of human agency collectives at the microsystem level.

Implementation concepts	**Implementation factors**
Implementation processes of interaction involve: • exploration, • making decisions to adopt, • planning and preparation, Implementation steps conducted within the specific setting, uses implementation strategies to encourage change and adaption to the innovation or practice. Interactions occur between individuals within teams, sub-units and at the clinical interface between multiple individuals. This involves exchanges and transfer of information, communications, care and treatments etc.	Collective human behaviour that presents opportunity and motivation. Collective capability (physical and psychological) that includes the collective capacity to have a shared understanding of the task and 'buy in' to work together with all individuals feeling involved and respected. The implementation task needs collective co-operation that brings sets of skills and clinical experience and knowledge operating at the local microsystem level. This involves both leadership and facilitation skills and capacity. This microsystem culture for effective implementation requires receptivity, trust, stability, shared vision and learning capacity to enable changes that might involve staff roles, practices and identities.

Social CAS – Self-organisation

Describes and explains the autonomy of organisation in social systems at the meso- to macro-levels.

Implementation concepts	**Implementation factors**
As above	Resources for implementation Strategies (push, pull, facilitation)

	Transformational leadership (active and shows cultural competence of the system) Leaders are engaged, committed, accountable The process of fostering adaption of interventions over time needs the scope for resilience to embed the desired innovation or change. Formal and informal networking between individuals is occurring all the time in established social networks within healthcare systems. These social health care networks are self-organising to respond to multiple change events, instruction etc.

Social CAS – Emergence

- Describes and explains the structures and behaviours that are created by the interactions and organisation of human agents

Implementation concepts	**Implementation factors**
As above	From the perspective that systems self-organise to meet their imperatives, emergent adaption occurs within systems that are incentivised and have scope to change. This involves collective, reflexive action. Accepting practice change involves multiple agents and multiple aspects of the system. This means we should take a distributed perspective. This distributed practice involves interactivity between agents to embed change (emergent practice) and underpins Social CAS as a concept.

Social CAS – History

Describes and explains the current system state and its historical development to reach that current state.

Implementation concepts	Implementation factors
Implementation context – this is the system status that pre-exists the point of innovation and practice change. Systems are not isolated and are constantly responding to multiple influences, which in turn develop the system.	Health policy: guidelines, fiscal measures, regulation, service provision, legislation, communication and marketing, environmental and social planning. Descriptions of the health system are multi-layered and include its social architecture and networks, age, maturity, size, resources, geography (region, country etc.), regulatory infra-structure internal and external to the system, socio-cultural aspects including professional culture and political, legal and ethical influences. This in turn leads to the health systems' capacity to respond to change and includes its absorptive capacity, readiness and motivation that may be influenced by its status with similar systems.

Social CAS – Temporality

Describes and explains system fluctuations and change, adaption and evolution over time.

Implementation concepts	Implementation factors
Implementation process as dynamic and recursive	Innovation needs to embed into the system to sustain over time and is modified to fit within the specific system. Innovation will adapt and evolve over time. Therefore, at any moment, change may be in process but not result in

	expected outcomes – with other influences constantly at play. Temporality describes the passage of time from the past to present and anticipation of the future. Implementation processes are not static and, although time is linear, practice change is not linear.

Social CAS – System Organising Principle (SOP)

Observes and identifies the imperative, key determinant for the systems existence or rationale for organisation.

Implementation concepts	Implementation factors
Implementation drivers	Systems exist to meet pre-existing objectives. They will continue to need to meet certain imperatives to sustain their existence. Strong rationales that incentivise or reward change that fit with system objectives and imperatives are expected to be more successful. Implementation of changes are occurring all the time, and the system modifies and responds to these changes. However, strong habitual practice secures certain imperatives important to the systems survival. Challenges are likely to meet resistance.

Social CAS – Innovation

For example, intervention or technology, evidence-based practice, research guideline etc. Describes the event (and triggers) and its intention or expectation followed by the impact it has on the system.

Implementation concepts	Implementation factors
Implementation object (intervention or event)	Knowledge of the intervention/ innovation/change needed to address not just

	the aspects of its target but also other related factors to which the target is connected or embedded within a system. Implementation of change in healthcare involves how it will be perceived by various stakeholders, its credibility, believability and quality of the evidence for its implementation. Its relative advantage, adaptability, trialability, workability, complexity, (difficult, disruptive, radical, intricacy, number of steps to implement), design and cost are also factors. Meeting the implementation object's intention needs ongoing evaluation to understand fidelity, adaptation, uptake and acceptability, spread and scale up throughout the system and its ongoing impact on the system. Important requirements include re-structure that is needed, dependency on other parts of the system not targeted for change and aspects that restrict or enable parts of the system. Adoption of an innovation needs a level of coercion, incentivisation or persuasion.

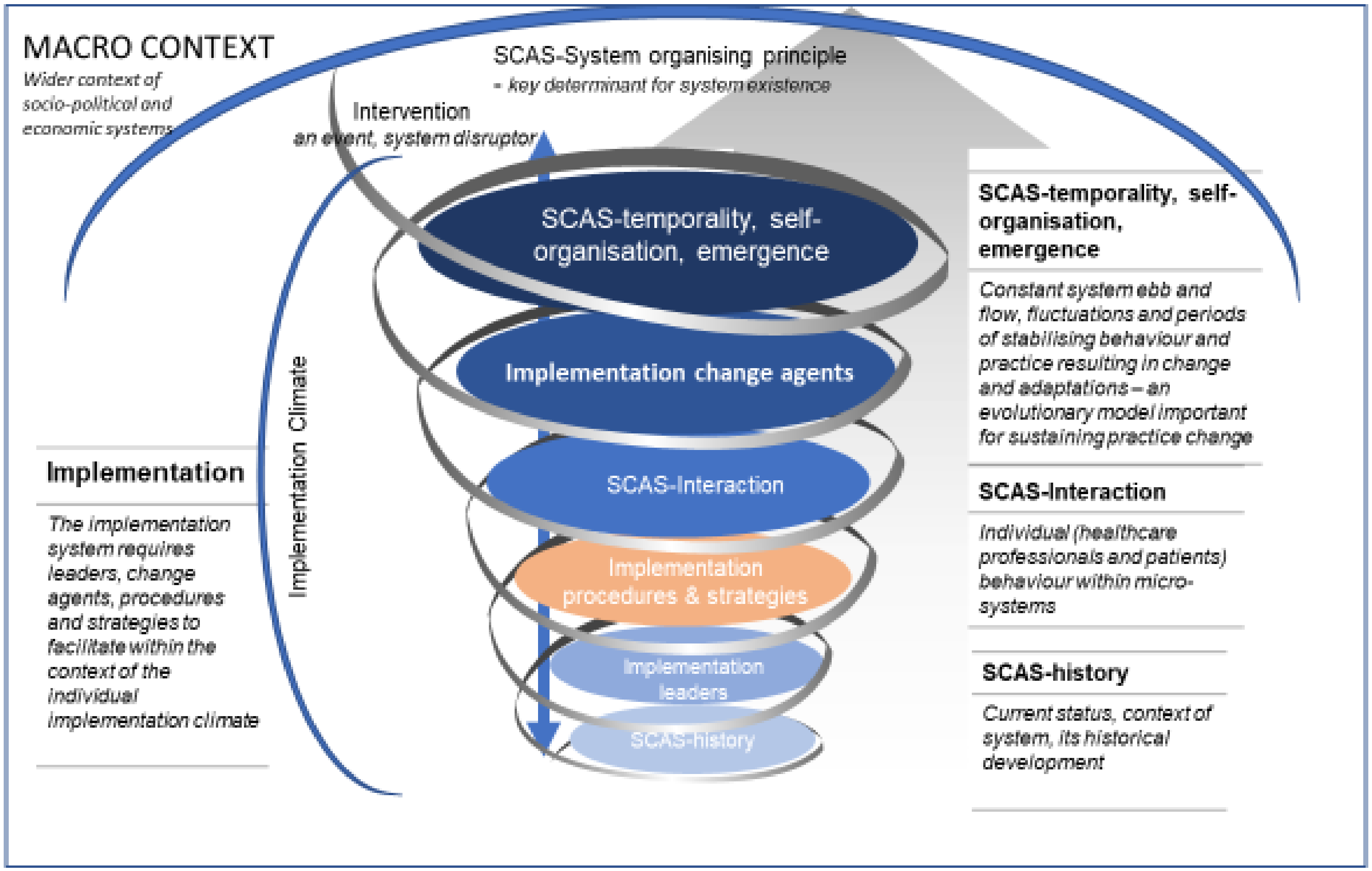
4.5.1.2 Diagrammatic representation of the novel conceptual framework

The diagrammatic representation of the framework is presented in Fig. 4.5.2. The diagram aims to represent a constant evolution (the spiral), however, components feed back and forth on the different elements and structures that are created and recreated in an evolutionary and adaptive pattern. Implementation as a concept of deliberate action to introduce innovation or change behaviour is represented by the event and the integrated implementation components into an existing system that is not static. As with tidal waters, implementation needs to work with the flow of the system. Hence by integrating social CAS concepts with implementation concepts in a framework I seek to explain how social systems behave and react to perturbations such as implementation events. The diagram is a simplification of reality but presents a structure on which to map the specific aspects of an implementation programme and the context it seeks to transform. For ease of use, from this point, I will refer to the Framework for Implementation in Social Complex Adaptive Systems – FISCAS.

Fig. 4.5.2. The Final Conceptual Framework – Implementation in Complex Systems

The Framework for Implementation for Social Complex Adaptive Systems (FISCAS)

An interpretative tool



4.5.1.3 Application of the novel conceptual framework for implementation research

This novel conceptual framework that integrates concepts of social CAS with core implementation concepts was used to frame the QCA study, its findings and subsequent interpretation. Examples of factors and processes to identify in the POISE study data (Rycroft-Malone et al 2013, 2012, 2010) that cover the social CAS domains are shown in Table 4.5.1:

Table 4.5.1. Conceptual Framework Domains mapped to potential factors and processes

Framework domain	Potential data from the POISE study: causal factors and processes
Individual agent	• Healthcare professionals: anaesthetists, surgeons, nurses, operating department practitioners • Patients • Implementation roles: facilitators, opinion, leaders, key contacts, local investigators • Power relationships • Professional cultures • Differences in professional objectives and ways of working • Good practice role models • Surgeon input invited but absent • Assignment of change roles 'built on' rather than integral to job role. These roles require different skill sets • Positive experience for local investigators • Leadership and responsibility for fasting practice unclear • Gaining authority to make change • Handling conflict and competing priorities • Need for individuals to maintain caution in practicing individualised fasting, others more relaxed about allowing water less than two hours pre-op. • High emotion at times in highly pressurised environments
Interaction	• Ward teams: day surgery, inpatient surgery • Theatre teams: anaesthetist, surgeon, nurse, ODP, co-ordinators Administrative staff supporting operating list management • Communication: individuals, teams and departments and the quality of that communication between theatres and wards. What techniques or improvements were made to improve

	communication and whether it translated to a net effect across the Trust during trial period. • Centred around the management of the operating list • Trust capacity to engage in push for change was challenging in many Trusts • Ability of some individuals to maintain momentum and motivation to change practice • Inter-professional cultures exposed by trial process evaluation • Managing competing priorities at time of trial – 'a bad time' (staffing issues, lack of time) • Gaining senior staff support and buy-in variable across Trusts
Self-organisation	• Implementation of trial strategies for change: PDSA (quality improvement), opinion leadership and web, passive dissemination. This also included feedback of audit of duration of fast data. • Key point was whether these strategies by themselves contributed at all to change. • Changes to management of operating lists • Use of current structures and adapting them – training in real time scenarios
Emergence	Process evaluation outcomes: • Struggles between professionals and who owns the practice (typically area of responsibility for anaesthetists) • Capturing intermediate steps to change and adaptation as precursors for reaching outcome of interest • Raising awareness of problem and guideline • Making changes to out of date fasting policy • Making changes to patient information • Development of communication tools for practice • Changes to operation list management leading to net effect change in Trust • Fasting is a distributed practice within the surgical system in NHS Trusts. • Required re-modelling habituated behaviour to become the new routinised practice • Inflexibility of rule-based hierarchies

History	• 19 NHS Trusts (the cases) based in England, Scotland, Wales and Northern Ireland. • Self-selecting of a wider group of a potential 188. • Trusts developing their own policies rather than following guidance • Impact of macro-level influences: reconfigurations within Trusts, changes to medical training, financial deficits impacting on staff turnover, workforce reviews and re-organisations • Patient behaviour and expectations • Shifts from inpatient surgery as routine to patients admitted on day of surgery.
Temporality	Individual NHS Trust response to implementation – individual trust by trust key activities undertaken • Intermediate outcomes (impact along a continuum) that did not follow through to impact on duration of fasting times – primary outcome • Starting points within trial design (some ahead, more motivated, ready) – adaption already in progress.
System Organising Principle	• Management of the operating list to ensure patients invited for surgery received their operations • Questionable as to whether changing fast practice was a priority for change in many trusts
Innovation (intervention/ implementation event)	• Well-established, credible evidence-based guidance to reform fasting practice before routine surgery • Up-to-date fasting policy in place or not • Guidance objective required shift from blanket fasting system to one of individualising fast titrated to patient's position on the operating list system and the potential for movement. • Accepted by health care professionals. Already embedded in many hospital policies, and some staff believed they were following recommended practice, although their individual audit findings of mean fast duration contradicted this experience. • Limitations of intervention phase • Tracking or tracing dissemination of guidance through NHS Trusts – not obviously done in most cases.

	• Outcome measurement– mean duration of fast at timepoints before and after intervention: No trend, no strategy emerged as overall more effective.

4.6 Limitations and conclusion

There are inevitably limits to identification comprehensiveness of relevant implementation frameworks, models and theories. Although a relatively broad spectrum was included, the searches focussed specifically on ‘implementation’ as a key term and did not include terms such as ‘knowledge translation’ or ‘utilisation’. Although Ellen et al (2017) was picked up in the searches, other Knowledge Translation models were not in this wide field. Knowledge Translation uses a broader set of terms (utilisation, dissemination, exchange etc.) and focusses on distribution and uptake (Khalil 2016) whereas implementation science or research focusses on *how* to get new knowledge or intervention implemented (Khalil 2016, Eccles et al 2006). However, with greater sophistication and developments in both areas these fields are probably best viewed on a spectrum with implementation as a component of or extension to the knowledge translation process (Kitson et al 2017). However, for my purpose, the novel conceptual framework is focussed on implementation, although knowledge dissemination of guidance was a principle strategy in the standard care arm in the POISE trial (included in all arms).

Implementation is “too multi-faceted and complex a phenomenon to allow for universal explanations” (Nilsen 2015, p. 9). This novel conceptual framework forms a specific focus to understand system-wide behaviour accounting for behaviour that emerges from the inter-connecting micro-systems and processes of practice and care.

To conclude, a novel conceptual framework was produced to explain implementation in healthcare social systems and needed itself to be implementable through the methodological mechanisms of QCA. My synthesis of both social CAS concepts and implementation concepts intended to provide an explanatory framework to balance comprehensiveness with utility, which would allow application using QCA methods to re-synthesise process and outcome data to produce a different explanation from the original trial data.

Chapter 5: A methodological review of Qualitative Comparative Analysis use in healthcare research

5.1 Introduction

In this chapter I report on a methodological review that examined the application of Qualitative Comparative Analysis (QCA) methodology and its set of methods within health research. I describe QCA in more detail and my rationale for using it in Chapter 2, section 2.4.2.1. I conducted the review to examine how authors understood QCA methodology and how they applied QCA methods to achieve their objectives.

Implementation research seeks to explain complexities within social healthcare system contexts to deliver new treatments, new practice or changes through evidence-based guidelines. System complexity needs disentangling to a degree that provides useful explanations that connect mechanisms and processes to causes and their effects. This is important so that we can explain 'how' and 'why' interventions work or do not work and, also, seek a better understanding of how healthcare systems function as they deliver and organise care. QCA methods have potential to enable data analysis that accommodates such complexities within individual case contexts by identifying which factors need to come together to bring about the outcome.

5.1.1 Why is a review of Qualitative Comparative Analysis in health studies needed?

Linear logic and statistical approaches dominate health research, although integration of qualitative research and other data from process evaluations, for example, are increasing (Sutcliffe, 2016, Glenton et al 2013). Researchers who wish to explore complexity, that is, make sense of their real-world observations, find information is lost from more typical multiple regression techniques (Moore et al 2015). Approaches using realist synthesis (Charles et al 2016, McClean et al 2016) and qualitative methods (Bazeley 2018) seek to identify factors in complex causal patterns. Recent usage and application of QCA (Thomas 2014, Candy 2013, Blackman 2013, 2011) within the healthcare context to address the evaluation of complex interventions within complex contexts confirms that a review of this method and its applications in the healthcare field would be timely.

An informative review would enhance my own QCA study. At the time of completion of this thesis such a review has not been conducted.

5.2 Approach

My review explored authors' understanding of QCA logic and epistemology when appropriating it into the health research field. Ragin (1987) presents QCA as a third strategy between typical case study and net effects approaches. The comparison with other methods was not undertaken to test whether this method was more appropriate or effective than other methods. The purpose was to explore how QCA methodology was used in healthcare research to investigate complex causality. Initially, although a small number of studies was expected, the subsequent update showed an exponential rise in QCA application in health research. I followed systematic review methods to address the question (Petticrew 2013, Higgins and Green 2011).

Key steps were question formulation, the development of inclusion criteria, the conduct of a systematic search for studies, data extraction, study appraisal of QCA application and a framework synthesis of key statements made by authors regarding causality and their rationale for using QCA. In addition, I explored the authors' experience of QCA methods and their findings.

5.2.1 Review objective

To identify and evaluate applications of QCA in health research to explore and assess this methodology and its set of methods to examine 'complexity', such as context, mechanisms and variation and heterogeneity across cases.

5.2.2 Research question

How has Qualitative Comparative Analysis been used in the field of healthcare?

5.2.3 Inclusion criteria

Broad inclusion criteria to formulate and address the research questions were developed following a social science approach to question formulation (Booth, 2005): **S**etting, **P**henomena of **I**nterest **C**omparison and method of **E**valuation (SPICE). See table 5.2.3 for inclusion criteria. Based on an initial scope and prior knowledge, I did not expect to be overwhelmed by studies and wanted to capture as many examples as possible. Many records reported methodology or guidance on applying this method. I rejected any studies not specifically evaluating interventions within the health field. Non-English language articles were excluded as resources were not available for translation.

Table 5.2.3 Inclusion criteria

***S**etting-where*	All health contexts are included with no restrictions on geographical location, treatment or intervention under investigation, or whether in primary, secondary or tertiary care. The study can involve any health topic relating to patient and healthcare participants or organisations. The study can involve any intervention relevant to the healthcare field.
***P**henomena of **I**nterest*	Use and application of QCA methodology and its set of methods.
***C**omparison*	Application of QCA methods, rationale for their use and the theoretical and causal assumptions underlying this rationale are of interest.
***E**valuation*	To investigate using criteria for best practice QCA (Rihoux and Ragin, 2009) and how its methodology and methods were applied in the primary studies. To evaluate whether this methodology and its set of methods are a fit with the field of health sciences. To better understand the notion of complex causality assumed by the methodology and those that might apply it. Furthermore, to understand how the method does or does not facilitate study of the social healthcare contexts as complex systems.

5.3 Methods

5.3.1 Search

Initial searches were undertaken from January 1987 to September 2015 using the highly specific and conceptually secure term ‘Qualitative Comparative Analysis’ across electronic databases: MEDLINE, CINAHL, PsycINFO, ASSIA, ERIC, HMIC, Sociological Abstracts and Web of Science, plus a QCA specific bibliographic database (www.compasss.org). Embase was unavailable. The search was comprehensive to capture as many examples as possible. It was not necessary to conduct an exhaustive search as the review did not seek to determine whether QCA was more effective than other methods. Download records were sifted by title and abstract and duplicates removed. Full text papers were obtained for those meeting inclusion criteria. Following review of the full text papers, further exclusions were made. An updated search was conducted between September 2015 and February 2019 to ascertain ongoing interest in the use of the method.

5.3.2 Data extraction

The data extraction checklist was designed to obtain the study report’s health topic and context, data sources, a detailed breakdown of QCA methods used, the rationale for using QCA, and whether in using this method the authors conclude, within their specific field, that their objective was met. The data extraction checklist and subsequent methodological assessment checklist were developed based on good practice guidance about conducting QCA in key reference manuals published in 2009 (Rihoux and Ragin) and 2012 (Schneider and Wagemann). Phrases used by authors to convey the epistemology of QCA were also extracted to garner whether causal complexity was addressed within the authors’ research strategy. The data extraction checklist was independently reviewed by an expert in QCA methodology, and her comments incorporated into an updated version before use. Extracted data went into three extraction tables for each study: 1. study summary, 2. sources of data used, breakdown of the methodological steps undertaken, key findings and interpretation, and 3. the authors’ rationale and causal assumptions (templates, Appendix 5.1).

5.3.3 Assessment of methodological quality of included studies

A quality assessment of the included articles assessed whether QCA methods were applied appropriately and, for example, whether the premise of causal sufficiency and necessity was understood by authors. The quality checklist designed specifically for this review evaluated the completeness and integrity of QCA methods applied. Each included study was individually assessed against these criteria. Eighteen key QCA step-by-step criterion comprise the quality checklist (see Appendix 5.2). Each criterion has several identifying signalling questions and an elaboration. Judgements were made about whether these criteria were fully or partially met, not met or unclear. This was conducted by a single reviewer (thesis author). To quality-check my judgements, as to whether they were fair and consistent, a random sample of ten papers were quality-checked using the checklist by two other researchers. Random selection was conducted using Excel to randomly allocate numbers 1-100 to the individual papers by the original reviewer. Discussions and changes were negotiated with the original reviewer and the quality-checker, a third researcher arbitrated on disagreements.

5.3.4 Framework synthesis

I used the framework approach (Ritchie and Spencer 1994) to synthesise statements extracted from the included studies on causality and authors' rationale for using QCA. This approach systematically organises extracted data into a matrix for examination of concepts across cases. It was originally developed to provide a pragmatic but defensible approach to analysing large amounts of qualitative data for application in social policy contexts (Ritchie and Lewis 2003). However, it has shown to have broader use in other contexts (Barnett-Page and Thomas 2009). It was used in this methodological review to structure data extracted from the included studies to examine the included study objective, author rationale and epistemological concepts to ascertain why authors were seeking to use this methodology as a research strategy and judge whether QCA provides a set of methods (Gomm 2009) useful for health research. The framework approach examines data across studies and created categories of interest with aggregation into higher order themes of description of phenomena. It transparently retains the data for re-examination, allowing the development of descriptions and explanation of the phenomena (Ritchie and Lewis 2003). Key steps are data familiarisation, identifying a thematic framework, indexing, charting, mapping and interpretation (Ritchie and Spencer 1994). I conducted the framework synthesis in the following steps:

1. Familiarisation: This typically involves immersion in qualitative data (interview tapes, transcripts, observational notes, etc.). This review focussed on the application of QCA methodology, its set of methods and underlying concept of complex causality. This initially involved development of the data extraction checklist and repetitive reading of the included study reports.
2. Identifying a thematic framework: The framework was structured around the review's key objectives and areas of interest eliciting study authors' understanding of QCA methodology to examine complex causality.
3. Indexing: Study reports were scanned for statements describing or providing explanation on key QCA concepts (set relations, necessary and sufficient conditions, equifinality, asymmetry, and conjunctual causation), rationale for using QCA and

other theoretical concepts related to notions of causation. These were extracted into individual study tables for the study rationale for QCA application recording causal assumptions.

4. Charting: A matrix was designed by case (study) and purpose of study, authors' rationale and authors' understanding, explanation and application of key QCA concepts, subdivided into notions of causal complexity, application of core concepts of set relations and underlying assumptions of causal processes expressed. Each study's extracted data were summarised for collation and examination of rationale for QCA application and notions of complex causality.
5. Mapping and interpretation: Key overarching categories were defined to provide some comparison with the methodology as conceived by its originator and subsequent QCA methodological leads and its actual application in the studies reviewed. The study (case by case) summaries were pulled into these overarching categories from which overarching themes were drawn for interpretation.

A quality audit of this synthesis was conducted by two researchers to provide an independent check on the judgements and assumptions made and changes negotiated as appropriate.

Study authors' key findings were also reviewed to ascertain whether the application of the QCA methodological strategy satisfied their objectives. Key learning points suggested authors were noted for future application.

Throughout the process of data extraction, quality appraisal and aggregation of data, a log of observations and issues regarding application of the method were collated.

5.3.5 Update to review (2015-2019)

An update to this review was conducted during thesis final write up. Due to the limited timeframe for completion, a full review of the studies identified was not practical. However, a summary is presented which provides a commentary on the general contribution these additional studies make to the use of this method in health studies.

5.4 Findings

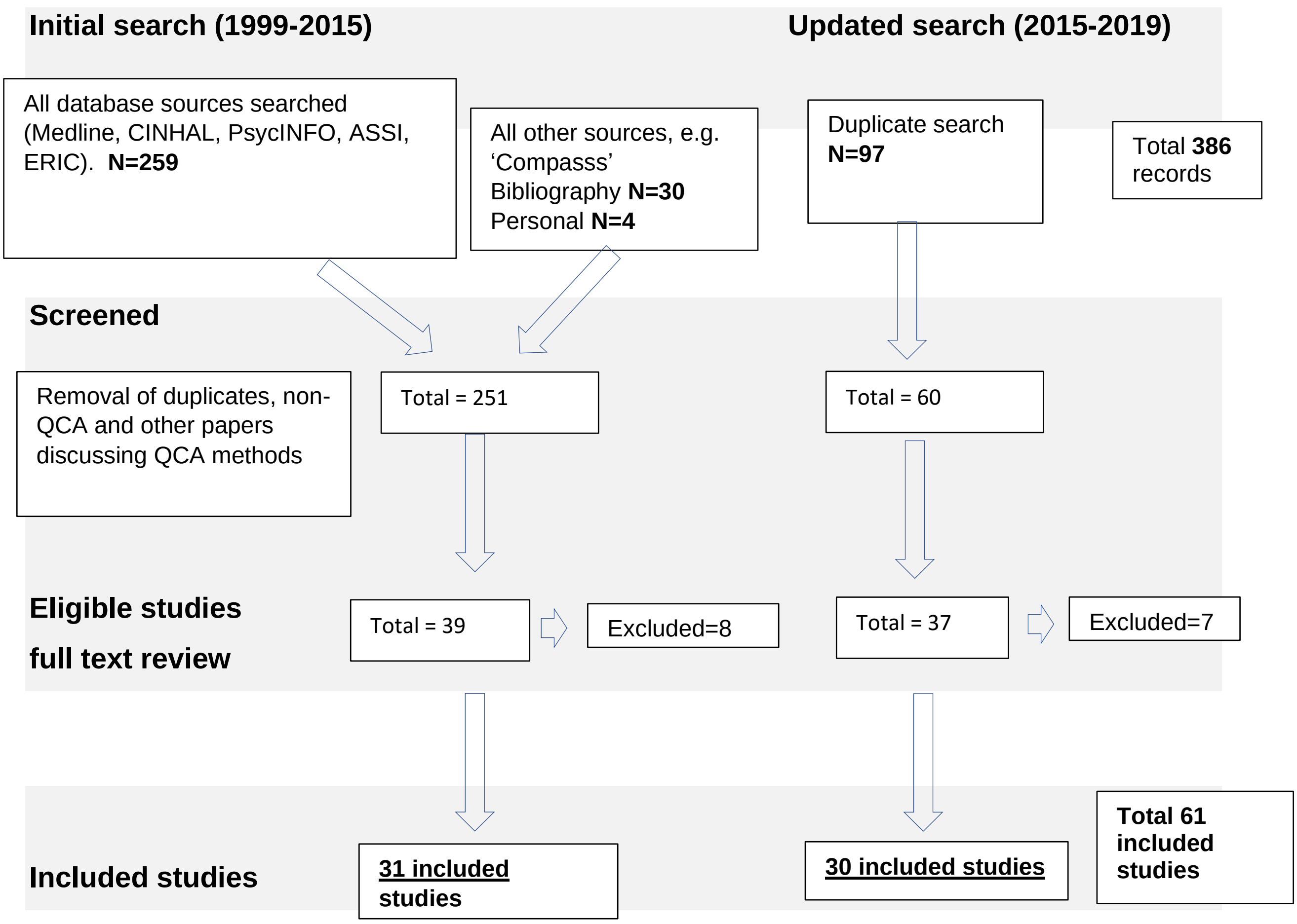
Due to repeated citation of references in this chapter, for references of included and excluded studies only the first author and year are reported. All other references used will remain in the standard format using et al for multiple authors.

5.4.1 Search results

Searches identified 31 studies meeting inclusion criteria that covered healthcare topics from the macro-system and policy level to the individual patient between 1999 and January 2015. A further 32 studies were identified in an updated search conducted between September 2015 and February 2019, showing a continued increase in the use of this method in health research. See search flow diagram (Table 5.4.1). Review of full papers resulted in a total of 15 exclusions reported at Appendix 5.3. Excluded papers covered technical examples and topics beyond the scope of the review.

Below a flow diagram (Moher et al 2009) shows results from both search period, screening of abstracts and retrieval of full papers for further examination as to relevance to reach a final set of 61 included studies from both search periods.

Fig. 5.4.1 Flow of studies from identification to inclusion and exclusion



5.4.1.1 Study characteristics

Appendix 5.4 lists and summarises the individual characteristics of the 61 included studies. see Table 5.5.1.1. presents a brief summary of countries of origin and range of health topics covered. From 1999 to 2005, six studies were published, between 2006 and 2010, a further six studies were published and during the remaining search period of under four years (2011 to 2015), 19 studies were published. Subsequently, 30 studies were published between 2015 and early 2019. Overall numbers suggest QCA remains a niche strategy within healthcare, although it is currently increasing exponentially as some authors adopt the method in more than one study and others are adopting the method as more examples become available.

Table 5.5.1.1 Summary of included studies country origin and topics covered

Study country of origin	**Initial review**: US (16), UK (7) and two from Australia. Brazil, Spain, Taiwan and Sweden were other countries represented. **Update:** US (12), UK (6) and 10 from other European countries, 1 New Zealand and 1 Iran.
Clinical topics covered	**Initial review:** Chronic diseases, smoking cessation, life expectancy, genetics, neonatal care, multiple foetal pregnancies, disadvantaged women, myocardial infarction treatment, alcohol addiction, homicide, vaccine deployment, health service response to intimate partner violence, eating disorders, implementation of weight management programmes, stress management and promotion of breastfeeding **Update:** Breast and skin cancer care and interventions, interventions for asthma, chronic disease prevention, end of life care, weight management, (paediatric and adult), utilisation of mental health services (adults, youth centres and paediatric care), medication adherence.
Service delivery and organisation of care topics	**Initial review:** Screening for tumours and adherence to policy recommendations or goals **Update:** Integrated care models, function of multi-sectorial networks and inter-sectoral policy

	networks, macroeconomics and austerity, patient-centred medical homes model, hospital investment and expenditure impact on health
Other topics covered	**Initial review:** Several studies addressed health inequalities and deprivation in both high and lower middle-income countries. One typical topic from the political science field addressed the identification of factors to explain the US' reluctance (pre-Obama Care) towards instigating a national health insurance plan. **Update:** Use of mobile medical apps, behaviour of nurses, meat consumption and food purchasing, nurse emotional intelligence and career development of frontline works and health inequalities.

5.4.2 Initial review 1999-2015

Several steps were undertaken to evaluate the included studies. A methodological quality assessment of each study determined application of QCA by study authors against a novel quality criteria checklist. A qualitative synthesis examined authors' rationale, assumptions and their awareness of the epistemic basis underlying QCA methodology. Each study raised different methodological issues and key learning points.

5.4.2.1 Quality assessment of included studies for initial review

Quality assessment conducted only in the initial set of studies showed improved application in later studies from those conducted earlier. However, this systematic methodological assessment of the QCA methods exposed poor reporting of, and compliance with, core methodological components. There was wide variability in application and interpretation of underlying concepts in the study reports. Table 5.4.2.1 summarises the methodological assessment undertaken using the 18-item checklist. Checklist items could be considered inappropriate to apply to studies before 2008, when Ragin (2008) introduced robustness checks for consistency and coverage measures. However, it provided a tool to guide examination of the papers and best practice.

Table 5.4.2.1 Methodological quality summary of all included studies by QCA step

	Key QCA steps																		
Author	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	
	Set relations	**Case selection**	**Condition selection and calibration should be documented in detail**	**Outcome selection and calibration should be documented in detail**	**Raw data matrix**	**Application of software**	**Truth table**	**Assessment of necessary conditions**	**Assessment of sufficiency**	**Logical remainders (understanding limited diversity)**	**Treatment of contradictory rows**	**Consistency (raw)**	**Coverage**	**Analysis of the negative outcome**	**Presentation of results**	**Boolean minimisation and appropriate notation**	**Overall robustness check**	**Coherence of interpretation of solutions/ minimal formula**	***FM**
Harkreader 1999	✓	✓	✓	✓✓	**X**	**X**	✓✓	**X**	**X**	✓	✓✓	**X**	**X**	**X**	**X**	✓	**X**	✓	**3**
Britt 2000	✓	✓✓	✓	✓✓	**X**	**X**	✓✓	**X**	**X**	**N/A**[1]	✓✓	**X**	**X**	**N/A**[1]	**X**	✓	✓	✓	**4**
Haworth-Hoeppner 2000	✓	✓	✓	✓	**X**	**X**	✓✓	**X**	**X**	✓	**N/A**[2]	**X**	**X**	**X**	**X**	✓	**X**	✓	**1**

Blake 2001	✓	✓✓	✓✓	✓✓	**X**	✓✓	✓	**X**	**X**	**X**	✓	**X**	**X**	✓	**X**	**X**	**X**	**X**	**4**
Melinder 2001	**UC**	✓	✓	✓	✓✓	**X**	**UC**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**UC**	**X**	**1**
Dy 2005	**UC**	✓✓	✓✓	✓	✓	✓	✓	**X**	**X**	**X**	**X**	**X**	**X**	**UC**	**X**	**UC**	**X**	**X**	**2**
Britt 2006	**X**	✓	✓	✓✓	**X**	**X**	✓✓	**X**	**X**	**N/A**[1]	✓✓	**X**	**X**	**N/A**[1]	**X**	✓	**UC**	✓	**3**
Ford 2005	**UC**	✓	✓	**UC**	**X**	**X**	✓✓	**UC**	**UC**	**X**	**X**	**X**	**X**	**X**	**X**	✓	**X**	✓	**1**
Britt 2007	**UC**	✓✓	✓	✓✓	**X**	**X**	✓✓	**X**	**X**	**X**	✓✓	**X**	**X**	**N/A**[1]	**X**	✓✓	✓	✓	**5**
Blackman 2008	✓	✓✓	**UC**	**UC**	**X**	✓✓	✓	**X**	**X**	**X**	**N/A**[3]	**X**	**X**	**X**	**X**	✓✓	**X**	**X**	**3**
Gilligan 2010	✓	✓	✓	✓	✓✓	**X**	**X**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**	**N/A**[4]	**1**
Glatman-Freedman 2010	✓	✓	✓	✓	**X**	**UC**	✓✓	**X**	**X**	**X**	**X**	**X**	**UC**	**X**	**X**	**X**	**X**	✓	**1**

Blackman 2011	✓✓	✓✓	✓	✓✓	**X**	✓	**X**	**UC**	✓	✓	✓	**X**	**X**	**UC**	✓✓	✓	**X**	✓	**7**
Chuang 2011	✓✓	✓	✓	✓✓	**X**	✓✓	✓	**UC**	✓✓	**X**	**UC**	✓✓	✓✓	**X**	**X**	✓✓	✓	**UC**	**7**
Kahwaiti 2011	✓✓	✓✓	✓	✓✓	**X**	✓✓	✓	✓	✓	**X**	**N/A**[5]	**X**	✓✓	✓✓	✓✓	✓	✓	✓	**7**
Thygeson 2012	✓✓	✓	✓✓	✓✓	**X**	✓✓	✓✓	✓✓	**UC**	**X**	**X**	✓✓	✓✓	**UC**	✓✓	✓✓	✓	✓✓	**11**
Bell 2012	✓	✓	✓	✓✓	**X**	✓✓	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**UC**	**X**	✓✓	**X**	**UC**	**3**
Eng 2012	**UC**	✓	✓	✓	**X**	✓✓	**X**	**X**	**X**	**X**	**X**	**X**	✓	**X**	✓✓	✓✓	**X**	✓	**3**
Longest 2012	✓✓	✓	✓	✓✓	✓✓	✓✓	✓✓	**X**	✓✓	**N/A**[6]	**N/A**[6]	✓✓	✓✓	**X**	**X**	✓✓	✓✓	✓✓	**11**
Weiner 2012	✓✓	✓	✓	✓✓	✓✓	**UC**	✓✓	**X**	✓✓	✓✓	**X**	✓✓	✓✓	**X**	**X**	**UC**	✓✓	✓✓	**10**
Blackman 2013	✓	✓✓	✓	✓✓	**X**	✓✓	✓	**UC**	**X**	**X**	✓✓	**X**	**X**	✓	**X**	✓✓	✓	✓	**5**

Candy 2013	✓	✓✓	✓	✓✓	**X**	✓✓	**UC**	**X**	**X**	✓	✓✓	**X**	**X**	✓✓	✓✓	**X**	✓✓	✓	**7**
Chang 2013	✓✓	✓	✓	✓✓	**X**	✓✓	**X**	**UC**	**UC**	✓	**X**	**UC**	✓✓	**X**	✓✓	**X**	✓	✓	**5**
Warren 2013	✓✓	✓	✓	✓✓	**X**	✓	✓✓	**X**	**X**	✓✓	✓	✓✓	**X**	**X**	**X**	✓	**X**	✓	**5**
Brunton 2014	✓✓	✓✓	✓	✓✓	✓✓	✓✓	✓✓	**X**	✓	**X**	**UC**	✓✓	✓✓	✓✓	**X**	✓✓	✓✓	✓✓	**12**
de Andrede 2014	✓✓	✓	✓	**UC**	**UC**	**X**	✓✓	**X**	**X**	**X**	**UC**	**X**	**X**	**X**	**X**	✓✓	**X**	✓✓	**4**
Leykum 2014	✓	✓	✓	✓	✓✓	**X**	✓✓	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**2**
Sheehy 2014	✓✓	✓	✓	✓✓	✓	✓✓	✓✓	**X**	✓✓	**X**	**X**	**UC**	✓✓	**UC**	**X**	✓✓	✓✓	✓✓	**9**
Thomas 2014	✓✓	✓	✓✓	✓✓	✓✓	✓✓	✓✓	**UC**	✓✓	✓✓	✓✓	✓✓	✓✓	**X**	✓✓	✓	✓	✓✓	**13**

Cragun 2015	✓*	✓✓	✓✓	✓✓	✓✓	✓✓	✓✓	**X**[7]	**X**[7]	✓	✓✓	✓✓	✓✓	✓✓	**X**	✓✓	✓✓	✓✓	**13**
Goicolea 2015	✓	✓	✓✓	✓✓	✓✓	✓✓	✓✓	**X**	✓✓	**X**	**UC**	✓✓	✓✓	**X**	**X**	✓✓	✓	✓	**9**
Fully met	**12**	**11**	**6**	**21**	**9**	**16**	**18**	**1**	**8**	**4**	**8**	**9**	**11**	**3**	**7**	**13**	**6**	**10**	

✓✓Yes authors have met this criterion, ✓ Authors have partially met this criterion, **X** No authors have not met this criterion, **UC** It is unclear whether authors met this criterion, N/A Not applicable (Authors' approach either clearly stated that this item would not be conducted or it was clear that there was no intention to conduct this procedure) FM Number of criterion fully met

Footnotes:

1. Britt (2006, 2000) steps 10 and 14 (and 2007): Argues that logical remainders are theoretically not plausible. Britt's approach uses odds ratios to determine the ratio of cases to the configuration to a given outcome occurring; also, does not undertake analysis of cases with negative outcomes.
2. Haworth-Hoeppner (2000) step 11: No contradictory rows present
3. Blackman (2008) step 11: Not mentioned. 19 configurations do not appear contradictory. hHwever, this accounts for 2617 of cases leaving 265 unaccounted for. Authors report *analysis generated 19 combinations with more than 30 cases, accounting for 94 per cent of the sample.* So, with 32 possible configurations there were 13 logical remainders theoretically but also cases not allocated.
4. Gillighan (2010) steps 8-18: QCA process stops at step 8.
5. Kahwati (2011) step 11: 22 unique configurations.
6. Longest (2012) steps 10 and 11: Not present or observed.
7. Cragun (2015) steps 8 and 9: Authors report rationale that their hypothesis is that no condition is expected to be necessary, so therefore not pre-specified.

Authors are listed in chronological order rather than alphabetically in Table 5.4.2.1. as this shows development and increased usage of the robustness checks over time. In Table 5.4.2.1 'not applicable' items are explained in the notes. Key points are:

- The concepts 'sufficiency' and 'necessity' are either not referred to at all (e.g. Gilligan 2010, Britt 2007, 2006, 2000) or they are referenced but it is not clear whether tests were conducted (e.g. Candy 2013, Chang 2013, Dy 2005) or, in more recent studies where there is improved reporting, the terms are more appropriately applied (e.g. Goicolea 2015, Sheehy 2014, Thomas 2014, Blackman 2011 ,). Although these terms are referred to, or the language of sufficiency or necessity is used or both are used, it is unclear in reporting whether formal tests were conducted. For example, only one study clearly conducted separate necessity tests (Thygeson 2012) as recommended (Schneider and Wagemann 2012).
- Handling logical remainders and contradictory configurations were other areas that were either a result of poor reporting (de Andrede 2014, Brunton 2014, Chaung 2011) or a conduct issue (Bell 2012, Eng 2012, Glatman Freedman 2010, Dy 2005, Melinder 2001). Other studies more explicitly addressed these key methodological components (Cragun 2015, Thomas 2014, Candy 2013, Warren 2013).
- Authors use a range of data sources for the QCA synthesis such as trials, surveys, routinely collected data and qualitative non-research data, opinion (researcher judgement) and qualitative research. In addition, they use documentary evidence and literature reviews and, more specifically in some examples, Cochrane systematic reviews (Thomas 2014, Candy 2013).
- Some authors conduct a full QCA strategy (Cragun 2015, Thomas 2014, Thygeson 2012), others only use early steps to configure factors and not proceed to minimisation. They either use other methods or stop at that point (e.g. De Andrede 2014, Leykum 2014, Gillighan 2010).
- Calibration techniques to validate set membership are variable and not always explicit with some 'mechanical' (de Andrede 2014, Kahwati 2011, Gillighan 2010, Ford 2005) rather than 'theoretical' approaches used.

5.4.3 Qualitative findings

A qualitative exploration of the studies sought to ascertain why authors used QCA as a research strategy, what learning was achieved and whether authors understood underlying assumptions of QCA, and so used methods appropriately.

5.4.3.1 Study author rationale and epistemological perspectives

Authors were primarily using QCA to ascertain the conjunction of multiple conditions sufficient for a pre-determined outcome. Using QCA methods does not necessarily imply engagement with QCA methodology (Eng, 2012, Ford 2005). Findings (see framework synthesis stages 3 and 4, supplementary tables at Appendix 5.6) suggest adherence to underlying epistemological concepts, such as sufficiency and necessity, were not undertaken in many studies. Others make loose reference but do not utilise these concepts in their results or discussion sections.

Study descriptions

Areas of health research

Authors' research focuses on multiple organisational levels, macro (by region or area, large-scale beyond single site (policy)), meso (within sites or individual organisations (delivery of care)) or micro (by individual case (patient/practitioner)). Topics of interest for QCA analysis are broad and cover:

- Health policy (Bell 2012, Blake 2001 Harkreader 1999)
- Patient decision making and behaviour choices (Chang 2013, Eng 2012, Longest 2012, Gillighan 2010, Britt 2007, 2000, Haworth-Hoeppner 2000)
- Intervention (treatment) effectiveness (Brunton 2014, Leykum, 2014, Sheey 2014, Thomas 2014, Candy 2013, Britt 2006)
- Health inequalities and socio-economic (Brunton 2014, Blackman 2013, 2011, 2008, Melinder 2001)
- Service delivery and organisation of care (Cragun 2015, Goicolea 2015, Warren 2013, de Andrede 2014, Glatman-Freedman 2010, Chuang 2011, Kahawati 2011, Thygeson 2012, Dy 2005)
- Organisational decision making (Weiner 2012, Ford 2005)

Rationale for using QCA

To identify a research method to suit their purposes, authors provide a range of consistent reasons as to why the method fitted their question and field of interest (Box 5.4.3.1).

Overwhelmingly, authors reached for this method as a methodological device to aggregate and synthesise data generated in complex systems as well as an approach that was systematic, transparent and maintained some detail from the cases throughout. QCA facilitated authors' engagement with complexity, within their context, exploring multifactorial causal pathways leading to an outcome of interest. Thygeson (2012) found the method useful when typical statistical approaches were limited due to small sample size.

Box 5.4.3.1a Rationale for application of QCA

Rationale	**Examples**
Complexity of intervention and/or outcome	Candy 2013
Multiplicity of factors or influences along a given pathway to an outcome of interest	Chang 2013, Chuang 2011, Glatman-Freedman 2010
Addressing contextual and mechanistic factors	Bell 2012
Multiple different pathways to outcome	Brunton 2014
Small sample sizes not suitable for quantitative approaches	Chang 2013, Thygeson 2012
Maintaining complexity of the 'case'	Goicolea 2015
Explanation of heterogeneity and variation between cases	Goicolea 2015, Ford 2006
Correspondence between cases, data and theory	Blackman 2011
Managing and maintaining greater level of case detail and information	Eng 2012
Providing a formal, systematic and transparent approach	Britt 2007
Develop or test hypotheses, conceptual frameworks and theories	Leykum 2014, Gillighan 2010
Providing real world synthesis maintaining levels of detail	Cragun 2015
Searching data to identify patterns and relationships or exploring complicated patterns identified in data	Warren 2013, Ford 2005
Formal method for conceptualising and analysing qualitative information	Weiner 2012, Longest 2012
An empirical approach for complex systems	Blackman 2013

Authors' assumptions for use of QCA

Authors assume (Table 5.4.3.1b) complex causality, heterogeneous, and other research strategies were inadequate. Several authors used multiple methods to synthesise data sources (Goicolea 2015, de Andrede 2014, Chuang 2011, Haworth-Hoeppner 2000). Some used QCA just to identify conditions and moved on to other methods (Gillighan 2010) whilst others combined QCA with statistical techniques (Sheehy 2014). Reasoning and logic, rather than probability and statistical inference, were also deliberate strategies of choice (Cragun 2015, Goicolea 2015, Chang 2013), as well as exploring results achieved by other methods (Warren, 2013). The interaction of factors and their collective role in achieving outcomes was central to the objective of the authors' research strategy.

Box 5.4.3.1b Underlying assumptions used by authors

Assumptions	Examples
Multiple factorial approach	Weiner 2012, Kahwati 2011
Multiple causal pathways	Thomas 2014
Factors need to act in concert rather than operate alone to result in a given outcome of interest	Longest 2012, Haworth-Hoeppner 2000
Apply reasoning in discerning causal models	Blackman 2011
Different underlying assumptions to epidemiological studies (confounding), net effect designs (trials) or sampling (large N, randomisation)	Warren 2013
Using logic rather than statistics to understand causal or associative relationships	Blackman 2011
Assume complex system is under exploration	Leykum 2014, Thygeson 2012, Blackman 2011
Assume heterogeneity and complex factors involved in attaining outcome	Bell 2012

5.4.3.2 Authors' use of Qualitative Comparative Analysis methodology and its methods

In summary, authors reported a prevailing need for a method that allowed greater flexibility in managing complicated contexts, interventions, programmes and policy questions. QCA was used as either the primary (e.g. Sheehy 2014, Longest 2012, Haworth-Hoeppner 2000) or secondary (e.g. Brunton 2014, Candy 2013) research strategy, or as part of a much wider strategy (e.g. Goicala 2015, Thomas 2014, Leykum 2014). Some authors used the software as a technical tool but did not meet Ragin's original objective to invite a dialogue between theory and method (e.g. de Andrede 2014, Kahwati, 2011, Gillighan 2010, Ford 2005).

Key themes for application were:

- **Managing complexity:** Notions of complexity range from system complexity (context), to managing multiple factors and exposing complex causal patterns in the data. QCA handles more variables than other typical regression techniques. It also allows exploration of multiple factors within the QCA modelling developing interaction (combination) terms. Authors also seek to understand how the 'parts' fit together, thus the configurational causal paths.
- **Systematic and transparent methods:** QCA provides a systematic, transparent and reproducible set of methods that engages with complex, mixed data.
- **Maintaining detailed case information:** Although a synthesis method that aggregates data, it is not applying net effect averages across cases. The cases are not lost because they are retained throughout by their individual configurations (truth table row). Also, by maintaining positive and negative cases it examines the role of non-confirmatory cases.
- **Provides causal explanation:** Data exploration allowed the evaluation and development of hypotheses or theory. This method permitted an explanation for the possible mechanisms underlying areas of interest using the 'causal' configurations developed in the authors' study QCA models. Although authors refer specifically to causal relationships, association or correlation they either mix these terms or use the method QCA without engaging with its underpinning notion of causal complexity (Chapter 2, section 2.6.1).
- **Alternative approach to quantitative techniques:** This was either based on:
    - sample size too small.
    - limits of techniques to adequately address or expose underlying process.
    - desire to maintain multiple factors in the model.

> Also, authors used a spectrum of approaches from theory exploration or development to the use of the method as an adjunct to regression techniques to qualify or explain their results.

One key issue, however, for authors, was managing multiple factors of interest. The QCA model manages one outcome and its negation in each QCA analysis. For some, the limitations on the number of factors or conditions viable led to loss of valuable information. Others managed larger numbers of factors than QCA modelling can manage by conducting multiple QCAs. These are then integrated into a final model. Thygeson 2012 and Sheehy 2014 both illustrate this layered QCA modelling approach.

5.4.4 Summary of methodological issues raised by the included studies in the initial review

Overall, authors could utilise the method to elucidate complex aspects of treatment, care or service delivery to establish pathways of factors leading to the outcome of interest. However, as shown by the quality assessment, the internal validity of many studies was impaired, so findings and interpretation were compromised.

Examination of the methodological strengths and limitations of the included studies and summaries of the study authors' own key findings and the reviewer's observations are summarised in Table 5.4.4 (expanded table Appendix 5.7), along with key methodological learning points drawn from this review. In summary, authors believed the method successfully assisted in disaggregating complex components that might result in synergistic effects (Goicolea 2015, Chang 2013, Weiner 2012, Glatman Freedman 2010, Britt 2007, 2006, 2000).

QCA provides a systematic approach to examine potential causal relationships (Bell 2012). Some authors refer to causality but also challenge to what degree causation can be inferred (Warren 2013, Haeworth-Hoeppner 2000) and refer to association (Sheehy 2014) and correlation (Melinder 2001). Therefore, the notion of causal inference within the healthcare context needs greater philosophical examination. Chapter 2, section 2.3 discusses causality and how we might understand and use it.

Finally, the studies raised several methodological issues warranting attention, but also learning points for future studies and further discussion. These are listed in Table 5.4.4.

Table 5.4.4 Summary of methodological issues and learning points (Initial review 1999-2015)

Examples of methodological issues warranting attention	Learning points raised by authors
Large number of logical remainders (Bell 2012)	Unpicking complexity increases complexity (Bell 2012)
Sampling cases excluding many relevant cases presents issues with validity of interpretation of QCA models (Blackman 2013, 2008)	When mapping the causal pathway authors need to take account of proximal and distal factors (Bell 2012)
Not managing contradictions in the truth tables (Blackman 2011)	Application of a priori theory strengthens subsequent interpretation of QCA models (Blackman 2013, 2011, 2008)
Limited diversity and producing a unique set of combinations (Blackman 2013, Kahwati 2011)	Use of odds ratios to determine discrete outcomes to manage large N (Britt 2007, 2006, 2000)
Managing the process of data collection using multiple methods and techniques, data reduction and calibration for transformation into QCA analysis – assessing the validity and quality of these data sources (Chang 2013).	Use of systematic reviews to disaggregate intervention components into effective and ineffective addressing issues of asymmetry not undertaken in systematic reviews. (Brunton 2014, Thomas 2014, Candy 2013,)
Multi-method approaches involving regression analyses alongside QCA (Chuang 2011, Glatman-Freedman 2010, Ford 2005)	Using frameworks to structure and manage condition reduction (Cragun 2015, Sheehy 2014)
Over-focus on presence and absence rather than necessity and sufficiency (Eng 2012, Dy 2005)	Reporting detailed steps undertaken and decisions made (Cragun 2015)
Concerns that condition reduction results in lost information (Goicolea 2015, Weiner 2012, Harkreader 1999)	Complex models involving multiple QCA analyses in stepwise process using two-stage approaches and multiple outcomes combining in a final QCA model (Sheehy 2014, Thygeson 2012).

Whether authors choose to stop halfway through and do not conclude analysis (Leykum 2014)	
Limited diversity of identified factors across all possible/logical configurations is a challenge (Thomas 2014)	
Concerns on identifying all relevant data and that data sources do not skew the final models in a particular direction (Warren 2013)	
Authors use correlation, association and causal to interpret findings – clarity warranted, e.g. Melinder 2001.	

This initial review of QCA showed:

- examination of configurational pathways when the outcome is either absent or present bringing coherence to the data (Brunton 2014, Blackman 2013). However, these configurational patterns should not be assumed to mirror each other (Schneider and Wagemann 2012);
- the importance of an underlying theory to test the plausibility or not of the findings (Longest, 2012);
- that the determination, selection and factor reduction could result in the exclusion of potential influencing factors (Cragun 2015, Candy 2013, Weiner 2012, Harkreader 1999) limiting interpretation of findings;
- that findings are based upon the choice of influencing factors (Thomas 2014);
- the problem with unpicking complex contexts (de Andrede 2014, Thygeson 2012) could lead to the removal of relevant contextual information (Goicolea 2015).

Data source identification, theoretical rationale and decision-making judgements pre-QCA analysis are vital to the method providing legitimate set relation results and was a key observation in this initial review.

5.4.5 Update review 2015-2019

An update to this review was conducted in February 2019 to ascertain progress and development. It was not feasible to incorporate the thirty studies identified into the full review and conduct full data extraction and methodological quality assessment. However, an overview is presented, especially because interest continues with this methodology and its accompanying methods in healthcare. This includes the development of approaches, most notably its application in systematic reviews. Appendix 5.4 presents two tables of study characteristics for both reviews which provide study setting, context, health focus and field, study objective and the primary components – cases, conditions and outcome. Drawing on findings in the first review and my own subsequent QCA study reported in Chapters 6 and 7, I present in Table 5.4.5 some key quality indicators (Box 5.4.5) with an explanation to indicate the importance of their presence or reporting in the articles. It also provides a summary of key important methodological features of QCA that are mentioned elsewhere (Chapter 2, section 2.6).

Box 5.4.5 Quality indicators applied to studies in the updated review

Quality indicator	**Elaboration**
Case to condition ratio (Case: Condition)	The truth table provides a property space of 2^k, where 'k' is the number of conditions and therefore the number of multiples of 2. For example, 2^4 is 2x2x2x2. This represents the number of logical possibilities of configural patterns of the conditions within that property space, in this case 32. Due to limited diversity within the social world it is unlikely that actual cases will correspond to all configurations and therefore are redundant, referred to as logical remainders. Low numbers of cases and a high number of conditions lead to many configurations with unobserved cases. These empty truth table rows warrant explanation based on the context of the study as to their relevance and therefore subsequent interpretation of findings.

Calibration description	All data sources for the condition or factor and outcome sets are transformed for QCA analysis. This important step should be explicitly reported and is key to ensuring that the logic of the method maintains both internal validity (Thomann and Maggetti 2017) and credibility.
Use of sufficiency and necessity terminology	Use of this terminology ensures that authors are grasping the essential multiple causal conjunction epistemology that underpins QCA (Chapter 2, section 2.4.2.2).
Data source/method/approach	There are clearly developments occurring in systematic reviews of complex interventions (N=10/30), RCT and process evaluations (N=2/30) as well as combining linear or logistic regression techniques with QCA (N=7/30). Schneider and Wagemann (2012, pp. 83-90) provide an account as to why logistic regression and QCA do not mix, that is, set relations are not correlations. However, Verissimo (2018) suggests an approach to triangulation noting the different stances of the two methods. Other approaches will collect data from a range of routine collected data and surveys as the key data sources for the QCA analysis
Condition reduction conducted	This is related to the case condition ratio in that authors adopt a variety of approaches to condition reduction, selection and elimination. This might involve forms of clustering or grouping or use of a two-stage approach whereby factors are modelled through QCA analysis leading to reduction of conditions, examined further using QCA. As an example, Scott Parrot (2018) provides a detailed account of multi-component intervention in a meta-analysis of paediatric weight management programmes as the causal factors of interest.

	These components are grouped by different analytical levels: the individual component level, the mix of components that define the weight management programme and, finally, families of components that group together but differently across studies. Authors seek to evaluate these families of intervention components within weight management programmes.
Consistency and coverage parameters of fit reported	This indicates that authors are using software, which is highly recommended (Schneider and Wagemann 2012), particularly for large N and instances where checking back with the cases is not viable (Emmenegger et al 2014). These are important assessments that determine the potential for application beyond the study. These tests assess whether configurations and solutions are consistent within the dataset and cover a greater or lesser proportion of the cases. These checks test the trustworthiness of the results obtained, although not necessarily confirming the underlying causal assumptions made by the authors (Emmenegger et al 2014).
Theory or conceptual framework used a priori	QCA synthesises data to aid interpretation of the findings. Both substantive prior knowledge and theoretical framing are recommended to validate findings. QCA can be used inductively and deductively, but generally evaluates theory or tests hypotheses (Thomann and Maggetti 2017).

5.4.5.1 Narrative summary of included studies

Two sets of studies overlap, Harting (2017) with Peters (2017) and Dill (2014) (missed in initial review) with Chuang (2012). There seems to be overlap with data sources in both but QCA analyses reported have a different focus. Two studies, Beifus (2017) and Matheson (2017), are protocols and therefore information is unavailable rather than absent. Generally, these later studies bring a greater level of sophistication supported by the use of the software. However, nine studies (Bianchi 2018, Burchett 2018, Hartmann-Boyce 2018, Kneale 2018, Scott Parrot 2018, Verissimo 2018, Vickery 2018, Matheson 2017, Mendal 2017) chose not to use the language of necessity or sufficiency even though procedures advise their examination. These terms underpin any causal assumptions that were made. The focus in these articles tends to address the relationship of presence and absence to the outcome, which is a simplification and does not lend itself to the deeper appreciation of configurations as presenting INUS condition arrangements. This arrangement of causal necessity and sufficiency describes a complex causal arrangement of factors that are not necessary on their own but are necessary as part of a configuration of factors, which itself is not necessary but sufficient to achieve an outcome. This in turn also leads to the possibility that different arrangements of factors lead to the outcome (equifinality). Most authors describe their calibration procedures, often in appendices or supplementary tables.

Two studies, Burchett et al (2018) and Chiappone et al (2018), did not present consistency and coverage parameters of fit. Chiappone et al (2018) presents truth tables listing individual configurations of high performing and low performing early care and education programmes and reports narratively the number of programmes that contain a certain factor.

Twelve studies do not frame or use theory, a conceptual framework or logic model and thus took a technical (use of software) approach to the use of QCA methods. Goicolea and colleagues (2018), for example, examine conditions that support mental and psychosocial health in Swedish youth centres and work from previous reports and knowledge of variability amongst the youth centres. Others use the QCA to manage complex interventions within systematic reviews, such as behaviour change techniques for medication adherence (Kahwati et al 2016) or food purchasing behaviour to promote healthy choices (Harmann-Boyce 2018), which may have a variety of theories underpinning the individual interventions.

Two studies (Forman-Hoffman et al 2017 and Kien et al 2018) use the implementation framework CFIR (Chapter 4, section 4.3.2). One protocol (Matheson et al 2017) and one study (Scott Parrot 2018) apply Complexity Theory terminology. A third study, Lubold (2017), makes a very brief mention of the CAS lens in the background suggesting it is useful but with no further reference when presenting or discussing results. Scott Parrot and colleagues (2018) limit themselves to addressing non-linearity and context dependence for interpreting complex interventions in a systematic review. Matheson (2017) makes brief reference to Complexity Theory in social systems. Neither author directly apply Complexity Theory in QCA methodology, they use the theory to rationalise their assumptions of the complex systems under study. As an ongoing multiple case study design, Matheson may develop application further. Other than Leykum and colleagues (2014) earlier work reported above, efforts to utilise Complexity Theory through QCA methodology have not yet presented themselves.

Table 5.4.5 Overview of key quality indicators in studies identified in update 2015-2019

Author and year	Case to condition ratio (*Small <10 Medium 10 - 50 Large > 50)*	Calibration description Not described Not fully described Fully described	Use of sufficiency and necessity terminology YES/NO	Data source/ methods/approach 1. *Systematic reviews of effectiveness for complex interventions* *2. Combined as mixed method approach with linear or logistic regression* *3. Other*	Condition reduction conducted (or two step/stage approach)	Consistency and coverage parameters of fit reported YES/NO	Theory conceptual or substantive knowledge used Theory or framework used a priori
Beifus 2017	Not available	Not available	Yes	1. – Intervention component focus	Not available	Not available	Analytical framework based on history of disease and steps for prevention
Bianchi 2018	24:12	Not described	No	1. – Intervention component focus	No	Yes	No
Bicknell 2017	9:6	Fully described Appendix	No	2. – Hierarchical models	Clustering of themes to six composite conditions	Yes	No
Breuer 2018	10:11	Fully described Supplementary file 2	Yes	3. – QCA alone using routinely available data	No	Yes	Theory of change - logic model Online supplement 1
Burchett 2018	15:3 and 2	Fully described	No	1. – Intervention component focus	Three QCA truth tables for different outcomes but same conditions	No	Inductive approach
Castellano Rioja 2018	161:5	Yes	Yes	2. – Traditional regression models	No	Yes	No
Chiappone 2018	30:9	Fully described	Yes	2. – QCA followed by a document review to describe and contextualise the necessary and sufficient conditions	No	No	No

Author and year	Case to condition ratio (*Small <10 Medium 10 - 50 Large > 50)*	Calibration description Not described Not fully described Fully described	Use of sufficiency and necessity terminology YES/NO	Data source/ methods/approach 1. *Systematic reviews of effectiveness for complex interventions* *2. Combined as mixed method approach with linear or logistic regression* *3. Other*	Condition reduction conducted (or two step/stage approach)	Consistency and coverage parameters of fit reported YES/NO	Theory conceptual or substantive knowledge used Theory or framework used a priori
Dill 2014 Missed in previous (overlap with Chuang 2012)	291:4	Fully described in Appendix C	Yes	2. – QCA integrated with regression	No	Yes	Conceptualisation of career ladders
Eicher 2016	19:5 (3 and 2)	Fully described	Yes	3. – QCA based on survey data	Yes (remote and proximate factors)	Yes	No
Forman-Hoffman 2017	19:5	Reported	Yes	1. – Intervention component (implementation strategy components) focus	Tested several different models with different outcomes	Yes	Consolidated Framework for Implementation Research
Gimenez-Espert 2018	460:9	Fully described using descriptive statistics	Yes	2. – Hierarchical regression	Three outcome models using the same factors	Yes	Hypothesis testing
Harris 2018	27:5	Fully described in Additional table 1 and Appendix 8	Yes	1. – Intervention component focus (synthesis of process evaluation data)	Five QCA models consolidated into a final sixth model	Yes	Yes, pre- and post-logic models
Harting 2017(overlap with Peters)	29:5	Fully described Supplementary appendix S1	Yes	3. – QCA alone – data collection through three surveys	Condition cluster analysis	Yes	Conceptualisation of active networks of project leads needed to achieve success

Author and year	**Case to condition ratio** **(***Small <10 Medium 10 - 50 Large > 50)*	**Calibration description** **Not described Not fully described Fully described**	**Use of sufficiency and necessity terminology YES/NO**	**Data source/ methods/approach** 1. *Systematic reviews of effectiveness for complex interventions* *2. Combined as mixed method approach with linear or logistic regression* *3. Other*	**Condition reduction conducted (or two step/stage approach)**	**Consistency and coverage parameters of fit reported YES/NO**	**Theory conceptual or substantive knowledge used** **Theory or framework used a priori**
Hartmann-Boyce 2018	35:5	Yes, Supplemental tables 5 and 6	No	1. – Intervention component focus	No	Yes	No
Goicolea 2018	18:4	Fully described Additional file 2	Yes	3. – Multiple case study design	Yes, conducted process of restricting and dropping conditions based on criteria	Yes	No
Kahwati 2016	60:9	Fully described	Yes	1. – Intervention component focus	No	Yes	No
Kien 2018	24:5	Fully described	Yes	3. – QCA of process evaluations conducted in a cRCT.	No	Yes	Consolidated Framework for Implementation Research
Kneale 2018	28:6	Not fully described	No	3. – Mixed qualitative method approach – thematic synthesis, charting and tabulation prior to QCA	No	Yes	No
Leas 2017 (Abstract only)	49:6	Fully described	Yes	1. – Intervention component focus	No	Yes	Analytical framework
Lubold 2017	18:9	Fully described	Yes	3. – QCA only – using routine collected data and information from a variety of sources	No	Yes	Family policies within a broader framework of Welfare state theories

Author and year	Case to condition ratio (*Small <10 Medium 10 - 50 Large > 50)*	Calibration description Not described Not fully described Fully described	Use of sufficiency and necessity terminology YES/NO	Data source/ methods/approach 1. *Systematic reviews of effectiveness for complex interventions* *2. Combined as mixed method approach with linear or logistic regression* *3. Other*	Condition reduction conducted (or two step/stage approach)	Consistency and coverage parameters of fit reported YES/NO	Theory conceptual or substantive knowledge used Theory or framework used a priori
Matheson 2017 (protocol)	Unavailable	Unavailable	No	3. – QCA conducted post in-depth case study evaluation of quality improvement activities.	Unavailable	Unavailable	Yes (Complexity Theory)
Melendez-Torres 2017	20:5	Fully described Appendix S1 Table 1	Yes	1. – Intervention component focus and conducted separate qualitative synthesis of studies of users and provider views	Split for two outcomes same conditions	Yes	No – informed by analytical synthesis of actor views
Mendal 2018	20:	Fully described Appendix SA3	No	3. – QCA preceded by thematic analysis of data, conventional cross-case analysis.	Developed conceptual domains combining indicators	Reported in Appendix SA4	Yes – developed specific conceptual model
Paykani 2018	131:5	Fully described Additional file 3	Yes	3. QCA – data from different international data sources	No	Yes	Yes – conceptual framework
Peters 2017	25:4	Fully described Tables 1 & 2	Yes	3. – QCA – using data from three web-based surveys	No (composite conditions)	Yes	No
Saltkjel 2017	29:4	Table A5 in online technical appendix	Yes	3. – QCA – using data from routinely conducted surveys	Two outcome model	Yes	Yes – theoretical argument presented
Scott Parrott 2018	28:6	Fully described	No	1. – Intervention component focus (intervention level effects and context level effects)	Cluster and reduction approach to condition (intervention component) – models produced for follow-up intervals	Yes	Yes – two CAS characteristics: nonlinearity of effects and context-dependence plus intervention analytical framework

Author and year	Case to condition ratio (*Small <10 Medium 10 - 50 Large > 50)*	Calibration description Not described Not fully described Fully described	Use of sufficiency and necessity terminology YES/NO	Data source/ methods/approach 1. *Systematic reviews of effectiveness for complex interventions* *2. Combined as mixed method approach with linear or logistic regression* *3. Other*	Condition reduction conducted (or two step/stage approach)	Consistency and coverage parameters of fit reported YES/NO	Theory conceptual or substantive knowledge used Theory or framework used a priori
Thygeson 2016 Abstract only	203:7	Unavailable	Unavailable	2. Multivariate regression and QCA	Unavailable	Unavailable	No
Verissimo 2018	199:6	Fully described (example of fuzzy set direct method)	No	2. Both methods analyse the same data	No	Yes	No
Vickery 2018	35:8	Fully described Table 1	No	3. QCA using qualitative analysis of interview data	Conditions were composites of factors	Yes	Yes – specific conceptual model

5.5 Review discussion

I examined how QCA was used in the field of healthcare by identifying and evaluating applications in health research. I wanted to assess this methodology and its set of methods because it investigated 'complexity', such as context, mechanisms, variation and heterogeneity across cases. Interest in QCA methodology is gathering pace in health research particularly between 2015 and 2019. Some authors provide multiple examples of the application (Britt (2000, 2006, 2007), Blackman, (2008, 2011, 2013), Thygeson (2012, 2012, 2016), Kahwati et al (2011, 2016) and Goicolea (2015, 2018), which indicates the value of the method in addressing their questions.

Overall, authors were generally positive about the application of QCA within their context. A broad range of examples were observed from exposing health inequalities to addressing the complexity of individual patient decision-making, from service delivery and implementation of healthcare interventions (complex interventions) to ascertaining whether policy goals are met. The common feature is complexity of the intervention or context and the need to expose the combination of relevant factors that might result in a specific outcome. Particularly, the social context of delivery, organisation of care, individual factors and socio-economic inequalities were key features. Many authors familiar with more traditional approaches (typically quantitative) struggled with the underlying methodology of sets and the logic of necessity and sufficiency. Later examples in the 2015-2019 update cohort begin to indicate patterns of usage in systematic reviews and alongside linear regression methods. Veríssmo (2018) compares QCA with logistic regression (binary data) on usage intensity of medical mobile apps and observes that assumptions of symmetry in logistic regression cannot be applied in QCA, although reporting suggests some triangulation between results in both methods and thus supports using this mixed method approach.

In the following sections I draw attention to several methodological challenges for further consideration in health studies.

5.5.1 Methodological challenges

I have drawn together key issues observed in this data that future applications should consider when planning and designing a QCA study.

5.5.1.1 Limited diversity and logical remainders

With the limited diversity of social reality, unobserved (no cases) configurations are likely (section 5.4.5). The ratio of cases to conditions is therefore an important study design feature. Extreme examples of logical remainders shown by Eng (2012), Kahwati (2011) and Lubold (2017) indicates a greater need for theoretical appreciation and explanation of the unobserved configurations. Either the configurations are plausible or not and therefore authors should apply greater attention to condition management. But, also, logical remainders may not be at all relevant or just an arithmetic artefact (Schnieder and Wagemann 2012).

Open and closed case sets

Researchers should justify and explain within their theoretical context whether remainders are relevant configurations which might impact on the findings if additional cases were ever found. Otherwise, it should be made clear that they do not have any relevance within the current analysis and a justification made (Schneider and Wageman 2012). If, for example, the set of cases represents the total sample set (the universal set), which occurs often in political studies (e.g. all democratic countries), I would describe this situation as a *closed case* set. By this I mean that for the purpose of the study context the set of cases are defined as complete for the study purpose. I argue this point for the QCA study reported in Chapter 7. Similarly, in the systematic review examples (e.g. Kahwati 2016, Hartmann-Boyce 2018, Forman-Hoffman 2017 and Harris 2018) where authors identify all relevant examples of interventions for a given clinical question, the individual study (or study arm) is the case for QCA purposes. This then provides a complete set of cases (studies). This is time sensitive with systematic reviews because additional studies are potentially incorporated in future systematic review updates. Breuer and colleagues include all 10 health facilities in the Chitwan province of Nepal in their study, thus a *closed case* set. Examples of an *open case* set in my view are when sampling approaches, such as those conducting surveys, receive response rates under 100%, therefore missing cases. These missing cases, if in theory included, may lead to different solutions and, therefore, will limit explanatory inference of the final QCA models. As an example of an open case set, Lubold (2017) had data available for 18 out of 34 countries on breastfeeding initiation support. For Harting (2017), the gap was narrower with 29 out of 34 public policy network cases included, however the other five cases may present deviant or discriminant cases that could change the final QCA models. Blackman et al (2013) were only able to obtain data from a sample of 27 of a wider set of cases of 70. Authors checked baseline differences for those cases not included, which present different causal factor configurations. Authors did note this limitation.

5.5.1.2 Missing data (or truth table values)

QCA cannot manage missing data, therefore cases can get excluded on that basis, increasing limited diversity, although limited diversity does not correspond to a missing value (Schneider and Wagemann 2012). QCA does not tolerate missing values in the truth table because it does not fulfil the logic of set theory. Set theory defines whether a case is in or out of condition set, or ambiguously neither in nor out, which is describing a state not a missing value (Befani 2016).

5.5.1.3 Case selection

Given my suggestion of *open* and *closed case* sets, extracting subsets of samples from much larger populations, limits QCA conclusions to generalise to the wider case set. Therefore, the conclusion drawn needs to consider the cases not within the QCA model and how they might, if entered in the model:

a. change the factors considered and,

b. change the configurational patterns and subsequent minimisation solutions (results).

As an adjunct, the decision to use QCA should not be based on the number of cases, but on the principle that a set theoretic approach assuming causal complexity is most relevant (Schneider and Wageman 2012). The principle of the method is to retain a degree of intimate knowledge of the cases, as with other case comparative approaches, but allow the handling of a greater number of cases in a comparative technique (Schneider and Wageman 2012).

The selection of negative cases is an important component in observing the differences between why some cases result in the outcome and others do not (Rihoux and Ragin 2009, Mahoney and Goetz, 2004). This is exploited by those using QCA in systematic reviews that identify individual studies (the cases for the purpose of QCA) with positive (most effective) and negative (least effective) interventions (e.g Melendez-Torres et al 2017). This has, in some examples, excluded the ‘middle’ cases (e.g. Melendez-Torres et al 2017). I explore the ‘middle’ as part of a change process in Chapter 7, indicating whether implementation explanations utilising QCA configurations revealed a pattern of change overtime.

5.5.1.4 Managing the identification and selection of conditions

Decisions on which factors or conditions are of interest in the causal pathway are challenging. Procedures are elaborated in most papers as to how they determine a final set of factors for QCA modelling. The key problem is deciding which of the large number of conditions to include in the model.

Sheehy (2014) illustrates a two-stage strategy. They use a logic model to explicate the links between conditions and outcomes. They present a series of QCA models with 14 cases with three to five conditions across six outcomes. Thygeson (2012) conducted a complex analysis mapping a range of potential factors to three key outcomes of interest. A formal two-step approach developed by Schneider and Wagemann (2006) separates proximate and remote factors, although Cooper and Glaesser (2016) suggest using a different algorithm (Baumgartner 2015) might manage this condition reduction better. Cragun (2015) deleted possible relevant conditions based on their lack of variability across cases or inconclusive survey results. Decision-making details on condition reduction are reported in their paper (Cragun 2015). Goicolea (2015) raised the point of the complex task of selecting conditions to go into the QCA analysis and the implications of those not in the model thereby limiting the interpretation of findings from the synthesis. Warren (2013) proposed that care is required when making any inference from the data collected, as the data may not present all available or known data relevant to the focus under study. In addition, other factors or conditions not measured may lead to different conclusions (Weiner 2012). Methodological trials undertaken by Marx (2006) examine whether QCA's design affects its capacity to distinguish random from real data. Marx (2006) argues that, optimally, the number of cases needs to far outweigh the number of conditions. As QCA works on managing complexity by drawing out patterns across cases, maintaining the balance between cases and conditions needs cases in a higher ratio to conditions (e.g. Chiappone 2018, Kahwati 2016, see table 6.4.2). This will provide some contradictions, typical in real world situations, whereas full complexity (uniqueness) arrives when cases are equal to or less than the number of conditions (Marx 2006). Marx concluded that the analysis should minimise contradictions but not eliminate all contradictions (Marx 2006).

The process and procedures to manage the number of conditions reported by authors are diverse and, unsurprisingly, contextually specific to the field under study. Interestingly, in approaching causality a key feature of condition identification is understanding the proximity and remoteness of these factors to the outcome of interest, that is, to "unravel the configuration of proximate conditions that link a well specified remote context to the outcome" (Schneider and Wagemann 2012).

5.5.1.5 Calibration of conditions and outcome – making threshold decisions

Calibration is a relative term rather than a data measurement. It requires specific rules or criteria in assigning specific values for set membership, that is, for example, whether a given value is above or below the line for set membership in crisp sets. Calibration is a skilful exercise requiring a detailed and explicit plan. Calibration is generally covered well by more recent studies.

Calibration is akin to preparing an instrument for measurement against known standards (Ragin 2008). The researcher determines (based on theoretical justification) the threshold point in the dataset that allocates a case to its set membership in that condition set (Rihoux and Ragin 2009). The use of medians and means as threshold points are unsound because they are within data values, whereas calibration is external to the data relative to the context (Schneider and Wagemann 2012). Glatman Freedman (2010) and Britt (2007, 2006) illustrate specific approaches to calibration and measurement by using odds ratios and correlation coefficients. However, it is the qualitative set membership assignment levels that are most pertinent within QCA. Schneider and Wagemann (2012 p. 32) propose that success of calibration “requires the following:

a) A careful definition of the relevant population of cases;
b) A precise definition of the meaning of all concepts (both the conditions and the outcome) used in the analysis;
c) A decision on where the point of maximum indifference about membership versus non-membership is located (signified by the 0.5 anchor in fuzzy sets and the threshold in crisp sets;
d) A decision on the definition of full membership (1) and full non-membership (0);
e) A decision about the graded membership in between the qualitative anchors.”

More importantly, what constitutes the cases’ membership in that condition set ,may require multiple empirical sources (Schnedier and Wagemann 2012). Chang (2013) use multiple research techniques to obtain, prepare and calibrate data source material for QCA synthesis. They specifically developed a questionnaire for use in QCA rather than opportunistically identified source data.

5.5.1.6 Data sources

Ragin (1987) refers to the need for ‘substantive knowledge’ prior to a QCA synthesis which entails a broad range of source data. This source data can include routine and documentary evidence, other studies both quantitative and qualitative, survey data collection and qualitative research. Such data sources should provide sound and theoretically informed knowledge to test the dialogue between ideas and evidence (Ragin 1987).

Authors reported limitations with their source data and its use in QCA. Routine census interview survey data used by Blackman (2008), although collected for other purposes, was obtained via an independent marketing agency on behalf of the local government body. A very high response rate of 90.7% was obtained. Blackman (2008) reduced the original sample size from 7,351 to 2,882 based on their case definition requirements. They acknowledge that some sampling bias is possible. For any research strategy, data sources are a critical component. These data are not derived by the methods of QCA. QCA utilises and synthesises this source data, that is, it seeks to transform data previously analysed or assembled for different objectives (Sandelowski et al 2012).

Data sources provide information for all cases on the outcome and conditions of interest and can present the problem of missing data (Befani 2016). A large proportion of the studies in this review use data collected for other research purposes, rather than specifically for a QCA designed study. Using QCA as a research strategy does require considerable efforts to amass and prepare both quantitative and qualitative types of data already analysed in preparation for the QCA synthesis (Cloverdill & Finley 1995). Justifications for using this type of data and the match with the theoretical basis for the study is important. I present justifications for the transformation for my own QCA study in Chapter 6.

The data sources are firstly organised by case and condition into a raw data table before transformation through calibration into set membership values. It is important for transparency to report this raw data matrix with the uncalibrated values taken from the source data (Schneider and Wagemann 2012, Rihoux and Ragin 2009). This is missing in some studies. Future quality checks would need to evaluate this transformation from raw source data to the truth table.

Data source examples

The following exemplars illustrate data source approaches where I frame them as either *closely* or *remotely* coupled to the QCA analysis. By this I mean that the study design collects data for the specific purpose of QCA analysis as opposed to use of data not originally obtained for QCA analysis. It is important to ensure close correspondence between the theory or conceptualisation of conditions and the outcome in relation to the cases, and the data sources used to ensure credibility of the interpretations of the QCA models derived using the software. I illustrate my point using the following two studies.

Cragun 2015: Closely coupled data

QCA is used to investigate routine tumour screening for Lynch syndrome, a common cause of hereditary colorectal cancer, to identify patient and system factors that might impact on the effectiveness of screening in twenty institutions. A survey of these institutions is designed specifically for the purpose of analysis using QCA because inferential statistics are not relevant. The outcome of interest is the patient follow-through (PF) and how this varies across institutions. Data is sought directly to identify conditions that might influence programme effectiveness (PF). An online survey was used specifically for the purpose of the QCA study. The design of the study used cancer experts and behavioural theory aided by implementation of conceptual frameworks CFIR and RE-AIM (Chapter 4) to develop relevant survey questions on implementation (Table 1, Cragun 2014, p. 775). The survey content, validation and piloting are reported in a separate published report (Cragun et al 2014). Authors use the RE-AIM dimension descriptions to report all the study findings, that is, the identification of 'High PF institutions' and 'Low PF institutions' based on the twenty cases assessed. Thus, there was close correspondence between data, theory and synthesis in the design and data collection through to the interpretation of the findings.

I would describe this study as one where the data is *closely coupled* with the QCA synthesis and it is strongly framed within well-recognised conceptual frameworks within implementation research throughout. They refer to the development of 'tentative causal models', which led to further research based on the results of the QCA synthesis.

Thomas 2014: Remotely coupled data

Thomas et al (2014) provides an example of using QCA to identify configurations of participant, intervention and contextual characteristics associated with public health and health promotion interventions in a systematic review. The objective was to identify the effective components of complex interventions to promote breastfeeding directed at expectant and new mothers. This approach was post hoc and was used as a further analysis to identify components of community engagement present in effective interventions promoting breastfeeding.

Data were obtained from a subset of studies identified in a systematic review of community engagement (O'Mara Eves 2013). Conditions were pre-selected based on authors overarching conceptual framework of community engagement. Authors sought to test this framework and found that additional conditions provided greater explanation for unexplained differences between the studies. Thus, the QCA synthesis was used to examine previously obtained data within the confines of multi-method systematic review methodology. For their purposes, the authors selected 12 included studies, a subset of 131 studies included in a meta-analysis conducted in the original review. However, authors note that statistical heterogeneity and conceptual variation across studies remained. Authors state that the selection of studies did not meet recommended practice of purposive sampling in QCA and that data available are confined to previously conducted studies. These additional data are not obtainable unless in the study reports. Authors did return to original study reports and extract additional data not extracted by the original review authors to re-define factors or conditions of interest which 'work' in the QCA modelling.

Systematic review methodology, when conducted well, provides a systematic and transparent methodology. Re-use of the data to conduct an exploratory QCA allowed the authors to clearly delineate cases (studies) and an outcome (effective community engagement). They used theory of change to provide coherent reasoning based on the data at hand. In principle, the systematic review should obtain all evidence available at the time of reporting.

I suggest that in this example, the data is *remotely coupled* as opposed to the Cragun (2015) design of closely coupled data, but both datasets are in close correspondence throughout. Subsequently, the use of QCA in systematic reviews has become popular to manage multiple complex interventions.

5.5.1.7 Large N designs

Within this review between 2000 and 2013, there were eight large N examples (defined as above 50 cases here): Britt 2000 (n=142), 2006 (n=174 and 152), 200- (n=54), Blackman 2008 (n=2,882), Chuang 2011 (n=661), Longest 2012 (n=528), Warren 2013 (n=130) and Chang 2013 (n=600). In addition, between 2014 and 2019 there are a further seven examples: Castellano Rioja 2018 (n=161), Dill 2014 (n=291), Gimenex-Espert 2018 (n=460), Kahwati 2016 (n=60), Paykani 2018 (n=131), Thygeson 2016 (203) and Verissmo 2018 (n=199). Use of QCA for large N continues to evolve. One of its principle tenets is to maintain close correspondence with the cases particularly for checking the coherence and consistency of the findings and their subsequent interpretation (Rihoux & Ragin 2009). Thomann and Maggetti (2017) outline methodological considerations for both the smaller N substantive case approach and the larger N, typically redundancy-free model of logical remainders. The researcher might focus on types and categories of cases (Rihoux and Ragin 2009), although thick description is sacrificed (Rihoux and Lobe, 2009). These designs might use routine collected survey data for their source data, and therefore larger N is likely. However, large samples may provide greater generalisability to the wider context under study. Large N, though, does not power the study in the way that experimental designs that use statistical techniques do. This is set theory not probability (Chapter 2). Issues more likely with large N are missing values or degrees of freedom, which are not the same as unobserved cases in logically possible configurations (Schneider and Wagemann 2012).

Ragin (2008) takes up this development: “However, it became clear to me that the set-theoretic methods I had developed for small- and medium *N* research could be productively extended to large-N research” (p. 7). He goes on to elaborate four key areas of comparison between QCA and other techniques and how QCA offers something different for large N designs:

1. Set theoretic versus correlational connections: the difference between symmetrical and asymmetrical relations. Correlation techniques obscure subset relations of social phenomena and how they are related (Ragin 2008). However, it provides a predictive

element to single conditions (Veríssimo 2018). Also, hierarchical approaches to regression tests are used that include multiple factors of interest from which the results are used to calibrate condition factor sets (Giménez-Espert 2018).

2. The practice of calibration versus measurement: Calibration assigns set membership. Measures are transformed into meaningful relationships that are pre-defined and based on prior substantive knowledge and theory (Ragin 2008) and are defined qualitatively.
3. Configurations of conditions versus independent variables: This moves away from identifying single factors but investigates configurations of factors.
4. The analysis of causal complexity versus the analysis of net effects: This crucial difference in techniques is particularly argued by Ragin (2008) to explore all logically possible combinations. Given that limited diversity in the social world will not provide cases across all configurations, he specifically engages with counterfactuals (Ragin 2008).

5.5.1.8 Addressing causal complexity using set relations

Ragin (1987) articulates his *social* causal complexity rationale as “social causes often modify the effects of other social causes, sometimes mutating and transforming their impact” (Ragin 1987, p. 83). Such a description fits with the social Complex Adaptive Systems (CAS) perspective adopted in this thesis (Chapter 4). In addition, qualifying the analytical aspect of QCA allows “investigators to specify and study the major features of social units and processes, the parts that combine indifferent ways to produce different wholes” (Ragin 1987, p. 83). In his original work Ragin did not align with Complexity Theory explicitly but has done so more recently in collaborative work with David Byrne (Ragin and Byrne 2009).

Authors’ understanding of the principle concepts to express causal complexity, multiple conjunctual causation, equifinality and asymmetry using necessity and sufficiency terms for causal relationships was very variable. However, several authors provided detailed accounts or technical appendices to explain key terms to facilitate this method in health research.

5.5.1.9 Final comments

A major issue, when transferring this methodology from its more typical home of political science and social policy to health research driven by evidence-based concepts, is to what extent a researcher can claim generalisable findings and causal connection between the conditions and the outcome using QCA beyond the examined cases. There are debates within the field regarding notions of causality and to what extent QCA methods permit, within the parameters of their own logic, causal connection beyond association. There is an active debate on the notion of causation within philosophy generally (Cartwright 2007, Illari and Russo 2014). However, as applied to social contexts, the use of both quantitative (experimental and non-experimental) and qualitative research to infer causal relationships is equally debated (Cooper et al 2012). Cooper et al (2012) sum their view:

“The overall argument is that outcomes may be strongly path-dependent, that we need to understand how outcomes were reached in particular cases because the sequence and pacing of causal factors may be different across cases, and differences in these may have affected the nature of the outcome.” (Cooper et al 2012, p. 50)

In addressing the application of QCA, Cooper and colleagues (2012) highlight reliance on theory to elaborate potential causal factors and missing causal factors, whilst accounting for causes to precede their effects. However, these methods offer a strategy for causal analysis (Cooper et al 2012). Befani (2016) in applying QCA methodology to evaluate development interventions, proposes that QCA, “can drastically shorten the distance between qualitative and quantitative methods, sometimes referred to as a divide. By translating qualitative data, including potential causal factors, into a numerical format and systematically analysing it, causal patterns in the data can be found, thus allowing for causal claims to be tested without the need of a counterfactual situation.” (p. 5). Befani (2016) also proposes that the analysis of INUS conditions (Chapter 2, section 2.4.2.2) allows assessment of complex system dynamics and affords an opportunity to determine the ‘tipping point’ (phase transition, Chapter 3, section 3.5.2) of change. In addressing the premise of generalisation in quantitative and qualitative research, Polit and Beck (2010) suggest that replication and integration are key components to provide generalisation.

5.5.2 Review limitations

This review of QCA did not systematically assess source data in reviews or the underpinning logic and assumptions made by authors in the use of this data for the QCA synthesis and causal modelling. Topics were broad, and such assessment would require topic expertise. Neither did it assess the validity of study findings derived from the QCA model, nor the efficacy or effectiveness of this methodology and its set of methods. Instead, the purpose was to examine the robustness of QCA application in each study examined. The review is essentially descriptive with a focus on complex causation as the primary focus for application.

When undertaking a review of such studies, there is an issue as to whether to assess the quality and validity of the source. This is a strength of the evolving systematic review model of QCA where all studies are previously quality assessed. Factors are associated with studies providing affirmative results, although not impeded by the risk of bias in the study. In such studies the reader needs to view the quality assessment separately.

5.6 Conclusion

This review examined the application of QCA in the field of health research to ascertain its applicability and appropriateness. Poor application and reporting with a lack of understanding of the methodology impaired this assessment, however, increasing numbers of examples indicate the development of approaches and strategies. This review, however, established that QCA methods provide:

- A research strategy that engages with complexity and causal relations in healthcare's complex social systems.
- A systematic set of methods supported by software.
- A third approach rather than a bridge between qualitative and quantitative data.
- The capability to utilise and synthesise both qualitative and quantitative data within set theoretic relations.

This review is the first and currently the only review of QCA methodology (October 2019) migrating from social and political science to healthcare and the evidence-based methods context. A novel quality checklist tool for assessment of such studies was developed with a view to establishing good practice standards in future applications of QCA (Section 5.3.3).

This review also shows the need for methods to address complex causality in real world settings. Grasping the epistemic basis of QCA and determining which modifications are most appropriate will require further methodological research. Finally, authors found it a useful method to manage complex phenomena permitting multiple factors to be examined simultaneously.

5.6.1 Recommendations for future applications

Use of QCA methods in health research indicates a need for greater understanding of QCA logic and methodology to improve its potential application. Likewise, future authors need to engage with QCA methodologists and recent developments regarding methodological work to ensure the ongoing quality of application. Journals allow supplementary data to be published online, and authors should take advantage of this. Adding available raw data matrices and truth tables, for example, would improve several reporting issues.

Chapter 6: Methods of the Qualitative Comparative Analysis study

6.1 Introduction

My purpose has been to illustrate causal complexity as a closer approximation of what happens in the ‘real world’ of the implementation research context. My thesis tests whether Qualitative Comparative Analysis (QCA) methods can operationalise social Complex Adaptive System (CAS) concepts integrated into the novel conceptual FISCAS framework. I used data obtained from a cluster randomised implementation trial (Rycroft-Malone et al 2012) and its accompanying process evaluation (Rycroft-Malone et al 2013). In this chapter I report the methods for the QCA study I undertook.

Two distinctive methodological phases were conducted. First phase entailed case definition and within-case pathway processing of fasting practice. In the second phase I undertook an across-case factor analysis (using QCA methods) to determine complex causal arrangements that occur in implementation projects, in this case making changes to fasting practice. Three key steps were undertaken across these two phases (Table 6.3): 1] the development of conceptually informed causal condition (or factor) sets for the QCA cross-case comparison, 2] development of individual case narratives of the NHS organisations, a within-case strategy, using process tracing techniques, and 3] the QCA analysis of cross-case comparison to identify patterns of factors or conditions that lead to successful change in practice.

Trial and process evaluation methods and QCA methodology differ with respect to their purpose. The former seeks to aggregate data by intervention comparison with the loss of individual case definition whereas the latter conducts cross-case comparisons and assumes across case heterogeneity and maintains individual case definitions. Implementation research conceptual frameworks (Chapter 4) focus on multiple aspects of reality that include contextual influences that impact on multiple aspects of an intervention’s implementation (or event), which need to take account of human behavioural responses. This clearly indicates the need to manage causal complexity. From the social system perspective, both process tracing and QCA methods seek to expose such causally complex arrangements.

This chapter sets out the methods, and the following chapter describes the findings. Following the thesis questions set out in Chapter 1, this chapter addresses:

Can Qualitative Comparative Analysis methods operationalise Complexity Theory concepts? And, specifically,

> How can QCA be adapted to implementation research?
>
> What contribution do QCA methods make in enabling a Complexity Theory perspective?

6.1.1 Study conceptual framework

The ontological position of complex realism (Byrne and Callaghan 2014, Reed and Harvey 1992, see Chapter 2) adopted in this thesis states that reality exists beyond the observable realm. This reality is composed of multiple nested natural and social Complex Adaptive Systems (CAS) that are connected at multiple levels within the observer's gaze but can also be hidden. These social CAS have emerged over time to form complex structures distinct from their original elements.

For the purposes of research on such systems, it is assumed that parts of these systems, from a complex realist perspective, will remain unobserved and we will need to make inference from our observations to those unobserved aspects. Unobserved aspects continuously influence all levels of the system under observation, and to gather observations in one part of a system excludes these other potential influences. Research only ever takes an abstracted view of the shifting dynamics of reality and so caution is exercised with any generalisation beyond our observations both in time and space.

The novel conceptual framework (FISCAS) developed in this thesis integrates social CAS and implementation concepts and was used to frame and re-structure the POISE trial data to explain what combination of factors led to successful change to fasting practice, and likewise to unsuccessful change (Chapter 4, section 4.3.6.1). These eight (FISCAS) concepts were: Individual agent, Interaction, Self-organisation, Emergence, History, Temporality, System Organising Principle, and Innovation.

I reason practice, and practice change, as procedures integrated into a complex system that emerge over time, cannot be easily disassembled and reassembled (Chandler et al, 2016). Fasting practice presents a good example (section 1.4) due to its long history. I further assume that implementation as an activity seeks to change practice, healthcare professional behaviour and systems of care delivery, treatment etc. and will need to work within the pretext of social CAS.

Within the language of social CAS, I drew out the ‘system organising principle’ as a separate concept to identify when and where change occurs to facilitate implementation projects. Systems of practice, in this example fasting before routine surgery, will have several multiple competing system imperatives or drivers that organise the current system of practice. I propose that ‘system imperative’ presents an organising principle, an overriding reason to resist change, irrespective of the system’s capacity or ability and healthcare professionals’ willingness to change. For fasting practice, I speculate the system imperative is management of the operating list (Chandler et al 2016), further evaluation and explanation were undertaken in the QCA study.

6.1.2 Regulating patient fasts before surgery

Guideline recommendations, generally, are based on retrieval and assessment of evidence and consensus techniques using expert panels to provide a general recommendation statement for a type of context (e.g. surgical departments) but not for specific contexts (e.g. individual NHS organisation). The Royal College of Nursing (RCN) guideline (Westby 2005), in providing an implementation guide for its recommendation for fluid fasting before routine surgery, did not state there were implications to practice to meet its two-hour minimum fast for individual patients, nor how that might be enacted in practice.

The POISE trial indicated that to improve fasting times in line with the guideline recommendations, a shift away from a blanket ‘nil by mouth’ from midnight or breakfast rule for patients was needed, to an approach that focused on a patient’s individual fasting requirements. I subsequently refer to *fasting regulation* to better describe this RCN guideline recommendation. Due to the inevitable delays, cancellations etc. to operating list times, patient fasts will require regulating.

6.1.3 Original primary data

NHS surgical departments, theatres, day and inpatient wards and surgical recovery, manage the throughput of patients requiring both routine and emergency surgery. In some surgical departments, an emergency may trump routine surgery, in others, dedicated theatres run routine surgical lists. The original implementation trial focused on routine surgery. In the trial, observational data was collected on duration of fasting from the cessation of both fluid and food intake to the induction of anaesthetic. This primary outcome measure was obtained at baseline and follow up. It was used to indicate (separate for food and fluid) whether any influence or change to practice had occurred from the presentation to the surgical departments of the RCN guideline via the three different implementation strategies. These strategies were the trial interventions undergoing evaluation. The guideline recommended limiting fasting periods of two hours for fluids and six hours for food. Previous data had shown prolonged mean fasting times of 9+ hours for fluids (Hebballi et al 2002). A range of process data was collected alongside the trial. Also, the funders conducted an evaluation of quality improvement approaches across nine studies, including POISE. A summary of the potential data for use in the QCA study are:

- Documentary (including final report to funder), standard dissemination feedback forms
- Interviews: key contacts, change agents
- Focus group
- Survey (Learning Organisational Survey and local investigator audit)
- Patient data survey and interview
- Assignment to strategy documentation
- Key activities report
- Duration of fasting collection form
- Researchers' perspectives/other data reported

As a researcher on the POISE trial I was involved in recruitment, ethics application, intervention development, dissemination and training, data collection, data analysis and report write up. I, therefore, experienced the translation of the original study design into the real world of healthcare. This entailed management of local NHS organisation investigators, site key contacts and the change agents who undertook the implementation strategies. These three strategies were:

1. Opinion leadership introducing an educational web-based tool,
2. Plan Do Study Act (PDSA), quality improvement cycles
3. Standard guideline dissemination with audit feedback.

All NHS organisations recruited received standard dissemination and audit feedback and one trial arm received standard dissemination and audit feedback alone. The trial was a cluster design using interrupted time series set up to determine which strategy, when implemented, was most effective at ensuring changes to fasting practice.

6.1.3.1 A comment on the implementation strategies – POISE study interventions

The POISE trial sought to evaluate three types of implementation strategies. These intervention strategies were designed to mimic standard approaches undertaken and considered viable at the time. First, the standard dissemination approach followed the current NICE practice, which included an implementation guide. NHS organisations were not instructed to disseminate in any way, they were expected to undertake whatever activity they considered necessary within their context. The response to the standard implementation intervention model for guidelines varied from no activity to a high level of activity. The second strategy, opinion leadership to encourage use of a web-based tool to foster implementation, equally lacked any uniformity in application. The web-based tool was poorly accessed across the board and opinion leadership (that followed a rigorous procedure to identify the right person) seemed to flounder under capacity, access issues, and the inability to gain any traction within some NHS organisations. Finally, NHS organisations in the trial struggled to gain any purchase in applying the PDSA strategy. PDSA facilitators met several challenges, which included failure to get people to meetings, difficulties in running audits to monitor changes made and lack of engagement of local staff to support changes. The trial design was compromised by poor implementation of the strategies with several contradictory messages. For example, more ‘activity’ occurred with a case assigned standard dissemination. Other cases that accessed support and training for the PDSA intervention found they were constrained to implement the PDSA trial and test approach. The POISE trial was unable to establish conclusively whether any of these strategies was more effective. Process data raised several issues for each intervention; however, no specific difference was found between implementation strategies, complicated by lack of fidelity to the strategy.

NHS organisations (n=19) were a self-selected sample from the total of all acute surgical departments (N=300 (2005)) invited to join the study. They were not selected by the study investigators. The key reporting documents are the study report (Rycroft-Malone 2009) and published papers (Rycroft-Malone et al 2013, 2012). An embedded evaluation was conducted by an independent evaluator on behalf of study funders which provided potentially usable data. As one of the original researchers, I was able to access the raw data e.g. interview transcripts. All data used in this thesis is anonymised.

Original (POISE) study ethics

Original prospective trial registration was ISRCTN18046709 – Peri-operative Implementation Study Evaluation (POISE).

6.1.4 Quality of POISE data

The POISE trial was considered one of the largest implementation trials within an acute care setting at the time, combined with a theoretically informed and substantive process evaluation (Rycroft-Malone 2012). This process evaluation preceded MRC guidance on process evaluations (Moore et al 2015). The conduct and reporting of the POISE trial were compliant with subsequently published standards (StaRi checklist, Pinnock et al 2017). Statistical analysis took account of cluster randomisation (intra-cluster correlation). Patients were conveniently recruited into the trial within the NHS organisation (the unit of analysis). To determine any issues of bias (Eldridge et al 2016), risk of bias for cluster randomised trials was considered. Allocation concealment was met independently from the trial researchers and local investigators using computer-generated randomisation of cluster ID numbers. Clusters were balanced across intervention arms with one having seven and two arms having six. It was not possible to blind local investigators to intervention allocation and therefore recruiting patients with shorter fasts was possible. However, recruitment of the patients occurred prior to either commencing fast for some, and certainly before induction of anaesthesia was known. However, any improvement to practice could have occurred irrespective of any intervention or activity and was possibly a result of the presence of the trial itself. Primary outcome data was based on data obtained from different patients pre- and post-intervention. All patients recruited were included in the analysis according to the intervention they were allocated. Patients were unaware of allocation and would not have assumed any direct benefit to themselves. It is not possible to rule out any effect on selection by local investigators because patients were recruited post-randomisation (by NHS organisation). Numbers of patients recruited across sites was variable given the target number of 40 patients per timepoint (four pre and post) was not achieved for most sites. Therefore, missing outcome data was similar across intervention groups. Overall, based on this the cluster design of the trial was considered low risk of bias with some concerns. The key challenge to the reliability of the trial was the impact of local investigators possibly recruiting patients based on the knowledge of implementation strategy allocation. This may have varied across sites and intervention arms. Given the impact of the overall results and the spread across interventions this does not seem to be the case, although some sites were anomalies in the QCA analysis, and this is discussed. More recently, the study's inclusion in a Cochrane Review considered the trial as at overall low risk of bias (Flodgren et al 2019).

6.2 Aims and objectives

Aim: To demonstrate the use of QCA methods in implementation research when the implementation context is viewed as a social CAS and model the configurations of complex causal factors that result in the outcome. In addition, extend learning from this novel synthesis of process and outcome data.

Objectives:

- Test the hypothesis that the conceptual framework (integration of implementation models and theories synthesis with simplified social CAS concepts) can explain the challenges in implementing evidence in healthcare systems.

- Build the study components: Individual case narratives, causal factors of interest (the conditions) using the conceptual framework and re-defining the trial outcome for QCA modelling.
- Demonstrate the utility of a configurational approach to causality in social CAS.

6.2.1 Study-specific research question

What configurations of factors were identified in the cross-case comparison of NHS surgical departments that led to either successful or unsuccessful implementation of recommended guidance on fasting before routine surgery?

6.3 Study design

Table 6.3 sets out the five-stage research strategy undertaken within the two-phase, three-step approach. Briefly, this study developed hypothesised process steps, with integration of these steps into the thesis conceptual framework and their transformation through QCA procedures for cross-case comparison. This was to determine which key factors configured across these individual NHS organisations to explain successful or unsuccessful implementation of changes to practice to improve fasting before routine surgery. This study involved a secondary synthesis of mixed methods data (experimental (cluster trial design), survey and qualitative data (process)), to trace these hypothesised causal process steps in each individual NHS organisation. Two compatible methods were used, process tracing (Beach and Pederson 2013) and QCA methodology (Schneider and Wagemann 2012, Rihoux and Ragin 2009, Ragin 2008, 2000, 1987,).

Table 6.3: Overview of study structure

KEY METHODOLOGICAL PHASES	THREE KEY STEPS	RESEARCH STRATEGY STAGES	DATA AND METHODS
		DEVELOPMENT AND PREPARATION FOR QCA SYNTHESIS AND ANALYSIS	
	The development of conceptually informed causal condition (or factor) sets for the QCA cross-case comparison	Stage 1: Build hypothesised causal conceptual framework for QCA study	Prepare the **QCA study version** of the conceptual framework for construction of the causal factor/conditions.
Case definition and **within case** pathway processing of fasting practice	Development of individual case narratives of the NHS organisations, a within case strategy, using process tracing techniques	Stage 2: Specifying individual NHS case narratives	Use **process tracing techniques** to ‘case’ the pre-selected cases within the dataset to identify within case mechanisms between condition and outcome.
Factor analysis **across cases** to determine complex causal arrangements that occur in implementation projects; in this case, making changes to fasting practice	The QCA analysis of cross-case comparison to identify patterns of factors or conditions that lead to successful change in practice	Stage 3: Specification of conditions and outcome prior to transformation (calibration) for analysis	Apply theoretical framework to conceptually inform conditions identified in the dataset as mechanisms that lead to the outcome. From the raw data matrix transform conceptually informed data into the numerical coding of QCA.

		QCA SYNTHESIS AND ANALYSIS	
		Stage 4: Conduct QCA transformation and analysis	Using relevant software available conduct analysis to examine the data for patterns, contradictions and issues of limited diversity within the dataset. Undertake robustness checks on the results using software. Iterative steps may be required whereby removal or addition of cases or conditions, or re-specification of either, is required to achieve a plausible, logical and coherent internally valid dataset.
		Stage 5: Present final solutions (configurations of factors or conditions)	Interpret solutions within the original dataset providing a comparison between findings of the original dataset (conceptual framework, trial and process evaluation) and the subsequent theoretical framework developed in this thesis.
		Present theoretical interpretation and validation of solutions	Discussion and validation of models within the theoretical framework and hypothesised causal model, clarifying limitations.

6.3.1 Thesis study ethics procedures

The PhD study protocol was submitted to Bangor University Research Ethics committee, and approval to proceed was received. A memorandum of understanding was drawn up with the POISE trial Chief Investigator Jo Rycroft-Malone that agreed procedures for data sharing and subsequent authorship of publications from the thesis. I did not have access to individual medical records at any time. Local investigators collected demographic information, and data collection forms were anonymised by ID codes. Therefore, local NHS organisation sites retained personal identifiable information for all individual participants. The original researchers only had access to identifiable information on the consent forms for patients and NHS staff (name and signature only). These POISE researchers had access to contact details of staff and the NHS organisations during the POISE Trial. Original consent procedures permitted access to the POISE trial data for secondary purposes. All consent forms were checked for re-use of data in the thesis study to ensure that individuals had provided permissions for secondary use of their data. This was undertaken by me. The consent forms were made available on site at University of Warwick from the data custodian Professor Kate Seers. I was able to view the consent forms, note any discrepancies and they were then returned to their secure location. No papers were removed from the location in which they were viewed by me or copies made. These consents were paper copies and were not digitised. They were held securely in a locked archive at Warwick University. On inspection of the consent forms with the agreement of the original trial investigator, forms that had all the boxes ticked or all the boxes empty but forms were signed, and interview conducted, would go into analysis. Forms that had a couple of but not all boxes (i.e. relevant box) ticked or initialled would be removed from the analysis.

However, following due diligence as described, only aggregated data by NHS organisation was used, for example patient survey data, as well as interview transcripts from staff participants in the NHS organisations. Other data such as fasting policies held by NHS organisations identified those that participated in the original Trial and were well known to the thesis author. However, all aggregated data was reported using ID identifiers. The Data Protection 2018 and General Data Protection Regulations 2018 seek to protect personal individual data. The study preceded these regulations but meets their expectations and fell outside the Data Protection Act 1998 (see memorandum of understanding at appendix 6.1), which covered the bulk of the thesis data analysis period.

No personal identifiable material of either individual patient or staff member participants was required for the secondary data synthesis conducted for this thesis. A series of double coding steps were undertaken to remove any identifying material from both individuals and NHS organisations, first numerically and then by using letter identifiers in the original trial. Staff interview and focus group transcripts used were previously anonymised in the trial and these anonymised transcripts were retained for secondary use on a password-protected computer.

The thesis ethical approval letter, response to minor amendments, copies of original trial consent templates and copy of the memorandum of understanding are available at appendix 6.1.

6.4 Methods

I used two distinct interconnected methods: Process Tracing (Beach and Pederson 2013) and QCA (Ragin 1987). Process tracing, a *within case* method, was used to develop individual process narratives for each NHS organisation included in the analysis. This method forms the case specification required to conduct a QCA study. QCA is an *across case* comparative method that is used to discover patterns of factors identified in arrangements of causal sufficiency and necessity to bring about the outcome differently in each case, although, of course, some may repeat patterns. It is expected that several patterns (configurations) of factors or conditions will cover the set of cases. I introduce QCA definitions and terms in chapter 2. I elaborate on process tracing methodology in this chapter and subsequently report on both procedures undertaken in the QCA study in the following sections.

6.4.1 Developing individual NHS organisation cases

The process of interest within an individual case was broken down into a series of steps that were logical, observed or expected, e.g. an instruction as to when to start the patients' fasting period which needs to occur before induction of anaesthesia. This is an obvious and relatively simple linear cause and effect relationship. However, tracing what occurs between the instruction to commence the fast and when the patient is anaesthetised uncovered what occurred in each case. Each of the 19 NHS organisations' process and outcome data were traced separately. This retrospective tracing of each NHS organisation process narrative provided detailed individual accounts constructed systematically and uniformly in preparation for cross-case comparison.

6.4.1.1 What is process tracing?

Process tracing is a social science research method for tracing causal mechanisms in social systems using detailed within case empirical analysis to show how causal relations play out in an individual case. It allows greater understanding of the causal mechanisms that link causes and their outcomes within a case. Beach (2017) describes this process as the '*in-between*' a cause and its effect that is a '*productive relationship*'. This is in line with Cartwright's (1989) 'capacities' to allow a cause to result in an effect and other philosophers' notion of powers to allow a cause to connect to its effect (Chapter 2, section 2.7.1). Each part of the process should logically lead to the next part of the process as a sequence that takes us from cause to effect (Beach and Pederson 2013). Core elements of process tracing provide:

- Theorisation about causal mechanisms linking causes and outcomes
- The analysis of the observable empirical manifestations of the operation of the theorised mechanisms; and
- When used with other methods (e.g. QCA), process training allows some limited generalisability from a single case to other causally similar cases.

The function of process tracing is to produce a hypothesised causal pathway of theoretically relevant and plausible factors that connect mechanisms and processes to produce the outcome. Once the causal pathway is specified empirical data is identified that either confirms, disconfirms or explains the relevance or not of these process steps between cause and effect. Process *mapping* techniques, familiar to the NHS (Trebble et al 2010), are similar. The function of process mapping techniques in quality improvement initiatives is to identify improvement points to re-design a patient journey. This involves mapping key aspects of the patient pathway and can also involve subsequent data collection activities. Process mapping was conducted as part of the PDSA implementation intervention strategy at allocated sites in the POISE trial. These maps in the POISE trial provided an opportunity to consider how to change practice and where the problem points might be, for example, ensuring all healthcare professionals along the pathway were providing consistent information on recommended fasting times to patients. This is a pragmatic visual tool conducted within the context of a specific single case. Information from these mapping exercises assisted in creating the hypothesised steps in the process tracing.

6.4.1.2 Rationale for using process tracing

Process tracing creates a shift in analytical focus from causes (e.g. an implementation strategy) and an outcome (reduction in NHS case mean duration of fast) to the hypothesised causal process *in-between* these *Cause* and *Effect* arrangements. I select Beach 's (Beach 2017, Beach and Pederson 2013) *systematic* approach to process tracing to identify how cause leads to effect in a specific case because it was identified as a companion method to QCA (Beach and Pederson 2013, Schneider and Rohlfing 2013). The approach facilitated data extraction in a structured manner to prepare case narratives for across case comparison. Finally, it permits a degree of granular description to connect complex causal pathways typical in social systems.

Process tracing in line with other case-based approaches provides detailed descriptions at a lower level of abstraction than population focussed approaches that result in net effect measures and results. It is also analogous to the identification of the ‘parts’ of the whole (case or process within a case) that fits with the notion of a social Complex Adaptive System, as an organisation or a practice. Beach (2017) specifies the elements of process tracing as entities (actors, organisations or structures) that engage in activities (developing policy for practice, interventions) that will result in change. These *in-between* steps provide the capacity or power to permit transmission from effect to cause (Pawson 2006, Beach 2018).

For the purpose of implementation, we need to understand how and why something does or does not work, hence accompanying process evaluations to trials. Process tracing is most practicable for social CAS that are dynamic and evolving and where causal inference needs tracing to establish connectivity between agents and their activities (Illari and Russo 2014).

6.4.1.3 Other process approaches

Logic models are another processing approach (Anderson 2011, Rohwer et al 2016) usually presented in graphic form that hypothesise theories of change and provide a visual representation of the relationships between a cause (intervention) and its effect (outcome). They can take the form of describing systems with their contextual influences or temporal processes, or both simultaneously (Rohwer et al 2016). These logic models operate at a macro-system level. Process tracing operates at the micro-system level within an individual case.

Chapter 2, section 2.4.2.1. defines mechanisms and elaborates that not all processes are mechanisms (Illari and Russo 2014). Mechanisms in realist research conducted in social systems (Williams 2018) work on the assumption that they are real activities and, although unseen, they are discoverable (Westhorp 2018), by virtue that their effects exist. Mechanisms connect cause to its effect due to an underlying structure. Causes exist but do not always result in effects because some quantity (Cartwright 1989) or power (Illari and Russo 2014) needs to enable the cause to produce its effect.

Also described as a within case method (Marchel et al 2018), realistic evaluations based on their specification of case (programme or setting) have not typically compared across more than six cases (Rycroft-Malone 2019, personal communication 9th May 2019). Examples of using realistic evaluation with QCA exist (Goicolea et al 2015) to identify the factor (or condition components for the QCA), and interest is growing in its application (Marchel et al 2018).

In this study process tracing technique was used to identify parts of mechanisms that need to connect to implement the recommended fasting guidance.

6.4.1.4 Process tracing and QCA

Process tracing and QCA are complementary approaches (Beach and Pederson 2013, Schneider and Rohlfing 2013). Process tracing can either precede QCA (Schneider and Rolfing 2013) or be conducted post-QCA (Beach and Pederson 2013). I used process tracing as preparatory step before conducting a QCA study. The general purpose of this approach is to test causal factors identified within one or a small number of cases to support a more generalisable across case comparison of multiple cases. The combination of systematically conducting a within case process exercise and following it by an across case comparison strengthens the basis for causal explanation when linking the single case process to a comparison of multiple similar case processes structured in the same manner. This strengthens the potential for explanatory inference (Beach 2018). This method created structured individual NHS organisation case narratives of fasting practice implementation to prepare for cross-case comparison in the QCA analysis. From this method I devised a novel data extraction tool to extract relevant data from the POISE trial data output. How this was conducted is reported below in section 6.4.3.2

6.4.2 Qualitative Comparative Analysis methods

In summary, QCA as case-based methodology for investigating social systems starts with the underlying premise that assumes heterogeneity between cases. Different patterns of potential causal factors combine in different mutually nonexclusive paths (referred to as equifinality) to obtain an outcome. Furthermore, these differently combined factors do not present mirror opposites for a positive outcome and its negation. Therefore, different combinations of factors can result in the outcome not occurring and this feature of causality is described as asymmetry. Cases with a well-defined common outcome of interest within a QCA data table should include both the outcome and its negation to permit comparison as to why the outcome occurred and did not occur. Once the cases and outcome of interest are specified, the bulk of the method requires the identification and specification of a set of factors or conditions that are linked within the case set to the outcome. Using the principles of set theory, these conditions/factors are defined as sets, and the cases are assigned membership scores relative to the whole set of cases, describing the degree of membership each case achieves across each factor. This can simply be binary, a member or not a member (Crisp set QCA), or by degree fully in, partially in or partially out, fully out (fuzzy set

QCA) or neither in nor out (ambiguous membership (Schneider and Wagemann 2012)). General QCA methodology is presented in Chapter 2, section 2.6. The following sections present the methods specific to this QCA study undertaken.

6.4.3 Five-stage procedure undertaken

Five stages were undertaken, as set out in table 6.3 above and further elaborated in the following sections. I used Thomman and Maggetti's (2017) QCA design framework because it provided an up-to-date summary on the current state-of-the-art of QCA, methods and limitations of different approaches. This framework takes a step-by-step approach that identifies strengths and limitations of different ends of the QCA spectrum (redundancy free (large N) and case-orientated) and includes addressing external validity, internal validity, measurement error and mode of reasoning (conceptual and theoretical approach to develop or test hypotheses). Using this framework, I justify and explain my approach (Appendix 6.1), and I report on issues such as potential errors, limitations, and confirmation bias in the following Chapter 7. I also set out proposed strategies to manage contradictions and logical remainders. Primarily, these will involve dropping cases, dropping or adding conditions or re-evaluating their qualitative anchors (Schneider and Wagemann 2012). Justifications for undertaking these strategies are given.

Stages 1, 2 and 3 (Table 6.3), reported in detail here, focus on development and preparation for QCA synthesis. Stages 4 and 5 (Table 6.3), reported fully in Chapter 7, present the processes for conducting QCA synthesis and analysis.

6.4.3.1 Stage 1: Construct hypothesised causal conceptual framework for Qualitative Comparative Analysis study

Following the eight concepts derived for the conceptual framework (section 6.1.1), QCA procedures need to manage the number of conditions in a single truth table analysis (see explanation in Box 5.4.5), so I undertook further work to manage this number of conditions to create a workable set. First, I combined the influence of individual actors and their interaction. Second, these evolve into micro-systems and micro-structures and so I combined self-organisation and emergence. It is assumed that healthcare practices are distributed amongst individuals and teams. This resulted in five core concepts. Table 6.4.3.1 elaborates these five *condition* concepts to frame the QCA models. They are provided with simplified terms (codes) that will be used in the technical software steps and solutions: Individuals (IND), Microsystems (MIR), System history (HIS), System imperative (IMP), Intervention/Change Event (CHAN). These *conditions* are aligned to both social CAS concepts and implementation theories (Table 6.4.3.1) and inform calibration for set membership in both the *condition* and *outcome* sets. Also, in the Table 6.4.3.1, these conceptual *condition* sets are aligned with the POISE study data type used and a reasoned causal argument to support the formation of these conceptual *condition* sets for QCA modelling.

Formal conceptual modelling for the QCA study

To achieve individual patient **fasting regulation** (**FR**), the ambition of the original RCN guidance, I formulate FR is *f* (IND, MIR, IMP, CHAN, HIS), elaborated below.

To regulate individual patient fasts (FR) before routine surgery more tightly requires first an assessment at admission for day patients or overnight for inpatients to ensure they have not fasted longer than first on the list. Subsequent monitoring is required when their theatre position is known, allowing some margin for flexibility (to ensure patients are fasted adequately) and to ensure that fasts do not become unnecessarily prolonged. This means, not fasting all patients as if they are all first on the list or not doing any monitoring so that day patients over fast and inpatients assigned 12MN fasting do not receive any fasting regulation. To implement FR requires leading, championing and monitoring by ***<u>individuals (IND)</u>*** *supported by the function of the* ***<u>micro-system (MIR)</u>*** *of both the ward and the theatre co-operating, communicating and deciding on change by making judgements to allow a margin around the two hours specified by the guidance. This is to accommodate the* ***<u>imperative (IMP)</u>*** *to complete the operating list, accommodating some patient movement on the list. To implement practice change requires* ***<u>strategies/interventions (CHAN)</u>*** *to foster the routinisation of the practice that has influenced each NHS organisation case* ***<u>historical (HIS)</u>*** *policy and practice starting point.*

Table 6.4.3.1. Five hypothesised condition concepts drawn from the social CAS and implementation concepts

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
Concept 1: Individuals Capacity for influence of, and on, individual professionals, allied healthcare workers and patients when implementing guidance and NHS case-wide policy changes. Individuals operate within this framework as the	Individual agent (entity) and their interactions are key to change but each individual plays a part in a wider sphere of influence and change and distributed processes, for which rarely a single individual has complete control or knowledge of what is happening at any given moment.	These are the key agents of both cause and effect in human-based systems. Individual capacity, professional role, response to incentives, beliefs, attitudes, authority, power, emotion and ability to self-regulate behaviour. Human response to each other and their context. Individuals in roles of leadership, facilitation of change or opinion leaders as catalysts for change.	All professionals in their roles, e.g. anaesthetist, nurse, further defined as recovery, anaesthetic, ward etc., and given implementation roles as change agents (opinion leaders).	In social healthcare systems individual healthcare professionals work closely together in multiple complex arrangements in team structures in which individual patients pass through from an entry point at admission to discharge. Each patient will engage with multiple members of the health team. In varying degrees of interaction, typically through either verbal, written or electronic systems, communication of patient needs, and status are transmitted.

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
key entities that transmit like electrical impulses firing around and along neural networks. This is a key image that understands the distributed nature of systems and includes human communication pathways.				The individual professional will behave in a multiplicity of ways affected by, for example, their personality, position within teams and the hospital, their profession, ethnicity, and cultural backgrounds. Individuals may have designated roles to act in specific ways or are naturally inclined towards strong opinion leadership and positive role modelling. Individuals are also subject to pressure of their work and the decisions they need to make. NHS staff also receive multiple instructions including guidelines to maintain their knowledge of practice and care etc. up to date. Staff will prioritise their efforts in their daily routines.

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
				Passing knowledge and information requires opportunities to feed information from person to person. Healthcare is reliant on the passing of information between individuals.
Concept 2: microsystems The ongoing interaction and perpetual (sustaining) communication within human systems develops higher orders of organisation and embedded or habituated systemic practice	Self-organising, interactions within micro-systems that evolve into emergent higher-level organisational order	Defined planned implementation steps to prep and conduct implementation activities require and need communication and transfer of knowledge but also require the capacity, (Illari and Russo 2014, Cartwright 1994), opportunity and motivation to enable those activities. This is shared amongst individuals in the systems and needs co-operation amongst them.	Theatre teams, wards and ward management, administration, ward rounds, pre-list meetings etc. managing and preparing patients for theatre, placement on operating list – changes to list. Cautionary patient influence. Communication between system parts that is habituated – hospital routines and expectations. Quality of	Communication between individuals across units, teams and wards is crucial as the individual patient passes through the system. Knowing the status of the patient and ensuring that it is passed on is a critical aspect of communication within healthcare. This entails co-operation between teams and units as they perform different functions in their care of the patient. Fasting practice starts from pre-op assessment and patient preparation to attend hospital, through admission to

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
		Incentivised systems find ways to adapt and change. System adaption needs to respond to the distributed nature of practice (Cilliers 1998) within local health systems.	communication and ability to act on own authority.	induction of anaesthesia, (post-operation fluids not such an issue). Fasting practice is a strong, habituated practice well established and routinised into local surgical systems as part of operation management.
Concept 3: System history Origins and prior rationales of practice can impact on its capacity to change due to the system structure that has evolved to sustain it. Managing and sustaining practice	System history and temporality – how and why the system started and has evolved over time.	Implementation context and status of system pre-intervention/innovation as part of a constant state of evolution and adaption as well as its absorptive capacity, readiness and motivation. Process of implementation dynamic and recursive and liable to fluctuate. Past, present and the anticipated future is context (case) sensitive.	Individual hospital culture and practices, guidance delivery and dissemination responses to interventions and innovation are NHS case specific. Changes to current habituated practice – strategies, activities, process change steps – are sensitive to local circumstances within	Fasting practice is a historical – original rationale of serious consequences of aspirating stomach contents into the lungs pervades that the notion of ensuring fast is held and that with operating list changes patients need to be held waiting, ready to go. Trial assumed the same starting point to practice change. However, it was clear that (as if starting a race) surgical departments were at different stages

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
to maintain stability as other impacts affect the system point to the need to understand temporal sequence of the system history and its future trajectory.			individual NHS case systems at specific times. Regarding the trial, their starting point in the change process was variable across sites and therefore this impacted on their pre-post audits for mean fasting times.	along the implementation pathway and the variability of surgical departments to respond in a timely manner within the fixed trial intervention period meant surgical departments were not starting at the same at baseline. Changes took time to embed and outcomes were liable to fluctuate. (Trial looked for trend, not shown, and key contacts that were contacted three months later on progress post trial and future plans).
Concept 4: System imperative Systems of practice evolve to meet a principle objective. If the system of practice	(SOCIAL CAS) System organising principle (system imperative) – this notes the rational for the very existence of a practice and why it needs or does sustain stubbornly.	Implementation Frameworks refer to drivers/incentives and the rationale for the instigation of the practice. These indicate the system imperative.	Management of the operating list	The imperative is that patients are fasted and ready for theatre and that is the priority (culture of 18-week targets for routine surgery at the time of trial). Changing lists or order of patients etc. impacts on fast, but the system practice struggles to adopt a reflexive approach to regulate fasting times for individual patients.

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
continues in the face of a rational, credible and legitimate argument, it indicates something fundamental and lawlike to the system (regularity causality)				
Concept 5: Intervention – the change event Any form of intervention or change process that is deliberate in nature needs to	Innovation/intervention (system disruptor) or event (Hawe et al 2009)	Implementation object or event. Nature of e.g. credibility, believability, adaptability, complexity (difficult, disruptive, intricacy), acceptability. Needs re-structure or is dependent on other system parts. Evaluating fidelity, adaptation or tailoring and	Evidence based guidance deemed credible by most. Guidance supported by the nursing and anaesthetic professions. [absent profession – surgeons]	Fasting practice guidance had simple recommendations to reduce prolonged fasting before routine surgical procedures. This recommendation was believable, credible and acceptable to most, but needed practice and communication re-structure and effort. This effort needed a level of coercion, incentivisation or persuasion.

QCA Study Condition concepts	Integrated conceptual framework components		Data sources	Rationale
	Social Complex Adaptive System concepts	**Implementation theory (models and frameworks) synthesis**	**NHS organisation case data**	**Causal arguments for each condition in the context of the study data**
consider the context of the system it seeks to influence and the probable unintended impact beyond the primary purpose of the proposed intervention.		the level of coercion, incentivisation or persuasion needed to implement.		Changes disrupt systems and threaten current system behaviour (creating fear and caution amongst healthcare professionals). This also requires attention to previous 'unconscious' (habituated) routine activity.

6.4.3.2 Stage 2: Composing individual NHS case narratives

Process tracing establishes evidence of mechanisms within the defined 'domain' step of the *postulated mechanism* (Beach and Pederson 2013) by obtaining supporting empirical evidence from the dataset. The purpose of the process tracing methodology in the context of this study was two-fold, first to extract data from a pre-existing trial and process evaluation (POISE) to create well defined individual NHS organisation cases for QCA analysis. Second, extracted data was broken down into a series of process steps hypothesised to be the causal pathway of the process pertinent to the implementation of guideline recommendations for fasting practice. Causal explanations in process tracing involve more than the production of detailed, descriptive narratives of events between the occurrence of theorised cause and outcome (Beach 2013) – but they should *link* cause and outcome. Process tracing hypothesised steps assumed an optimal pathway that was then populated with trial and process evaluation data that attempts to capture actual events of change or no change throughout the pathway, across the individual NHS organisation cases.

As one of the investigators on the trial, it was clear to me that there were individual stories for each NHS case, although there were common issues across surgical departments entangled with NHS case context specific issues. Context sensitivity influencing this type of change management occurs again and again within theoretical models for implementation (Chapter 4).

I undertook the following preparatory step-by-step approach to process tracing that built the model framed within the five condition concepts (Table 6.4.3.1) for QCA analysis.

1. To build the process tracing template I used prior knowledge and hypothesised the process steps by separation into two process *chains,* one to process trace policy implementation of the guidance and two facilitate its subsequent translation into practice with the objective of regulating individual patient fasts. I tested the template on a subset of cases (n=7) and modified as appropriate and then applied to all cases (n=12). The seven initially selected cases represent those that provided 'significant results', suggesting there was adequate power or a large enough sample and therefore available data to use.
2. The process tracing template evolved into a data extraction tool for the POISE dataset. I used a broad range of both qualitative and quantitative data from the trial and process evaluation to provide evidence of what occurred at each step for each NHS organisation site recruited to the trial.

3. These hypothesised steps and accompanying data were mapped on to the key conceptual factors derived from the original conceptual framework (Chapter 4). The purpose was to specify the *condition* causal factors for the QCA analysis.

Processing POISE data

In the trial the difference of effect was weak and inconclusive (Rycroft-Malone et al 2012). The process evaluation sought to explore the evidence of mechanisms to explain these outcome findings to expose some of the vulnerabilities when trying to establish causal relations within complex contexts, more formally here described as social CAS. The process data collected in the trial raised interesting challenges across the surgical departments "in that individual staff and patient responses such as caution influenced decision-making. The implementation context was challenging, in which individuals and teams were bounded by professional issues, communication challenges, power and lack of clarity for the authority and responsibility for practice change." (Rycroft-Malone 2013, p.1)

In the POISE trial, two distinct implementation phases were apparent. These were the dissemination and implementation of policy phase, followed by the implementation of practice change phase. For example, although an NHS case-wide policy recommending two-hour fluid fasts before induction of anaesthesia was in place, it did not ensure that fasting regulation of an individual patient occurred in practice. The translation of fasting policy into practice involves surgeons, anaesthetists, nurses, administrative staff, housekeeping staff and other practitioners, such as operating department assistants and theatre co-ordinators. Co-ordination of practice change across the surgical department system requires assessment and monitoring of patient fast either by an anaesthetist or delegated to a nurse, from admission to induction of anaesthesia.

Development of process chains

Discrepancies in practice between different departments within NHS organisations impact on audits of organisation fasting times for routine surgery. This was lost in the trial aggregated data. NHS organisation-wide policy in place does not necessarily impact on mean duration of fast, although absence of policy does not preclude some health professionals from following the readily available guidance. The process tracing exercise permits some disentangling of within case issues. To reflect the distinct phases of policy dissemination and practice implementation, I devised two 'process chains' that required separate synthesis and analysis. Conceptual resonance occurred with each process chain covering four of the five conceptual condition sets. Across process chains there were three overlapping concepts

(IND, MIR, IMP). The fourth, History (HIS), was appropriate for policy implementation, and the Intervention/change event (CHAN) was most relevant to practice change and the presence of strategies in the trial design. An overview of these two chains is provided in Table. 6.4.3.2.a providing starting points and key milestones in the process.

To create the process narratives for each case within the structured format of the process steps and to enable extraction of information from the original trial dataset a series of hypothesised process steps were identified. For example, we can ask what evidence in the dataset would show the mechanism ‘delay to operation’. In this example, any statement that indicates surgeon or patient factor resulted in re-arrangement of the operating list. The data needs to explain that re-arrangement of operating lists leads to delays and whether this leads to longer fasting times for patients. Also, there might be several cause-mechanism-effect relationships that impact on the lengthening of the duration of fasting in each case. Therefore, the objective was to break down the steps from the surgeon’s decision to change the list order and whether this resulted in patients fasting longer. Much of the data relied upon recall weaker than in vivo observation.

Table. 6.4.3.2.a Overview of the causal pathway for practice change (two processes)

PROCESS CHAIN 1 – Policy dissemination and implementation			**PROCESS CHAIN 2 – Practice change implementation**		
Starting point	**Action required**	**Process intermediate outcome**	**Starting point**	**Actions required**	**Trial Outcome**
Policy does not reflect guidance (or is not in place) or does reflect current guidance	Change policy to reflect guidance and ensure its active dissemination	Revised or new policy in place	Initiate practice changes to follow policy: -Arrival of letter for operation with date and fasting information and date for pre-op assessment	Intermediate changes to fast when operation list slot: known/not known, or suffers delays, cancellations etc. -Fasting commencement remains unchanged or is regulated by nursing staff either with	Beneficial change (as determined by the trial (results) Promising intermediate change to fasting practice with unclear benefit (not determined successful by trial) Negative change in audit results between pre and post audit results

			-Pre-op assessment – Fasting information -Arrival in hospital of the day patient who is already in their fast or inpatient, who will commence fast in hospital	delegated authority or instruction from anaesthetist. -Patient arrives in theatre for operation and is anaesthetised.	Negative change (as determined by the trial results)

Extracting POISE data into process chain templates

A judgement was made as to whether data provided ‘evidence’ for the process step and to what degree the NHS case did or did not meet the process step criteria.

So, for example, this might entail documentary evidence of the list change or presence at a pre-operating day meeting, followed by communication to the ward staff and the subsequent decision made either to give water or not to that individual patient based on their expected induction of anaesthesia. Decisions and choices were recorded as best possible given the data available. This required a level of sifting around of the different forms of data for each NHS organisation to build a narrative that fitted the process step. These narratives built a picture of each surgical departments: fasting guidance status and practice (audit times), intention to change and strategies deployed to bring about change, NHS case imperatives or influences that optimised or inhibited change to fasting practice, and what key factors did or did not bring about change.

The following Table 6.4.3.2.b lists the empirical POISE study data used and how it was used to populate the individual NHS case process templates.

Table 6.4.3.2.b Manipulation of original study data

Original study data type	**How data was used**
Documentary: Trial reporting (including funder evaluation and reporting documents)	These data were used to qualify or pick up any comments that might explain decisions made by individual surgical departments by the researchers in communication with the NHS case key contacts and local investigators, if respondents were not clear or unavailable in their interviews, for example.
Standard Dissemination of the guidance feedback forms	Records were kept on fasting practice policy before and after intervention at completion of trial period. A record was made of any activity that described distribution of the trial standard dissemination pack (mimicked NICE practice).
Interviews: key contacts (N=28), change agents (assigned to implementation strategies) (N=21)	The trial had 19 key contacts and 12 change agents. Not all provided interview data, and interviews were conducted pre- and post-intervention. Main data for process tracing was taken directly from interview transcripts. Transcripts were scanned to address and provide evidence to support the hypothesised steps in the process tracing template and quotes extracted as exact statements.
Focus group (N=5, 32 participants)	Focus groups were [run/organised/conducted] for five surgical departments. They provided useful detailed information on what happens at the micro-system level.
Survey of local investigators (N=54)	Collected post-intervention only. Only four questions were relevant for extraction: awareness of fasting raised in NHS case, receptivity to using guidance, NHS case positive attitude to guideline implementation and whether fasting practice became a strategic priority.
Patient data survey	A 17-item questionnaire was given to all recruited patients providing pre- (N=1069) and post-intervention (N=1215) data. This was aggregated by NHS case and provided in the individual NHS case summaries. Relevant questions targeted were whether patients received information, chose to stop drinking and eating differently to information given to them, and whether they were happy with staff keeping them up to date. The % results of the three different questions

	were cut according to the overall spread across the surgical departments.
Assignment to implementation strategy documentation (researcher site reports for PDSA and opinion leader strategies)	Reports that provided insights into level of activity and actual changes made either to policy or practice were extracted, particular the PDSA model that provided detail diagnostic reports, minutes of meetings held in the NHS case and actions taken.
Key activities report	Researchers pulled a list of activities conducted by the surgical departments irrespective of the assignment to implementation strategy. I used counts of activities and types for data extraction.
Duration of fasting collection form	Primary outcome data. Data collection was variable across surgical departments and timepoints. The summary mean difference of fasting times were available in the POISE NHS individual site summaries.
Researchers' perspective/ other data reported	Via various reports during the trial.

Mapping original data to the process steps in the process chains

I assumed Chain 1 preceded Chain 2; logically, practice follows policy. Another assumption that occurred were some steps might not be necessary, and the sequence might alter for some steps but overall there is a clear pathway in the example I am presenting here. A sample data extraction template based on Beach (2013) can be viewed at appendix 6-2. An initial sample of seven cases who provide confirmatory audit results because they had enough data, were used to develop hypothesised process steps towards both positive and negative practice change. Initial data were extracted from the different data collection activities for these cases. From this I created a checklist for data extraction (appendix 6-3), where each hypothesised step is broken down into a series of questions that are applied to the different sources of data. Below in Table 6.4.3.2.c I provide an example from each process chain. Each step is then given an overall rating (membership assignment). Tables 6.4.3.2.d and 6.4.3.2.e each provide the hypothesised step and the expected observable data in the study dataset to support that hypothesised step with descriptions of where that data might be found in the POISE study dataset.

Table 6.4.3.2.c Sample questions from the data extraction template

Data extraction question	**Rating (present/yes (1), not present/no (0)** **Provide quantity (% or count provided in dataset) or text response**	**Evidence description**
Chain 1 sample questions for hypothesis step		
1h 1* Is there documentation or a report of NHS case policy? This may include sight of, or description of, policy delivered through patient information given when notification of operation date is provided?		
Is this NHS case policy in place close to the two-hour fluid fast rule?		
Is it clear that the NHS case does not have a policy guidance in place and either assumes traditional practice or the traditional practice is clearly policy?		
Do NHS case contacts describe structures, committees or processes that can *in principle* disseminate new policy? Is this structure, if present, used to develop fasting policy in keeping with guidance?		
Is a specific structure set up to develop fasting practice?		
Is there a description of individuals given who take the role to develop and negotiate fasting practice?		
Overall judgement for set membership		
Chain 2 sample questions for hypothesis step		
2h 5a**		

Is there or is there not an account as to whether, in general, at the start of the list known changes are used to revise individual patient fasts?		
Is there an account, whether initiated by ward or theatre, of routine, regular or an intermittent feedback system between ward and theatre staff on delays and changes to the operating list, once the list is underway??		
Whether there are blocks to receiving or giving this feedback.		
Whether there is an intention to respond or responses occur for some patients (1), or whether there is no intention once the list is underway and patients are held in fast (0).		
Overall judgement for set membership		

*Chain Policy dissemination and implementation 1h hypothesised step 2

**Chain Implementation of practice change 2h hypothesised step 5a – 5b presents an alternate at the same step point

Post-intervention data were selected primarily because the focus of the process was on whether a change or no change was achieved. I explored pre-intervention data if post-intervention NHS organisation data was thin.

POISE data limitation for secondary purpose

Data availability across surgical departments in the original study was variable either due to the choices made in the trial (sampling strategies for qualitative data) or the planned interviews and focus groups did not take place or responses to survey data were missing. This was due to availability of staff and their capacity to support research activity due to competing priorities. Also, data were collected for the purpose of thematic analysis, which limited my ability to obtain case specific information. There were also occasions when respondents were not as forthcoming as I hoped, which was probably due to pressures within the clinical environment at the time.

The following lists limitations that constricted data extraction and subsequent interpretations of the findings:

- Good data was obtained from some of the focus groups (covering five cases only). Some interviews provided very little extractable information.
- *Data quality* was also variable across surgical departments, e.g. thicker and more informative descriptions were available at some but not all sites.

- *Original study purpose* topic guides and schedules were focussed on the objectives of the trial which were not aimed, obviously, to meet some of the specific questions addressed by the process steps here.
- *Other data issues* observed were:
    - The interviewer was not always able to speak to the 'right' person to inform what happened at local level.
    - Managing opinion rather than reportage of events, as well as vagueness or proximity of the respondent to the events described or referred to in their response.
    - Some respondents also reported good practice but felt that the outcome audit data was skewed by several severe cases of fasting within their site.
    - Although respondents might state aspirations for change or activity, for my purpose here I needed to focus on actual evidence of change, that is, on statements that clearly indicated something had been done or achieved.
    - Different informants provided different perspectives, and a degree of piecing the narrative together was required.

My experience of collecting the data in the POISE study did assist with some of these judgements. The patient survey provided an example. Information to prepare patients for their admission to hospital and operation includes fasting information. However, patients answering the survey question had not always received this information pre-operatively. The survey was conducted pre- and post- intervention. For some cases, receipt of information improved from 60% to 80% between pre- and post-intervention. But this remains low in comparison to other trusts who showed no improvement between pre and post surveys at 93-94% or slight decrease 95-92%. Therefore, I judged that the post-intervention figure was the one to extract, as it provided a final position, and that other information would triangulate to further inform calibration. It should also be noted that the original data could not determine whether the patient was an inpatient or a day patient, and lack of information on fasting might have occurred for inpatients rather than day patients.

Hypothesised process steps in the two-chain theorised causal pathway to enable the implementation of fasting guidance: expected observable evidence

Table 6.4.3.2.d Process tracing Chain 1: Dissemination and implementation of fasting policy

Hypothesised step (h)	Expected observable evidence	Descriptions permissible (Yes/No responses)
1h 1 Setting up committee or putting dissemination structures in place, such as a hospital committee structure specifically for clinical staff to set fasting policy.	• A record of current policy that does not match the fasting guidance recommendations for fluid fast. • NHS case has in place or puts in place a designated structure or process that is either used generally for guidance implementation or specifically for implementation of fasting guidance. • Process or structure would involve all or some of the relevant clinical professionals (nurse, anaesthetist, surgeon).	• Access to NHS case policy documents. This also may include sight of, or description of, policy delivered through patient information given when notification of operation date is provided. NHS case has a guidance policy in place (or close to the 2/6 rule). NHS case does not have policy guidance in place at all or provides traditional practice. • NHS case contacts describe structures, committees or processes that can, in principle, disseminate new policy, but are these structures used to develop fasting policy? • Whether a specific structure is set up to develop fasting practice. • Description of individuals given or taken the role of developing and negotiating fasting practice.
1h 2 Time for process of discussion and deliberation, such as a hospital committee structure specifically for	• A record of meetings held. • A record of discussions held and deliberation on what the fasting policy would include or not (issues around clear fluids and chewing gum).	• Description of meetings held and outcomes of meetings. • Any record of discussion on development of the fasting policy to be implemented. • Focus is on the two-hour fluid rule.

clinical staff to set fasting policy.		
1h 3 Decisions made to enact policy Champions on committee	• A record of decision made. • Verbal record of an NHS case lead or champion (designated trial change agent) involvement.	• Articulated decision making and agreements made at the relevant meeting or committee structure. • Whether the trial change agent reported their role in making that change occur through structures or processes described.
1h 4 Revisions and changes to fasting policy via administrative or medical secretarial support or the healthcare professional	• A record of change made – documentation received by administrative staff	• Report of changes to documentation sent out by administrative staff, e.g. patient letters.
1h 5 New NHS case policy Specific staff member tasked with dissemination	• Existence of new policy • A designated individual(s) expected (job role) or authorised to disseminate policy.	• Documentation of new policy stated or seen. • Whether a lead is designated or self-designates to take on overseeing implementation, or not.

1h 6
Dissemination activities – meetings, training, transfer to other information objects, e.g. patient information at pre-op assessment
	• A record of examples of how the new policy is disseminated:
	  ○ By a strategy
	  ○ By a number of key activities
		Type of activity
		• Training the key staff on policy
		• Via specific and relevant staff meetings
		• Record of changes made to patient information
		• Record of distribution through intranet systems
		• Other awareness raising activities, e.g. posters

Technological/ intranet systems		Number of dissemination activities

Table 6.4.3.2.e Process tracing chain 2: Implementation of change to fasting practice

Hypothesised step (h)	Expected observable evidence	Descriptions permissible (Yes/No responses)
2h 1 Pre-op fasting information is provided to the patient in an initial letter from the surgeon's medical secretary	• A record of patients' receipt of information from the medical secretary, done on behalf of the surgeon responsible for the operation.	• Patient survey data for each NHS case between 75-100% post-intervention – receipt of information. • Patient decision % to act differently to advice (tendency to caution). • Description or evidence of the information provided and the emphasis on positive messages of drinking up to two hours pre-op. • Any description of potential for contradictory information for different surgeons in the NHS case.

2h 2
 	
The surgeon (organised by the medical secretary) agrees their initial patient order that is disseminated to theatre and ward staff. This list provides an estimated start time for each listed patient. This
	• A record of and details on the development and delivery/dissemination of the operating list.
	• A record specifying the timing of receipt of the list by others in the surgical department.
		• An account from individual respondents that details:
		  ○ Timing when delivered to wards and theatre staff
		  ○ How delivered, via
		    ▪ computer system or
		    ▪ in printed format.

initial list is constructed by the surgeon's medical secretary.		

2h 3
 	
Pre-op instructions given to patients will set fasting start times as if first on the list (all day lists, am/pm lists) *. Morning lists will start fast at 6 am, afternoon lists start fast at 11am, for example. This information is reinforced (or changed) when patients attend a pre-op assessment clinic where a nurse will emphasise required fasting instructions.
	• A record of the details on how fasting policy (e.g. 2 and 6) is translated into practice in patient information given by letter and followed up at pre-op assessment:
	  ○ Fasting time instructions different for different lists, e.g. am, pm and all day.
	  ○ Record of differences given between the initial letter and pre-op assessment and between patients admitted as inpatients (rather than as day patients).
		• An account of the impact of how guidance is implemented regarding the 'first on the list syndrome'.
		• An account of differences between inpatients and day patients that indicates either:
		  ○ No change in practice to follow fasting guidance for inpatients, or
		  ○ Practice for inpatients follows guidance more closely.

2h 4 Patient arrives on ward and is prepared for theatre by a ward nurse. They receive a visit by an anaesthetist and the	• A record that fasting status on arrival in hospital is noted to ascertain length of fast. • A record of patient fasting longer than necessary – cautionary behaviour. • A record of any response to amend these patients fasting times.	• An account by a respondent of the status of patient fasting on arrival – tendency to longer fasting possible. • Whether staff take an opportunity to address this for those later on the list.

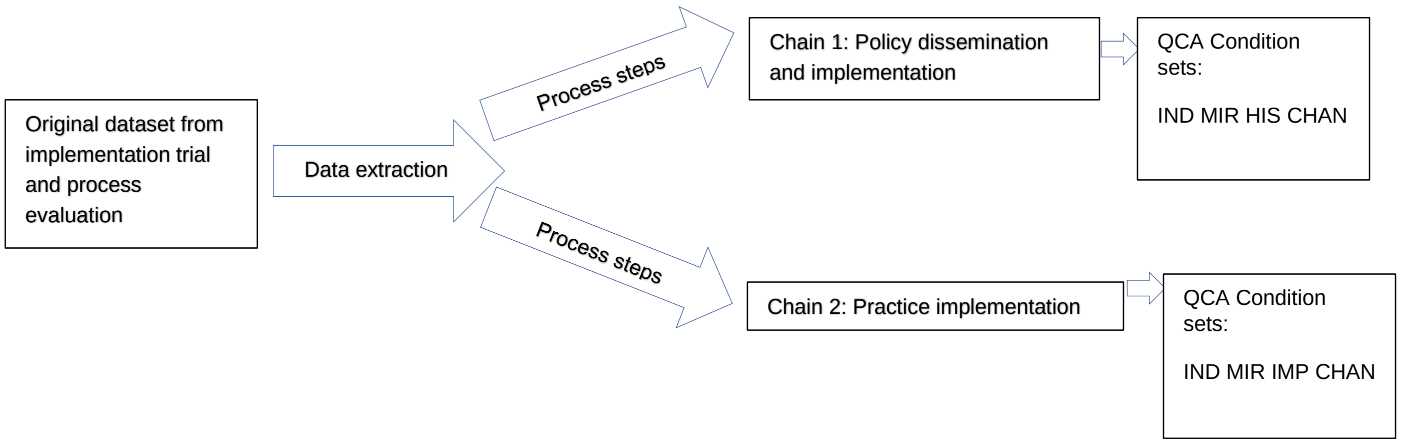
surgeon. Both the nurse and the anaesthetist will check when the patient last ate or drank anything to ensure the patient has followed information given pre-operatively – relevant for day patients. Nursing staff (who instruct housekeeping staff) control inpatient fasting times.	• A record of any pre-op fasting messages to patients to address this challenge.	
2h 5a Patient or nurse are informed or not of position on list or receive an updated list (or any changes in the list) from surgeon or theatre staff – these changes are received in a timely manner to allow changes to be made to patient	• A record of any communication between theatre and ward on changes or updates made to the list order on the operating list. • A record that these changes are timely to adjust patient fasting times. • A record that these changes are not timely to adjust patient fasting times. • A record that ward staff are unable to respond and make changes to fasting times.	• An account in the data as to whether in general or not. Changes to the operating list before it starts are reported to ward staff, for example. • Account of whether there is routine, regular, intermittent feedback system between ward and theatre staff on delays and changes to the list, once the operating list is underway. • Whether obtaining the current list position for the patient is initiated by the ward or reported back to the ward by theatre staff. • Whether there are blocks to receiving or giving this feedback.

fasting times, if warranted.		• Whether there is an intention to respond or responses occur for some patients, or whether there is no intention once the list is underway and patients are held in fast.
2h 5b Regular updates of list changes (or any changes during list) from surgeon or theatre staff. Patient or nurse *informed* of position on list and adjusted fast time agreed.	• A record of any communication on changes or updates made to the list order on the operating list. • A record that these changes are timely to adjust patient fasting times. • A record that ward staff received delegated authority to alter fasting times as required. • A record that patients received adjusted fasting times.	• As above but also includes the timeliness of this reporting of operating list time, and whether fasting times are subsequently adjusted either by anaesthetist or the ward is delegated authority to do so.
2h 6a Patient remains fasted according to original pre-op instructions Housekeepers remove water at set time from patients on afternoon lists. No further communication on fasting other than anaesthetic nurse and anaesthetist,	• A record that blanket fasting practice continues and that once fasting commences, no changes are made. • A record that any instructions for change to fast, desired or intended by staff (e.g. nursing), are either ignored or prevented from execution.	• Overall practice in NHS case post-trial intervention suggests, through respondent accounts, that blanket and 'first on the list syndrome' is maintained. • An account that practice of change is deliberately thwarted by individuals in senior or professional roles who block practice change.

who check for fasting status.		
2h 6b Patient allowed fluids up until new fast time set to two hours before estimated arrival time for the start of their operation. Practice of regular communication on fasting between ward nurse, anaesthetic nurse and anaesthetist, who then check fast status at new time.	• A record that regulating fasting times to match operating time ETA on the basis that a patient is encouraged to take clear fluids up to two hours before surgery. Added note: realistically, each patient on a list is unlikely to receive a fluid fast limited to two hours. However, given audits these *means* suggested very exaggerated fasts for many patients, with of course some (usually first on the list) reaching closer to two-hour fasts.	• An account that regulating fast has occurred on occasions when and where possible within the NHS case.

Fig. 6.4.3.2. provides the procedure flowchart. This links the within case processing for individual cases to the next step of transformation into set memberships to set up QCA synthesis and analysis. Using the conceptual framework, I allocated the occurrence or the non-occurrence of the observation to the individual process steps as constituent parts of the underlying mechanism I sought to expose. Managing missing information for QCA is a different state to non-occurrence and is a further limitation for discussion.

Fig 6.4.3.2 QCA procedure flow chart prior to set membership calibration



6.4.3.3 Stage 3: Specification of conditions and outcome prior to transformation for analysis

These numbered hypothesised sequence steps were mapped to the conceptual conditions below in Table 6.4.3.3., and they combine in different ways across the conceptual conditions with steps repeating. The descriptive factors found in the extracted data explain the translation of these process steps with conceptual conditions. It is these conceptual conditions supported by degrees of triangulated data from the original dataset that were calibrated and tested in the QCA models.

Table 6.4.3.3 Mapping of process steps to conceptual conditions

Chain 1 Policy dissemination and implementation [h] hypothesised [n] step number

Chain 2 Practice change implementation, as above and *n* a and *n* b present an alternate step at the same step point

Condition concept	**Hypothesised steps for both process chains 1h and 2h***	**Descriptive factors**
C1 (IND) - Individual behaviour: patients, staff Capacity for influence of and on individual professionals, allied healthcare workers and patients when implementing guidance and NHS case wide policy changes.	1h 3, 1h 5, 2h 2, 2h 4, 2h 5a, 2h 5b, 2h 6b	Attitudes, beliefs or behaviour that either supports or does not support implementation. Individual characteristics of championing or leadership to push implementation of guidance and its translation into action. Individual behaviour that hinders implementation of guidance
C2 (MIR) – Micro-system level interaction: individuals on wards and in theatres The ongoing interaction and perpetual (sustaining) communication within human systems develops higher orders of organisation and embedded or habituated systemic practice.	1h 1, 1h 2, 1h 6, 2h 5a, 2h 5b, 2h 6a, 2h 6b	Communications between different structures created within the NHS case to develop and develop policy and guidance. Strategies and activities for dissemination of policy and guidance. Communication between departments, wards, surgeons and colleagues and to patients that either enables or hinders implementation of guidance.

Condition concept	**Hypothesised steps for both process chains 1h and 2h***	**Descriptive factors**
C3 (HIS) - Previous NHS case history and practice prior to study plus culture for guidance implementation. Origins and prior rationales of practice can impact on its capacity to change due to the system structure that has evolved to sustain it. Managing and sustaining practice to maintain stability as other impacts affect the system point to the need to understand temporal sequence in system history and its future.	1h 1, 1h 4	Starting point: policy in place, policy not in place, desire or consideration of need to change practice, not considered the need for change – unaware of problem/concern not raised.
C4 (IMP) - Principle driver or imperative described to maintain the operating list. Systems of practice evolve to meet a principle objective. It is the rationale for a system of practice to continue in the face of rationale, credible and legitimate argument that indicates something	2h 1, 2h 2, 2h 3, 2h 5a, 2h 6a	Adherence to the imperative to not threaten the smooth running of the operating list. Cautious behaviour by both staff and patients to ensure readiness for list including any delays or changes that might occur.

Condition concept	Hypothesised steps for both process chains 1h and 2h*	Descriptive factors
fundamental and lawlike to the system (regularity causality).		
C5 (CHAN) - The nature of the intervention “guidance” in this context via strategies (randomised). Any form of intervention or change process that is deliberate in nature needs to consider the context of the system it seeks to influence and the probable unintended impact beyond the primary purpose of the proposed intervention.	1h 5, 1h 6, 2h 5b, 2h 6b	Delivery of evidence through implementation strategies (trial interventions or other). Expected mechanism of action and so delivery of intervention to reach target change. Trial conceptual framework and the logic of strong credible evidence should support change to behaviour - guidance/intervention target. Delivery of evidence through implementation strategies (trial interventions).

Specification of POISE outcome

The trial primary outcome measure was average mean difference of fasting duration measured in hours for each NHS organisation between pre- and post-intervention phase. The QCA needs to reflect the trial structure whilst simultaneously expose complex patterning, such as capturing the case specific causal *in-between* processes. As the trial was a cluster randomised design, the numerical results are powered at the level of the trust (section 6.1.3). Therefore, the individual NHS organisation primary outcome results are considered cautiously and are treated as audit results. Individual patients were conveniently selected within each site. However, audit data was analysed for each NHS organisation and evaluated by a hypothesis test. This is used to determine a qualitative cut-off for the QCA calibration procedure for data transformation (section 6.2.4.5) but has limited viability statistically with respect to the trial design and indicates only whether there is enough data to draw any conclusions (section 2.5.3).

Befani (2017) makes clear that missing data or values are not relevant for the 0.5 anchor point that determines greatest ambiguity in set membership (neither in nor out). In other words, it is not possible to assign membership as either in or out. This is a qualitative judgement based on data and not because the data is unavailable. Therefore, QCA does not manage missing values, and attempts should be made to ascertain some data to determine set membership above or below the 0.5 cut-point between fully in and fully out. Befani (2017) suggests a fuzzy value 0.51 might be appropriate if calibrating interval data into pre-defined set membership groups. I decided upon a 4-value fuzzy set this avoids the 0.5 as advised (Befani 2017), 1- full membership (in condition set), 0.66 mostly in, 0.33 mostly out, 0 not a member, see Fig. 2.6.2.3. It is important that 0 is determined by evidence of absence, not missing information, in this context information required not reported or not available in the data.

Calibration for the outcome for a four-value fuzzy set were:

- For positive audit results, full membership in the outcome set is assigned 1, fully in.
- For any mean difference above 1 hour but results were not significant, set membership assignment is partially in at 0.66.
- Less than an hour change for the better or negative partially out (0.33).
- Significant negative audit results fully out (0).
- 0.5 cross over avoided (neither in nor out).

This set membership assignment is qualifying, for example, to what degree an individual case meets the condition (fully, partially, not at all). These anchor points determine degrees of set membership and are qualitatively defined. Crisp set creates binary separation between partially in and partially out. Both analyses were conducted.

6.4.3.4 Stage 4: Conduct Qualitative Comparative Analysis transformation and analysis

The raw data matrix

The function of the raw data matrix is to gather the data across the cases that will define the set membership level for each case across the conceptual condition sets. Based on the data extracted from each case, membership values were assigned allowing both crisp and fuzzy set analysis based on calibration rules. Appendix 6-4 illustrates a raw data table for process chain 2, with initial calibration values added. A description of the process follows.

Calibration

I follow theory-consistent calibration (Befani 2017) and calibrate qualitative data along with numerical survey data, such as patient views and the duration of fast means (*outcome*), which are all qualitatively anchored, described fully in appendix 6-5. The important step in QCA calibration is to define the qualitative anchors to reflect the meaning of the conceptual condition to identify the data that will decide set membership assignment (Schneider and Wagemann 2012). The data I was using was principally qualitative. I conducted calibration exercises on quantitative data, such as data from the patient survey and the quantification of implementation activities conducted in the trial. Each hypothesised process step was populated with several data parts (data triangulation (DeBlock and Vis 2017)), presenting a composite that was then assigned condition set membership based on the weight and overall message (interpreted by researcher). I report a summary in the next chapter.

I initially adopted fuzzy set calibration, which can revert easily to crisp set as required because the 0.5 anchor crossover point is retained in both types of sets and is crucial to membership assignment. Initial crisp set analysis undertaken allowed examination of the data for contradictions and procedures to be rectified and this is discussed fully in the findings section. However, fuzzy set calibration for the condition sets (IND, MIR, HIS, IMP, CHAN) are set out for Chain 1 and 2 at appendix 6-6. Clear definition of the anchor points (1, 0, 0.66, 0.33) ensured allocation of set membership to each case and was applied as even-handed as possible across cases.

Calibration transforms the data to enable analysis using appropriate software. The calibrated raw table was transformed using software into a ‘truth table’. This table provided the calibrated data by case giving all possible logical combinations of the conceptually informed conditions and groups cases that shared the same combination and reveals combinations of conditions whereby no cases were observed. This truth table was the principle tool for analysis. Truth table analysis is a lengthy procedure of examination and re-examination to maintain a coherent logic to findings for interpretation. In this study, this required iterations to ensure the transformation step from the dataset to calibrated set was logical and contradiction free. Contradictions needed to be resolved, because cases with the same configuration and conflicting outcomes falsifies that configuration and it becomes meaningless. The original dataset was limited and not obtained for the purpose of this study. It was also not possible to go back to the NHS organisations to qualify missing data. For a variety of reasons individual to any QCA study, the researcher may need to re-conceptualise, add or remove conditions, and add or remove cases to maintain the integrity and internal validity of the truth table.

6.4.3.5 Transfer to software for analysis

To conduct the analysis, I used Tosmana 1.6 (Cronqvist and Lasse 2018) and fsQCA 3.0 (Ragin and Davey 2016).

Analytical steps undertaken describe the decisions made to manage contradictory configurations found on completion of the truth table. First analyses conducted examined whether a single condition or configuration of conditions was necessary or sufficient (Chapter 2, section 2.4.2.2) for the outcome.

I used both software simultaneously following the development of the raw data matrix and calibration. Tosmana provides Venn diagrams of the data enabling visualisation of where the cases align with the different logically possible combinations, but it does not conduct fuzzy set analysis. fsQCA conducts all required analyses. Software's fsQCA and Tosmana were used to run analyses on the truth table and conduct the following procedures (Table 6.3.4.5).

Table 6.4.3.5. QCA software procedures

Truth table analysis	This provides a summary of the calibrated raw data and will provide all the logically possible combinations of the causal conditions/factors with case assignment. Cases are assigned to their combination of factors. This table is then examined, and various tests are conducted.
Test of necessity	Is any condition/factor or combination of conditions or factors necessary for the outcome to occur.
Tests of sufficiency	Is any condition/factor or combination of conditions sufficient to allow the outcome to occur, noting other factors or combination of factors may also be sufficient.

Robustness checks	The software will provide measures for consistency and coverage. Consistency provides a % score that explains to what degree the subset relationships are consistent and do not result in contradictions. Fully consistent = 1. For necessity tests this needs to be above 0.9 and possibly 0.75 for sufficiency. Coverage assessment provides a value for how much of the outcome value is covered by a sufficient condition. These measures are provided for individual conditions and logical combinations.
Identification of contradictory configurations	A certain degree of tolerance is allowed with contradictory set memberships. Fuzzy sets can be visualised with XY plots and Venn diagrams for crisp sets. These diagrams will be used as appropriate. Contradictions need resolving, otherwise underpinning logic is compromised. Options include recalibration, including additional conditions or dropping cases.
Logical reminders	If crisp set membership has the option of two responses, 1 or 0, and the number of causal factors is 3 or 4 or 5, for example, the possibilities of the logical combinations is $2^{3 \text{ or } 4 \text{ or } 5}$. That is 2x2x2 = 8, 2x2x2x2 = 16 and 2x2x2x2x2=32. There is a relationship between the number of cases and the number of conditions a QCA analysis can manage. Further explanation, Chapter 2, section 2.6.
Minimisation procedures	These are referred to as solutions, recipes or models. I prefer model and will use this throughout. The data through minimisation to identify combinations that cover most cases will present three types of QCA model. Complex (or conservative) model will have the maximum inclusion of cases and the combinations covered. Intermediate will have some minimisation and parsimonious will have fullest minimisation logically possible. This will provide what are identified as the prime implicants, those factors that are most implicated in the dataset across the cases.

The QCA methodology is iterative and involved several iterations to the above steps, reported in the following chapter 7.

6.4.3.6 Stage 5: Present final solutions

Final solutions are presented in the following chapter 7 with an interpretation to make sense of the solution models derived. From the results, a discussion ensues first as to whether, and to what degree, QCA methods can operationalise Complexity Theory concepts. Second, I will discuss what adaptions or considerations are needed for implementation research and, finally, what contribution do QCA methods make in enabling a Complexity Theory perspective. In addition, consideration is given as to whether the configurations of factors that lead to successful or unsuccessful change to fasting practice within the NHS organisation sites provides a more informative explanation than the original POISE trial findings.

Presentation of results

Results presented include visual representations of the data using Venn diagrams and the solutions for all QCA models derived: complex (or conservative), intermediate and parsimonious (Chapter 2, section 2.6.2.3).

6.4.4 Discussion

By assuming case heterogeneity and complex causality in social systems, QCA methodology can expose the complexity in real systems and has potential in implementation research to explain patterns that emerge across similar cases undertaking a common implementation activity. The implementation trial was inconclusive in showing which implementation strategy was better at ensuring guideline implementation to reduce prolonged fasting practice in routine surgery in the UK. However, the process data was able to indicate, more generally, a range of barriers to implementation. Therefore, this re-evaluation of the trial and process data could provide a more informative explanation of the original trial and process outcomes. The process of calibration and the systematic transformation of the data into set assignment values to a set of case narratives can be investigated potentially in a variety of ways to explore patterns of mechanisms that need to combine to achieve the outcome. The next chapter explores patterns of change within the set of NHS surgical department cases.

Chapter 7: Findings of the Qualitative Comparative Analysis Study

7.1 Introduction

My rationale for undertaking this study was based on providing an explanation of the difficulty and complexity involved in the implementation of a simple guideline recommendation based on credible and undisputed evidence to make changes to fasting practice in routine surgery. This, I argue, was due to the distribution of existing fasting practice throughout the local healthcare system of NHS surgical departments. Following the methods set out in Chapter 6, this chapter presents the findings of the Qualitative Comparative Analysis (QCA) I undertook to see whether my approach exposed CAS behaviour in the POISE trial data. I used my novel framework (FISCAS: Framework for Implementation in Social Complex Adaptive Systems, Chapter 4) operationalised through QCA methods to test whether I could arrive at a better explanation of implementation of evidence-based guidance given the problems of inconclusive implementation trials. This chapter reports stages 4 and 5 (Chapter 6, Table 6.3).

Tables 7.2.a and 7.2.b summarise the FISCAS informed condition (factor) sets that, as a hypothesis, obtain the outcome. The trial primary outcome measure was average mean difference of fasting duration measured in hours for each NHS organisation between pre- and post-intervention phase. They are presented separately for the two process chains (Chapter 6, section 6.4.3.2) for policy and practice implementation and specify the qualitative anchors for QCA crisp set membership only at this point.

Table 7.2.a Calibration for condition and outcome sets Chain 1 (dissemination and implementation of fasting policy)

Factor: condition or outcome	**Definition for *fully in* set membership (1)**	**Definition for *fully out* set membership (0)**
C1: Individual behaviour (IND)	NHS surgical department shows evidence of a positive attitude and co-operation between individual healthcare professions to implement fasting practice that indicates strong leadership or successful	NHS surgical department shows evidence of mainly resistance by individuals to adopt the proposed guidance for fasting practice.

	championing within the designated trial area.	
C2: Microsystems (MIR)	NHS surgical department shows good evidence of structures, processes or systems to implement fasting policy (committees, procedures etc.).	NHS surgical department shows evidence that it has a poor structure or system to implement policies such as fasting.
C3: History (HIS)	Correct policy in place with staff awareness and attempts to ensure its implementation prior to trial	No written policy or incorrect policy in place and no plans prior trial to change policy.
C5: Intervention/ change (CHAN)	NHS surgical department shows evidence of high level of action or activity to change policy and implement fasting policy, irrespective of intervention allocation. There is evidence of NHS surgical department strategy.	NHS surgical department shows evidence of not undertaking any activity or action on promoting fasting practice policy (based on RCN guidance) in response to the trial.
Outcome (OUT)	Beneficial change (as determined by the trial results)	Negative change (as determined by the trial results)

Note not factor 4

Table 7.2.b Calibration for condition and outcome sets Chain 2 (implementation of change to fasting practice)

Factor: condition or outcome	**Definition for fully in set membership**	**Definition for fully out set membership**
C1: Individual behaviour (IND)	NHS surgical department shows evidence of a positive attitude and co-operation between individual healthcare practitioners to implement fasting practice that indicates strong leadership or successful championing.	NHS surgical department shows evidence of mainly resistance by individuals to adopt the proposed guidance for fasting practice.
C2: Microsystems (MIR)	NHS surgical department shows strong evidence of timely communication between ward and theatre and other related departments that indicates opportunities for individual patients to receive regulated fluid fasts before surgery.	NHS surgical department shows evidence of no communication between ward and theatre that could provide an opportunity to regulate individual patients' fluid fast.
C4: System imperative (IMP)	NHS surgical department shows evidence that it can manage the operating list flexibly and with some stability as well as allow many patients to have fluids close to 2 hours before induction of anaesthetic.	NHS surgical department shows evidence of a clear preference towards maintaining fasted patients so as not to jeopardise the management of the operating list and the patient flow through theatre.
C5: Intervention/ change (CHAN)	NHS surgical department shows evidence that active implementation of the guidance (through a strategy or number of activities) has had a	NHS surgical department shows evidence of not being able to respond to the trial's agenda to implement the guidance for fasting. This might include

	positive effect on those areas involved in the trial.	NHS surgical departments allocated to standard dissemination who actively decided not to respond in an active way.
Outcome	Beneficial change (as determined by the trial results)	Negative change (as determined by the trial results)

Note not factor 3

7.2 Qualitative Comparative Analysis and synthesis (stage 4 and 5)

Following full calibration of the raw data into condition set membership as described in Chapter 6, section 6.4.3.4 (accompanying appendices provide greater detail), transformed data was imported into the QCA software for analysis (fsQCA 3.0 and Tosmana). The principle analytical structure is the truth table which summarises all logical configurations of the conditions with or without case examples observed.

7.2.1 Overview

Preliminary Venn diagram visualisation of the truth table (Chapter 6, section 6.4.3.6) identified issues that required adjustment. The two truth tables, one for each process chain (policy and practice), were examined. I will now abbreviate to *Chain 1 – policy* and *Chain 2 – practice.* I undertook an iterative analysis strategy creating a third process chain to build a logical solution model that fitted the data as well as maintained the theoretical construction of the FISCAS framework. In addition to the minimisation process undertaken by the software, I will also comment on the individual NHS surgical department configurations and the potential for examining other patterns using this case-based set theoretic approach.

The cases are identified by letter identifiers A-S (N=19). One case provided no process data at all, only the trial primary outcome data and patient survey were collected. This was insufficient for this case to meaningfully proceed further in analysis. This NHS surgical department (case P) did show a mean difference towards improvement between baseline and post-intervention of average duration of fasting times that met levels of significance (P 0.041) (Rycroft-Malone 2009)). However, this is viewed cautiously because the study was powered at the cluster level of the NHS surgical department. I observed during the original trial that this NHS surgical department had an efficient set of anaesthetic healthcare professional (medical staff) local investigators collecting data. However, mean duration of fasting at baseline across the organisation's surgical departments was high at 12.93 hours, which reduced to 11.19 hours post-intervention. No activities or plans for distribution of the standard dissemination pack were recorded. In addition, no other activity was recorded to aid implementation to change practice. It is only speculation, but I suggest that the presence of the trial had an effect via the local (data collection) investigators. Further speculation might suggest that such changes are not likely to be sustained post trial.

My analysis strategy evolved as further exploration of the cases and their configurations exposed contradictions. I therefore report this process in two major iterations below, followed by an examination of the individual case configurations. Chains 1 and 2 are first analysed separately with the subsequent creation of Chain 3, as mentioned, that forms Chain 1 into a condition set for Chain 2. For the second iteration I continued to test the data input and the subsequent QCA models derived by re-entering removed cases and reviewing condition sets. I present a final model of the QCA solution configurations for interpretation. This iterative analytic process is analogous to other mixed method and mixed data approaches (Bazeley 2018) and realist research generally (Emmel et al 2018).

7.2.2 First analytical iteration

Each chain has four of the potential five condition sets, whereby $2^4 = 16$ logically possible configuration combinations are available for these four conditions (e.g. IND, HIS, MIR CHAN or IND, MIR, IMP, CHAN). The Venn diagrams at Fig. 7.2.2. (Chain 1) and 7.2.2.2. (Chain 2) are an early view of the remaining 18 cases, following the removal of case P. Contradictions shown by the pink and green stripped areas need resolution because it is illogical to have the same condition configurational patterns lead to both the positive and negative outcome. The white areas have no observed cases for these logical combinations and are referred to as logical remainders. Pink areas refer to the negated *outcome* (0) and the green to the positive *outcome* (1). Subsequent tables Fig. 7.2.2. and 7.2.2.2. translate the Venn diagrams into a tabular format identifying the contradictory rows in red.

To obtain a contradiction-free model for Chain 1, I further removed the following cases and provide a rationale:

> **Case L** is an anomaly. This NHS surgical department provided very little audit information into the study – two timepoints pre-intervention (54% of total observation target) and one timepoint post-intervention (25% of total observation target). As shown, it is negative on all factors and positive on the outcome. Pre-intervention mean fasting duration was 5.76 hours, much lower than other surgical departments. It reduced to 4.21 hours post-intervention. Given that this is based on low audit data and even less information for Chain 2, Case L was removed from further analysis.
>
> **Case A** presents the same model, that is, negative on all factors but resulting in a positive outcome, a disconfirming case for the FISCAS framework. Many NHS surgical departments already had a recommended policy or something very close to it in place. Although a correct policy was already in place for this case, no activity

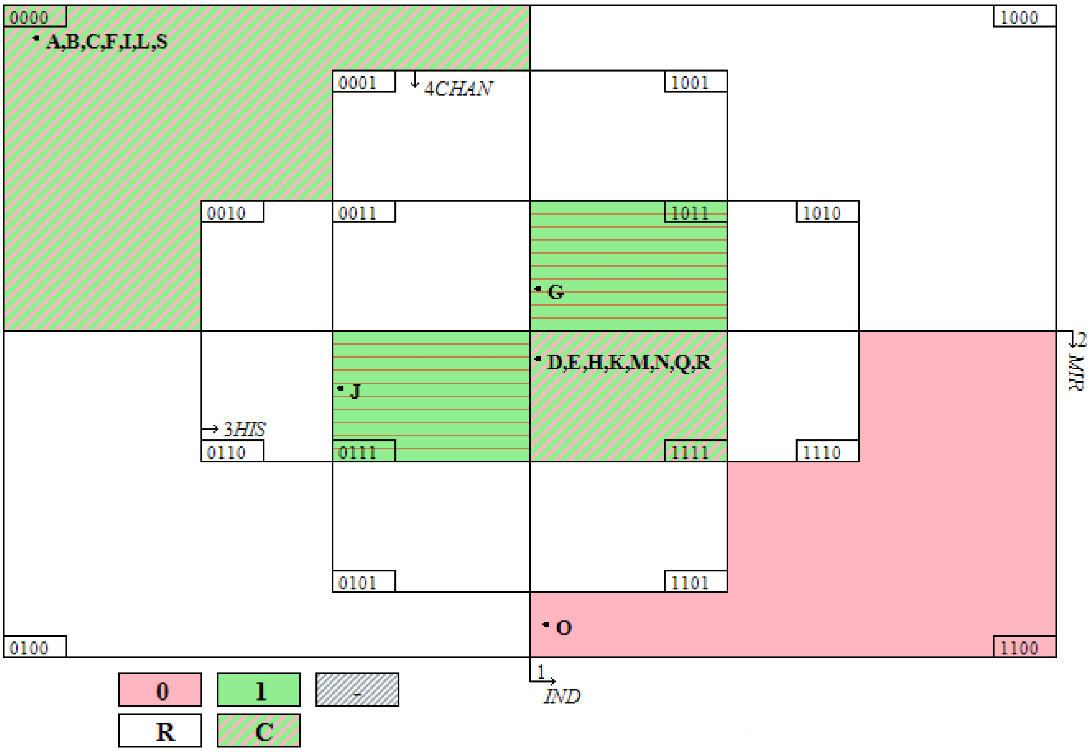
was conducted, and no leadership or championship was available to push the dissemination of the policy. However, case A reduced their average fasting time post intervention. Case A's positive result based on statistical inference indicated it was not a chance result. I have already noted that the POISE trial was powered at the cluster level rather than at the individual patient level. This case started with a high mean duration of fast of 12.3 hours which was reduced to 10.5 hours post-intervention. This might suggest the Hawthorne effect (effect not due to intervention but the impact of the trial) occurred because of the effect of the anaesthetic local investigators. No other factor was identified. This case was removed from the analysis. This NHS surgical department provided outcome data from four timepoints both pre and post achieving 76% and 63% of total observation target. However, process data was more limited to provide explanation of these results.

Case E presents the opposite configuration formation with all factors positive but resulting in negation of the outcome (mean fast increased from 8.62 to 9.78 hours). This NHS surgical department started with a policy in place that was close to the recommended policy. It conducted several activities for dissemination to reinvigorate its policy; therefore, the overall dissemination was active. However, it should be considered that these mean times were towards the lower end of the mean duration of fast across all NHS surgical departments. Allocation of '0' for membership in the outcome set may be purely arbitrary in this case. Result of audit was not statistically significant, and thus was possibly a chance result.

Following removal of these cases, Chain 1 became contradiction-free with 15 cases retaining four conditions. However, I note that there are implications when removing cases to the validity of the final QCA solutions and the conceptual assumptions underpinning the FISCAS framework. Nevertheless, the secondary use of the POISE was a constraint. Due to case knowledge I justify these cases as deviant for the purpose of this illustration. I continue to follow an iterative approach to exploring adding and removing cases.

Fig 7.2.2. Chain 1 – policy

Implementation of a fasting policy and its dissemination



0= Fully out of the set
1= Fully in the set
R= Remainders. Remainders are logically possible configurations without any observed cases.
C=Contradictions. Contradictions are configurations that match but result in both the outcome and its negation.

Table 7.2.2. Data table for Chain 1 – policy (18 cases)

Case ID	IND	MIR	HIS	CHAN	Outcome	Contradictions
A	0	0	0	0	1	X
B	0	0	0	0	0	
C	0	0	0	0	0	
D	1	1	1	1	1	
E	1	1	1	1	0	X
F	0	0	0	0	0	
G	1	0	1	1	1	
H	1	1	1	1	1	
I	0	0	0	0	0	
J	0	1	1	1	1	
K	1	1	1	1	1	
L	0	0	0	0	1	X

M	1	1	1	1	1	
N	1	1	1	1	1	
O	1	1	0	0	0	
Q	1	1	1	1	1	
R	1	1	1	1	1	
S	0	0	0	0	0	

7.2.2.1 Initial minimisation procedures for Chain 1

Chain 1, contradiction-free with 15 cases, presented two configurations as the solution model: CHAN*HIS*MIR OR CHAN*HIS*IND. This solution model's coverage was fully consistent (result 1) because it covered all cases in the model with a positive outcome. This solution model consistency of 1 indicated that to achieve the outcome either configuration was possible. Each configuration was therefore *sufficient* to achieve the outcome, but not necessary, as either configuration was possible. This suggests that an identified champion with pro-active processes for dissemination (CHAN) combined with having the correct guidance in place (HIS), and either the support of championing individuals (IND) or good system communication (MIR) will lead to the outcome of improvement to fasting practice. These results suggest that change is mediated by individuals showing leadership or facilitation skills (IND) or it is the efficiency of the local microsystem (ward and theatre) co-operating (MIR) to disseminate the guidance. This suggests that passive placement of policy on the intranet was not effective (~CHAN). In addition, further interpretation of the relationship between IND and MIR could suggest that effective individual (IND) activity does not necessarily indicate an effective microsystem (MIR) response, but an effective microsystem (MIR) indicates effective interaction between individuals.

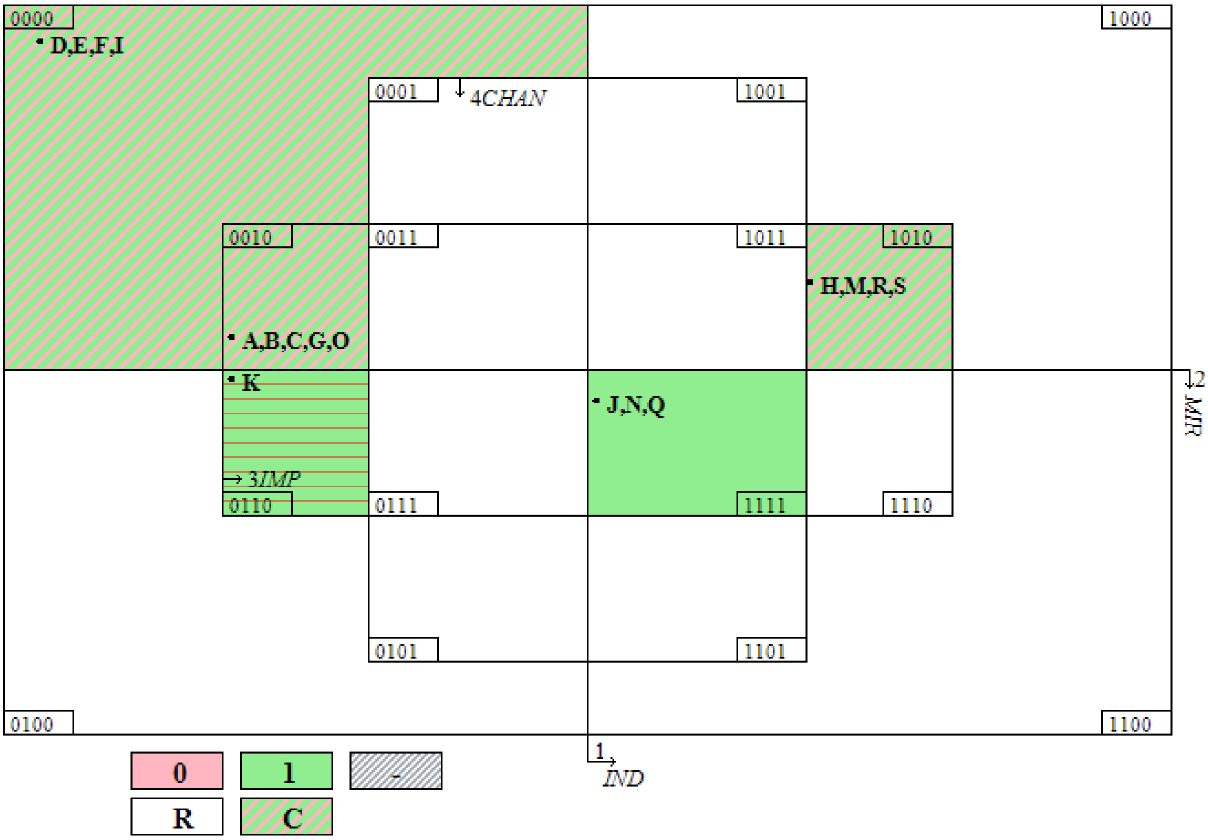
Negation of the outcome did not necessarily result in a mirrored reversal of the solutions, e.g. ~CHAN etc. QCA analysis is asymmetrical. Therefore, a separate analysis was conducted in the software on not achieving the outcome, unsuccessful improvement to fasting practice. The intermediate solution provided individual conditions ~ IND and ~ MIR as separately covering 80% of the cases with a consistency of 0.8. This supported the above by indicating that both the absence of the organisation at the microsystem level and the degree to which individuals influence change impacted on not achieving a positive change in mean difference in duration of fasting (outcome).

7.2.2.2 Implementation of practice (Chain 2)

A similar pattern emerged in Chain 2 where there were contradictions for all bar one case configuration (O) (Fig. and Table 7.2.2.2.). The tabulated version lists the individual configurations uses red highlights to indicate the contradictions that needed resolving. For example, case E had a full set of positive *conditions* present and *outcome* was not achieved, whereas D also did but the *outcome* was achieved. Cases I and A contradict B, C and F, where all conditions were negative, but I and A achieved a positive outcome. However, B, C and F achieved a negative outcome, which theoretically makes more sense based on the conceptual framework. Therefore, it was expected that if all conditions were negative then a successful outcome was not expected. Case L did not provide any raw data for Chain 2 and therefore was removed from further analysis resulting in 17 cases remaining in Chain 2.

Fig. 7.2.2.2. Chain 2: Practice (17 cases)

Regulation of fasting duration whilst patients wait for induction of anaesthesia



0= Fully out of the set
1= Fully in the set
R= Remainders. Remainders are logically possible configurations without any observed cases.
C=Contradictions. Contradictions are configurations that match but result in both the outcome and its negation.

Table 7.2.2.2. Initial data table for Chain 2 (N=17 cases)

CASE ID	IND	MIR	IMP	CHAN	OUT
A	0	0	1	0	1
B	0	0	1	0	0
C	0	0	1	0	0

D	0	0	0	0	1
E	0	0	0	0	0
F	0	0	0	0	0
G	0	0	1	0	1
H	1	0	1	0	1
I	0	0	0	0	1
J	1	1	1	1	1
K	0	1	1	0	1
M	1	0	1	0	1
N	1	1	1	1	1
O	0	0	1	0	0
Q	1	1	1	1	1
R	1	0	1	0	1
S	1	0	1	0	0

Red highlight indicates rows contradicting each other on the outcome.

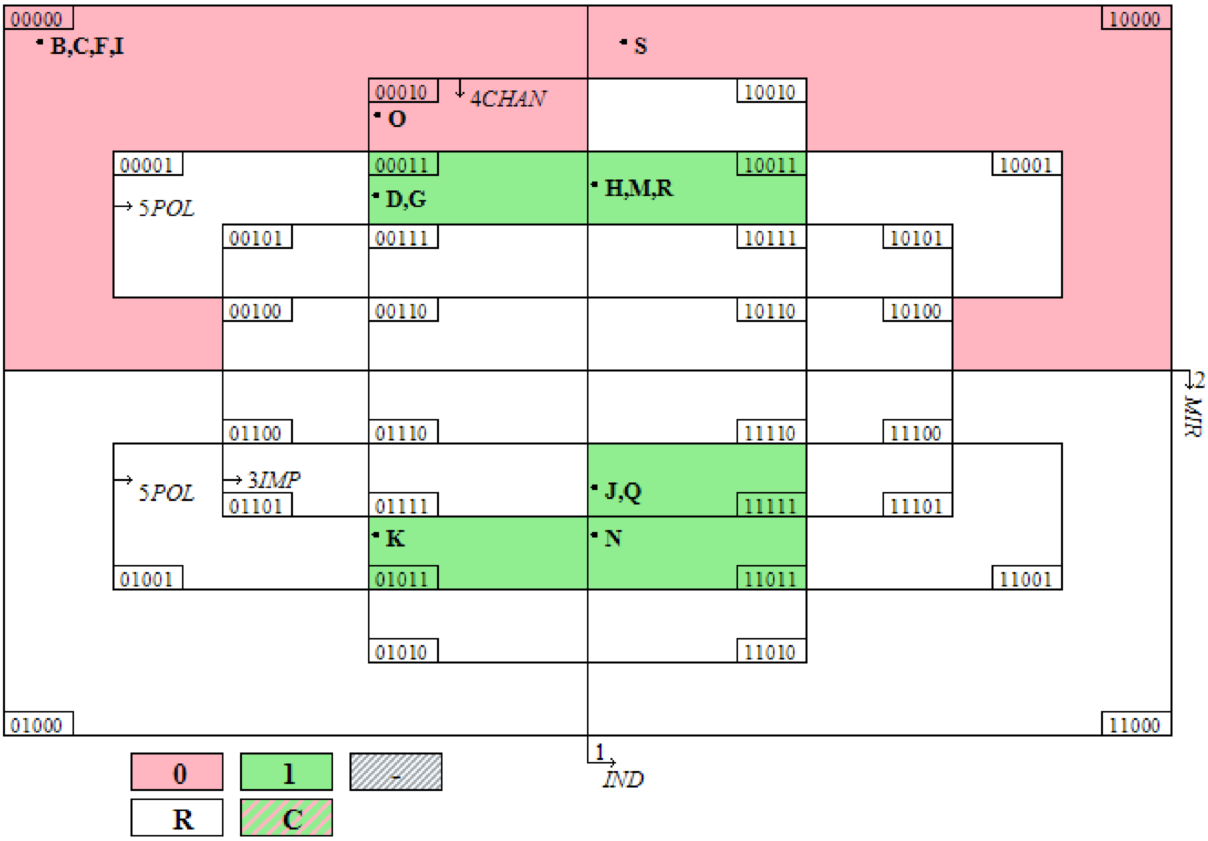
To manage contradictions in Chain 2 I created and added an additional condition ‘POLR’. This stands for policy revised condition. This condition was created to assign NHS surgical department by their policy status. Chain 1 solutions indicated successful dissemination of a policy relied upon an appropriate policy in place with active dissemination. Some cases had no policy or an incorrect policy in place. Those NHS surgical departments that did have a policy in place potentially had a starting advantage within the trial timeframe. Therefore, the POLR condition was drawn from the CHAN condition in Chain 1, which assessed the activity level to disseminate the policy and was identified in both configurations in the solution for Chain 1, strengthening its role in covering all cases when combined with other conditions. This blending between both Chains presents a contradictory free model (Chain 3). However, the number of logical remainders ($2^5 = 32$, logically possible combinations of factors) was much higher (N=11).

Logical remainders required consideration as to whether they represented plausible configurations, whereby it was reasonable to observe cases or whether they were impossible untenable configurations (Schneider and Wagemann 2012). To ensure that solutions themselves were not untenable, logical remainders were removed from the minimisation procedures. If it were possible to obtain more cases to test the model, this might have reduced the logical remainders and possibly the contradictions. However, this was not possible in this instance. I make the point regarding case selection (or sampling), as to whether the QCA analysis includes all cases (closed case set) or only a subset of relevant cases (open case set), see Chapter 5, section 5.5.1.1. On retrospective examination of trial and process data in this study, I considered it a closed case set and therefore logical remainders were not relevant in this study. I proceeded to test the condition set for combined Chain 3.

7.2.2.3 Combined implementation of policy and practice (Chain 3)

The following Venn diagram (Fig. 7.2.2.3) of the combined Chain 3 shows a contradiction-free model with two further cases (A and E) removed from above Chain 2. They were also contradictions in Chain 1, and their removal is explained above (Section 7.2.2.). Fifteen cases remained in the Chain 3 analysis.

Fig. 7.2.2.3. Chain 3 (Chain 2 adding condition POLR) 15 cases



0= Fully out of the set
1= Fully in the set
R= Remainders. Remainders are logically possible configurations without any observed cases.
C=Contradictions. Contradictions are configurations that match but result in both the outcome and its negation.

Tests of necessity and sufficiency

Initial analyses (conducted in the software) tested whether any single condition was necessary or sufficient for the outcome. *Necessity* analysis examines whether any single condition is always present when the outcome is present and whether any condition is *necessary* to achieve the outcome on its own. Chain 1 did not present any single condition as necessary and no condition was sufficient on its own. In Chain 3 POLR was indicated as a necessary condition supporting its addition to Chain 2. It was always present when the outcome was present and had consistency of 1 and coverage of 1. It was theoretically possible to stop at this point. However, active dissemination of policy to enable changes to practice was obviously a necessity. It was the relationship between *active* policy dissemination and *active* implementation to change practice that required further scrutiny and explanation.

In the spirit of dialogue between data, theory and QCA solutions (Ragin 1987, 2000, 2008), I explored further my calibration and condition definitions to bring cases, if possible, back into the QCA models. These were the only available analytical strategies because neither returning to the original data to obtain additional information from the cases (given the thoroughness of the process tracing method to extract data and prepare the individual case narratives), nor adding NHS surgical department cases were options.

7.2.3 Second analytical iteration

There is an analytical struggle in QCA methodology between an increase in conditions and removal of cases that leads to extreme limited diversity with high numbers of logical remainders and each case presenting a unique configuration. Therefore, I conducted several sensitivity steps to include cases previously excluded in the first iteration back into the QCA model. My rationale was to create a stronger generalisable model to the cases at hand, by retaining as many cases from the original 19 as possible.

7.2.3.1 Sensitivity strategy

Review of the calibration for the outcome

The outcome was based on the mean difference in hours between pre- and post-intervention audit data for average fasting times. The objective of the trial was to determine degree of change (mean difference in hours) between pre- and post-implementation strategy intervention. Therefore, rather than assume the final mean of duration of fasting was relevant I assumed the degree of change, the mean difference between pre and post duration of mean fasting time was relevant. However, some NHS surgical departments started from a relatively low mean average of 7 hours and others higher at around 12 hours. Thus, there is a plausible assumption that the mean difference drop in hours might be higher for those at the top end of the fasting duration range and less at the lower end. Therefore, I considered ranking the post-intervention mean fast duration time duration for each NHS surgical department rather than the mean difference. This created several changes to case membership assignment. For example, case S set membership for the outcome went from 0 to 1 because although in the trial it was an NHS surgical department whose mean fast duration got worse, statistically not likely due to chance (P=0.021, Rycroft-Malone et al 2009), its post-intervention mean fast was lower than most at 7.9 hours. Further testing of this new calibrated outcome ranking led to a new set of contradictions and did not make sense as illustrated by Case Q. This NHS surgical department based on the condition sets showed every effort to reduce its mean fasting time and was successful in doing so by a mean difference of 4.84 hours (P< 0.001), although it reached nearly the same final overall mean fasting time as S. It could be argued that Case Q made much more effort than Case S to implement change. I therefore retained the first outcome specification of mean difference based on degree of change. There was a clearer narrative of effort and strategy to make change in case Q. Case S's narrative involved an opinion leader who struggled to engage in her role and this, with other contextual pressures in the surgical department, may explain this worsening result.

Review of the conceptual conditions

Following the creation of a sixth condition (POLR) that indicated an NHS surgical department-wide fasting policy in place was a necessary step, along with other conditions, to lead to improvement in fasting duration times, I reviewed conditions CHAN and IMP.

I reviewed condition CHAN in Chain 2 that differed from its focus in Chain 1 and decided to determine a *level* of implementation activity based on the observation of Case Q assigned to standard dissemination, to differentiate better between cases and thus set assignment. Implementation activity and assignment to intervention strategy were not coherent in the POISE trial. To provide a fair, less judgement-based assessment of available data I disaggregated CHAN into three core change activities that embraced intended implementation strategy elements but were not confined to those assigned strategies. Three core activities were assessed and ranked individually to reach an overall assignment for each case. These were:

- the number (>5 for positive assignment) of separate activities undertaken (reported for 12 sites in the trial);
- an identified leader (someone taking change forward); and
- whether the NHS surgical department described its own implementation strategy to make changes to practice. An example was the use of role modelling: because fasting policy was running well in the trauma wards, routine surgical wards tried to 'piggy-back' that initiative into elective surgery. Other examples were the use of pre-theatre safety briefings as an opportunity to routinely review patient fast times at the

start of the operation list or placing signs above the patient's bed giving fasting start time/finish time.

This resulted in changes to this condition (CHANRV) and reallocation of case membership assignment.

Finally, based on the importance and conceptual understanding of the condition for defining the imperative (IMP) set membership, I reviewed the extracted data, and the overwhelming theme was that fasting practice improvements drifted to meet 'first on the list', which did not reflect fasting regulation of individual patients as indicated by the formal model FR = *f*(IND, MIR, HIS, IMP, CHAN) (Chapter 6, section 6.4.3.1) and the intention of the RCN guidance. The process data extraction exercise provided some clarity on a case-by-case basis regarding this pervasive response to implementation of the fasting guidance. So, the re-calibration for this condition IMPRV would only assign 1, if the NHS surgical department showed that it intended to undertake individual patient review as opposed to targeting first on the list. Appendix 7.1 presents separately the re-calibration for condition IMP. I could only allocate full membership (1) to two NHS surgical departments that clearly articulated that intention to override the imperative to have patients ready for surgery. Others very clearly were aiming, at best, for first on the list and therefore were allocated 0 because they did not override this imperative.

7.2.3.2 Modified Chain 3 (implementation of policy and practice) – crisp set analysis

Re-calibration of conditions with 17 cases (excluding L and P due to lack of data) resulted in removal again of A and E. In addition, I had to address contradictions, which left 14 cases. The parsimonious solution of these 14 cases indicated that POLR continued to be a necessary condition with a solution coverage of 1 and consistency of 1. The intermediate solution also presented a configuration of POLR*CHANR with a solution coverage of 1 and consistency of 1. Use of the parsimonious solution is discussed further due to concerns about oversimplification and loss of information from the model. Nevertheless, disseminating policy effectively is a consistent key factor. I also removed POLR, as I thought it had shown within the limits of the above analysis to be an important factor close to necessity. Unfortunately, case O then presented as a contradiction, so in the final contradiction-free model there were 13 remaining cases. The analysis then reverted to explore the four revised conditions as pre-specified in the Chain 2 (IND, MIR, IMPR, CHANR).

This analysis of 13 cases and four conditions revealed condition CHANR as necessary with a consistency of 1. No other condition was found to be necessary. This indicated the need for a degree of activity (above five activities) and included an identified leader or strategy to take forward implementation. The original trial could not show whether any of the implemented strategies were effective, and the process evaluation component of the study identified lack of fidelity to the assigned implementation strategy. Nevertheless, it captured details on activities irrespective of intervention allocation. These QCA results suggest that the capacity to conduct a range of activities combined with leadership or active facilitation, and possibly with a well-defined strategy, could lead to improvements to practice. However, care with this interpretation was highlighted by the FIRE study which tested dedicated facilitation implementation strategies, which showed the same inconclusive results as POISE, although there was promise (Seers et al 2018, Rycroft-Malone 2018, Harvey 2018). Therefore, in summary, the results suggest that the commitment and capacity of individuals, supported by the system, or the ability of the microsystem to change the system-wide practice could bring about change, rather than the specifically prescribed implementation strategies of facilitation (Chapter 6, section 6.1.3.1). The diffusive nature of habituated practice will be discussed further in Chapter 8. The final truth table (7.2.3.2) is below and contradiction free. There were seven configurations covering the 13 cases and nine logical remainders (shaded rows). These nine logical remainders were deemed not relevant in study and were removed from analysis. This is because I considered this a retrospective exploration of an event (the trial) and therefore unobserved cases were not relevant as they were non-existent in this context.

Table 7.2.3.2. Final truth table of configurations for 13 NHS surgical departments and revised condition set

Conditions				**Cases**	**Outcome**	
CHANR	**IMPR**	**MIR**	**IND**	**Number of cases allocated to configurations**	**Mean difference in duration of fasting**	**Raw consistency* of each truth table row**
1	0	0	1	3	1	1
1	1	1	1	2	1	1
1	0	1	0	1	1	1
1	0	0	0	2	1	1
1	0	1	1	1	1	1
0	0	0	1	1	0	0
0	0	0	0	3	0	0

0	1	1	1	0		
0	0	1	1	0		
0	1	0	1	0		
1	1	0	1	0		
0	1	1	0	0		
1	1	1	0	0		
0	0	1	0	0		
0	1	0	0	0		
1	1	0	0	0		

* Raw consistency of a truth table row expresses the % of cases that are aligned with the subset relations of the conditions. Between 0.9 and 1 (perfect subset relationship) qualifies necessity. Above 7.5 is acceptable for sufficiency, because subset relations are rarely perfect (Schneider and Wagemann, 2012).

7.2.3.3 Final solutions modified Chain 3 – crisp set analysis

Minimisation procedures were undertaken using fsQCA 3.0 software. This summarises the information in a truth table and determines sufficiency of the solution output. The formulisation of the assumption for regulating fasting practice (FR) is FR = *f* (CHANR, IMPR, MIR, IND).

Complex solution

Following Boolean minimisation two configurations together provide a solution coverage of 1 and solution consistency of 1. These are CHANR*~IMPR and CHANR*MIR*IND. The initial interpretation of these results suggests a level of activity that includes both key individuals facilitating (IND), and the function of the micro-system (MIR) combine to bring about the outcome. Alternatively, a level of activity combined with a drive to at least reduce fasting times to first on the list, rather than a regulated fast (~IMPR) did impact on a positive outcome of reduction in mean duration of fasting time. Using QCA in process evaluation of future similar trials would be based on the trial sampling (and the representativeness of the sample). However, conducting a similar trial with different cases could provide different results.

Intermediate and parsimonious solutions

For both the intermediate and parsimonious solutions, CHANR alone supported the necessity analysis. Solution coverage and consistency were 1. This was based on whenever the outcome is present, so is the condition CHANR. CHANR also appears sufficient because cases that have the condition CHANR also have the positive outcome. There were no cases with CHANR and the negative outcome. CHANR was the degree of activity undertaken by NHS surgical department staff to attempt to implement changes to practice and was also sufficient for the outcome. Whenever the outcome was positive, this condition was present.

7.2.3.4 Final solutions modified Chain 3 – fuzzy set analysis

Following the challenges of the crisp set analysis and the original intention to explore the more nuanced fuzzy set analysis to see whether further refined condition sets and finer-grained approach would work subsequently to the crisp set analysis. I replaced some excluded cases as a result of crisp set binary assignments (1,0) to see whether fuzzy set calibration would allow their retention. I did this because they might still have some value in the analysis, such as cases E, I and O. However, based on previous my previous rationales, P, L and A remain excluded. Set membership assignment for each case is presented in the data in Table 7.2.3.4.a.

Table 7.2.3.4.a Fuzzy set assignment Chain 3 – N 16 cases

Case ID	IND	MIR	IMPR	CHAN RV	POLR	Improvement to fasting regulation
B	0.33	0	0.33	0	0	0
C	0	0	0	0	0	0
D	0	0	0	1	1	0.66
E	0	0	0	1	1	0
F	0	0.33	0	0	0	0.33
G	0.33	0.33	0.33	1	0.66	0.66
H	0.66	0.33	0.33	1	1	0.66
I	0.33	0.33	0	0	0.33	0.66
J	0.66	0.66	1	1	0.66	1
K	0.33	0.66	0.33	0.66	0.66	1
M	0.66	0.33	0	1	1	0.66
N	0.66	0.66	0.33	0.66	0.66	1
O	0.33	0.33	0	0.66	0.33	0.33
Q	1	1	1	1	0.66	1
R	0.66	0.33	0	1	1	0.66
S	0.66	0.33	0.33	0.33	0.33	0

The following truth table (7.2.3.4.b) presents the cases assigned to truth table row configurations of conditions. The logical remainders are not presented. Eight configurations of conditions, shown in the table, are populated with cases. This number of observed configurations was not unexpected due to the limited number of cases included in the analysis. Assigned outcome values to the rows are based on consistency levels above 0.8. Rows lower than that were assigned 0 values for the outcome membership for the row, as undertaken by a command in the software. The fsQCA output is produced below.

Table 7.2.3.4.b Truth table prior to minimisation (fsQCA 3.0 output)

POLR	**CHANR**	**IMPR**	**MIR**	**IND**	**No. cases (total no. 16)**	**Improvement to fasting regulation**	**Raw (row) consistency**
1	1	1	1	1	2	1	0.888889
1	1	0	1	1	1	1	0.888889
1	1	0	1	0	1	1	0.889262
1	1	0	0	1	3	1	0.909341
0	0	0	0	0	4	0	0.457666
0	0	0	0	1	1	0	0.573276
1	1	0	0	0	3	0	0.667331
0	1	0	0	0	1	0	0.671642

Analysis by the software fsQCA 3.0 for the model FR = *f* (POLR, CHANRV, IMPR, MIR, IND) provides the following three solutions. The relevance of these solutions is discussed in chapter 2, section 2.6.2.3. The simplifying process of minimization produces first a complex solution that explains the broadest solution or the superset of solutions from which the parsimonious reduces to the majority of cases covered by the condition terms and includes logical remainders. The intermediate represents a middle step between these two solution options. The use of these solutions and their interpretation requires careful consideration due to the inclusion of plausible logical remainders or counterfactuals. In other words, the researcher should only include logical remainders (configurations with no cases) in solutions if they are plausible. I have omitted logical remainders based on my closed case set argument (chapter 5, section 5.5.1.1). However, for completeness I present all solution types.

7.2.3.5 Chain 3 analysis solutions (fuzzy set)

The software fsQCA 3.0 provides three solutions, provided in Table 7.2.3.5:

Table 7.2.3.5 Solutions for Chain 3 fuzzy set

Solution type	Configurations covering cases	Solution coverage measure % of cases	Solution consistency measure % of cases
Complex (conservative) solution	POLR*CHANRV*~IMPR*MIR POLR*CHANRV*~IMPR*IND POLR*CHANRV*MIR*IND	0.61	0.94
Intermediate solution	POLR*CHANRV*MIR POLR*CHANRV*IND	0.61	0.94
Parsimonious solution	MIR POLR*IND CHANRV*IND	0.72	0.95

No conditions separately achieved above 0.9 consistency for analysis of necessary conditions. CHANR was close at 0.8. Overall, no single condition is sufficient alone, and it is the combined solution of configurations that provide an explanation for the set of cases in this example. Seven cases covered the complex solution, that is, all cases with a positive outcome, six for both intermediate and parsimonious. The other nine cases that did not achieve above 0.5 (fully or partially in set) membership were also those that did not achieve the outcome (partially out, fully out). The pattern of configurations for those cases that did not achieve improvement in fasting regulation were clearly negative on most, but not all, the conditions.

Interpretation of the complex solution

Three configurations POLR*CHANRV*MIR*IND, POLR*CHANRV*~IMPR*IND and POLR*CHANRV*~IMPR*MIR explained the data underpinning membership assignment. Coverage is reasonable at 0.6 and, more importantly, consistency is 0.9. A degree of certainty can be held that these subset relationships exist in the data. The pattern that I highlighted in the crisp set analysis was the relationship between IND and MIR. So, again, with fuzzy set analysis both POLR and CHANR together were sufficient. POLR and CHANR were present in all three configurations, so these need to be present to achieve the outcome but cannot be achieved alone without either IND or MIR. MIR and IND then alternate with the addition of ~IMPR in the full configuration that included POLR and CHANR. This exposed the complex 'causal' relationships in the data, which were reliant on the quality of the data. I have previously indicted any findings should be viewed with caution. It was my intention to test how this method could be used to explore and expose the complexity within the dataset based on the premise of social Complex Adaptive System (CAS) operating within the field of implementation research. Together, the five conditions define the need for active dissemination of policy (POLR) with a measurable level of activity (CHANR) to achieve the outcome (improvement to fasting regulation) that are sufficient combined with either active leaders promoting change (IND) or impact on improvements at the microsystem level (MIR), or both. Dissemination of policy and a measurable level of activity together ensured that patients were at least fasted appropriately as if first on the list (~IMPR).

Complex solution for not achieving the outcome (~Out)

I conducted a separate analysis on the negation of the outcome ~Out to test, based on asymmetry, the configuration paths to not achieving the outcome. I had to set the consistency level for negation to 0.7 to be able to determine those that achieved ~Outcome. ~POLR*~CHANRV*~IMPR*~MIR had a solution coverage of 0.5 and consistency 0.78. This solution covered five of the nine negative outcome cases. This indicates that four cases did not effectively contribute to this solution. This single configuration affirms that not having these four conditions in play led to not achieving the outcome.

Interpretation of intermediate and parsimonious solutions

For completeness I report both intermediate and parsimonious solutions, although they retain logical remainders in their assumptions. The intermediate solution has dropped ~IMPR from the two possible solution configurations. Only two cases were positive on IMPR. Therefore, reduction suggests that the outcome of improvement to fasting practice can be achieved by policy, implementation activity and either active individual champions or effective function of the microsystems of ward and theatre. The parsimonious reduction becomes less interpretable based on the theoretical assumptions made here and reflects the relatively small number of cases. For example, effective microsystem communication alone may be sufficient to achieve improvements to fasting. Although, feasible it maybe an artefact of the minimisation process and does not sit well with the overall narrative.

I explore further the conceptual narrative I am employing of social CASs and view the individual case configurations from a different perspective not based on minimisation.

7.2.4 Individual case narratives

All NHS surgical departments had issues with the implementation of guidance. The pathway to implementation of guidance was riven with obstacles to enable and meet the RCN guideline (2005) objective of minimising patient fasting times for fluids to two hours. The original study struggled to gain traction on testing the implementation strategies to enable implementation, and intervention infidelity was high in the trial. The core components of these strategies to foster team working, provide facilitation and leadership were thwarted by inter-professional issues, organisational buy-in and decision-making authority – who decides on fasting practice (Rycroft-Malone et al 2013). Also, the influence of the individual healthcare professional facilitating or thwarting implementation of guidance was noted (Rycroft-Malone et al 2013). QCA as a case-based method seeks to retain the uniqueness of each case whilst allowing comparison to seek common patterns across the cases with a key objective to reach a pre-defined outcome of interest. Appendix 7.2 provides an overview of each case with a summary of evidence with regard to the NHS surgical departments' ability to meet the guideline key objective to regulate patient fasting as envisaged by the recommended guidance and, whether individually, they were able to do so or not, irrespective of intervention allocation in the POISE trial. There was a strong pattern across the cases included in analyses towards meeting two hour fasts as if all listed patients were first on the list, which indicates the strong imperative to preference management of the operating list to ensure patients receive their operation. However, individual patient fasting regulation practice (IMPR) did not seem impossible for cases J and Q, when there was capacity and commitment towards communication between ward and theatre to enable fast regulation as I have described.

The POISE trial revealed great *complexity* behind the simplicity of the recommendation of this guidance. This QCA study confirms that complexity and explains that what happened in the trial was an expected outcome based on the social CAS's imperative to continue current prolonged fasting practice to ensure patient readiness for theatre was the priority. This was in the context that there were well-known drivers, at the time, to meet operation targets. The system of fasting practice was so well embedded, due to its long history, that the fasting practice system evolved to meet that imperative and so was not easily dismantled. Many individual healthcare professionals understood the rationale to reduce pre-operative fasting times but were often overwhelmed by the system to maintain theatre throughput. Those healthcare professionals that were identified in NHS surgical departments as thwarting change to practice wanted to focus on ensuring they could manage change on the list by ensuring patients were ready and fasted appropriately:

"So now everybody drinks up to about two hours, then a patient gets cancelled and the next one can't be moved forward because it's been fed and drunk. It's a disaster. We should go back to the old days when they were fasted from midnight and that would be that…"

Focus group participant, site F (medical professional).

The response to that comment was:

"Well I think it's really unfair for the patient's sake because a lot of times surgery is cancelled and cancelled and I have trauma patients who've been kept nil by mouth for three days consecutively and not been fed and cancelling, cancelling and it's really frustrating for the patient and for nurses as well."

Focus group participant, site F (nursing professional).

7.2.5 Using Qualitative Comparative Analysis for implementation research

Operationalisation of Complexity Theory within an implementation research context was the key impetus for this thesis. I wanted to provide an additional explanatory level as to why implementation activity fails overall to gain a hold in the individual case context and is patchy across a set of cases given planned efforts to engage and facilitate implementation. The QCA study assumed all five conceptual conditions played a part within implementation practice. These five conceptual conditions were populated with POISE study data subsequently synthesised through QCA analysis. Given the previously expressed caveat regarding incompleteness of empirical data extracted to populate the process steps assigned to the five condition sets, data reformation and transformation has exposed complex causal arrangements of conditions. Overall the explanation of the complex solution POLR*CHANRV*MIR*IND, POLR*CHANRV*~IMPR*IND and POLR*CHANRV*~IMPR*MIR indicated the need for all conditions to be present but in different combinations. The original model argued optimal fasting regulation should occur as a *f* (CHANRV, IND, MIR, IMPR, HIS (POLR)) to meet the assumptions of the conceptual framework. The complex solution does not include the logical remainders and based on my argue that it was not of relevant in this analysis to include configurations of unobserved cases. This is because they do not make sense in the case context here (Rhioux and Ragin 2009). Hence, I only interpret the complex solution.

The 'solutions' provide a logical synthesis of the available data managed in a transparent and plausible manner with set theoretic logic follow-through. The QCA modelling in this manner can only be reasonable, if the logic of the condition sets in relation to the outcome are also plausible along with the datasets used. QCA as a methodology relies upon the interpretability of the findings in relation to the theoretical premise of the study. Given these caveats, the method seeks patterns rather than data aggregation across cases. It also provides an opportunity once the individual case configurations are defined, to observe other patterns of interest before necessarily, proceeding to minimisation.

Befani (2016) proposes that QCA might allow for the investigation of phase transitions (Chapter 3, section 3.5.2) when studying complex systems. For implementation research investigating the case context in a comparative manner across cases, provides important information that addresses what makes the difference in one case and not the other. It is well recognised that the individual case context is a strong influential factor, and it is explored further here. As set out in this thesis, an underlying assumption of social CAS is that they do not operate with neat linear responses to change, and that multiple factors are involved as the synthesis of implementation concepts (Chapter 4) indicates. However, structuring the data in the manner of membership assignment to some of these identified factors, as Befani (2016) suggests, may reveal key points of change based on the influence of the different configured factors or conditions and their relationship with the outcome. One key narrative thread in the QCA study analysis and the iterations undertaken was the NHS surgical departments' 'starting point' to change. Beyond the timeframe of the POISE trial, temporal sequence of each case context seen collectively may show change based on their start point in the change process.

Investigating temporal sequence and change points

Previously, minimisation procedures formulated configurations that combine across the cases. Another approach is to examine all individual case configurations and consider whether any other pattern occurs, for example whether there are progressive steps (by degree using fuzzy set assignment) between successful and unsuccessful implementation. As a researcher in the trial, I noted there was a view that NHS staff felt confined by the trial timescales to get organised and make changes to practice. Issues of sustaining the change activity or people's focus etc. were also noted as factors (Rycroft-Malone et al 2013).

Table 7.2.5.a is constructed in an ordinal arrangement with the cases by outcome from fully in 1 to fully out. The objective is to consider whether the configurations spanning by degree from fully in (successful implementation to improve fasting regulation) to fully out (unsuccessful implementation of fasting regulation) reveal progressive condition patterns across the cases to influence implementation. Based on original assignment it is not possible to contrive this table. Secondly, the assumption underpinning the QCA study is that all five conceptual conditions based on a social CAS perspective were needed to ensure successful implementation of guidance.

I have colour-coded the table to reveal a potential pattern using the fuzzy set Chain 3 with 16 cases. The table places the outcome in sequential order from the 'fully in' assignment 1.

Table 7.2.5.a Chain 3 (N=16 cases) – fuzzy set – investigating phase transitions

	Conditions						
Case ID	**Individual behaviour IND**	**Micro-system MIR**	**System imperative MPR**	**Intervention/ change CHAN RV**	**Policy POLR**	**Outcome**	**Phase transition**
J	0.66	0.66	1	1	0.66	1	In these four cases resulting in fully achieved outcome there is clearly activity across all conditions, although values on some conditions vary between 0.33-0.66. The value 0 is not present in any condition.
K	0.33	0.66	0.33	0.66	0.66	1	
N	0.66	0.66	0.33	0.66	0.66	1	
Q	1	1	1	1	0.66	1	
D	0	0	0	1	1	0.66	These middle outcome values could indicate a transition change point from below to above. F should not have resulted in any change, however small. D was affirmative on CHANRV and POLR, however, it contradicts E.
G	0.33	0.33	0.33	1	0.66	0.66	
H	0.66	0.33	0.33	1	1	0.66	
I	0.33	0.33	0	0	0.33	0.66	
M	0.66	0.33	0	1	1	0.66	
R	0.66	0.33	0	1	1	0.66	
F	0	0.33	0	0	0	0.33	
O	0.33	0.33	0	0.66	0.33	0.33	
S	0.66	0.33	0.33	0.33	0.33	0	Except for case S, these cases are populated with 0 values on nearly all conditions. S suggests some low-level activity across all conditions. This NHS surgical department started from a relatively low mean fasting time that went up post-intervention. This suggests that
B	0.33	0	0.33	0	0	0	

E	0	0	0	1	1	0	perhaps the NHS surgical department was already pushing good practice and that the timing of the trial was an influence or just a normal fluctuation.
C	0	0	0	0	0	0	

This table shows that observing affirmative data across all five conditions led to full membership in the outcome set (change greater than an hour in the mean difference in fasting time between pre- and post-intervention). Mostly negative data across all five conditions led to not satisfactorily achieving the outcome – non-membership of the outcome set. Inconsistencies remain in the membership patterns across the configurations in some cases (E and D). The capacity to investigate whether there is a causal combination of conditions or a single condition that can indicate a change point seems potentially very valuable in implementation research. In eyeballing the table, potential progress in microsystem communication between the green highlighted cases and the teal highlighted cases occurs suggesting that co-operative working between theatre and ward to communicate on fasting times is possibly a key factor. Again, a level of implementation activity and active dissemination of policy seems to make a difference. Case I seems rather weak on all conditions whereas others achieving values of 0.66 (mostly in set membership of the outcome set) indicate a strengthening pattern across conditions towards full membership in the teal zone in Table 7.2.5.a. Table 7.2.5.b isolates the crossover zone between 1 and 0 in Chain 3 fuzzy set analysis. I re-jigged the list to emphasise POLR and CHANR (highlighted in red) as those conditions that set the bar for change because they are present in all three solution configurations. Based on this, cases D to R suggest movement towards potentially achieving full set membership. I state this as a principle (or possibility) rather than a fact based on the data.

Table 7.2.5.b The crossover zone

Case ID	**IND**	**MIR**	**IMPR**	**CHAN RV**	**POLR**	**OUT 1**
	0	0	0	1	1	0.66
G	0.33	0.33	0.33	1	0.66	0.66
H	0.66	0.33	0.33	1	1	0.66
M	0.66	0.33	0	1	1	0.66
R	0.66	0.33	0	1	1	0.66
I	0.33	0.33	0	0	0.33	0.66
O	0.33	0.33	0	0.66	0.33	0.33

F	0	0.33	0	0	0	0.33

Case F is appropriately at the bottom, nearly falling into 0 set membership across all conditions. I and O would fit the pattern nicely if they were reversed. However, the QCA transformation, organisation of data and use of logic does allow the systematic investigation and exposure of patterns in the data that might not arise within more conventional quantitative and qualitative methods.

7.3 Summary

The POISE implementation trial created a unique set of cases that I used to test application of QCA methods to operationalise the social CAS conceptual framework for implementation of evidence-based guidance. Using within-case process tracing (Chapter 6, sections 6.4.3.2) I disaggregated the original dataset and reformed this data using set theoretic principles, which maintains the integrity of the individual case and its data contribution. Cases were assigned membership to a set of four or five conditions theorised to be causally relevant as part of different configurations different across the cases in relation to the outcome. These configurations underwent Boolean or fuzzy set minimisation procedures to determine the conditions that were prime implicants (across the individual cases), aided by software. The individuality of the case was retained throughout to allow back and forth iteration and interpretation of the results. This represents a distinctly different approach from average net effects and aggregation of qualitative themes, conducted in the original study.

I conducted a procedure similar to Schneider and Wagemann's (2016) two-step approach in which they describe how to manage a large number of conditions by dividing conditions into those that are proximal to the outcome and those that are more remote, either in time or space. This makes sense when operating within a system at multiple levels. My approach showed there were two major steps to implementation of fasting regulation that were temporal in sequence. These were policy status (macro-level) change that were, if necessary, followed by active policy dissemination. Second step required implementation of the policy into practice to promote individual fasting regulation (meso/micro level). In the final analysis there are seven configurations covered by at least one case out of a logically possible 16 configurations. Theoretically unobserved cases, that is other NHS surgical departments, could be added and might show very different patterns to achieve a positive outcome of a reduction to their mean fasting times and in principle change the overall model. However, this set of cases was constrained within the parameters of a trial. I describe this as a closed case set and so the QCA results relate only to what happened in this trial. It might possibly inform future similar implementation trials but cannot be generalised beyond the specific set of cases in this QCA model. The final analysis given the limits of the POISE study data indicated the promise of the conceptual framework for future application in exposing complex mechanisms within practice implementation in healthcare systems.

7.3.1 Study limitations and evaluation

In the following sections I discuss the limitations and constraints that impact on the findings of the QCA study from two methodological angles. First, I discuss the POISE dataset I used for secondary purposes to conduct the QCA study, with the purpose of operationalising the FISCAS concepts. Second, I discuss my approach to applying QCA methods in this context, specifically the analytical iterations and the subsequent examination of using the whole case set to suggest a temporal change pattern (phase transition).

7.3.1.1 Study data

Limitations are addressed throughout my reporting of the study and are also reflected in the comments I make in the QCA in health studies review (Chapter 5). A primary issue raised in the review is the quality of the source data and the methods to obtain that data. Likewise, it is important to reflect on the quality of the POISE trial methods. Subsequent to my use of the data in this thesis, two references (Flodgren et al 2019, McIntyre 2018) have commented favourably on the quality of this study’s trial design (low risk of bias) and its process evaluation, which met most quality criteria. Therefore, limits in the data are most likely related to using it for secondary purposes, with a new set of questions. The risk is overlaying a set of assumptions that are not appropriate. QCA studies use data accumulated for other purposes, as many examples in Chapter 5 show. Hence, I would describe QCA as a synthesis method that juxtaposes different data to reveal patterns and potential causal arrangements in complex social settings not visible in other designs. My approach was to disaggregate the data by case rather than data collected by intervention, the POISE trial approach. This revealed patchy data not evenly distributed across all cases. There was either poor audit data or no process evaluation data. At least two cases were eliminated early from the analysis based on data limits.

7.3.1.2 Study methods

I would suggest that process tracing to extract data was both a strength and a safeguard to systematically gain the necessary information for the current study. I developed the framework for the hypothesised implementation steps based on a small number of cases. I applied these process steps to all cases. This careful data extraction process failed at times to find adequate evidence for a process step. A more rigorous approach would involve checking and questioning data extracted by another independent researcher to ensure my judgments were consistent. Also, I made judgements regarding the inclusion and exclusion of cases, as well as my redefinition and re-calibration of condition sets. These are judgements of a single researcher and may inevitably skew data towards my expectations discussed further below in confirmation bias. I hope that transparency of my reporting mitigates rather than eliminates that risk.

7.3.1.3 Study evaluation

Thomann and Maggetti (2017) provide a framework to facilitate design of a QCA study that differentiates between case orientated and redundancy free (large N) designs. The authors set out the parameters for consideration: external validity, internal validity, measurement and mode of reasoning used. I used this framework a priori addressing how this study would meet those expectations, e.g. sampling of cases, case knowledge and testing robustness by adding and dropping cases etc. (Appendix 6.1). I conducted a case-orientated model and draw out key points below related to the conduct of this QCA study addressed by the framework.

Confirmation bias

Bias, as with any research study, needs to be addressed to provide an account of any undue influence that impacts inappropriately on the findings jeopardising their validity. Within QCA, confirmation bias is something to guard against when managing case selection and condition specification. As a researcher of the original dataset, I could create undue influence, consciously or unconsciously, that would confirm the premises of my study. The conceptually informed conditions and the hypothetical process steps used to extract the data were highly structured, thus I would argue that structuring the data extraction selection should have limited any undue influence on my part.

Subsequently, my integration of the implementation conceptual synthesis with my own synthesis of social CAS concepts to conceptualise the conditions is supported by other work (Braithwaite et al 2018). My influence cannot, however, be totally removed from a study like this, and the reader should note this point.

Potential errors

If there were errors in the original dataset, when extracted and transformed they would become systematic errors in the QCA analysis. The dataset is already acknowledged as setting limits with missing data that resulted in removal of cases. Process tracing provided a transparent coding framework for the extraction of the original data into the condition sets. Whenever, I revised the coding of the condition sets to manage contradictions in some cases, I reapplied the set membership assignment across all cases. However, throughout the analytical iterations I reviewed and revised coding of the condition sets and applied this to all cases maintained within the analysis. Calibration errors were limited due to strong conceptual criteria. The analytical strategy conducted also involved condition management to ensure contradiction free models along with case exclusion. Some judgements were made to include evidence from an interview or focus group transcript that resulted from piecing together the evidence when very clear statements of intent were not available. Therefore, a degree of overinterpretation of the available evidence is a factor.

Limited diversity

There is an expectation that in the social world it is most likely that, given all logically possible configurations of a set of conditions, 2^k that some configurations will not have observed cases. These empty configurations should be explained within the context of the study datasets and theoretical framework. Those that conduct large N QCA studies are at risk of losing in-depth case detail but may gain a redundancy free model, with no logical remainders. The ratio of the conditions to cases can become invalid with small case sets and a large number of conditions of interest and requires a strategy to manage the number of conditions. This may require several prior steps to reduce the number of relevant conditions. Four to seven conditions are recommended for a typical 10-40 cases (Rihoux and Ragin 2009). I undertook several steps to build a QCA model that eventually retained 16 cases of the original 19 with five conditions. Given my argument for a closed case set, adding new cases was neither an option nor appropriate within this study.

Validity of explanation

Thomann and Maggetti (2017) propose that explanation of findings is reliant on the strength of the conceptual framework and the interpretability of the findings. I suggest this is a strength of this QCA study due to the efforts made to both develop and apply conceptually informed condition sets. Therefore, the strength of interpretation in this study relies upon the credibility of the FISCAS framework, which warrants further testing in other studies. The narrative of the framework appeared to play out in the study, however, all caveats on both data and methods used remain.

Mode of reasoning

This QCA study set out to test a conceptual framework and indicates that aspects of a social CAS are identifiable in the dataset which, when worked through the QCA analytical process, suggests the conceptual framework has potential. Reasoning plays a strong part and assumes that individual cases, whilst retaining unique context-specific responses to implementation events, can also provide common patterns of behaviour.

7.3.2 Interpretation

The language of sets used in QCA methodology uses the complex causal arrangements of sufficiency and necessity and INUS conditions (Chapter 2, section 2.3.2), which are defined as those conditions that are **i**nsufficient to achieve the outcome alone but are **n**ecessary as part of a conjunction of conditions that are **u**nnecessary but are **s**ufficient to achieve the outcome. Conditions need to combine in multiple conjunctions rather than operate as single causes. POLR*CHANRV (fasting policy in place combined with high level activity to implement practice change) are linked conditions because they are present in all configurations. These conditions are insufficient alone but are necessary as part of the other configurations, which are not necessary (for outcome to occur) but are sufficient (outcome will occur with these conditions). A further observation includes the negation of IMPR in two complex solution configurations. This condition investigated the degree to which the imperative was to maintain or overturn the imperative to link fasting practice to the management of the operating list and indicates in many cases, that there was evidence of a clear preference towards maintaining fasted patients so as not to jeopardise the management of the operating list and the patient flow through theatre. This is a plausible explanation given the knowledge of the original dataset and research experience. Use of QCA methods has provided a clear link and explanation in a structured manner.

Studies that include intervention time period limits are restricted in tracing the potential for fuller implementation that could occur over a longer timeframe. Also, an important factor in this study was that each NHS surgical departments' starting point was not the same (imagine a race). Use of QCA to investigate whether there was a temporal pattern across the whole set of individual case configurations, which suggests a transition *tipping* point towards positive membership of all conditions with a positive outcome, shows QCA has potential for implementation studies. It also fits within the expectation that individual NHS surgical department systems do not operate in a steady state scenario (Chandler et al 2016). Apparent large changes in a system can have a small effect whilst small changes may result in a large effect; it is not the change as such but the way it can feed through the system. In other words, some change event may build a momentum and tip across the system providing a large effect, whilst a larger effort can also get diluted and dispersed creating little overall effect. Thus, it is possible to ask specific questions of the QCA configurations such as, are there clearly defined change points and what conditions might matter and when. On this point, QCA is critiqued for not permitting temporality in the model (Schneider and Wagemann 2012), however, when used in this manner the individual cases can represent different stages in transition, which was very clear at the outset with the original POISE study.

7.3.3 Conclusions

QCA methods are used to synthesise data using the logic of sets. QCA maintains the uniqueness of the case context whilst also permitting an investigation of behavioural patterns across the cases that might indicate useful information generalisable to other settings (Befani 2013). The method requires a strong analytical and theoretical approach to reason out the logic the researcher seeks to imply. The QCA study process undertaken, I suggest, has tested the FISCAS framework, which permitted operating a different lens over data collected for an implementation trial to better understand what happened and why. Key findings indicate the necessity for a certain level of activity (rather than implementation strategy assignment) to achieve both policy and practice implementation success by healthcare professionals, wards and theatre systems of communication. However, the surgical department system impetus is driven towards ensuring operating lists are not compromised and patients receive their surgery. Therefore, any change activity is pushing against this important system imperative. Finally, although my judgment and influence are a consideration, the systematic structure, data transformation procedures and use of software provide a degree of reassurance regarding these study findings.

Chapter 8: Discussion

I keep six honest serving men (they taught me all I knew); Their names are What and Why and When and How and Where and Who.

Rudyard Kipling: Just So Stories, "The Elephant's Child" (1902)

8.1 Introduction

Implementation research questions include all of Rudyard Kipling's honest men. *What* intervention and implementation strategy, *how* they work, *why* do they work or not work, and for *whom* and in what context (*where*), and *when*. Taking for example *when*, implementation needs to account for many aspects of the individual case context, but also, as the Qualitative Comparative Analysis (QCA) study findings suggest, the starting point of each case *when* introducing changes to care and practice. Implementation of change as a key activity occurring in the NHS is context specific (Chapter 1, section 1.1). Patterns of behaviour observed across individual case contexts can provide a better understanding when organising future implementation activities, or at least make sense of what happened and why. Methods such as RCTs are limited in disaggregating the behaviour of complex contexts of NHS organisations due to the loss of this case context information (Chapter 2, section 2.5). My thesis developed a social Complex Adaptive Systems (CAS) conceptual lens and borrowed a method from political science to disaggregate this contextual complexity to further implementation research.

In this discussion chapter, I reflect on my findings and contribution to implementation research. From learning gained in the process of developing a novel framework, and operationalising it in the QCA study, I propose several recommendations for the application of QCA in health research. I consider the main assumptions underlying my thesis which are causal complexity and Complex Adaptive Systems and how these inform implementation. I also address the limitations of my research.

My principal contributions are the development of the conceptual Framework for Implementation in Social Complex Adaptive Systems (FISCAS) and its operationalisation using QCA as an enabling methodological device. I illustrate an approach that enables a synthesis of process data with outcome data to provide greater explanatory power to the findings of an inconclusive implementation trial. This approach maintained the individual case entity as the central unit of analysis creating explanatory models of conceptually informed factors. These configured across the individual cases creating patterns for exploration and explanation. In the following discussion I distil my contribution to implementation research, specifically:

- Framework for Implementation in Social Complex Adaptive Systems (FISCAS): A Complexity Theory informed implementation explanatory framework that balances comprehensiveness with utility for implementation research.
- The addition of QCA methods within the evidence-based methods tool kit, that is, alongside RCTs and systematic reviews of RCTs.
- I raise several methodological aspects for consideration when using QCA methods as an additional methodological tool in evidence-based implementation research and make recommendations for future application.

8.1.1 Thesis overview

From my experience of working on trials of interventions that were sensitive to and contingent on their contexts and given my previous knowledge of Complexity Theory at the time, I took the view that healthcare practice functioned as a social CAS. This assumes that practice is an activity distributed (Cilliers 1998) throughout healthcare micro- and macrosystems involving multiple healthcare professionals, and therefore not easily dismantled or changed. Likewise, individual context response to practice change is unique. I was also aware of the link between Complexity Theory and Qualitative Comparative Analysis (QCA) methodology and its accompanying methods (Byrne 2002), which assumes individual case 'complexity' and heterogeneity. My initial idea was to investigate how we can gain a better insight into what really happens in the implementation healthcare context. I was particularly interested in exploring how methods can capture and explain this context-specific complexity in these implementation projects. At the same time allow for transferable learning beyond the individual case context.

By synthesising the process and outcome data of an inconclusive implementation trial from this different theoretical perspective, I unpicked the complexity of the different case contexts to gain greater explanatory power. I presented a unique example that uses process tracing to *case* the NHS organisations, the unit of analysis in the original POISE cluster randomised trial. Application of the FISCAS framework using QCA methods suggests implementation of evidence-based guidance involved:

  - The relevance of practice history and individual NHS surgical department starting points.
  - Impact of individual healthcare professionals in practice microsystems.
  - The powerful influence of practice imperatives.

- An opportunity to understand non-linear phase shift patterns towards practice change.

The critical realist position is increasingly popular in evaluation and implementation research (Emmel et al 2018). This thesis has taken a more nuanced complex realist position (Byrne and Callaghan 2014, Chapter 2, section 2.3.2.1). I draw attention to causal pluralism as a direction of philosophy that addresses more fully the complex causality in real world contexts (Illari and Russo 2014, Cartwright 2007). By-products of my work include conducting the first review on QCA application in health studies (1999-2019), a novel quality assessment tool for QCA, and an exemplar of process tracing for implementation research. This revealed individual case causal pathways, thereby providing increased explanatory power for the across-case analysis. I elaborate and surmise key elements of my thesis in the following sections.

8.1.2 An implementation problem

The POISE trial presented as a deviant case in relation to the premise of the PARIHS implementation framework (Rycroft-Malone 2013, 2010, Kitson 2008, 1998) that proposed that credible evidence facilitated in an enabling context should lead to successful implementation of guidance (improvements to fasting practice). Credible evidence (the guideline) was not enough to bring about change. Fidelity to the implementation strategies to facilitate implementation did not hold either in the POISE trial. Contextual issues seemed to overwhelm NHS organisations impairing their response to the trial, although these responses were variable across cases. QCA methodology allowed an exploration of the POISE data to explain the trial's inconclusive findings as well as its poor impact in reducing prolonged fasting for patients in receipt of routine surgery.

To achieve the objective of the high-quality evidence underpinning the RCN guideline (Lambert and Carey 2016), individual patients needed their fasting times regulated and monitored throughout the pre-operative period because of possible changes to list order due to delays or cancellations. However, the POISE trial seeking to improve practice resulted in nearly 27% of patients exceeding fluid fasts of twelve hours, across all NHS surgical departments, and with 62.7% exceeding six hours (Rycroft-Malone 2012). As an average, this was not close to the two hours for individual patients recommended by the evidence-based RCN guideline. There is a paucity of current data on fasting practice in the UK. Small-scale audits in single surgical departments indicate that individual fast times before anaesthesia continue to range between two hours and 17 hours for fluids (e.g. Roberts 2013). This author implied patients were excessively fasting prior to admission. However, this also clearly indicated that patients were not reviewed and updated after admission for their day surgery. Another small-scale clinical audit indicates the need to promote a positive message to patients to drink up to two hours before admission (Krytatos et al 2014). Results showed a small improvement in mean fasting times from eight hours (range 2-21 hours) to seven hours (range 2-18 hours) mean fluid fast duration. Authors again indicate the onus on patients to follow advice prior to admission. These audit results support POISE findings (Rycroft-Malone 2013) that those with shorter fasts tend to be first on the list. More importantly, authors also confirmed that there were no 'starve checks' or 'un-starving' of patients who were at the end of the list (Krytatos et al 2014). Around two million elective surgical admissions occur annually in England, and there was a 51% increase in cancellations on the day of admission or later between 2010 to 2019 (Nuffieldtrust.org.uk/resource/cancelled-operations, accessed 1 November 2019). This data postdates the trial but shows that fasting practice remains an important care and practice problem, particularly considering this increase.

The POISE trial indicated varying degrees of improvement to mean duration of fasting times across the individual NHS organisation cases. The implementation strategies evaluated in the POISE trial as the levers for change did not bear out within the trial comparison. Intermediate changes to practice were identifiable in the process data towards the outcome of mean duration of pre-operative fast. It was not possible to quantify this impact within the confines of the POISE trial design, although process data captured activities conducted. However, I do not discount the original process findings that were elaborated into a set of propositions that suggested that better implementation required:

- organisational priority,
- clear leadership and responsibility for fasting practice,
- a better understanding of the function of the multiple micro-subsystems,
- use of current practice structures,
- staff with capacity and requisite skillsets to bring about change to practice; and
- greater depth on the mechanisms of the intervention and the context into which they are being implemented (Rycroft-Malone 2012).

However, I shift the emphasis from the underpinning trial conceptual framework PARIHS (Rycroft-Malone et al 2010) that specifies:

> Successful implementation (of evidence-based guidance) is a function of the receptive and enabling *context*, the credibility of the *evidence* base and its active *facilitation;* to
>
> Successful implementation (changes to practice as a result of evidence-based guidance (CHAN)) is a function of optimal *interaction* and *connectivity* between

individuals (IND), evolving in a *dynamic self-organising* feedback loop forming higher *emergent* order into *micro-subsystems* (MIR), which requires the understanding of the practice diffusion throughout the health system and the strong influence of the practice *imperative* (IMP) and practice *history* (HIS).

The POISE trial data presented an elegant example to expose complexity within the apparent simplicity of a guideline recommendation, to implement shorter fasting times for patients before routine surgery. Re-examination of data collected in the trial and process evaluation viewed through a different conceptual framework permitted an investigation to explain what happened and why. My research addressed two key questions:

1. Can Complexity Theory provide a better understanding and explanation of implementation of evidence in healthcare systems?
2. Can Qualitative Comparative Analysis methods operationalise Complexity Theory concepts?

I also started with a set of secondary questions:

How has QCA been used in the field of healthcare? I address this question in Chapter 5 and pick on how its use in the health field is developing particularly with systematic reviews to manage complex interventions across multiple studies.

The following questions are addressed throughout this discussion.

How should Complexity Theory (specifically CAS) be adapted to the field of implementation research in healthcare systems?

How can QCA be adapted to implementation research?

What contribution do QCA methods make in enabling a Complexity Theory (specifically CAS) perspective?

How can the QCA approach to causal complexity benefit implementation research?

For purposes of discussion I discriminate between the implementation object or event, an implementation strategy (defined) or activity (not defined), and the implementation context which operates both in time and place. The importance of addressing the individual case context is a major thread in my thesis.

8.2 The Framework for Implementation in Social Complex Adaptive Systems: An explanatory framework for implementation research

Navigating complex systems in healthcare requires explanation (Moore et al 2015, Byrne and Callaghan 2014, Russo and Williamson 2007) of the processes and mechanisms that bring about both desirable and unintended outcomes. Although other implementation models (e.g. Greenhalgh et al 2017, Damschroder et al 2009) provide more details on system aspects, Fig.8.2.1, whilst acknowledging the wide scope for any system explanation, also suggests more general *social Complex Adaptive System* behaviour. Therefore, whether an implementation event or object succeeds or fails could be due to the system phenomena of:

1. A stronger system imperative and history to continue current system behaviour.
2. Non-linear system behaviour overtime, which needs to reach a level of impact before change becomes noticeable or measurable.

History, time, imperatives and non-linear shifts in adaption and change are key concepts and themes which impact on the responses of healthcare professionals and patients in their care. My intention with FISCAS was the direct *operationalisation* of these key Complexity Theory informed concepts for social systems through a methodological device rather than a post hoc interpretation (e.g. Long et al 2018, Simpson et al, 2013, Trenholm et al 2013,). Such a post hoc explanation could be argued as a confirmation error or bias (Thomann and Maggetti 2017). My conceptual focus draws attention to the *imperative* of the healthcare system and practice, its *historical* development and the patterns of change that are not assumed to be neither linear nor straightforward in implementation.

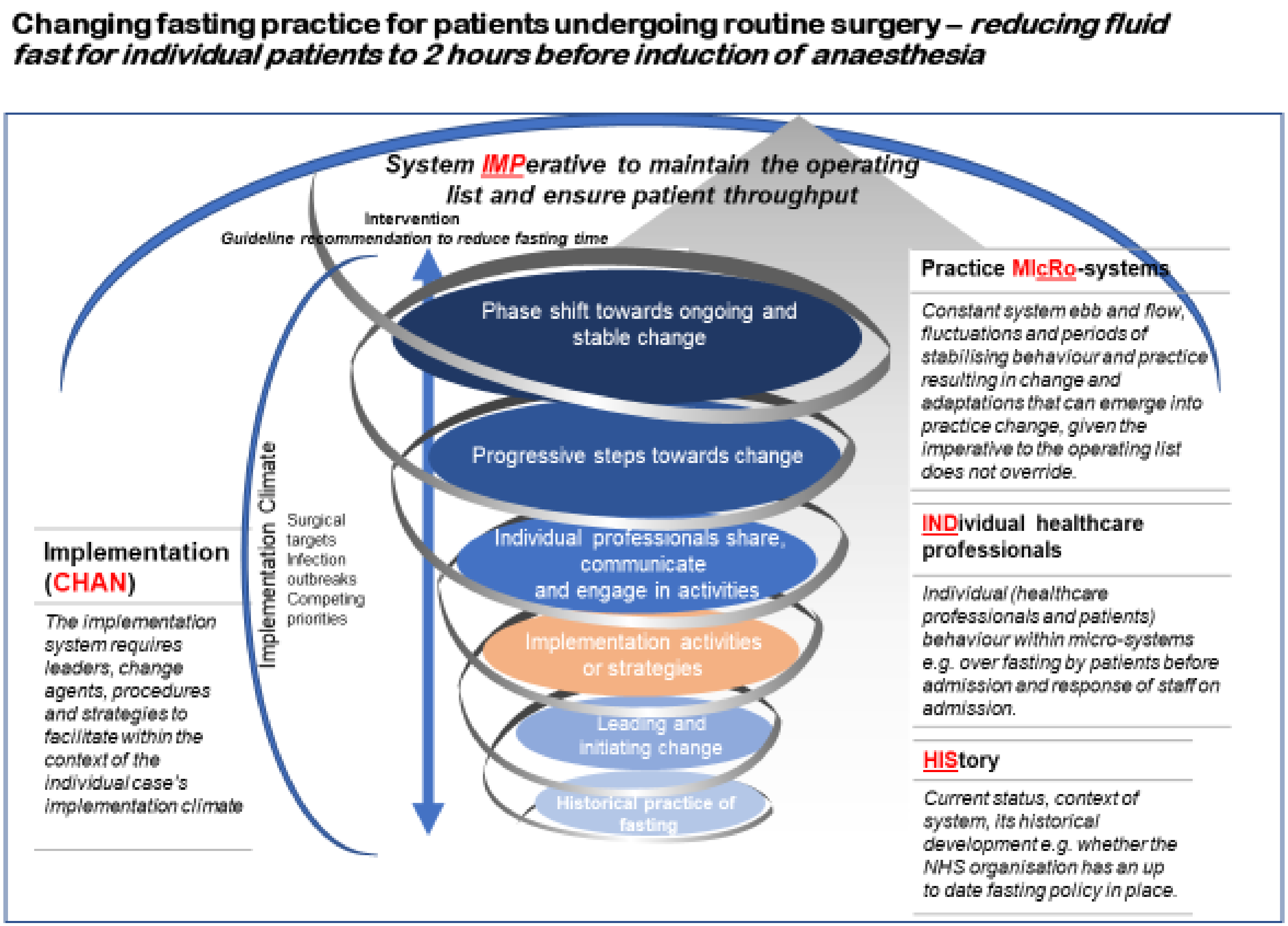
8.2.1 Modelling the findings into the conceptual framework

Fig. 8.2.1. utilises the structure of FISCAS, presented in Chapter 4, section 4.5, to demonstrate how the QCA modelling maps onto the conceptual framework. Red highlight indicates the condition concept codes used in the QCA modelling: HIS (history), IND (individual), MIR (microsystem), IMP (imperative) and CHAN (change/activity). The iterative process to change a historically embedded practice takes time. The QCA configurations for each NHS organisation indicated that the pattern across the cases might reveal progressive steps towards change. In building the conceptual framework as the theoretical basis for the QCA analysis of the dataset, I surmised the conjunction of all condition factors were required to obtain successful change to fasting practice. Therefore, for each case, I was examining which conjunction of conditions indicated successful, or not successful implementation. An initial necessity for active dissemination of the correct policy was followed by all other conditions being neither necessary nor sufficient alone but sufficient in combination. In the

final fuzzy set model, a pattern emerges suggesting that a progressive inclusion of each of the conceptual conditions aligns with the presence of the outcome and incremental improvements to fasting practice. The fasting pathway involves:

- administrative management of patients into theatre timeslots;
- preparation of the patient for their operation that includes setting fasting start and finish times;
- managing theatres: surgeons, anaesthetists, nurses, equipment for each operation and length of operations;
- managing changes to operating list times: cancellations and delays as a result of multiple factors, e.g. patient fitness, equipment failure, failure to receive necessary test results;
- pressures to ensure patients receive their operation; and
- ensuring policy targets specified to reduce wait times for operations are met.

Fig. 8.2.1 Aligning fasting practice to the Framework for Implementation in Social Complex Adaptive Systems (FISCAS)



The QCA analysis indicated potential in creating social CAS models for implementation research because it illuminated progressive configurations of system factors that led to a greater likelihood of successful implementation. FISCAS needs further testing in similar implementation research projects and with different methods where the research focus seeks to maintain case context specificity, whilst also identifying patterns of change across cases.

8.2.2 Consistency with similar approaches

Other recent applications of a social CAS perspectives to implementation research support the research undertaken here (Braithwaite 2018, Reed et al 2018, May 2016). As authors with an interest in applying Complexity Theory concepts to the social healthcare system (I include myself in this group), we generally characterise the need for adaption, lack of control over contexts in which we focus, uncertainty in delivering improvements and changes as prescribed and surmise that there are multiple factors to consider in each unique instance. I have particularly kept my conceptual framework *simple* to enable some ease of transfer to other future research implementation projects, given the emerging conceptual confusion for applying Complexity Theory in healthcare (Thompson et al 2016). Both Complexity Theory informed frameworks and implementation frameworks (Chapter 4) overlap in thinking and content building on previous work (Chandler et al 2016). My work is consistent with Braithwaite et al 2018, Reed et al 2018, and May 2016 who apply Complexity Theory within the implementation research context. I address these three works separately in the following sections.

8.2.2.1 The framework for Successful Healthcare Improvement From Translating Evidence in complex systems (SHIFT-evidence)

Reed and colleagues (2018) acknowledge that interventions occur within a complex system and that there is a need to adapt to that system. Also, continual improvement requires "teams to navigate both system inertia, attempting to pull practices back to the 'way things have always been done'" (Reed et al 2018, p. 11). They recognise the following:

- systems have multiple parts which are interdependent and need to navigate the social dimensions of both the individual and the micro-system (group, team, department) and are constantly responding to stimuli;
- the need to work with the system rather than against it aligning with system factors;
- need to understand current practice and motivation for change and provide resources to bring about change;
- historical path dependencies with internal system control where each agent does not have full access to the whole care system;

- persistent efforts to manage factors inhibiting systemic change can still result in a return to previous system behaviour.

I indicate in my research a need to understand the system imperative rather than assume it is a matter of habit or inertia that inhibits change. I align with this work in that systems are context-specific even if there are common goals across systems. Also, the change or improvement intervention is initially a system disruptor that requires system accommodation.

8.2.2.2 Informing implementation with complexity

Braithwaite and colleagues present a theoretical argument for aligning Complexity Theory concepts with those in implementation research and conclude:

“Construing healthcare as a Complex Adaptive System implies that getting evidence into routine practice through a step-by-step model is not feasible. Complexity science forces us to consider the dynamic properties of systems and the varying characteristics that are deeply enmeshed in social practices, whilst indicating that multiple forces, variables, and influences must be factored into any change process, and that unpredictability and uncertainty are normal properties of multi-part, intricate systems” (Braithwaite et al 2018, p. 1).

Authors provide detailed descriptions of aligning both natural and social system function and apply this to implementation research as a distinct field of research. They address the oversimplification of linear, reductionist approaches and present examples that reveal that over time, systems can build up the momentum for change not captured in typical methods, such as RCTs. Retrospective examination of these cases revealed points where there was a tip towards more substantial and sustainable change. Therefore, again, system history and where it is along a pathway etc. are concepts that are becoming increasingly pertinent to the field of implementation research, given that any implementation object or event needs “to find a place in an intricate, pre-existing milieu” (Braithwaite et al 2018, p. 7). By linking implementation with Complexity Theory, Braithwaite and colleagues suggest practice improvement needs to be “re-etched or re-inscribed such that its culture, politics, and characteristics are altered” (Braithwaite et al 2018, Table 3, p. 7).

8.2.2.3 Extension to Normalisation Process Theory

May and colleagues (2016) develop further their Normalisation Process Theory model (Chapter 4) for micro-system function to incorporate concepts of self-organising adaptation within the context of implementing complex interventions. Authors give an account of the context as a Complex Adaptive System and how healthcare professionals are, on the one hand, constrained by their contexts but, on the other hand, how they also might be enabled, when complex interventions take account of those constraints.

8.2.2.4 Appropriation of Complex Adaptive System concepts

The variability of appropriation of Complexity Theory and CAS concepts (Thompson 2016) will require further investigation. I make the following points in response to my own appropriation.

I agree with Reed and colleagues' (2018) approach of working *with* the system based on my conceptual focus to gain clarity of the system's imperative, its organising principle. Braithwaite and colleagues (2018), however, suggest the development of a new system with a new imperative. As a broad statement, it seems to conflict with working within a pre-existing milieu and, I suggest, perhaps falls into the paradox trap (Chandler 2018) of assuming full control of a self-organising system.

Another fallacy, when applying Complexity Theory to the sophisticated social world of healthcare systems, is the design of 'simple rules' as an implementation strategy (Reed et al 2018, Kitson et al 2017). This suggests that knowing or creating the simple rules will somehow lead to mastery of knowledge translation or implementation. In Complexity Theory, the use of 'simple rules' as in game theory and agent-based modelling (Holland 1998, Castellani et al 2019), refers to the simple rules that lead to emergence of complex behaviour in complex physical systems (Chapter 3). Once a Complex Adaptive System and, specifically here, social systems, are in place, their reduction to simple rules is to misunderstand the phenomena of emergence and the complex structures that become distinct from the elements that created them as well as the ongoing emergence from those emergent structures (Byrne and Callaghan 2014). With greater complex organisational levels within social systems, we can instinctively understand that causal power can lie within the emergent structure, for example, the NHS organisation, and not be determined by the interactions of individuals. Also, simple rules typically explain the development of complex structures that are not adaptive (Chapter 3, section 3.2.1.1). That is not to say that creating rules or algorithms is not applicable to facilitate certain aspects of implementation guidance.

However, Kitson and colleagues (2017) and Reed and colleagues (2018) share an important insight into the need to work with the system and the importance of how you recognise and use the energy within systems rather than fight it.

In recent work, the application of *Complex Adaptive Systems* to social science per se was argued as providing a theorising and explanatory framework for social systems (Turner and Baker 2019) indicating the persistence to utilise Complexity Theory concepts. Authors extracted thirty CAS definitions from the literature, as well as lists of CAS characteristics and identified the core tenets of CAS as: path dependence, system history, non-linearity, emergence, irreducible, adaptive, operates between order and chaos, and self-organising.

Path dependence, a term not used in my conceptualisation, refers to a *force* that might act differently in similar systems. I suggest this is congruent with the context dependence addressed throughout by my thesis. Similarly, I avoided the notions of order and chaos, as typically these refer to complex physical systems (Holland 2014) but can be used metaphorically to describe stability and instability in CAS (natural, biological and social) whereby a critical breakdown occurs and the system is seemingly unable to function. All other tenets defined in this work are incorporated into the FISCAS framework. Interestingly, our references for social complexity do not overlap, suggesting Complexity Theory concepts at the simplest level converge across much of the literature.

8.2.3 From the conceptual framework to condition sets

Five QCA condition factors derived from the eight FISCAS concepts conceptually informed data extraction and QCA transformation and analysis. These conditions were the key analytical tool to provide explanatory inference of the dataset. Therefore, the data was tightly and systematically tied to theory to form explanatory configurations of factors that reflected the real-world complexity of 'what happened'. The assumptions of the FISCAS conceptual framework suggested a change to fasting practice based on a credible guideline recommendation needed:

- to conduct a level of activity to support change (factor – the change event (CHAN));
- facilitators and leaders to push change forward (factor – interaction of individuals to initiate and direct change (IND));
- the capacity and ability of the micro-practice system to respond (factor – microsystem function in healthcare settings (MIR));
- the capacity and ability to change practice and over-ride any practice imperative to maintain the current practice status (factor – the practice imperative (IMP)); and take account
- of practice history and the starting position of each individual case context (factor – the influence of historical practice (HIS)).

The findings from the QCA study, given the caveats about the limits of the dataset, indicated strongly the problem of the practice imperative to maintain the flow of patients into theatre for their operations. This needed to be responsive to delays, cancellations and movement of patients on the operating list (Chapter 7, section 7.2.3.). Also, the implementation trial design assumed a similar starting point to the change process for each NHS organisation whereas some NHS organisations were, in principle, adopting the recommended guidance before the trial commenced and others had not adopted the current guidance in their policies at the start of the study.

8.3 Qualitative Comparative Analysis and the evidence-based methods toolbox

It can seem like a wasted opportunity and expense to invest in study designs, such as RCTs, that cannot determine whether there is an effect and can neither assume intervention integrity nor provide contextual and case specific information for future intervention implementation (Deaton and Cartwright, 2018, Marchal et al 2013). Hawe (2015) articulates the frustration in using designs in situations where the complexity and influence of the unique context proximal to the intervention inhibits furthering our understanding of implementing such complex interventions in other contexts. Furthermore, looking for standard dose-response relationship (or trend) in intervention implementation, when there are long lags of little response followed by a large shift in response, requires different approaches (Hawe, 2015).

Multiple debates now challenge the applicability of RCTs for real world situations (Ashcroft 2013, Devisch and Murrey 2009), whether they are used appropriately (Deaton and Cartwright 2018, Pearl 2018) and achieve confirmatory evidence (Ioannidis 2018, Strumberg 2009). However, RCTs can eliminate other explanations (confounders) by using randomisation and other control parameters, which is their strength. Other study designs (e.g. observational) reflect better real-world scenarios providing evidence with greater relevance (Pearl 2018, 2000). Likewise, the importance of local experts to determine best treatments for individual patients (Charlton 2009, Miles 2009). These methods primarily use statistical approaches based on probability. Thus, differences with set theoretic (QCA) approaches for causal complexity are:

1. **Conjunction of factors (necessity and sufficiency)** covering a limited number of cases is deemed theoretically, empirically and substantively informative (Thomann and Maggetti 2017, Ragin 2008) although not statistically significant in a binary logistic regression.
2. **Equifinality assumes different combinations of factors** lead to an outcome and thus explains cases, but not that a specific combination of factors will explain all cases (Schneider and Wagemann 2012).
3. **Conditions as defined as a set or subset relation using multiple sets of factors provides logical conjunctions of conditions,** thus neither single nor additive combinations are relevant to produce the outcome (Schneider and Wageman 2012).

4. **Asymmetry assumes that the occurrence and non-occurrence paths do not mirror each other** and therefore separate analyses are expected (Grofman and Schneider 2009).

Increasing application of QCA since 2010 (Chapter 5) indicates an evolution of evidence-based practice examples of QCA application. Specifically, these are synthesis of RCT outcome data with process evaluation data and systematic reviews of RCTs synthesising outcome data of effectiveness with additional data from sibling process evaluations or non-sibling process studies (Noyes et al 2016). There is an increasing push to take account of systems and context within the trial design, whilst allowing it to produce secure outcome results, even if the overall result is inconclusive. Fig.8.3 a and b illustrate how these approaches work within a QCA format.

Fig. 8.3.a RCTs with process evaluations and QCA synthesis

RCTs and process evaluation

Sibling process evaluation data	**Contextual factors**				**RCT outcome data by case**
	Factor 1	**Factor 2**	**Factor 3**	**Factor 4 (etc.)**	
Case 1	-	-	-	-	-
Case 2	-	-	-	-	-
Case 3	-	-	-	-	-
Case 4	-	-	-	-	-
Case 5 (and so on)	-	-	-	-	-

Fig. 8.3.b Systematic reviews of RCT's with process studies and QCA synthesis

Process data from sibling or non-sibling studies	**Intervention components**				**RCTs' outcome data by study**
	Factor 1	**Factor 2**	**Factor 3**	**Factor 4 (etc.)**	
Study 1	-	-	-	-	-
Study 2	-	-	-	-	-
Study 3	-	-	-	-	-
Study 4	-	-	-	-	-
Study 5 (and so on)	-	-	-	-	-

Application in systematic reviews is used to disaggregate multi-component interventions that vary across studies (treated as individual cases) to identify effective active constituents of interventions (Kneale 2019, Thomas 2016, Candy 2013). Meta-analysis and narrative synthesis struggled to make sense of these multi-component interventions when considering whether, and which, intervention components are effective. These studies do not specifically subscribe to a CAS perspective but seek to disaggregate multi-component interventions that have synergistic effects (Thomas et al 2019). Interestingly, some compare the most or least effective interventions (e.g. Burchett et al 2018, Melendez-Torres 2017) and leave out the 'missing middle', the transition of a potential phase shift. I illustrated this possibility with the 'middle', whereby the graduation of change from least to most effective might be informative in exposing the relationship between causal factors as progressive steps towards tipping the balance in favour of successful implementation (Chapter 7, section 7.2.5).

Kien and colleagues (2018) conduct a QCA analysis using data from a cluster RCT process evaluation on influencing factors for primary school children's emotional and social experience, when participating in a school-based health programme. Their approach utilised selected contextual factors determined by the Consolidated Framework for Implementation Research (Damschroeder et al 2009, Chapter 4), from which multiple data collection activities undertaken in the original trial inform five condition factors. Authors report their calibration procedures. This example, along with my own research, indicates the potential for exposing explanatory pathways to success or non-successful implementation projects. For future use, they recommend selection of relevant conditions should be based on theoretical assumptions, as I have done. Although it will take many more examples to show consistency in application, a pattern of use in both primary and secondary research synthesis is emerging.

I would therefore define QCA as a method that allows the synthesis of multiple datasets and different types of data to approximate a closer representation to reality, which maintains the individual case, potentially allowing a systems-based approach. Case-level information is maintained whilst seeking across case patterns of pre-selected factors (*conditions*) that configure in different arrangements towards the *outcome* of interest, thus exploring and accommodating across-case heterogeneity. Therefore, QCA can manipulate data for implementation research purposes, taking account of the uniqueness of the case context treated as a *whole* system, whilst seeking patterns that can explain how collectively the cases arrive at outcomes.

8.3.1 Assessment of wholes and parts maintaining case sensitivity

A CAS perspective requires an understanding of the function of the emergent whole. A whole can be one case in a set of cases or the whole set of cases. My QCA study adopted an internal case argument for the enclosed set of cases from the original POISE trial. Transfer of findings from this case set to other NHS surgical departments in the UK is limited when taking account of contextual differences between cases, but there are also commonalities across NHS organisation surgical departments. Research strategies can take a reductive approach and just examine a set of variables across a population of cases providing average treatment effects. Statistical approaches have become increasingly sophisticated in trials and their synthesis to account for initial and intermediate factors such as meta-regression, structural equation modelling and path analysis (Higgins et al 2019). However, RCTs are still unable to "understand the deep-seated mechanisms and contexts that allow intended changes and unintended variations to create the outcomes, nor do they necessarily convey what the outcomes might actually mean for the people experiencing them" (Bazeley 2018, p.115). This requires in-depth case knowledge to address multiple types of questions when implementing change to a system of care or practice.

Case definition and the boundary of the social CAS of interest need to be well defined and aligned within QCA methodology. My research used the NHS organisation surgical department as the 'bounded' case defined as a Complex Adaptive System, which is nested within the wider NHS organisation and the policy and regulatory framework of the NHS in the UK. This would undoubtedly influence the sub-system of surgery. These influences such as meeting operation targets are noted in terms of their impact and the surgical sub-system response. The 'case' in QCA can be an organisational entity or its sub-units. It can also be a care pathway, process or procedure, or a study, a country or a healthcare system. These system abstractions are real entities. However, it is a construct of the real case (Harvey 2010), because description will not entail all existing aspects of the system and its connections to other systems. Therefore, Harvey (2010) argues that descriptions of social CAS cases from a complex realist stance should:

- have a '*well- formed explanatory narrative*';
- form an integrated constellation of social structures;
- assume open systems are '*historically evolving'* and, finally,
- assume the role of human intentionality co-evolving the social system (Harvey 2010 p. 30).

NHS organisations and their sub-units (surgery) are well defined with discrete practices (fasting before surgery) so are suitable for casing in this manner, where it is also assumed, they are open, co-evolving systems whereby practice is historically contingent and emergent within the social system.

8.3.2 Managing complex causality and associations

Experimental designs work on the assumption that they are investigating a direct link between an independent variable and an outcome, based on a probability that predicts whether that outcome will occur in a percentage of cases. This approach will assume that multiple factors found to result in the same outcome are all independent and additive (Ragin 2008). Secondary outcomes and logistic regression can examine interactions, but the approach provided by QCA is very different in its assumptions. Ragin (2008) further challenges what he refers to as “net-effects thinking” (p. 177), that is, methods that result in average treatment effects are not appropriate for analysing causal complexity, specifically “its heavy emphasis on calculating the uncontaminated effect of each independent variable in order to isolate its independent impact” and, furthermore, “can be counter balanced and complemented with an approach that explicitly considers combinations and configurations of case aspects” (p. 182). I propose that increasing the utility of a process evaluation to manage individual case context and implementation of an intervention alongside a trial provides the elements for an additional synthesis using QCA analysis by:

- producing a well-conceived outcome and set of results,
- obtaining process data to illuminate
    - how the outcome was achieved,
    - why it was not achieved and
    - whether there are patterns of progressive steps towards the outcome.

Also, process data collection should be by case, not aggregated by intervention group typical in trials.

To mix ontologies or epistemologies such as a complex realist (QCA) with that of the positivist position (RCT) is seen as incompatible by some (Bonell et al 2013, Marchel et al 2013). However, my account in Chapter 2 on notions of causality leading to a pluralist position (Chapter 2, section 2.3.1.1) indicates that both outcome evaluation (Wensing and Grol 2018) and process evaluation (Moore et al 2015) are necessary elements and remain so for implementation research and improvement evaluation (Illari 2011). The divided positions adopted constrict the multiplicity of ways a system can be examined. Byrne (2012) uses QCA to explore social mobility and household income over time and expresses well the Cartwright voucher/clincher dichotomy (Chapter 2, section 2.5.1.2) that “allows exploration of both multiple and complex causation without moving into the difficult terrain of causal assertion" (Byrne 2012, p. 1). I think this is an important point, whereby we want to track processes and mechanisms to better understand system function to enable implementation of improvements to healthcare practice. This entails addressing some of the difficulties in causal assertion raised by Cartwright (2011, 2010, 2007, 1994) and recently Deaton and Cartwright (2018), who argue:

- Information at a population level does not transfer to making individual patient causal assertions.
- A large well-conducted RCT eliminates the need to understand any errors or underlying mechanisms or the need for theory and can provide an unbiased estimate that the treatment caused the outcome in some individuals in that sample, but not all.
- RCTs make few assumptions about heterogeneity, causal structure, choice of variables and functional form, but can make a causal assertion by establishing a difference using the experiment that controls for these factors beyond the comparators.
- Drug interventions have prior knowledge of the mechanisms before tests of efficacy and effectiveness in trials are conducted but most other types of interventions do not.

Randomised trial designs reach their limits when comparing interventions that are themselves complex, with multi-components that are inter-dependent and embedded in real world healthcare systems (Burke Johnson and Schoonenboom 2016). Trials are expensive to run with many returning inconclusive results (Ionnaidus 2018). Process evaluations evolved to supplement trials of complex interventions to observe the implementation of the intervention within its context and aid interpretation of the outcome (Oakley et al 2006), as well as explain discrepancies between participants within intervention arms (MRC 2008). Implementation activity, mechanisms and context are key elements for process evaluations to capture (Moore et al 2015). Also, unexpected outcomes, experiences of recipients, fidelity or changes to the intervention, who it works for, etc. (Burke Johnson and Schoonenboom 2016) to explicitly test an underlying conceptual framework, are also required (McIntyre et al 2018).

Overall, research strategies need explicit clarity on conception of reality and the theory underpinning expectations of how an intervention or process functions, and which then lends itself to both the type of method required for data collection and analysis. From this the researcher develops warranted arguments based on interpretation and explanation of their findings that can make real world sense (Olsen 2014).

8.3.3 Critiques and developments within the Qualitative Comparative Analysis community

Increasing methodological development and sophistication has occurred over the last thirty years, since Ragin's seminal 1987 work and subsequent contributions (Ragin 2000, 2008, 2010, Thomann and Maggetti 2017). My application of QCA followed standard practice rather than test newer approaches that have yet to embed within the wider QCA field. All examples identified in Chapter 5 suggest, for now, that researchers are utilising standard practices and software within health studies. Thomann and Maggetti (2017) separate QCA technique into case-orientated and condition-orientated strategies. My exemplar is situated in the case-orientated end of the spectrum reliant on substantive case knowledge. Newer approaches use QCA to assess configural patterns of factors across large N case sets using accompanying statistical approaches, specifically in using large surveys to provide both case and condition knowledge (Olsen 2018, Emmemegger et al 2014, Byrne 2010). I touch briefly on issues of causation, identifying causal pathways, retrospective vs prospective designs and use of QCA when synthesising data from high-quality studies.

8.3.3.1 Addressing causation

QCA in principle provides a systematic causal analysis within a clearly defined dataset of a complex set of conditions or factors. Although it is based on the logic of set relations and necessity and sufficiency, the validity of this method to determine the nature of its causality remains a question. There are different viewpoints on addressing causality within the context of QCA methodology (Cooper and Glaesser 2016, Munck 2016, Thiem and Baumgartner 2016). Some suggest set theory-based methods are a subset of the existing statistical framework (e.g. regression) and therefore not required (Schneider 2016). When not using randomisation methods, an association can show and, based on the strength of that association, decide whether causation is inferred. Causation occurs through a series of mechanisms and processes, and the potential to identify these can establish a pathway between cause and effect. However, Schneider asserts that neither regression methods nor QCA can "conclusively identify causality" (Schneider 2016, p. 782). There are always unseen mechanisms and processes, especially when we move outside the laboratory into the natural and social worlds. Within the context of social CAS, we are searching for patterns that might repeat across different cases indicating a causal connection. No method is perfect and without restraints. Schneider's riposte to critics is that there are fundamental conceptual differences between statistical and set theoretic methods; furthermore, arguments based on mathematical formulation miss the conceptual aspects of difference and purpose between these methods (Schneider 2016). Likewise, a philosophical account of validity suggests that statistical tests themselves are not sufficient to determine validity to extrapolate beyond the study population when the study purpose is to examine causal relations within a specific population (Illari & Russo 2014).

8.3.3.2 Causal chain analysis

Identifying causality is a primary task in research and the epistemological basis on which we understand causality I explored in Chapter 2. How this is done using methods, such as QCA, is a current debate within the literature. Baumgartner argues that Ragin designed QCA “from the outset… to analyse causal structures featuring exactly one effect and a possibly complex configuration of mutually independent direct causes of that effect” (Baumgartner 2013, p. 9). QCA software uses the Quine-McCluskey algorithm which presupposes that there are not causal dependencies between conditions and that they are mutually causally independent. Although it is the conjunction of these factors that leads to the outcome, the conditions do not present the causal chain.

Baumgartner’s (2013) coincidence analysis (CNA) provides an alternative algorithm to the Quine-McCluskey that underpins the logical minimisation techniques in QCA. This addresses specifically the underlying causal structure of the method and identifies the direction of causation via relationships of sufficiency and does not pursue necessity, if sufficiency is not there. This technique minimises conjunctions that are sufficient for the outcome and similar to each other and subsequently excludes logically redundant prime implicants (logical remainders) (Schneider and Wagemann 2012). QCA is said to provide a *one difference restriction,* whereas CNA presented by Baumgartner is based on the premise that unobserved cases for logically possible configurations, if observed, could change the minimised solutions and thus the causal analysis interpretation, is akin to a missing link in the chain. QCA always directly connects conditions to outcomes and does input data in manner that ascribes to a causal chain (Ragin 2008). To manage this lack of causal linking, Schneider and Wagemann’s (2012) Enhanced Standard Analysis (ESA) identifies causal substructures amenable to a ‘stepwise’ QCA model building the links between distal and proximate factors. However, Cooper and Glaesser (2015) suggest Baumgartner’s CNA algorithm is possibly preferable to engaging in Schneider’s two-step process. Thiem (2015) suggests there is potential for their integration.

My standard QCA approach application included creating hypothesised steps from which I process-traced the data to identify evidence of the causal pathway connections. In addition, the FISCAS framework provided both the pathway but also argues for a 3D view of the system. Causal analysis is not a single step and relies upon the initial data sources used and the subsequent processing of that information, finally synthesised in a QCA framework. QCA models identify patterns for further examination of causal linking. Baumgartner’s approach might be more relevant for the condition orientated large N QCA format (Thomann and Maggetti 2016).

8.3.3.3 Differences between retrospective and prospective designs

QCA using necessity and sufficiency sets out to identify regularities within the cases, although it examines combinations of multiple causes (Boolean intersection) as oppose to singular causes that might examine interaction (regression). QCA uses set theory to ascertain relations that have occurred, whereas experimental designs are designed to observe the effect occurring, thus predictive. Cooper and Glaesser (2016) take on the challenge by other critics that QCA does not account for patterns of chance and “generative randomness” (Cooper and Glaesser 2016, p. 1) that occurs in real social systems. The social world is given to regular stable patterns of behaviour (necessity), but apparent random events can dramatically change the course of social CAS (Illari and Russo 2014) and interrupt regular social processes (Ragin 2008). Cooper and Glaesser propose social systems produce “quasi-regularities” rather than the deterministic properties of complex physical systems (Chapter 3, section 3.2.1.1). Randomness in the real world, or what appears to be random, may not be so, if it were possible to track its pathway of causal connections from A to B (Cooper and Glaesser 2016). Cooper and Glaesser (2016) propose that given knowledge of the underlying generative processes, the use of the consistency parameter of fit used indicates that for some cases, a condition does occur and that for others, it does not occur, thus a probability can be derived under certain assumptions.

In social systems identifying the micro processes involved in bringing about social effects involves tracing, as best possible, those effects within each individual case to identify generative processes and mechanisms with theoretical judgement taking account of sampling and measurement (Cooper and Glaesser 2016). Thus, process tracing in individual case studies is recommended (Collier 2014, Chapters 6 and 7) and retrospective. These discussions suggest that QCA may present descriptive generalisation or causal generalisation (Rohwer 2011) based on the level of knowledge that underpins the analysis and is determined by the source data.

8.3.3.4 Methodological development within the evidence-based health context

Many authors who use QCA as a research strategy want to systematically disaggregate complex heterogeneous data and draw conclusions consistent with other work within their specialist field to enhance understanding of their phenomena of interest. Multi-method approaches provide a more comprehensive understanding of the phenomena under interest (Noyes 2008, Mays et al 2005, Dixon-Woods 2004). The application of QCA in systematic reviews to address complex interventions is a strong developing trend (Bianchi 2018, Burchett 2018, Harris et al 2018, Hartmann-Boyce 2018, Scott Parrott 2018, Beifus 2017, Forman-Hoffman 2017, Leas 2017, Melendez-Torres 2017, Kahwati et al 2016a). Complex interventions with their multiple components add a layer of complexity that requires a process (Craig et al 2008, Campbell et al 2000) to pin down how these might influence or be influenced by the setting and participants and are context dependent (Pawson and Tilley 1997). Increasing application within the context of healthcare will permit adaptations and application improvements by addressing the issues with integration of this methodology and its set of methods (Kahwati et al 2016b). QCA does seem a fit for multi-method approaches and open to invention and development including the application of statistical approaches, where appropriate (Rihoux 2011).

Application of QCA methods presents several issues and, as with any method, it needs correct and transparent application to justify any assumption made and the interpretation of its findings.

8.4 Using Qualitative Comparative Analysis for implementation research

The implementation focus addressed in my research was the assumption that credible and reliable evidence using an effective strategy will leverage this evidence into healthcare systems. Using QCA methods in implementation research needs a certain mindfulness about translation to healthcare questions. The FISCAS provided an explanatory framework in which to operationalise QCA methods. I highlight implementation factors from the framework for consideration in implementation projects and raise several method-specific considerations for future use of QCA.

8.4.1 Implementation factors

Both the original POISE trial (Rycroft-Malone et 2010) and its re-examination here question whether the mode of the strategy mattered or whether it is more about capacity, willingness and the stamina to turn the tide of a longstanding entrenched practice diffused throughout the system (managing operating lists). This also required a level of activity (interaction) to overturn the current embedded practice. However, focus remains on identifying the right strategy to fix the problem (Sarkis et al 2017). Identifying case-specific issues (the function of the PDSA strategy), I suggest, involved the question of what is the system imperative that maintains current practice. I also suggest that asking which strategy is the most effective in changing practice is possibly the wrong question. Instead an arrangement of different activities selected from a menu of approaches maybe more pertinent to the local NHS organisation context. My involvement in developing the implementation strategies, particularly the quality improvement model, subsequent training and observation in situ, indicated variance in the skillset of staff leading these strategies. The PDSA strategy required staff attendance at regular meetings, thus creating the need to prioritise attendance over other work. One should also note that PDSA is a complex activity to drop into a pre-existing system and should not be oversimplified as it requires tailoring to the context (Reed and Card 2016). In summary, key points from this research indicate the following.

8.4.1.1 The relevance of practice history and individual case starting points

Each NHS organisation case was shown to be at different stages along the practice change pathway and therefore the arbitrary trial cut-off might have implied lack of successful improvement to practice prematurely. History is an important aspect of CAS theory (Chapter 4, section 4.4.2), which suggests systems organise and adapt from micro processes that embed within macro social structures. Fasting practice, much like handwashing, has a very long practice history (Maltby 2006). Data collected indicated individual NHS organisations' fasting practice implementation position prior to the trial. Data were pieced together using process tracing for each case. On reflection, gaining a better historical analysis of prior practice and motivation to change consistently across all cases before the trial at baseline would have shown the influence of system history.

8.4.1.2 Impact of individual healthcare professionals in practice microsystems

The central idea is that microsystems of care evolve into macrosystems through processes of human agency interaction developing higher order social structures, teams, units, departments etc. Thus, they are inherently interconnected and interdependent with multiple interconnected activities dispersed throughout the micro sub-systems.

The interruption of an implementation event in a healthcare system requires human responses, which are not necessarily as controllable as expected. Practice change can come up against a range of barriers that involve individual beliefs and attitudes as well as other aspects, such as skill and capacity.

8.4.1.3 The power of practice imperatives

The system imperative to sustain practice, a key concept in the FISCAS and QCA factor sets, is based on my notion of the system organising principle (Chapter 3, section 3.5.1.1.). I hypothesised the system would hold to its current practice status to meet the system imperative, which was identified as the management of the operating list. This imperative was a key factor in the set of conditions evaluated in the QCA analysis. The findings suggest that reduction to prolonged fasting practice can occur up to a point, that of 'first on the list'. However, all NHS organisation cases included in the analysis, except for two, were inhibited by this imperative to allow flexible management of the operating list, that is, keep patients ready for theatre (fasted).

8.4.1.4 Understanding phase shift patterns towards practice change

In my exploration of QCA with the aid of the work undertaken by Befani (2016), I suggest there is a continuum to nudging a system in the right direction towards the desired or anticipated outcome. The conditions (mechanisms) needed to nudge the system may vary for each case. Examining the QCA configuration of factors across a set of cases might reveal a *tipping point* (Braithwaite et al 2018, Befani 2016) within the data. This point of transition might indicate a critical point at which change might accelerate across cases, suggesting a configuration of factors might be key to initiating progress towards successful implementation of recommended fasting practice.

The ability to recognise such *phase shifting* patterns towards change in implementation research in social and healthcare systems persists as a concept of interest (Petticrew et al 2019, Hawe 2015, Smith and Petticrew 2010, Levy 2005). Translating this concept of phase changes within a social system perspective Byrne (1998) suggests that within systems there are likely to be a restricted range of possible outcomes and that consideration is given not to final outputs but that outcome pathways exist on variable trajectories. Thus, using experimental designs to answer complex system questions, given their multiple interactive effects, nonlinear responses and that these are context specific, is limited in assessing or observing this type of system behaviour (Chapter 2, section 2.5.1).

8.4.1.5 Implementation and time: starting and changing

Implementation as an activity, argued by many (e.g. Pfadenhauer et al 2017, May et al 2016, Murdoch 2016, Squires et al 2015, Rycroft-Malone et al 2013, Damschroder et al 2009), is context specific, and change processes are non-linear in establishing change and its sustainability. This thesis has sought to expose some of the implementation issues that arise in real world systems and how better explanations of system function might aid future implementation of practice. This has involved exposing patterns and potential fluctuations and addresses fall back to the status quo and the importance of time in understanding how changes shift in social CAS. QCA can potentially expose some of these patterns, and I would suggest the importance of theoretical underpinning is crucial to sustain the argument, as is triangulation and confirmation across sources of data prior to QCA analysis (Hargreaves 2016).

8.4.2 Qualitative Comparative Analysis: Recommendations for implementation research

QCA may provide a methodological option to expose complex causal arrangements within the social healthcare system of practice. QCA addresses the over-simplification of trial designs. It does not challenge RCT's ability to detect difference when it does. However, its strength lies with providing explanation when it does not. Development of QCA explanatory models that uses the logic of sets and necessity and sufficiency to derive complex causal associations between factors provides a depth to explanation by managing factor complexity and case sensitivity. An emerging strength in the health field is the multi-method approach that operates as an adjunct to other well-established data gathering and evaluation methods such as RCTs with process evaluations and systematic reviews of RCTs along with a synthesis of other sibling or non-sibling studies (Noyes et al 2016). This has also included the use of QCA with other evaluation approaches, such as realistic evaluation (Goicolea et al 2015, Befani et al 2007). Therefore, given that more examples are required, developments of standards for both conduct and reporting of QCA with specific reference to the health and implementation research context still needs to be established. My specific recommendations based on learning from this research are:

- **Case sampling and transferability of findings beyond sample**
  I discuss my rationale for defining closed and open case sets in Chapter 5, section 5.5.1. A closed case set creates greater internal validity because explanations beyond the cases present are not necessarily relevant. In other words, additional cases are not required or missing. An open set will involve a sampling strategy and, based on the reasoning, logic applied and the data sources supporting the QCA analysis, the relevance of counterfactual or other explanations provided by 'missing' cases must be considered. A closed set indicates lack of generalisability beyond those cases. However, as suggested, commonalities across case contexts might provide transferable knowledge beyond the closed case set. Large N sampling strategies might secure transferability based on sampling strategy to other cases in an open set.
  I recommend, for healthcare and evidence-based practice that we discern transparently and consider whether we have a closed case set or an open case set.

- **Limited case diversity and logical remainders**
  If case context-sensitivity is key to explanation, generality beyond the case set requires reasoning and logic as to how the QCA models can inform either further

research or implementation/improvement practice. When using QCA to synthesise data from studies identified in a systematic review, the comprehensive inclusion of all relevant studies suggests that logical remainders are not important (Harris et al 2019).

I recommend, along with noting missing cases, that combinations of factors not covered by observed cases in an open set will require explanation.

- **Condition (causal factors): Number and relationship between conditions**

  I have discussed throughout the issues with the QCA model needing to restrain conditions (factors) with respect to total case numbers. Given the importance of mechanism identification in causal pathways, management of large numbers of conditions is crucial to sustain the logic of QCA analysis (Marx and Dusa 2011). Multiple approaches are undertaken specific to the dataset at hand. The FISCAS framework enabled modelling large concepts into core interpretable concepts. Likewise, the process tracing hypothesised steps (Chapter 6) enabled a close tie between theory, analysis and the final models. Given the broad range of factors incorporated into implementation theories and concepts, FISCAS enabled this condition management. I also conducted a two-chain process tracing approach to manage distinct aspects of implementation dissemination and implementation of practice change. Different examples of condition management are presented by other authors (Chapter 5, section 5.5.1.6).

  I recommend that these are considered either closely coupled or remotely coupled to the data (Chapter 5, section 5.5.1.6). Transparency and reporting are important to ensure coherence to the reader.

- **Source data for use in QCA analysis**

  QCA analysis is reliant on the quality of the data, its logic and underlying premise. Causal pluralism suggests multi-method approaches can be synthesised in using the logic of QCA methodology.

  I recommend greater attention is paid to the quality of the source data (quality assessed in systematic reviews) and its assessment, because this will either strengthen or weaken the QCA models derived.

- **Case sensitivity: back and forth validation**

  It is the back and forth check and dialogue between data and ideas that Ragin (Ragin 1987) originally had in mind. Ensuring internal validity of QCA methods

(Thomann and Maggetti 2017) and using high-quality data in a rational and reasoned manner needs the connection maintained between the interpretation of the QCA models and the individual cases.
I recommend that this strength with the method exemplifies the need to maintain context-sensitivity throughout.

- **QCA protocol development**
  Within evidence-based practice the development of protocols setting out the study plan and data needed with the anticipated methodological approach strengthens QCA application in the evidence-based implementation research field. Chapter 5 suggests most studies do not provide a prospective plan, although this is common practice in systematic reviews (Harris et al 2015).
  I recommend future applications develop a protocol to pre-specify data requirements, case and condition selection. This will establish a rigorous approach needed within healthcare research for transferable evidence. This does not inhibit iterative modelling.

8.5 Strengths and Limitations

The writing up of the research that supports my thesis was conducted over a longer than usual timeframe and so is at risk of losing currency. However, I would suggest that both application of Complexity Theory and separately the application of QCA methodology to manage real world complexity are advancing in health research. My research further contributes to this body of work in affirming the utility of both. Likewise, this work continues the paradigm shift of complexity thinking occurring more broadly in the sciences (Mitchell 2009, https://www.santafe.edu/) and in implementation research (Braithwaite et al 2018, Greenhalgh et al 2018). I systematically derived and operationalised social CAS concepts creating an analytical structure for the QCA causal conditions to test the conceptual framework's sense-making capacity to address causal complexity in social healthcare systems. Individual authors identify CAS concepts which, whilst overlapping, require some conceptual coherence (Thompson et al 2016). I discuss the following aspects undertaken to support my thesis and make a comment on the patient's perspective. Although not central to the thesis, it is central to the rationale for ensuring improvements to fasting practice.

- The credibility of FISCAS
- Validity and reliability of the QCA Models
- Transferability and credibility of the thesis

8.5.1 The credibility of the Framework for Implementation in Social Complex Adaptive Systems

I undertook a systematic approach using theory synthesis (implementation) and systematic across-text comparison using annotation of purposively selected texts and extraction of core concepts (social CAS). The work of Turner and Baker (2019) suggests that their core tenets map to my simplified concepts of social CAS from quite different routes, indicating coalesce within social CAS. Complexity-consistent approaches within implementation mapped to these concepts led to further concepts in the final FISCAS framework to ensure relevance to implementation. This considered the influence of individual behaviour and individuals working together in micro-systems. This generalised framework requires further application and take up to test its credibility as others have done with CFIR (Damschoeder 2009) and PARIHS (Harvey and Kitson 2015, Rycroft-Malone 2013).

8.5.2 Validity and reliability of the Qualitative Comparative Analysis Models

The dataset on which I relied was limited by missing data and the data was not framed for the secondary purpose I undertook. It was also not possible to return to the NHS organisations to complete missing data, some years post trial completion. The data would also now be considered old and NHS organisations may have improved fasting times, but the data available is inadequate to suggest that is the case, and what is available indicates it remains a problem (Lambert and Carey 2016, Krytatos et al 2014). On this basis alone, an explanation that suggests the imperative to maintain fasting practice that results in prolonged fasting to ensure list management is not compromised may retain some validity, when published.

Although, given my prior knowledge of the study and the data, the design of the FISCAS framework and subsequent decisions to identify factors for the QCA modelling could indicate confirmation bias (Thomann and Maggetti 2014). I would argue that while on the one hand such a possibility in my study cannot be eradicated, on the other hand I conducted a systematic and comprehensive approach to both framework development and data extraction ensuring consistency across cases, which would limit such bias. Once QCA transformation of the data has occurred and software is used and, for example, contradictions arise, greater scrutiny of decisions and judgements are made which require systematic attention (Chapter 7, section 7.2.3.1).

8.5.3 Transferability and credibility of the thesis

Cartwright (2017) discriminates between *individualised* evidence of an identified single case and *anonymous* evidence of RCTs and other group-based observational studies. Both types of evidence are limited in their ability to go beyond the target individual or group of individuals. Cartwright also notes that we do not know who in the RCT population benefits, just that someone does. Other methods may be required, including a well-articulated theory to support transfer beyond the study population. Process tracing methods gather evidence at the individual case level to track the causal chain between cause and effect and can provide within case singular causal claims:

- If there is a strong link between the evidence to support the claim and the conclusion (effect);
- How secure the strength of the link between evidence and conclusion is and whether the evidence truly represents its claim (Cartwright 2017).

First, the original trial was considered at low risk of bias (Flodgren et al 2019) and conducted well, with a high-quality process evaluation (McIntyre et al 2018). However, for the secondary purpose of QCA analysis, data were limited to ensure that the direct evidence for a claim at the individual level was adequate. However, the process tracing of the cases illustrated an approach that could provide strong confirmatory evidence. To backward-test the utility of the process tracing I use Cartwright's (2017) four tests. These are articulated with examples from the process tracing of individual cases (Chapter 7, Table 7.4.3.2.d and Table 7.4.3.2.e) of the hypothesised steps (e.g.1h x or 2h x).

Table 8.5.3 Cartwright's four tests used to evaluate process tracing

Cartwright (2017) Direct evidence test	**The claim (cause) (sample hypothesised steps (1h x or 2h x) in the process chains 1 and 2, see appendix 6.4)**	**Example from POISE data process tracing** **The evidence for the claim**	**Test assessment (for the individual case only)**
1. Does the outcome occur at the time, in the manner and of the size to	1h 4: Revisions to fasting policy (C) to ensure compliance with guideline recommendation (E).	A record of change made and documentation received by administrative staff with examples of	To ensure there is evidence for revisions to fasting policy requires knowledge of that change and sight of change, e.g.

be expected, had the causal agent caused it?		patient letters showing change.	revised policy (sight of previous policy for comparison).
2. Were there other 'symptoms' other than the effect itself that indicate the cause produced the effect?	1h 6: Dissemination of the revised policy (C) to ensure staff awareness of correct policy (E)	Strategy used described Activities used described	To ensure active rather than passive dissemination descriptions were provided by staff respondents in transcripts, e.g. awareness raising posters, changes to patient information distributed at pre-operative stage or through staff meetings. In reference to 'Other symptoms' includes staff respondent reporting on who conducted these activities. This reporting needed actual instances of evidence uptake.
3. Were other enabling factors present in order for the cause to bring about its effect?	2h 2: Dissemination of the operating list (C) to assess fluid fast start times of patients (E).	Receipt of the list by ward staff	Enabling factors arise when assessing timeliness of receipt and whether it was received via printed format, computer or not received at all until the start of the operating list.
4. Were expected additional	2 5a or 5b: Updating of staff on operating list changes (C) to	Account of list changes reported at different times before	Additional in-between steps are whether staff pass information

steps present between the cause and its effect?	reassess fluid fasts and give fluids to fasted patients if necessary (E).	list and during list etc. Active requests by ward staff for an update by theatre staff.	on, can act on information received (authority to do so) and can find the anaesthetist to request fluids for patient.

Therefore, there a strong rationale for employing methods, such as process tracing that assess the causal claim in the context specific single case which can then give strength to a subsequent across-case analysis approach (Beach 2017). I suggest based on my methodological examination in this thesis, when using good quality case specific source data processed by individual case using the conceptual structure of FISCAS to examine patterns across cases, QCA has potential within the implementation healthcare context. Finally, I make a note in this theoretical and methodological thesis for whom implementation of evidence based practice is expected to benefit, the patient.

8.5.4 The patients' perspective

I did not undertake to engage directly with the available patient data; however, the patient perspective was obtained through both a survey and interviews in the original POISE study. The survey data was used in determining calibration for the NHS organisations with set membership assignment to the condition sets, for example, were the patients happy with information received by healthcare professionals on the progress of their operating list position. Most notably, given the widespread shift in routine surgery today, it was observed that patients were cautious and therefore arrived over-fasted for their operations. Although staff regularly check patient fast status ('when did you last eat or drink?'), they are not necessarily providing drinks of water to ensure hydration once the operating list is known on the day of surgery. Therefore, evidence-based fasting practice recommendations to improve the quality of care and experience for the individual patient competed with the NHS surgical departments need to maintain the throughput of patients to ensure they received their operation.

Chapter 9: **Conclusion**

The following concludes my thesis and contribution.

9.1 Conclusion

Over the last decade or so, implementation research has proliferated in response to concerns that the development of evidence-based practice, treatments and guidance are not implemented. Implementation models and frameworks are themselves becoming increasingly complex with multiple components and factors that need consideration for implementation of practice change (See Box 9.1).

Box 9.1 Explaining implementation of practice change

- The need for implementation theory to explain the implementation processes and mechanisms for successful implementation.
- The need for theory to explain the mechanisms of how the implementation object - intervention, innovation guidance, knowledge etc. is expected to perform in its target setting.
- Detailing the intervention characteristics and features and noting their complexity and if, and how, its multi-components are interdependent.
- The use of implementation strategies to facilitate the implementation process and implementation of the intervention etc.
- The importance of assessing the implications or impact of multiple confounding factors or extraneous factors on which successful implementation is dependent – the implementation context, setting and wider environmental, socio-economic and socio-political factors.
- The importance of understanding human behaviour for the individual as well as individuals working together and the specific factors within healthcare of professional boundaries, responsibilities and power (hierarchical) structures.
- Key themes are capacity, capability, motivation (drivers), resources, sustainability and the importance of leadership in implementation efforts.

Methods to assess this complexity and engage with theory to explain implementation processes has required greater understanding and acknowledgement of causal explanation. This indicates a need to engage with a multi-method research strategy that defends causal claims, which depend on both evidence of difference making and of mechanisms, but also maintains case context sensitivity. Mechanistic links between cause and effect need tracing to reveal the connections between cause and effect, I argue this is non-linear and therefore difficult to capture. Qualitative Comparative Analysis (QCA) has shown flexibility as a synthesis method to disentangle and capture causal complexity utilising data from other approaches: RCTs, systematic reviews, survey designs and regression, and qualitative data syntheses, as examples. Thus, there are obvious strengths in taking a pluralistic approach to causation and methods.

Experimental, observational and sociological methods used in healthcare are limited in their capacity to address systems and causal complexity (Byrne 2011, Galea et al 2009, Ragin 2008, Cartwright 2007). I have proposed the application of QCA methods alongside a multi-method design to disaggregate the parts of systems that have interdependent combining effects, which function together to achieve an effect. QCA does not aggregate data across cases but focuses on the configural patterns of conditions. It provides an additional perspective on how the individual cases behaved within an implementation trial to explain success or failure of practice change. Findings from the QCA study exemplar suggest the operationalisation of the FISCAS has potential and requires further examples to establish utility. It provided an opportunity to add another layer of explanation to the original trial process evaluation and outcome data, giving them greater explanatory power. As setting up a trial and collecting raw data are time and resource intensive (Hemekins et al 2016), re-analysing data in different ways to address additional questions maximises use of that data.

Whole system approaches (Pfadenhauer et al 2017, Rohwer et al 2017, Greenhalgh et al 2017, 2004) are embedded in the implementation synthesis that informed the FISCAS framework indicating the increasing push for explaining practice behaviour from single, isolated factors to addressing whole system phenomena. Key phenomena exposed was the behaviour of individuals operating in interactive micro-systems, recognising the influence of practice history and the imperative for the establishment of the practice along with the potential to expose phase transition patterns, assuming that change is a non-linear process.

QCA methods are a distinctly different approach to trial and process evaluation methodology and synthesis, the data from a set of cases is viewed in a manner that supports individual contexts but exposes patterns of system and human agent behaviour in configurational arrangements within a set of cases that have a common outcome of interest, whether achieved or not. The cases remain 'whole', and various aspects of these individual systems (the case) comprise a set of attributes, factors or conditions of interest that combine in different ways across the cases to obtain, or not, the outcome.

It is an economic imperative in healthcare research to consider study designs that can reasonably provide an answer, whether positive or negative, as opposed to providing inconclusive results due to design issues (Seers et al 2018, Rycroft-Malone et al 2012). The POISE trial was an ambitious and innovative endeavour at the time (Rycroft-Malone et al 2013). However, it is clear that each NHS organisation represented a unique set of circumstances, whether those included common events, such as meeting 18-week theatre targets at the time, or unique events, such as internal re-organisation or infection breakouts occurring at the time of the trial. Respondents would also allude to different practices and care perspectives within the surgical department as ward and theatre sub-units operated differently. Therefore, sensitivity to case context was clearly necessary, which undermined the original study design. The original process evaluation data did identify inter-professional issues and a lack of overarching authority within key professions (medical and nursing) responsible for patient fasting to assert practice change (Rycroft-Malone et al 2013). My observation was twofold: fasting practice was a diffused activity within the social system of routine surgery, and the pressure to ensure the uninterrupted flow of patients into and out of theatre clearly dominated (Chandler et al 2016).

9.1.1 The Framework for Implementation in Social Complex Adaptive Systems

Whole system approaches adopted in implementation science (Pfadenhauer et al 2017, Rohwer et al 2017, Greenhalgh et al 2017, 2004) are embedded in the implementation synthesis that informs this conceptual framework. Over the life of this PhD, there has been an increased interest in Complexity Theory in the field of evidence based practice or medicine to make sense of how health systems, health evidence and delivery of healthcare function (Norris et al 2019, Reed 2018, Braithwaite 2016, Thompson 2016, Moore et al 2015). Also, the application of Complexity Theory concepts is pursued to explain implementation or knowledge translation (Braithwaite et al 2018, Reed et al 2018, Kitson et al 2017, May et al 2016).

Working from this framework, the *process* factors were identified that need to occur to deliver improvements to fasting practice, ideally regulation of the individual patient’s fast. I emphasise two important aspects to applying FISCAS. First, the rationale for the existence of the practice (pre-surgery fasting to prevent aspiration of stomach contents when paralysed by anaesthesia), and therefore its imperative (managing the throughput of patients on the surgical list) that drives continuation of old practice (prolonged fasting) because the system has historically built itself around this practice. Second, to change practice is not a matter of information, education or knowledge translation etc., although these are necessary elements; rather, change requires understanding of the historical and temporal embedment of the practice into the care delivery system. Practice, as well illustrated by the findings of the original POISE trial, was diffused across individuals, professions and departments of which no one had central control or authority (Rycroft-Malone et al 2013, 2012), even when an appropriate fasting policy was in situ at the NHS organisation. Finally, practice as a diffuse integrated activity is unlikely to adopt a simplistic linear process to change. This is due to long periods of slow change might tip into more sustained change across the system. I have shown QCA shows promise in identifying these transition or tipping, patterns illustrated in Chapter 8. Grasping this practice entanglement is to understand the difference between dismantling a machine or a living organism.

9.2 Contribution to implementation research

My contribution to implementation research has exposed the restriction of methods that do not account for the uniqueness of the implementation context in both time and place. I introduce to implementation research a set of methods with potential to explore across-case patterns in a systematic manner. This can also allow for the possibility of transferable knowledge to other settings beyond the study context. I indicate QCA methods application within the evidence-based methodology toolkit. I also make several recommendations when using QCA methods in evidence-based healthcare research.

My main contribution tested the operationalisation of a novel conceptual framework that accounts for a social rather than natural Complex Adaptive System perspective within the implementation context of the NHS. I make explicit, and discuss, issues with some of the crossover between Complexity Theory for natural and social systems. This work counterbalances the over-simplification and quantification of other methods that reduce information and especially context specific information. Therefore, identifying methods, such as QCA, that present opportunities to systematically explore real world contexts that accounts for complex adaptive system behaviour has potential in implementation research.

References

Aarons, G. A., Hurlburt, M., & Horwitz, S. M. (2011). Advancing a Conceptual Model of Evidence-Based Practice Implementation in Public Service Sectors. *Administration and Policy in Mental Health and Mental Health Services Research*, *38*(1), 4–23. https://doi.org/10.1007/s10488-010-0327-7

Aarons, G. A., Sklar, M., Mustanski, B., Benbow, N., & Brown, C. H. (2017). “Scaling-out” evidence-based interventions to new populations or new health care delivery systems. *Implementation Science*, *12*(1), 111. https://doi.org/10.1186/s13012-017-0640-6

Anderson, L. M., Petticrew, M., Rehfuess, E., Armstrong, R., Ueffing, E., Baker, P., … Tugwell, P. (2011). Using logic models to capture complexity in systematic reviews: Logic Models in Systematic Reviews. *Research Synthesis Methods*, *2*(1), 33–42. https://doi.org/10.1002/jrsm.32

Andrade, L. de, Lynch, C., Carvalho, E., Rodrigues, C. G., Vissoci, J. R. N., Passos, G. F., … de Barros Carvalho, M. D. (2014). System Dynamics Modeling in the Evaluation of Delays of Care in ST-Segment Elevation Myocardial Infarction Patients within a Tiered Health System. *PLoS ONE*, *9*(7), e103577. https://doi.org/10.1371/journal.pone.0103577

Ashcroft, R. E. (2013). Marc A. Rodwin, Conflicts of Interest and the Future of Medicine (New York and Oxford: Oxford University Press, 2011), 384 pages, $29.95/£18.99, hardback, ISBN: 978-0-975548-6. *Medical History*, *57*(1), 154–155. https://doi.org/10.1017/mdh.2012.98

Atkins, L., Francis, J., Islam, R., O’Connor, D., Patey, A., Ivers, N., … Michie, S. (2017). A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science*, *12*(1), 77. https://doi.org/10.1186/s13012-017-0605-9

Barnett-Page, E., & Thomas, J. (2009). Methods for the synthesis of qualitative research: A critical review. *BMC Medical Research Methodology*, *9*(1). https://doi.org/10.1186/1471-2288-9-59

Baumgartner, M. (2013). Detecting Causal Chains in Small- *n* Data. *Field Methods*, *25*(1), 3–24. https://doi.org/10.1177/1525822X12462527

Baumgartner, M. (2015). Parsimony and Causality. *Quality & Quantity*, *49*(2), 839–856. https://doi.org/10.1007/s11135-014-0026-7

Bazeley, P. (2018). *Integrating analyses for mixed methods research* (1st edition). Thousand Oaks, CA: SAGE Publications.

Beach, D. (2017). *Process-Tracing Methods in Social Science*. Retrieved from http://oxfordre.com/politics/view/10.1093/acrefore/9780190228637.001.0001/acrefore-9780190228637-e-176

Beach, D. (2018). Achieving Methodological Alignment When Combining QCA and Process tracing in Practice. *Sociological Methods & Research*, *47*(1), 64–99. https://doi.org/10.1177/0049124117701475

Beach, D., & Pedersen, R. B. (2013). *Process-tracing methods: Foundations and guidelines*. Ann Arbor: University of Michigan Press.

Befani, B. (n.d.). *Pathways to Change: Evaluating development interventions with Qualitative Comparative Analysis (QCA)* (No. 2016:05). Retrieved from Expertgruppen för biståndsanalys (EBA) website: https://eba.se/wp-content/uploads/2016/07/QCA_BarbaraBefani-201605.pdf

Befani, B., & Stedman-Bryce, G. (2017). Process Tracing and Bayesian Updating for impact evaluation. *Evaluation*, *23*(1), 42–60. https://doi.org/10.1177/1356389016654584

Befani, B., Ledermann, S., & Sager, F. (2007). Realistic Evaluation and QCA: Conceptual Parallels and an Empirical Application. *Evaluation*, *13*(2), 171–192. https://doi.org/10.1177/1356389007075222

Beifus, K., Breitbart, E., & Köberlein-Neu, J. (2017). Effects of complex interventions in ‘skin cancer prevention and treatment’: Protocol for a mixed-method systematic review with qualitative comparative analysis. *BMJ Open*, *7*(9), e017196. https://doi.org/10.1136/bmjopen-2017-017196

Bell, E., & Seidel, B. (2012). Understanding and benchmarking health service achievement of policy goals for chronic disease. *BMC Health Services Research*, *12*(1), 343. https://doi.org/10.1186/1472-6963-12-343

Bertram, R. M., Blase, K. A., & Fixsen, D. L. (2015). Improving Programs and Outcomes: Implementation Frameworks and Organization Change. *Research on Social Work Practice*, *25*(4), 477–487. https://doi.org/10.1177/1049731514537687

Bhaskar, R. (2015). *The possibility of naturalism: A philosophical critique of the contemporary human sciences* (Fourth edition). London; New York: Routledge, Taylor & Francis Group.

Bianchi, F., Dorsel, C., Garnett, E., Aveyard, P., & Jebb, S. A. (2018). Interventions targeting conscious determinants of human behaviour to reduce the demand for meat: A systematic review with qualitative comparative analysis. *International Journal of Behavioral Nutrition and Physical Activity*, *15*(1), 102. https://doi.org/10.1186/s12966-018-0729-6

Bickell, N. A., Moss, A. D., Castaldi, M., Shah, A., Sickles, A., Pappas, P., … McAlearney, A. S. (2017). Organizational Factors Affect Safety-Net Hospitals’ Breast Cancer Treatment Rates. *Health Services Research*, *52*(6), 2137–2155. https://doi.org/10.1111/1475-6773.12605

Birken, S. A., Powell, B. J., Presseau, J., Kirk, M. A., Lorencatto, F., Gould, N. J., … Damschroder, L. J. (2017). Combined use of the Consolidated Framework for Implementation Research (CFIR) and the Theoretical Domains Framework (TDF): A systematic review. *Implementation Science*, *12*(1), 2. https://doi.org/10.1186/s13012-016-0534-z

Blackman, T. (2008). Can smoking cessation services be better targeted to tackle health inequalities? Evidence from a cross-sectional study. *Health Education Journal*, *67*(2), 91–101. https://doi.org/10.1177/0017896908089388

Blackman, T. (2013). Exploring Explanations for Local Reductions in Teenage Pregnancy Rates in England: An Approach Using Qualitative Comparative Analysis. *Social Policy and Society*, *12*(1), 61–72. https://doi.org/10.1017/S1474746412000358

Blackman, T., Wistow, J., & Byrne, D. (2011). A Qualitative Comparative Analysis of factors associated with trends in narrowing health inequalities in England. *Social Science & Medicine*, *72*(12), 1965–1974. https://doi.org/10.1016/j.socscimed.2011.04.003

Blake, C. H., & Adolino, J. R. (2001). The Enactment of National Health Insurance: A Boolean Analysis of Twenty Advanced Industrial Countries. *Journal of Health Politics, Policy and Law*, *26*(4), 679–708. https://doi.org/10.1215/03616878-26-4-679

Boaz, A., Baeza, J., & Fraser, A., the European Implementation Score Collaborative Group (EIS), (2011). Effective implementation of research into practice: An overview of systematic reviews of the health literature. *BMC Research Notes*, *4*(1), 212. https://doi.org/10.1186/1756-0500-4-212

Bonell, C, Oakley, A., Hargreaves, J., Strange, V., & Rees, R. (2006). Assessment of generalisability in trials of health interventions: Suggested framework and systematic review. *BMJ*, *333*(7563), 346–349. https://doi.org/10.1136/bmj.333.7563.346

Bonell, Chris, Fletcher, A., Morton, M., Lorenc, T., & Moore, L. (2013). Methods don't make assumptions, researchers do: A response to Marchal et al. *Social Science & Medicine*, *94*, 81–82. https://doi.org/10.1016/j.socscimed.2013.06.026

Booth, A. (2006). Clear and present questions: Formulating questions for evidence-based practice. *Library Hi Tech*, *24*(3), 355–368. https://doi.org/10.1108/07378830610692127

Booth, A., & Carroll, C. (2015). Systematic searching for theory to inform systematic reviews: Is it feasible? Is it desirable? *Health Information & Libraries Journal*, *32*(3), 220–235. https://doi.org/10.1111/hir.12108

Bowman, C. C., Sobo, E. J., Asch, S. M., & Gifford, A. L., the HIV/Hepatitis Quality Enhancement Research Initiative, (2008). Measuring persistence of implementation: QUERI Series. *Implementation Science*, *3*(1), 21. https://doi.org/10.1186/1748-5908-3-21

Brainard, J., & Hunter, P. R. (2015). Do complexity-informed health interventions work? A scoping review. *Implementation Science*, *11*(1), 127. https://doi.org/10.1186/s13012-016-0492-5

Braithwaite, J., Churruca, K., Ellis, L. A., Long, J. c, Clay-Williams, R., Damen, N., … Macquarie University. (2017). *Complexity science in healthcare - aspirations, approaches, applications and accomplishments: A white paper*.

Braithwaite, J., Churruca, K., Long, J. C., Ellis, L. A., & Herkes, J. (2018). When complexity science meets implementation science: A theoretical and empirical analysis of systems change. *BMC Medicine*, *16*(1). https://doi.org/10.1186/s12916-018-1057-z

Brennan, C., Greenhalgh, J., & Pawson, R. (2018). Guidance on guidelines: Understanding the evidence on the uptake of health care guidelines. *Journal of Evaluation in Clinical Practice*, *24*(1), 105–116. https://doi.org/10.1111/jep.12734

Breuer, E., Subba, P., Luitel, N., Jordans, M., De Silva, M., Marchal, B., & Lund, C. (2018). Using qualitative comparative analysis and theory of change to unravel the effects of a mental health intervention on service utilisation in Nepal. *BMJ Global Health*, *3*(6), e001023. https://doi.org/10.1136/bmjgh-2018-001023

Britt, D. W. (2006). A qualitative comparative analysis of the conditions affecting early maternal transfer patterns. *Journal of Telemedicine and Telecare*, *12*(8), 392–395. https://doi.org/10.1258/135763306779378753

Britt, D. W., & Evans, M. I. (2007). Sometimes doing the right thing sucks: Frame combinations and multi-fetal pregnancy reduction decision difficulty. *Social Science & Medicine*, *65*(11), 2342–2356. https://doi.org/10.1016/j.socscimed.2007.06.026

Brunton, G., O'Mara-Eves, A., & Thomas, J. (2014). The 'active ingredients' for successful community engagement with disadvantaged expectant and new mothers: A qualitative comparative analysis. *Journal of Advanced Nursing*, *70*(12), 2847–2860. https://doi.org/10.1111/jan.12441

Burchett, H. E. D., Sutcliffe, K., Melendez-Torres, G. J., Rees, R., & Thomas, J. (2018). Lifestyle weight management programmes for children: A systematic review using Qualitative Comparative Analysis to identify critical pathways to effectiveness. *Preventive Medicine*, *106*, 1–12. https://doi.org/10.1016/j.ypmed.2017.08.025

Byrne, D. (2005). Complexity, Configurations and Cases. *Theory, Culture & Society*, *22*(5), 95–111. https://doi.org/10.1177/0263276405057194

Byrne, D. (2013). Evaluating complex social interventions in a complex world. *Evaluation*, *19*(3), 217–228. https://doi.org/10.1177/1356389013495617

Byrne, D. S. (2002). *Interpreting quantitative data*. London; Thousand Oaks, Calif: SAGE.

Byrne, D. S. (2011). *Applying social science: The role of social research in politics, policy and practice*. Bristol; Portland, OR: Policy Press.

Byrne, D. S. (2014). *Complexity theory and the social sciences: The state of the art* (First Edition). New York: Routledge, Taylor & Francis Group.

Byrne, D. S., & Ragin, C. C. (Eds.). (2009). *The SAGE handbook of case-based methods*. Los Angeles; London: SAGE.

Campbell, D. T. (n.d.). 'Downward causation' in hierarchically organized biological systems. In Studies in the philosophy of biology (pp. 179–186). Macmillian Press.

Campbell, M. (2000). Framework for design and evaluation of complex interventions to improve health. *BMJ*, *321*(7262), 694–696. https://doi.org/10.1136/bmj.321.7262.694

Candy, B., King, M., Jones, L., & Oliver, S. (2013). Using qualitative evidence on patients' views to help understand variation in effectiveness of complex interventions: A qualitative comparative analysis. *Trials*, *14*(1), 179. https://doi.org/10.1186/1745-6215-14-179

Carroll, C., Booth, A., Leaviss, J., & Rick, J. (2013). "Best fit" framework synthesis: Refining the method. *BMC Medical Research Methodology*, *13*(1), 37. https://doi.org/10.1186/1471-2288-13-37

Cartwright, N. (2007). *Hunting causes and using them: Approaches in philosophy and economics*. Cambridge; New York: Cambridge University Press.

Cartwright, N. (2010). What are randomised controlled trials good for? *Philosophical Studies*, *147*(1), 59–70. https://doi.org/10.1007/s11098-009-9450-2

Cartwright, N. (2013). Knowing what we are talking about: Why evidence doesn't always travel. *Evidence & Policy: A Journal of Research, Debate and Practice*, *9*(1), 97–112. https://doi.org/10.1332/174426413X662581

Cartwright, N. (2018a). Theoretical practices that work: Those that mimic Nature's own. *Spontaneous Generations: A Journal for the History and Philosophy of Science*, *9*(1), 165. https://doi.org/10.4245/sponge.v9i1.27045

Cartwright, N. (2018b). What evidence should guidelines take note of? *Journal of Evaluation in Clinical Practice*, *24*(5), 1139–1144. https://doi.org/10.1111/jep.12959

Brian Castellani, Peter Barbrook-Johnson & Corey Schimpf (2019). Case-based methods and agent-based modelling: bridging the divide to leverage their combined strengths, *International Journal of Social Research Methodology*, https://doi.org/10.1080/13645579.2018.1563972

Castellani, B., & Hafferty, F. W. (2010). *Sociology and complexity science: A new field of inquiry*. Berlin: Springer.

Castellano Rioja, E., Valero-Moreno, S., Giménez-Espert, M., & Prado-Gascó, V. (2019). The relations of quality of life in patients with lupus erythematosus: Regression models versus qualitative comparative analysis. *Journal of Advanced Nursing*, *75*(7), 1484–1492. https://doi.org/10.1111/jan.13957

Chakravartty, A. (2017). Scientific Realism. In *The Stanford Encyclopedia of Philosophy* (Spring 2014). Retrieved from https://plato.stanford.edu/archives/sum2017/entries/scientific-realism/>.

Chandler, J. (2018). The Paradox of Intervening in Complex Adaptive Systems Comment on 'Using Complexity and Network Concepts to Inform Healthcare Knowledge Translation'. International Journal of Health Policy and Management, 7(6), 569–571. https://doi.org/10.15171/ijhpm.2018.05

Chandler, J., Rycroft-Malone, J., Hawkes, C., & Noyes, J. (2016). Application of simplified Complexity Theory concepts for healthcare social systems to explain the implementation of evidence into practice. *Journal of Advanced Nursing*, *72*(2), 461–480. https://doi.org/10.1111/jan.12815

Chang, C.-W., Tseng, T.-H., & G. Woodside, A. (2013). Configural algorithms of patient satisfaction, participation in diagnostics, and treatment decisions' influences on hospital loyalty. *Journal of Services Marketing*, *27*(2), 91–103. https://doi.org/10.1108/08876041311309225

Charles, J. M., Rycroft-Malone, J., Aslam, R., Hendry, M., Pasterfield, D., & Whitaker, R. (2016). Reducing repeat pregnancies in adolescence: Applying realist principles as part of a mixed-methods systematic review to explore what works, for whom, how and under what circumstances. *BMC Pregnancy and Childbirth*, *16*(1), 271. https://doi.org/10.1186/s12884-016-1066-x

Charlton, B. G. (2009). The Zombie science of evidence-based medicine: A personal retrospective. A commentary on Djulbegovic, B., Guyatt, G. H. & Ashcroft, R. E. (2009). *Cancer Control*, 16, 158-168: The Zombie science of EBM. *Journal of Evaluation in Clinical Practice*, *15*(6), 930–934. https://doi.org/10.1111/j.1365-2753.2009.01267.x

Chatfield, S. L., DeBois, K., Nolan, R., Crawford, H., & Hallam, J. S. (2017). Hand hygiene among healthcare workers: A qualitative meta summary using the GRADE-CERQual process. *Journal of Infection Prevention*, *18*(3), 104–120. https://doi.org/10.1177/1757177416680443

Chenot, J.-F., Scherer, M., Becker, A., Donner-Banzhoff, N., Baum, E., Leonhardt, C., … Kochen, M. M. (2008). Acceptance and perceived barriers of implementing a guideline for managing low back in general practice. *Implementation Science*, *3*(1). https://doi.org/10.1186/1748-5908-3-7

Chiappone, A., Smith, T. M., Estabrooks, P. A., Rasmussen, C. G., Blaser, C., & Yaroch, A. L. (2018). Technical Assistance and Changes in Nutrition and Physical Activity Practices in the National Early Care and Education Learning Collaboratives Project, 2015–2016. *Preventing Chronic Disease*, *15*, 170239. https://doi.org/10.5888/pcd15.170239

Chuang, E., Ayala, G. X., Schmied, E., Ganter, C., Gittelsohn, J., & Davison, K. K. (2015). Evaluation Protocol To Assess an Integrated Framework for the Implementation of the Childhood Obesity Research Demonstration Project at the California (CA-CORD) and Massachusetts (MA-CORD) Sites. *Childhood Obesity*, *11*(1), 48–57. https://doi.org/10.1089/chi.2014.0049

Chuang, E., Dill, J., Morgan, J. C., & Konrad, T. R. (2012). A Configurational Approach to the Relationship between High-Performance Work Practices and Frontline Health Care Worker Outcomes. *Health Services Research*, *47*(4), 1460–1481. https://doi.org/10.1111/j.1475-6773.2011.01366.x

Cilliers, P. (2005). Complexity, Deconstruction and Relativism. *Theory, Culture & Society*, *22*(5), 255–267. https://doi.org/10.1177/0263276405058052

Cilliers, P. (2013). Understanding Complex Systems. In J. P. Sturmberg & C. M. Martin (Eds.), *Handbook of Systems and Complexity in Health* (pp. 27–38). https://doi.org/10.1007/978-1-4614-4998-0_3

Clark, A. M., Lissel, S. L., & Davis, C. (2008). Complex Critical Realism: Tenets and Application in Nursing Research. *Advances in Nursing Science*, *31*(4), E67–E79. https://doi.org/10.1097/01.ANS.0000341421.34457.2a

Collier, D. (2014). Comment: QCA Should Set Aside the Algorithms. *Sociological Methodology*, *44*(1), 122–126. https://doi.org/10.1177/0081175014542568

Cooper, B. (Ed.). (2012). *Challenging the qualitative-quantitative divide: Explorations in case-focused causal analysis*. London; New York: Continuum.

Cooper, B., & Glaesser, J. (2012). Qualitative Work and the Testing and Development of Theory: Lessons from a Study Combining Cross-Case and Within-Case Analysis via Ragin's QCA. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research*, *Vol 13*, No 2 (2012): Qualitative Computing: Diverse Worlds and Research Practices. https://doi.org/10.17169/FQS-13.2.1776

Cooper, B., & Glaesser, J. (2016). Qualitative Comparative Analysis, Necessary Conditions, and Limited Diversity: Some Problematic Consequences of Schneider and Wagemann's Enhanced Standard Analysis. *Field Methods*, *28*(3), 300–315. https://doi.org/10.1177/1525822X15598974

Cooper, H. C., & Geyer, R. (2009). What can complexity do for diabetes management? Linking theory to practice. *Journal of Evaluation in Clinical Practice*, *15*(4), 761–765. https://doi.org/10.1111/j.1365-2753.2009.01229.x

Coverdill, J. E., & Finlay, W. (1995). Understanding Mills via Mill-type methods: An application of qualitative comparative analysis to a study of labor management in southern textile manufacturing. *Qualitative Sociology*, *18*(4), 457–478. https://doi.org/10.1007/BF02404491

Cragun, D., DeBate, R. D., Vadaparampil, S. T., Baldwin, J., Hampel, H., & Pal, T. (2014). Comparing universal Lynch syndrome tumor-screening programs to evaluate associations between implementation strategies and patient follow-through. *Genetics in Medicine*, *16*(10), 773–782. https://doi.org/10.1038/gim.2014.31

Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ*, a1655. https://doi.org/10.1136/bmj.a1655

Dalkin, S. M., Greenhalgh, J., Jones, D., Cunningham, B., & Lhussier, M. (2015). What's in a mechanism? Development of a key concept in realist evaluation. *Implementation Science*, *10*(1). https://doi.org/10.1186/s13012-015-0237-x

Damschroder, L. J., Aron, D. C., Keith, R. E., Kirsh, S. R., Alexander, J. A., & Lowery, J. C. (2009). Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. *Implementation Science*, *4*(1), 50. https://doi.org/10.1186/1748-5908-4-50

Davidoff, F. (2019). Understanding contexts: How explanatory theories can help. *Implementation Science*, *14*(1), 23. https://doi.org/10.1186/s13012-019-0872-8

Davis, S. (n.d.). Annual Report of the Chief Medical Officer: Generation Genome. Retrieved from Department of Health and Social Care website: https://www.gov.uk/government/publications/chief-medical-officer-annual-report-2016-generation-genome

Dearing, J. W., Beacom, A. M., Chamberlain, S. A., Meng, J., Berta, W. B., Keefe, J. M., … Estabrooks, C. A. (2017). Pathways for best practice diffusion: The structure of informal relationships in Canada's long-term care sector. *Implementation Science*, *12*(1), 11. https://doi.org/10.1186/s13012-017-0542-7

Deaton, A., & Cartwright, N. (2018). Understanding and misunderstanding randomized controlled trials. *Social Science & Medicine*, *210*, 2–21. https://doi.org/10.1016/j.socscimed.2017.12.005

Devisch, I., & Murray, S. J. (2009). 'We hold these truths to be self-evident': Deconstructing 'evidence-based' medical practice: Deconstructing 'evidence-based' medical practice. *Journal of Evaluation in Clinical Practice*, *15*(6), 950–954. https://doi.org/10.1111/j.1365-2753.2009.01232.x

Dill, J. S., Chuang, E., & Morgan, J. C. (2014). Healthcare organization–education partnerships and career ladder programs for health care workers. *Social Science & Medicine*, *122*, 63–71. https://doi.org/10.1016/j.socscimed.2014.10.021

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B., & Sutton, A. (2005). Synthesising qualitative and quantitative evidence: A review of possible methods. *Journal of Health Services Research & Policy*, *10*(1), 45–53. https://doi.org/10.1177/135581960501000110

Dobbins, M., Robeson, P., Ciliska, D., Hanna, S., Cameron, R., O'Mara, L., … Mercer, S. (2009). A description of a knowledge broker role implemented as part of a randomized controlled trial evaluating three knowledge translation strategies. *Implementation Science*, *4*(1), 23. https://doi.org/10.1186/1748-5908-4-23

Dy, S. M., Garg, P., Nyberg, D., Dawson, P. B., Pronovost, P. J., Morlock, L., … Wu, A. W. (2005). Critical pathway effectiveness: Assessing the impact of patient, hospital care, and pathway characteristics using qualitative comparative analysis. *Health Services Research*, *40*(2), 499–516. https://doi.org/10.1111/j.1475-6773.2005.00369.x

Eccles, M. P., & Mittman, B. S. (2006). Welcome to Implementation Science. *Implementation Science*, *1*(1). https://doi.org/10.1186/1748-5908-1-1

Eccles, M. P., Armstrong, D., Baker, R., Cleary, K., Davies, H., Davies, S., … Sibbald, B. (2009). An implementation research agenda. *Implementation Science: IS*, *4*, 18. https://doi.org/10.1186/1748-5908-4-18

Eicher, B. (2016). Selection of asset investment models by hospitals: Examination of influencing factors, using Switzerland as an example: Selection of Asset Investment Models. *The International Journal of Health Planning and Management*, *31*(4), 554–579. https://doi.org/10.1002/hpm.2341

Ellen, M. E., Panisset, U., Araujo de Carvalho, I., Goodwin, J., & Beard, J. (2017). A Knowledge Translation framework on ageing and health. *Health Policy*, *121*(3), 282–291. https://doi.org/10.1016/j.healthpol.2016.12.009

Emmel, N., Greenhalgh, J., Manzano, A., Monaghan, M., & Dalkin, S. (Eds.). (2018). *Doing realist research* (First edition). Los Angeles: Sage.

Emmenegger, P., Schraff, D., & Walter Andre. (2014). *QCA, the Truth Table Analysis and Large-N Survey Data: The Benefits of Calibration and the Importance of Robustness Tests*. Retrieved from http://www.compasss.org/wpseries/ EmmeneggerSchraffWalter2014.pdf

Eng, S., & Woodside, A. G. (2012). Configural analysis of the drinking man: Fuzzy-set qualitative comparative analyses. *Addictive Behaviors*, *37*(4), 541–543. https://doi.org/10.1016/j.addbeh.2011.11.034

Evensen, A. E., Sanson-Fisher, R., D'Este, C., & Fitzgerald, M. (2010). Trends in publications regarding evidence-practice gaps: A literature review. *Implementation Science*, *5*(1). https://doi.org/10.1186/1748-5908-5-11

Fixsen, D. L., Naoom, S., Blase, K. A., Friedman, R. M., & Wallace, R. M. (2005). Implementation Research: A synthesis of the literature (No. FMHI Publication #231). Louis de la Parte Florida Metnal Health Institute: National Implementation Research Network, University of South Florida.

Flanagan, M. E., Ramanujam, R., & Doebbeling, B. N. (2009). The effect of provider- and workflow-focused strategies for guideline implementation on provider acceptance. *Implementation Science*, *4*(1). https://doi.org/10.1186/1748-5908-4-71

Flodgren, G., O'Brien, M. A., Parmelli, E., & Grimshaw, J. M. (2019). Local opinion leaders: Effects on professional practice and healthcare outcomes. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD000125.pub5

Ford, E. W., Duncan, W. J., & Ginter, P. M. (2005). Health departments' implementation of public health's core functions: An assessment of health impacts. *Public Health*, *119*(1), 11–21. https://doi.org/10.1016/j.puhe.2004.03.002

Forman-Hoffman, V. L., Middleton, J. C., McKeeman, J. L., Stambaugh, L. F., Christian, R. B., Gaynes, B. N., … Viswanathan, M. (2017). Quality improvement, implementation, and dissemination strategies to improve mental health care for children and adolescents: A systematic review. *Implementation Science*, *12*(1), 93. https://doi.org/10.1186/s13012-017-0626-4

Fraser, S. W., & Greenhalgh, T. (2001). Complexity science: Coping with complexity: educating for capability. *BMJ*, *323*(7316), 799–803. https://doi.org/10.1136/bmj.323.7316.799

Gagliardi, A. R., & Brouwers, M. C. (2012). Integrating guideline development and implementation: Analysis of guideline development manual instructions for generating implementation advice. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-67

Gell-Mann, M. (1995). *The quark and the jaguar*. London: Abacus.

Gerring, J. (2008). The Mechanismic Worldview: Thinking Inside the Box. *British Journal of Political Science*, *38*(01). https://doi.org/10.1017/S0007123408000082

Gerrits, L., & Verweij, S. (2013). Critical Realism as a Meta-Framework for Understanding the Relationships between Complexity and Qualitative Comparative Analysis. *Journal of Critical Realism*, *12*(2), 166–182. https://doi.org/10.1179/rea.12.2.p663527490513071

Gilligan, D. G., & Lennings, C. J. (2010). Psychopathic and Neuropathic Pathways to Homicide: Examination of Harris and Rice's Two-Path Model of Criminal Violence in Homicide. *Psychiatry, Psychology and Law*, *17*(1), 148–168. https://doi.org/10.1080/13218710903427875

Giménez-Espert, M. del C., & Prado-Gascó, V. J. (2018). The role of empathy and emotional intelligence in nurses' communication attitudes using regression models and fuzzy-set qualitative comparative analysis models. *Journal of Clinical Nursing*, *27*(13–14), 2661–2672. https://doi.org/10.1111/jocn.14325

Glatman-Freedman, A., Cohen, M.-L., Nichols, K. A., Porges, R. F., Saludes, I. R., Steffens, K., … Britt, D. W. (2010). Factors Affecting the Introduction of New Vaccines to Poor Nations: A

Comparative Study of the Haemophilus influenzae Type B and Hepatitis B Vaccines. *PLoS ONE*, *5*(11), e13802. https://doi.org/10.1371/journal.pone.0013802

Gleick, J. (1998). *Chaos: Making a new science*. London: Vintage.

Glennan, S. S. (2002). Rethinking mechanistic explanation. *Philosophy of Science*, *69*, S342–S353.

Glenton, C., Colvin, C., Carlsen, B., Swartz, A., Lewin, S., Noyes, J., & Rashidian, A. (2013). Barriers and facilitators to the implementation of lay health worker programmes to improve access to maternal and child health: Qualitative evidence synthesis. In The Cochrane Collaboration (Ed.), *Cochrane Database of Systematic Reviews* (p. CD010414). https://doi.org/10.1002/14651858.CD010414

Godfrey-Smith, P. (2003). *Theory and reality: An introduction to the philosophy of science*. Chicago: University of Chicago Press.

Godfrey-Smith, P. (2010). *Causal Pluralism* (Vol. 1; H. Beebee, C. Hitchcock, & P. Menzies, Eds.). https://doi.org/10.1093/oxfordhb/9780199279739.003.0017

Goicolea, I., Hultstrand Ahlin, C., Waenerlund, A.-K., Marchal, B., Christianson, M., Wiklund, M., … San Sebastian, M. (2018). Accessibility and factors associated with utilization of mental health services in youth health centers. A qualitative comparative analysis in northern Sweden. *International Journal of Mental Health Systems*, *12*(1), 69. https://doi.org/10.1186/s13033-018-0249-4

Goicolea, I., Vives-Cases, C., Hurtig, A.-K., Marchal, B., Briones-Vozmediano, E., Otero-García, L., … San Sebastian, M. (2015). Mechanisms that Trigger a Good Health-Care Response to Intimate Partner Violence in Spain. Combining Realist Evaluation and Qualitative Comparative Analysis Approaches. *PLoS ONE*, *10*(8), e0135167. https://doi.org/10.1371/journal.pone.0135167

Goldstein, J. (1999). Emergence as a Construct: History and Issues. *Emergence*, *1*(1), 49–72. https://doi.org/10.1207/s15327000em0101_4

Gould, D. J., Moralejo, D., Drey, N., & Chudleigh, J. H. (2010). Interventions to improve hand hygiene compliance in patient care. In The Cochrane Collaboration (Ed.), *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD005186.pub3

Graham, I., & Tetroe, J. (2010). The knowledge to action framework. In Evidence-Based Nursing Series. Models and Frameworks for Implementing Evidence-Based Practice: Linking evidence to action. Chichester, West Sussex, UK: John Wiley & Sons Ltd.

Grant, A., Treweek, S., Dreischulte, T., Foy, R., & Guthrie, B. (2013). Process evaluations for cluster-randomised trials of complex interventions: A proposed framework for design and reporting. *Trials*, *14*(1), 15. https://doi.org/10.1186/1745-6215-14-15

Greenhalgh, T., & Papoutsi, C. (2018). Studying complexity in health services research: Desperately seeking an overdue paradigm shift. *BMC Medicine*, *16*(1), 95, s12916-018-1089–4. https://doi.org/10.1186/s12916-018-1089-4

Greenhalgh, T., Plsek, P., Wilson, T., Fraser, S., & Holt, T. (2010). Response to 'The Appropriation of Complexity Theory in Health Care'. *Journal of Health Services Research & Policy*, *15*(2), 115–117. https://doi.org/10.1258/jhsrp.2010.009158

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., … Shaw, S. (2017). Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. *Journal of Medical Internet Research*, *19*(11), e367. https://doi.org/10.2196/jmir.8775

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., … Shaw, S. (2018a). Analysing the role of complexity in explaining the fortunes of technology programmes: Empirical application of the NASSS framework. *BMC Medicine*, *16*(1), 66. https://doi.org/10.1186/s12916-018-1050-6

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., … Shaw, S. (2018b). Analysing the role of complexity in explaining the fortunes of technology programmes: Empirical application of the NASSS framework. *BMC Medicine*, *16*(1), 66. https://doi.org/10.1186/s12916-018-1050-6

Gribbin, J. (2005). *Deep simplicity: Chaos, complexity and the emergence of life*. London: Penguin Books.

Grimshaw, J. M., & Eccles, M. P. (2004). Is evidence-based implementation of evidence-based care possible? *The Medical Journal of Australia*, *180*(6 Suppl), S50-51.

Grofman, B., & Schneider, C. Q. (2009). An Introduction to Crisp Set QCA, with a Comparison to Binary Logistic Regression. *Political Research Quarterly*, *62*(4), 662–672. https://doi.org/10.1177/1065912909338464

Guerrero, E. G., Fenwick, K., & Kong, Y. (2017). Advancing theory development: Exploring the leadership–climate relationship as a mechanism of the implementation of cultural competence. *Implementation Science*, *12*(1), 133. https://doi.org/10.1186/s13012-017-0666-9

Hamid, S. (2014). Pre-operative fasting—A patient centered approach. *BMJ Quality Improvement Reports*, *2*(2), u605.w1252. https://doi.org/10.1136/bmjquality.u605.w1252

Hammersley, M. (1992). *What's wrong with ethnography? Methodological explorations*. London; New York: Routledge.

Hannigan, B. (2013). Connections and consequences in complex systems: Insights from a case study of the emergence and local impact of crisis resolution and home treatment services. *Social Science & Medicine*, *93*, 212–219. https://doi.org/10.1016/j.socscimed.2011.12.044

Harris, K. M., Kneale, D., Lasserson, T. J., McDonald, V. M., Grigg, J., & Thomas, J. (2015). School-based self-management interventions for asthma in children and adolescents: A mixed methods systematic review. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD011651

Harting, J., Peters, D., Grêaux, K., van Assema, P., Verweij, S., Stronks, K., & Klijn, E.-H. (2017). Implementing multiple intervention strategies in Dutch public health-related policy networks. *Health Promotion International*, *34*(2), 193–203. https://doi.org/10.1093/heapro/dax067

Hartmann-Boyce, J., Bianchi, F., Piernas, C., Riches, S. P., Frie, K., Nourse, R., & Jebb, S. A. (2018). Grocery store interventions to change food purchasing behaviors: A systematic review of randomized controlled trials. *The American Journal of Clinical Nutrition*, *107*(6), 1004–1016. https://doi.org/10.1093/ajcn/nqy045

Harvey, D. L. (2002). Agency and Community: A Critical Realist Paradigm. *Journal for the Theory of Social Behaviour*, *32*(2), 163–194. https://doi.org/10.1111/1468-5914.00182

Harvey, G., & Kitson, A. (2015). PARIHS revisited: From heuristic to integrated framework for the successful implementation of knowledge into practice. *Implementation Science*, *11*(1). https://doi.org/10.1186/s13012-016-0398-2

Harvey, G., McCormack, B., Kitson, A., Lynch, E., & Titchen, A. (2018). Designing and implementing two facilitation interventions within the 'Facilitating Implementation of Research Evidence (FIRE)' study: A qualitative analysis from an external facilitators' perspective. *Implementation Science*, *13*(1). https://doi.org/10.1186/s13012-018-0812-z

Hawe, P. (2015). Lessons from Complex Interventions to Improve Health. *Annual Review of Public Health*, *36*(1), 307–323. https://doi.org/10.1146/annurev-publhealth-031912-114421

Hawe, P., Shiell, A., & Riley, T. (2009). Theorising Interventions as Events in Systems. *American Journal of Community Psychology*, *43*(3–4), 267–276. https://doi.org/10.1007/s10464-009-9229-9

Haworth-Hoeppner, S. (2000). The Critical Shapes of Body Image: The Role of Culture and Family in the Production of Eating Disorders. *Journal of Marriage and Family*, *62*(1), 212–227. https://doi.org/10.1111/j.1741-3737.2000.00212.x

Haynes, P. (2018). Understanding the influence of values in complex systems-based approaches to public policy and management. *Public Management Review*, *20*(7), 980–996. https://doi.org/10.1080/14719037.2017.1364411

Haynes, P. (2019). *Social synthesis: Finding dynamic patterns in complex social systems.* Oxford: Routledge.

Hebballi, R., Desai, P. J., & Jürgens, S. (2002). Pre-operative fluid fastingfor adult elective surgery: Correspondence. *Anaesthesia*, *57*(3), 308–308. https://doi.org/10.1111/j.1365-2044.2002.2520_37.x

Hegarty, J., Murphy, S., Creedon, S., Wills, T., Savage, E., Barry, F., … Drennan, J. (2019). Leadership perspective on the implementation of guidelines on healthcare-associated infections. *BMJ Leader*, *3*(2), 43–51. https://doi.org/10.1136/leader-2018-000111

Helfrich, C. D., Li, Y.-F., Sharp, N. D., & Sales, A. E. (2009). Organizational readiness to change assessment (ORCA): Development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework. *Implementation Science*, *4*(1). https://doi.org/10.1186/1748-5908-4-38

Heylighen, F. (2010). The Self-Organization of Time and Causality: Steps Towards Understanding the Ultimate Origin. *Foundations of Science*, *15*(4), 345–356. https://doi.org/10.1007/s10699-010-9171-1

Higgins, J. P. T., López-López, J. A., Becker, B. J., Davies, S. R., Dawson, S., Grimshaw, J. M., … Caldwell, D. M. (2019). Synthesising quantitative evidence in systematic reviews of complex health interventions. *BMJ Global Health*, *4*(Suppl 1), e000858. https://doi.org/10.1136/bmjgh-2018-000858

Hilborn, R. C. (2000). *Chaos and nonlinear dynamics: An introduction for scientists and engineers* (2nd ed). Oxford; New York: Oxford University Press.

Højberg, H., Rasmussen, C. D. N., Osborne, R. H., & Jørgensen, M. B. (2018). Identifying a practice-based implementation framework for sustainable interventions for improving the evolving working environment: Hitting the Moving Target Framework. *Applied Ergonomics*, *67*, 170–177. https://doi.org/10.1016/j.apergo.2017.10.001

Holland, D. (2014). Complex Realism, Applied Social Science and Postdisciplinarity: A Critical Assessment of the Work of David Byrne. *Journal of Critical Realism*, *13*(5), 534–554. https://doi.org/10.1179/1476743014Z.00000000042

Holland, John H. (1992). Complex Adaptive Systems. *Daedalus*, *121*(1), 17–30. Retrieved from JSTOR.

Holland, John H. (2014). *Complexity: A very short introduction* (First edition). Oxford, United Kingdom: Oxford University Press.

Holland, John Henry. (2000). *Emergence: From chaos to order*. Oxford: Oxford Univ. Press.

Holt, T. A. (2004). *Complexity for clinicians*. Oxford: Radcliffe Publishing.

Howick, J. (2011). *The philosophy of evidence-based medicine*. Chichester, West Sussex, UK: Wiley-Blackwell, BMJ Books.

Howick, J., Glasziou, P., & Aronson, J. K. (2009). The evolution of evidence hierarchies: What can Bradford Hill's 'guidelines for causation' contribute? *Journal of the Royal Society of Medicine*, *102*(5), 186–194. https://doi.org/10.1258/jrsm.2009.090020

Howick, J., Glasziou, P., & Aronson, J. K. (2013). Problems with using mechanisms to solve the problem of extrapolation. *Theoretical Medicine and Bioethics*, *34*(4), 275–291. https://doi.org/10.1007/s11017-013-9266-0

Hull, L., Goulding, L., Khadjesari, Z., Davis, R., Healey, A., Bakolis, I., & Sevdalis, N. (2019). Designing high-quality implementation research: Development, application, feasibility and preliminary evaluation of the implementation science research development (ImpRes) tool and guide. *Implementation Science*, *14*(1), 80. https://doi.org/10.1186/s13012-019-0897-z

Illari, P. M. (2011). Mechanistic Evidence: Disambiguating the Russo–Williamson Thesis. *International Studies in the Philosophy of Science*, *25*(2), 139–157. https://doi.org/10.1080/02698595.2011.574856

Illari, P. M., & Russo, F. (2014). *Causality: Philosophical theory meets scientific practice* (First edition). Oxford, United Kingdom: Oxford University Press.

Ioannidis, J. P. A. (2018). Randomized controlled trials: Often flawed, mostly useless, clearly indispensable: A commentary on Deaton and Cartwright. *Social Science & Medicine*, *210*, 53–56. https://doi.org/10.1016/j.socscimed.2018.04.029

Ivers, N., Jamtvedt, G., Flottorp, S., Young, J. M., Odgaard-Jensen, J., French, S. D., … Oxman, A. D. (2012). Audit and feedback: Effects on professional practice and healthcare outcomes. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD000259.pub3

Jane, R., & Liz, S. (2002). Qualitative Data Analysis for Applied Policy Research. In A. Huberman & M. Miles, *The Qualitative Researcher's Companion* (pp. 305–329). https://doi.org/10.4135/9781412986274.n12

Johnson, N. F., & Johnson, N. F. (2011). *Simply complexity: A clear guide to complexity theory*. Retrieved from http://public.ebookcentral.proquest.com/choice/publicfullrecord.aspx?p=1792154

Johnson, R. B., & Schoonenboom, J. (2016). Adding Qualitative and Mixed Methods Research to Health Intervention Studies: Interacting With Differences. *Qualitative Health Research*, *26*(5), 587–602. https://doi.org/10.1177/1049732315617479

Johnson, R. B., Russo, F., & Schoonenboom, J. (2017). Causation in Mixed Methods Research: The Meeting of Philosophy, Science, and Practice. *Journal of Mixed Methods Research*, *13*(2), 143–162. https://doi.org/10.1177/1558689817719610

Johnson, S. (2002). *Emergence: The connected lives of ants, brains, cities and software*. London: Penguin Books.

Kahwati, L. C., Lewis, M. A., Kane, H., Williams, P. A., Nerz, P., Jones, K. R., … Kinsinger, L. S. (2011). Best Practices in the Veterans Health Administration's MOVE! Weight Management Program. *American Journal of Preventive Medicine*, *41*(5), 457–464. https://doi.org/10.1016/j.amepre.2011.06.047

Kahwati, L., Jacobs, S., Kane, H., Lewis, M., Viswanathan, M., & Golin, C. E. (2016). Using qualitative comparative analysis in a systematic review of a complex intervention. *Systematic Reviews*, *5*(1), 82. https://doi.org/10.1186/s13643-016-0256-y

Kahwati, L., Viswanathan, M., Golin, C. E., Kane, H., Lewis, M., & Jacobs, S. (2016). Identifying configurations of behavior change techniques in effective medication adherence interventions: A qualitative comparative analysis. *Systematic Reviews*, *5*(1), 83. https://doi.org/10.1186/s13643-016-0255-z

Kaplan, H. C., Provost, L. P., Froehle, C. M., & Margolis, P. A. (2012). The Model for Understanding Success in Quality (MUSIQ): Building a theory of context in healthcare quality improvement. *BMJ Quality & Safety*, *21*(1), 13–20. https://doi.org/10.1136/bmjqs-2011-000010

Kauffman, S. A. (1995). *At home in the universe: The search for laws of self-organization and complexity*. New York: Oxford University Press.

Kennedy, A., Chew-Graham, C., Blakeman, T., Bowen, A., Gardner, C., Protheroe, J., … Gask, L. (2010). Delivering the WISE (Whole Systems Informing Self-Management Engagement) training package in primary care: Learning from formative evaluation. *Implementation Science*, *5*(1). https://doi.org/10.1186/1748-5908-5-7

Kernick, D., & Bevan, H. (2016). *Complexity and healthcare organization: A view from the street*. Retrieved from http://search.ebscohost.com/login.aspx?direct=true&scope=site&db=nlebk&db=nlabk&AN=1795786

Kernick, D., & Mitchell, A. (2010). Working with lay people in health service research: A model of co-evolution based on complexity theory. *Journal of Interprofessional Care*, *24*(1), 31–40. https://doi.org/10.3109/13561820903012073

Khalil, H. (2016). Knowledge translation and implementation science: What is the difference? *International Journal of Evidence-Based Healthcare*, *14*(2), 39–40. https://doi.org/10.1097/XEB.0000000000000086

Kien, C., Grillich, L., Nussbaumer-Streit, B., & Schoberberger, R. (2018). Pathways leading to success and non-success: A process evaluation of a cluster randomized physical activity health promotion program applying fuzzy-set qualitative comparative analysis. *BMC Public Health*, *18*(1), 1386. https://doi.org/10.1186/s12889-018-6284-x

Kilbourne, A. M., Neumann, M. S., Pincus, H. A., Bauer, M. S., & Stall, R. (2007a). Implementing evidence-based interventions in health care: Application of the replicating effective programs framework. *Implementation Science*, *2*(1). https://doi.org/10.1186/1748-5908-2-42

Kilbourne, A. M., Neumann, M. S., Pincus, H. A., Bauer, M. S., & Stall, R. (2007b). Implementing evidence-based interventions in health care: Application of the replicating effective programs framework. *Implementation Science*, *2*(1), 42. https://doi.org/10.1186/1748-5908-2-42

Kim, D. H. (1992). Toolbox: Guidelines for drawing causal loop diagrams. The Systems Thinker, 3, 5–6.

Kirsh, S. R., Lawrence, R. H., & Aron, D. C. (2008). Tailoring an intervention to the context and system redesign related to the intervention: A case study of implementing shared medical appointments for diabetes. *Implementation Science*, *3*(1). https://doi.org/10.1186/1748-5908-3-34

Kitson, A. L., Rycroft-Malone, J., Harvey, G., McCormack, B., Seers, K., & Titchen, A. (2008). Evaluating the successful implementation of evidence into practice using the PARiHS framework: Theoretical and practical challenges. *Implementation Science*, *3*(1). https://doi.org/10.1186/1748-5908-3-1

Kitson, A., Harvey, G., & McCormack, B. (1998). Enabling the implementation of evidence-based practice: A conceptual framework. *Quality and Safety in Health Care*, *7*(3), 149–158. https://doi.org/10.1136/qshc.7.3.149

Kitson, Alison, Brook, A., Harvey, G., Jordan, Z., Marshall, R., O'Shea, R., & Wilson, D. (2017). Using Complexity and Network Concepts to Inform Healthcare Knowledge Translation. *International Journal of Health Policy and Management*, *7*(3), 231–243. https://doi.org/10.15171/ijhpm.2017.79

Kneale, D., Rojas-García, A., & Thomas, J. (2018). Exploring the importance of evidence in local health and wellbeing strategies. *Journal of Public Health*, *40*(suppl_1), i13–i23. https://doi.org/10.1093/pubmed/fdx152

Kontos, P. C., & Poland, B. D. (2009). Mapping new theoretical and methodological terrain for knowledge translation: Contributions from critical realism and the arts. *Implementation Science*, *4*(1). https://doi.org/10.1186/1748-5908-4-1

Kyrtatos, P., Constandinou, N., Loizides, S., & Mumtaz, T. (2014). Improved Patient Education Facilitates Adherence to Preoperative Fasting Guidelines. *Journal of Perioperative Practice*, *24*(10), 228–231. https://doi.org/10.1177/175045891402401003

Ladyman, J. (2016). Structural Realism. In E. N. Zalta (Ed.), *The Stanford Encyclopedia of Philosophy* (Winter 2016). Retrieved from https://plato.stanford.edu/archives/win2016/entries/structural-realism/

Lambert, E., & Carey, S. (2016). Practice Guideline Recommendations on Perioperative Fasting: A Systematic Review. *Journal of Parenteral and Enteral Nutrition*, *40*(8), 1158–1165. https://doi.org/10.1177/0148607114567713

Lavis, J. N., Boyko, J. A., Oxman, A. D., Lewin, S., & Fretheim, A. (2009). SUPPORT Tools for evidence-informed health Policymaking (STP) 14: Organising and using policy dialogues to support evidence-informed policymaking. Health Research Policy and Systems, 7(S1), S14. https://doi.org/10.1186/1478-4505-7-S1-S14

Leas, B. F., D'Anci, K. E., Apter, A. J., Bryant-Stephens, T., Schoelles, K., & Umscheid, C. A. (2018). *Effectiveness of Indoor Allergen Reduction in Management of Asthma*. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK493778/

Leykum, L. K., Lanham, H. J., Pugh, J. A., Parchman, M., Anderson, R. A., Crabtree, B. F., … McDaniel, R. R. (2014). Manifestations and implications of uncertainty for improving healthcare systems: An analysis of observational and interventional studies grounded in complexity science. *Implementation Science*, *9*(1), 165. https://doi.org/10.1186/s13012-014-0165-1

Leykum, L. K., Pugh, J., Lawrence, V., Parchman, M., Noël, P. H., Cornell, J., & McDaniel, R. R. (2007). Organizational interventions employing principles of complexity science have improved outcomes for patients with Type II diabetes. *Implementation Science*, *2*(1). https://doi.org/10.1186/1748-5908-2-28

Lipton, P. (2004). *Inference to the best explanation* (2nd ed). London; New York: Routledge/Taylor and Francis Group.

Litaker, D., Tomolo, A., Liberatore, V., Stange, K. C., & Aron, D. (2006). Using complexity theory to build interventions that improve health care delivery in primary care. *Journal of General Internal Medicine*, *21*(S2), S30–S34. https://doi.org/10.1007/s11606-006-0272-z

Long, K. M., McDermott, F., & Meadows, G. N. (2018). Being pragmatic about healthcare complexity: Our experiences applying complexity theory and pragmatism to health services research. *BMC Medicine*, *16*(1), 94. https://doi.org/10.1186/s12916-018-1087-6

Longest, K. C., & Thoits, P. A. (2012). Gender, the Stress Process, and Health: A Configurational Approach. *Society and Mental Health*, *2*(3), 187–206. https://doi.org/10.1177/2156869312451151

Loudon, I. (2013). Ignaz Phillip Semmelweis' studies of death in childbirth. *Journal of the Royal Society of Medicine*, *106*(11), 461–463. https://doi.org/10.1177/0141076813507844

Lowson, K., Jenks, M., Filby, A., Carr, L., Campbell, B., & Powell, J. (2015). Examining the implementation of NICE guidance: Cross-sectional survey of the use of NICE interventional procedures guidance by NHS Trusts. *Implementation Science*, *10*(1). https://doi.org/10.1186/s13012-015-0283-4

Lubold, A. M. (2017). The effect of family policies and public health initiatives on breastfeeding initiation among 18 high-income countries: A qualitative comparative analysis research design. *International Breastfeeding Journal*, *12*(1), 34. https://doi.org/10.1186/s13006-017-0122-0

Mackie, J. L. (1990). *The cement of the universe: A study of causation* (5. Dr.). Oxford: Clarendon Press.

Magee, B. (1974). *Popper*. London: Woburn Press.

Maltby, J. R. (2006). Fasting from midnight – the history behind the dogma. *Best Practice & Research Clinical Anaesthesiology*, *20*(3), 363–378. https://doi.org/10.1016/j.bpa.2006.02.001

Marchal, B., van Belle, S., van Olmen, J., Hoerée, T., & Kegels, G. (2012). Is realist evaluation keeping its promise? A review of published empirical studies in the field of health systems research. *Evaluation*, *18*(2), 192–212. https://doi.org/10.1177/1356389012442444

Marchal, B., Westhorp, G., Wong, G., Van Belle, S., Greenhalgh, T., Kegels, G., & Pawson, R. (2013). Realist RCTs of complex interventions – An oxymoron. *Social Science & Medicine*, *94*, 124–128. https://doi.org/10.1016/j.socscimed.2013.06.025

Marcus Thygeson, N., Solberg, L. I., Asche, S. E., Fontaine, P., Gregory Pawlson, L., & Scholle, S. H. (2012a). Using Fuzzy Set Qualitative Comparative Analysis (fs/QCA) to Explore the Relationship between Medical "Homeness" and Quality. *Health Services Research*, *47*(1pt1), 22–45. https://doi.org/10.1111/j.1475-6773.2011.01303.x

Marx, A., & Dusa, A. (2011). Crisp-Set Qualitative Comparative Analysis (csQCA), Contradictions and Consistency Benchmarks for Model Specification. *Methodological Innovations Online*, *6*(2), 103–148. https://doi.org/10.4256/mio.2010.0037

Matheson, A., Walton, M., Gray, R., Lindberg, K., Shanthakumar, M., Fyfe, C., … Borman, B. (2018). Evaluating a community-based public health intervention using a complex systems approach. *Journal of Public Health*, *40*(3), 606–613. https://doi.org/10.1093/pubmed/fdx117

May, C. (2006). A rational model for assessing and evaluating complex interventions in health care. *BMC Health Services Research*, *6*(1). https://doi.org/10.1186/1472-6963-6-86

May, C. (2013). Towards a general theory of implementation. *Implementation Science*, *8*(1). https://doi.org/10.1186/1748-5908-8-18

May, C. R., Johnson, M., & Finch, T. (2016). Implementation, context and complexity. *Implementation Science*, *11*(1). https://doi.org/10.1186/s13012-016-0506-3

May, C. R., Mair, F. S., Dowrick, C. F., & Finch, T. L. (2007). Process evaluation for complex interventions in primary care: Understanding trials using the normalization process model. *BMC Family Practice*, *8*(1). https://doi.org/10.1186/1471-2296-8-42

May, C. R., Mair, F., Finch, T., MacFarlane, A., Dowrick, C., Treweek, S., … Montori, V. M. (2009). Development of a theory of implementation and integration: Normalization Process Theory. *Implementation Science*, *4*(1). https://doi.org/10.1186/1748-5908-4-29

Mays, N., Pope, C., & Popay, J. (2005). Systematically reviewing qualitative and quantitative evidence to inform management and policymaking in the health field. *Journal of Health Services Research & Policy*, *10*(1_suppl), 6–20. https://doi.org/10.1258/1355819054308576

McCormack, B., Kitson, A., Harvey, G., Rycroft-Malone, J., Titchen, A., & Seers, K. (2002). Getting evidence into practice: The meaning of `context'. *Journal of Advanced Nursing*, *38*(1), 94–104. https://doi.org/10.1046/j.1365-2648.2002.02150.x

McCormack, B., Rycroft-Malone, J., DeCorby, K., Hutchinson, A. M., Bucknall, T., Kent, B., … Wilson, V. (2013). A realist review of interventions and strategies to promote evidence-informed healthcare: A focus on change agency. *Implementation Science*, *8*(1), 107. https://doi.org/10.1186/1748-5908-8-107

McIntyre, S. A., Francis, J. J., Gould, N. J., & Lorencatto, F. (2018). The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: A systematic review. *Translational Behavioral Medicine*. https://doi.org/10.1093/tbm/iby110

McKillop, A., Shaw, J., Sheridan, N., Gray, C. S., Carswell, P., Wodchis, W. P., … Kenealy, T. (2017). Understanding the Attributes of Implementation Frameworks to Guide the Implementation of a Model of Community-based Integrated Health Care for Older Adults with Complex Chronic Conditions: A Metanarrative Review. *International Journal of Integrated Care*, *17*(2), 10. https://doi.org/10.5334/ijic.2516

McLean, S., Booth, A., Gee, M., Salway, S., Cobb, M., Bhanbhro, S., & Nancarrow, S. (2016). Appointment reminder systems are effective but not optimal: Results of a systematic review and evidence synthesis employing realist principles. *Patient Preference and Adherence*, 479. https://doi.org/10.2147/PPA.S93046

McWilliam, J., Brown, J., Sanders, M. R., & Jones, L. (2016). The Triple P Implementation Framework: The Role of Purveyors in the Implementation and Sustainability of Evidence-Based Programs. *Prevention Science*, *17*(5), 636–645. https://doi.org/10.1007/s11121-016-0661-4

Meijers, J. M. M., Janssen, M. A. P., Cummings, G. G., Wallin, L., Estabrooks, C. A., & Y.G. Halfens, R. (2006). Assessing the relationships between contextual factors and research utilization in nursing: Systematic literature review. *Journal of Advanced Nursing*, *55*(5), 622–635. https://doi.org/10.1111/j.1365-2648.2006.03954.x

Melendez-Torres, G. J., Sutcliffe, K., Burchett, H. E. D., Rees, R., Richardson, M., & Thomas, J. (2018). Weight management programmes: Re-analysis of a systematic review to identify pathways to effectiveness. *Health Expectations*, *21*(3), 574–584. https://doi.org/10.1111/hex.12667

Melinder, K. A., & Andersson, R. (2001). The impact of structural factors on the injury rate in different European countries. *European Journal of Public Health*, *11*(3), 301–308. https://doi.org/10.1093/eurpub/11.3.301

Mendel, P., Chen, E. K., Green, H. D., Armstrong, C., Timbie, J. W., Kress, A. M., … Kahn, K. L. (2018). Pathways to Medical Home Recognition: A Qualitative Comparative Analysis of the PCMH Transformation Process. *Health Services Research*, *53*(4), 2523–2546. https://doi.org/10.1111/1475-6773.12803

Michie, S., Johnston, M., Abraham, C., Lawton, R., Parker, D., Walker, A., & 'Psychological Theory' Group. (2005). Making psychological theory useful for implementing evidence-based practice: A consensus approach. *Quality & Safety in Health Care*, *14*(1), 26–33. https://doi.org/10.1136/qshc.2004.011155

Michie, S, Johnston, M. (2017). Optimising the value of the evidence generated in implementation science: The use of ontologies to address the challenges. *Implementation Science*, *12*(1). https://doi.org/10.1186/s13012-017-0660-2

Michie, Susan, & West, M. A. (2004). Managing people and performance: An evidence-based framework applied to health service organizations: Managing people and performance: an evidence-based framework applied to health service organizations. *International Journal of Management Reviews*, *5–6*(2), 91–111. https://doi.org/10.1111/j.1460-8545.2004.00098.x

Michie, Susan, van Stralen, M. M., & West, R. (2011). The behaviour change wheel: A new method for characterising and designing behaviour change interventions. *Implementation Science*, *6*(1). https://doi.org/10.1186/1748-5908-6-42

Miles, A. (2009). Evidence-based medicine: Requiescat in pace? A commentary on Djulbegovic, B., Guyatt, G. H. & Ashcroft, R. E. (2009) *Cancer Control*, 16, 158-168: Commentary on Djulbegovic *et al*. (2009). *Journal of Evaluation in Clinical Practice*, *15*(6), 924–929. https://doi.org/10.1111/j.1365-2753.2009.01349.x

Misangyi, V. F., Greckhamer, T., Furnari, S., Fiss, P. C., Crilly, D., & Aguilera, R. (2017). Embracing Causal Complexity: The Emergence of a Neo-Configurational Perspective. *Journal of Management*, *43*(1), 255–282. https://doi.org/10.1177/0149206316679252

Moore, G. F., Audrey, S., Barker, M., Bond, L., Bonell, C., Hardeman, W., … Baird, J. (2015). Process evaluation of complex interventions: Medical Research Council guidance. *BMJ*, *350*(mar19 6), h1258–h1258. https://doi.org/10.1136/bmj.h1258

Moore, G., Audrey, S., Barker, M., Bond, L., Bonell, C., Cooper, C., … others. (2014). *Process evaluation in complex public health intervention studies: The need for guidance*. BMJ Publishing Group Ltd.

Moore, Jennifer E., Titler, M. G., Kane Low, L., Dalton, V. K., & Sampselle, C. M. (2015). Transforming Patient-Centered Care: Development of the Evidence Informed Decision Making through Engagement Model. *Women's Health Issues*, *25*(3), 276–282. https://doi.org/10.1016/j.whi.2015.02.002

Moore, Julia E., Mascarenhas, A., Bain, J., & Straus, S. E. (2017). Developing a comprehensive definition of sustainability. *Implementation Science*, *12*(1), 110. https://doi.org/10.1186/s13012-017-0637-1

Morin, E. (2006). Restricted complexity, general complexity. In C. Gershenson, D. Aerts, & B. Edmunds (Eds.), *Worldviews, Science and Us: Philosophy and Complexity*. Retrieved from http://cogprints.org/5217/

Morris, Z. S., Wooding, S., & Grant, J. (2011). The answer is 17 years, what is the question: Understanding time lags in translational research. *Journal of the Royal Society of Medicine*, *104*(12), 510–520. https://doi.org/10.1258/jrsm.2011.110180

Moullin, J. C., Sabater-Hernández, D., Fernandez-Llimos, F., & Benrimoj, S. I. (2015). A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework. *Health Research Policy and Systems*, *13*(1), 16. https://doi.org/10.1186/s12961-015-0005-z

Mowles, C. (2014). Complex, but not quite complex enough: The turn to the complexity sciences in evaluation scholarship. *Evaluation*, *20*(2), 160–175. https://doi.org/10.1177/1356389014527885

Munck, G. L. (2016). Assessing Set-Theoretic Comparative Methods: A Tool for Qualitative Comparativists? *Comparative Political Studies*, *49*(6), 775–780. https://doi.org/10.1177/0010414015626453

Murdoch, J. (2016). Process evaluation for complex interventions in health services research: Analysing context, text trajectories and disruptions. *BMC Health Services Research*, *16*(1). https://doi.org/10.1186/s12913-016-1651-8

Murray, E., Treweek, S., Pope, C., MacFarlane, A., Ballini, L., Dowrick, C., … May, C. (2010). Normalisation process theory: A framework for developing, evaluating and implementing complex interventions. *BMC Medicine*, *8*(1). https://doi.org/10.1186/1741-7015-8-63

National Institute of Innovation and Improvement. (2005). Improvement Leaders' Guide—Improvement Knowledge and Skills—General Improvement skills [Guidance]. Retrieved from https://www.england.nhs.uk/improvement-hub/publication/improvement-leaders-guide-improvement-knowledge-and-skills-general-improvement-skills/

Neyens, J. C., van Haastregt, J. C., Dijcks, B. P., Martens, M., van den Heuvel, W. J., de Witte, L. P., & Schols, J. M. (2011). Effectiveness and Implementation Aspects of Interventions for Preventing Falls in Elderly People in Long-Term Care Facilities: A Systematic Review of RCTs. *Journal of the American Medical Directors Association*, *12*(6), 410–425. https://doi.org/10.1016/j.jamda.2010.07.018

Nilsen, P. (2015). Making sense of implementation theories, models and frameworks. *Implementation Science*, *10*(1). https://doi.org/10.1186/s13012-015-0242-0

Nilsen, P., Roback, K., Broström, A., & Ellström, P.-E. (2012). Creatures of habit: Accounting for the role of habit in implementation research on clinical behaviour change. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-53

Noyes, J., Booth, A., Moore, G., Flemming, K., Tunçalp, Ö., & Shakibazadeh, E. (2019). Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: Clarifying the purposes, designs and outlining some methods. *BMJ Global Health*, *4*(Suppl 1), e000893. https://doi.org/10.1136/bmjgh-2018-000893

Noyes, J., Hendry, M., Booth, A., Chandler, J., Lewin, S., Glenton, C., & Garside, R. (2016). Current use was established and Cochrane guidance on selection of social theories for systematic reviews of complex interventions was developed. *Journal of Clinical Epidemiology*, *75*, 78–92. https://doi.org/10.1016/j.jclinepi.2015.12.009

Noyes, J., Hendry, M., Lewin, S., Glenton, C., Chandler, J., & Rashidian, A. (2016). Qualitative "trial-sibling" studies and "unrelated" qualitative studies contributed to complex intervention reviews. *Journal of Clinical Epidemiology*, *74*, 133–143. https://doi.org/10.1016/j.jclinepi.2016.01.009

Noyes, J., Popay, J., Pearson, A., Hannes, K., & Booth, A. (2008). Qualitative Research and Cochrane Reviews. In J. P. Higgins & S. Green (Eds.), *Cochrane Handbook for Systematic Reviews of Interventions* (pp. 571–591). https://doi.org/10.1002/9780470712184.ch20

O'Mara-Eves, A., Brunton, G., McDaid, D., Oliver, S., Kavanagh, J., Jamal, F., … Thomas, J. (2013). *Community engagement to reduce inequalities in health: A systematic review, meta-analysis and economic analysis*. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK262817/

Oakley, A., Strange, V., Bonell, C., Allen, E., & Stephenson, J. (2006). Process evaluation in randomised controlled trials of complex interventions. *BMJ*, *332*(7538), 413–416. https://doi.org/10.1136/bmj.332.7538.413

Olsen, W. (2014). Comment: The Usefulness of QCA under Realist Assumptions. *Sociological Methodology*, *44*(1), 101–107. https://doi.org/10.1177/0081175014542080

Olsen, W. (2018). Social Statistics Using Strategic Structuralism and Pluralism. In M. Nagatsu & A. Ruzzene (Eds.), *Frontiers of Social Science*. United Kingdom: Bloomsbury Publishing PLC.

Olsen, W. (2019). Bridging to Action Requires Mixed Methods, Not Only Randomised Control Trials. *The European Journal of Development Research*, *31*(2), 139–162. https://doi.org/10.1057/s41287-019-00201-x

Paley, J. (2010). The Appropriation of Complexity Theory in Health Care. *Journal of Health Services Research & Policy*, *15*(1), 59–61. https://doi.org/10.1258/jhsrp.2009.009072

Pantoja, T., Opiyo, N., Lewin, S., Paulsen, E., Ciapponi, A., Wiysonge, C. S., … Oxman, A. D. (2017). Implementation strategies for health systems in low-income countries: An overview of systematic reviews. *Cochrane Database of Systematic Reviews*. https://doi.org/10.1002/14651858.CD011086.pub2

Parrott, J. S., Henry, B., Thompson, K. L., Ziegler, J., & Handu, D. (2018). Managing Complexity in Evidence Analysis: A Worked Example in Pediatric Weight Management. *Journal of the Academy of Nutrition and Dietetics*, *118*(8), 1526-1542.e3. https://doi.org/10.1016/j.jand.2018.01.016

Pawson, R. (2006). *Evidence-based policy: A realist perspective*. London; Thousand Oaks, Calif: SAGE.

Pawson, R., & Tilley, N. (1997). *Realistic evaluation*. London; Thousand Oaks, Calif: Sage.

Paykani, T., Rafiey, H., & Sajjadi, H. (2018). A fuzzy set qualitative comparative analysis of 131 countries: Which configuration of the structural conditions can explain health better? *International Journal for Equity in Health*, *17*(1), 10. https://doi.org/10.1186/s12939-018-0724-1

Pearl, J. (2000). *Causality: Models, reasoning, and inference*. Cambridge, U.K.; New York: Cambridge University Press.

Pearl, J. (2018). Challenging the hegemony of randomized controlled trials: A commentary on Deaton and Cartwright. *Social Science & Medicine*, *210*, 60–62. https://doi.org/10.1016/j.socscimed.2018.04.024

Peters, D. T. J. M., Verweij, S., Grêaux, K., Stronks, K., & Harting, J. (2017). Conditions for addressing environmental determinants of health behavior in intersectoral policy networks: A fuzzy set Qualitative Comparative Analysis. *Social Science & Medicine*, *195*, 34–41. https://doi.org/10.1016/j.socscimed.2017.08.036

Petticrew, M., & Roberts, H. (2006). *Systematic reviews in the social sciences: A practical guide*. Malden, MA; Oxford: Blackwell Pub.

Petticrew, M., Knai, C., Thomas, J., Rehfuess, E. A., Noyes, J., Gerhardus, A., … McGill, E. (2019). Implications of a complexity perspective for systematic reviews and guideline development in health decision making. *BMJ Global Health*, *4*(Suppl 1), e000899. https://doi.org/10.1136/bmjgh-2018-000899

Pfadenhauer, L. M., Gerhardus, A., Mozygemba, K., Lysdahl, K. B., Booth, A., Hofmann, B., … Rehfuess, E. (2017). Making sense of complexity in context and implementation: The Context and Implementation of Complex Interventions (CICI) framework. *Implementation Science*, *12*(1). https://doi.org/10.1186/s13012-017-0552-5

Pinnock, H., Barwick, M., Carpenter, C. R., Eldridge, S., Grandes, G., Griffiths, C. J., … Taylor, S. J. C. (2017). Standards for Reporting Implementation Studies (StaRI) Statement. *BMJ*, i6795. https://doi.org/10.1136/bmj.i6795

Plsek, P. E., & Greenhalgh, T. (2001). Complexity science: The challenge of complexity in health care. *BMJ*, *323*(7313), 625–628. https://doi.org/10.1136/bmj.323.7313.625

Plsek, P. E., & Wilson, T. (2001). Complexity science: Complexity, leadership, and management in healthcare organisations. *BMJ*, *323*(7315), 746–749. https://doi.org/10.1136/bmj.323.7315.746

Polit, D. F., & Beck, C. T. (2010). Generalization in quantitative and qualitative research: Myths and strategies. *International Journal of Nursing Studies*, *47*(11), 1451–1458. https://doi.org/10.1016/j.ijnurstu.2010.06.004

Pound, P., & Campbell, R. (2015). Exploring the feasibility of theory synthesis: A worked example in the field of health related risk-taking. *Social Science & Medicine*, *124*, 57–65. https://doi.org/10.1016/j.socscimed.2014.11.029

Prigogine, I. (1997). *The end of certainty: Time, chaos, and the new laws of nature* (1st Free Press ed). New York: Free Press.

Ragin, C. C. (2010) Reflections on Casing and case orientated research. In Byrne, D. S., & Ragin, C. C. (Eds.). (2009). *The SAGE handbook of case-based methods*. Los Angeles; London: SAGE.

Ragin, C. C. (2008). Redesigning social inquiry: Fuzzy sets and beyond. Chicago: University of Chicago Press.

Ragin, C. C. (2000). *Fuzzy-set social science*. Chicago: University of Chicago Press.

Ragin, C. C. (1987). *The comparative method: Moving beyond qualitative and quantitative strategies* (1. paperback print., [Nachdr.]). Berkeley, Calif.: Univ. of California Press.

Ramsay, C. R., Thomas, R. E., Croal, B. L., Grimshaw, J. M., & Eccles, M. P. (2010). Using the theory of planned behaviour as a process evaluation tool in randomised trials of knowledge translation strategies: A case study from UK primary care. *Implementation Science*, *5*(1). https://doi.org/10.1186/1748-5908-5-71

Reason, J. (2000). Human error: Models and management. *BMJ*, *320*(7237), 768–770. https://doi.org/10.1136/bmj.320.7237.768

Reed, J. E., & Card, A. J. (2016). The problem with Plan-Do-Study-Act cycles. *BMJ Quality & Safety*, *25*(3), 147–152. https://doi.org/10.1136/bmjqs-2015-005076

Reed, J. E., Green, S., & Howe, C. (2019). Translating evidence in complex systems: A comparative review of implementation and improvement frameworks. *International Journal for Quality in Health Care*, *31*(3), 173–182. https://doi.org/10.1093/intqhc/mzy158

Reed, J. E., Howe, C., Doyle, C., & Bell, D. (2018). Simple rules for evidence translation in complex systems: A qualitative study. *BMC Medicine*, *16*(1). https://doi.org/10.1186/s12916-018-1076-9

Reed, M., & Harvey, D. L. (1992). The New Science and the Old: Complexity and Realism in the Social Sciences. *Journal for the Theory of Social Behaviour*, *22*(4), 353–380. https://doi.org/10.1111/j.1468-5914.1992.tb00224.x

Reiss, J. (2009). Causation in the Social Sciences: Evidence, Inference, and Purpose. *Philosophy of the Social Sciences*, *39*(1), 20–40. https://doi.org/10.1177/0048393108328150

Richter, A., von Thiele Schwarz, U., Lornudd, C., Lundmark, R., Mosson, R., & Hasson, H. (2015). iLead—A transformational leadership intervention to train healthcare managers' implementation leadership. *Implementation Science*, *11*(1), 108. https://doi.org/10.1186/s13012-016-0475-6

Rihoux, B., & Ragin, C. C. (Eds.). (2009). *Configurational comparative methods: Qualitative comparative analysis (QCA) and related techniques*. Thousand Oaks: Sage.

Ritchie, J., & Lewis, J. (Eds.). (2003). *Qualitative research practice: A guide for social science students and researchers* (Repr). Los Angeles, Calif.: SAGE.

Ritchie, J. and Spencer, L. (1994) Qualitative Data Analysis for Applied Policy Research. In: Bryman, A. and Burgess, B., Eds., Analyzing Qualitative Data, Routledge, London.
http://dx.doi.org/10.4324/9780203413081_chapter_9

Roberts, S. (2013). Preoperative Fasting: A Clinical Audit. *Journal of Perioperative Practice*, *23*(1–2), 11–16. https://doi.org/10.1177/1750458913023001-201

Rohwer, A., Pfadenhauer, L., Burns, J., Brereton, L., Gerhardus, A., Booth, A., … Rehfuess, E. (2017). Series: Clinical Epidemiology in South Africa. Paper 3: Logic models help make sense of complexity in systematic reviews and health technology assessments. *Journal of Clinical Epidemiology*, *83*, 37–47. https://doi.org/10.1016/j.jclinepi.2016.06.012

Rothman, K. J., & Greenland, S. (2005). Causation and Causal Inference in Epidemiology. *American Journal of Public Health*, *95*(S1), S144–S150. https://doi.org/10.2105/AJPH.2004.059204

Russo, F., & Williamson, J. (2007). Interpreting Causality in the Health Sciences. *International Studies in the Philosophy of Science*, *21*(2), 157–170. https://doi.org/10.1080/02698590701498084

Rycroft-Malone, J. (2002). Ingredients for change: Revisiting a conceptual framework. *Quality and Safety in Health Care*, *11*(2), 174–180. https://doi.org/10.1136/qhc.11.2.174

Rycroft-Malone, J., Chandler, J., & Hawkes, C. (2009). Peri-operative Implementation Study Evaluation (POISE): Evidence, Context, Facilitation—Data synthesis report. Royal College of Nursing Research Institute.

Rycroft-Malone, Jo, & Bucknall, T. (Eds.). (2010). *Models and frameworks for implementing evidence-based practice: Linking evidence to action* (1st ed). Chichester, West Sussex: Wiley-Blackwell.

Rycroft-Malone, Jo, Burton, C. R., Wilkinson, J., Harvey, G., McCormack, B., Baker, R., … Williams, L. (2015). Collective action for implementation: A realist evaluation of organisational collaboration in healthcare. *Implementation Science*, *11*(1). https://doi.org/10.1186/s13012-016-0380-z

Rycroft-Malone, Jo, Harvey, G., Seers, K., Kitson, A., McCormack, B., & Titchen, A. (2004). An exploration of the factors that influence the implementation of evidence into practice. *Journal of Clinical Nursing*, *13*(8), 913–924. https://doi.org/10.1111/j.1365-2702.2004.01007.x

Rycroft-Malone, Jo, Seers, K., Chandler, J., Hawkes, C. A., Crichton, N., Allen, C., … Strunin, L. (2013). The role of evidence, context, and facilitation in an implementation trial: Implications for the development of the PARIHS framework. *Implementation Science*, *8*(1). https://doi.org/10.1186/1748-5908-8-28

Rycroft-Malone, Jo, Seers, K., Eldh, A. C., Cox, K., Crichton, N., Harvey, G., … Wallin, L. (2018). A realist process evaluation within the Facilitating Implementation of Research Evidence

(FIRE) cluster randomised controlled international trial: An exemplar. *Implementation Science*, *13*(1). https://doi.org/10.1186/s13012-018-0811-0

Rycroft-Malone, Jo. (2007). Theory and Knowledge Translation: Setting Some Coordinates. *Nursing Research*, *56*(Supplement 1), S78–S85. https://doi.org/10.1097/01.NNR.0000280631.48407.9b

Saltkjel, T., Holm Ingelsrud, M., Dahl, E., & Halvorsen, K. (2017). A fuzzy set approach to economic crisis, austerity and public health. Part II: How are configurations of crisis and austerity related to changes in population health across Europe? *Scandinavian Journal of Public Health*, *45*(18_suppl), 48–55. https://doi.org/10.1177/1403494817707125

Sandelowski, M., Voils, C. I., Leeman, J., & Crandell, J. L. (2012). Mapping the Mixed Methods–Mixed Research Synthesis Terrain. *Journal of Mixed Methods Research*, *6*(4), 317–331. https://doi.org/10.1177/1558689811427913

Sarkies, M. N., Bowles, K.-A., Skinner, E. H., Haas, R., Lane, H., & Haines, T. P. (2017). The effectiveness of research implementation strategies for promoting evidence-informed policy and management decisions in healthcare: A systematic review. *Implementation Science*, *12*(1), 132. https://doi.org/10.1186/s13012-017-0662-0

Sawyer, R. K. (2005). *Social emergence: Societies as complex systems*. Cambridge; New York: Cambridge University Press.

Scaccia, J. P., Cook, B. S., Lamont, A., Wandersman, A., Castellow, J., Katz, J., & Beidas, R. S. (2015). A practical implementation science heuristic for organizational readiness: R = MC ^{2}: A Heuristic for Organizational Readiness. *Journal of Community Psychology*, *43*(4), 484–501. https://doi.org/10.1002/jcop.21698

Schneider, C. Q. (2016). Real Differences and Overlooked Similarities: Set-Methods in Comparative Perspective. *Comparative Political Studies*, *49*(6), 781–792. https://doi.org/10.1177/0010414015626454

Schneider, C. Q., & Rohlfing, I. (2013). Combining QCA and Process Tracing in Set-Theoretic Multi-Method Research. *Sociological Methods & Research*, *42*(4), 559–597. https://doi.org/10.1177/0049124113481341

Schneider, C. Q., & Wagemann, C. (2012). *Set-theoretic methods for the social sciences: A guide to qualitative comparative analysis*. Cambridge: Cambridge University Press.

Schoville, R. R., & Titler, M. G. (2015). Guiding Healthcare Technology Implementation: A New Integrated Technology Implementation Model. *CIN: Computers, Informatics, Nursing*, *33*(3), 99–107. https://doi.org/10.1097/CIN.0000000000000130

Searle, J. R. (1996). *The construction of social reality*. London: Penguin.

Seers, K., Rycroft-Malone, J., Cox, K., Crichton, N., Edwards, R. T., Eldh, A. C., … Wallin, L. (2018). Facilitating Implementation of Research Evidence (FIRE): An international cluster randomised controlled trial to evaluate two models of facilitation informed by the Promoting

Action on Research Implementation in Health Services (PARIHS) framework. *Implementation Science*, *13*(1). https://doi.org/10.1186/s13012-018-0831-9

Sheehy, T. J., & Thygeson, N. M. (2014). Physician organization care management capabilities associated with effective inpatient utilization management: A fuzzy set qualitative comparative analysis. *BMC Health Services Research*, *14*(1), 582. https://doi.org/10.1186/s12913-014-0582-5

Shiell, A., Hawe, P., & Gold, L. (2008). Complex interventions or complex systems? Implications for health economic evaluation. *BMJ*, *336*(7656), 1281–1283. https://doi.org/10.1136/bmj.39569.510521.AD

Simpson, K. M., Porter, K., McConnell, E. S., Colón-Emeric, C., Daily, K. A., Stalzer, A., & Anderson, R. A. (2013). Tool for evaluating research implementation challenges: A sense-making protocol for addressing implementation challenges in complex research settings. *Implementation Science*, *8*(1), 2. https://doi.org/10.1186/1748-5908-8-2

Smith, R. D., & Petticrew, M. (2010). Public health evaluation in the twenty-first century: Time to see the wood as well as the trees. *Journal of Public Health*, *32*(1), 2–7. https://doi.org/10.1093/pubmed/fdp122

Squires, J. E., Graham, I. D., Hutchinson, A. M., Michie, S., Francis, J. J., Sales, A., … Grimshaw, J. M. (2015). Identifying the domains of context important to implementation science: A study protocol. *Implementation Science*, *10*(1). https://doi.org/10.1186/s13012-015-0325-y

Stacey, R. D. (2003). *Strategic management and organisational dynamics: The challenge of complexity* (4th ed). Harlow, England; New York: Prentice Hall/Financial Times.

Stetler, C. B., McQueen, L., Demakis, J., & Mittman, B. S. (2008). An organizational framework and strategic implementation for system-level change to enhance research-based practice: QUERI Series. *Implementation Science*, *3*(1). https://doi.org/10.1186/1748-5908-3-30

Sturmberg, J. P. (Ed.). (2016). *The Value of Systems and Complexity Sciences for Healthcare*. https://doi.org/10.1007/978-3-319-26221-5

Sturmberg, J. P., & Martin, C. M. (2009). Complexity and health—Yesterday’s traditions, tomorrow’s future. *Journal of Evaluation in Clinical Practice*, *15*(3), 543–548. https://doi.org/10.1111/j.1365-2753.2009.01163.x

Sturmberg, J. P., Martin, C. M., & Katerndahl, D. A. (2017). It is complicated! – Misunderstanding the complexities of ‘complex’. *Journal of Evaluation in Clinical Practice*, *23*(2), 426–429. https://doi.org/10.1111/jep.12579

Sutcliffe, K., Richardson, M., Rees, R., Burchett, H., Melendez-Torres, G. J., Stansfield, C., & Thomas, J. (2016). What are the critical features of successful Tier 2 weight management programmes for adults? A systematic review to identify the programme characteristics, and combinations of characteristics, that are associated with successful weight loss. London:

EPPI-Centre, Social Science Research Unit, UCL Institute of Education, University College London.

Suzuki, E., & VanderWeele, T. J. (2018). Mechanisms and uncertainty in randomized controlled trials: A commentary on Deaton and Cartwright. *Social Science & Medicine*, *210*, 83–85. https://doi.org/10.1016/j.socscimed.2018.04.023

Sweeney, K., & Griffiths, F. (2002). *Complexity and healthcare: An introduction*. Abingdon, U.K.: Radcliffe Medical Press.

Thiem, A. (2015). Using Qualitative Comparative Analysis for Identifying Causal Chains in Configurational Data: A Methodological Commentary on Baumgartner and Epple (2014). *Sociological Methods & Research*, *44*(4), 723–736. https://doi.org/10.1177/0049124115589032

Thiem, A., & Baumgartner, M. (2016). Back to Square One: A Reply to Munck, Paine, and Schneider. *Comparative Political Studies*, *49*(6), 801–806. https://doi.org/10.1177/0010414015626455

Thomann, E., & Maggetti, M. (2017). Designing research with qualitative comparative analysis (QCA): Approaches, Challenges, and Tools. *Sociological Methods & Research*, 004912411772970. https://doi.org/10.1177/0049124117729700

Thomas, J., O'Mara-Eves, A., & Brunton, G. (2014). Using qualitative comparative analysis (QCA) in systematic reviews of complex interventions: A worked example. *Systematic Reviews*, *3*(1), 67. https://doi.org/10.1186/2046-4053-3-67

Thomas, J., Petticrew, M., Noyes, J., Chandler, J., Rehfuess, E. A., Tugwell, P., & Welch, V. (2019). Intervention complexity. In *Cochrane Handbook for Systematic Reviews of Interventions* (2nd ed., pp. 451–478). The Cochrane Collaboration and John Wiley and Sons Ltd.

Thompson, D. S., Fazio, X., Kustra, E., Patrick, L., & Stanley, D. (2016). Scoping review of complexity theory in health services research. *BMC Health Services Research*, *16*(1). https://doi.org/10.1186/s12913-016-1343-4

Thygeson, N. M., Wang, M., O'Riordan, D., & Pantilat, S. Z. (2016). Self-Reported California Hospital Palliative Care Program Composition, Certification, and Staffing Level Are Associated with Lower End-of-Life Medicare Utilization. *Journal of Palliative Medicine*, *19*(12), 1281–1287. https://doi.org/10.1089/jpm.2016.0176

Trebble, T. M., Hansi, N., Hydes, T., Smith, M. A., & Baker, M. (2010). Process mapping the patient journey: An introduction. *BMJ*, *341*(aug13 1), c4078–c4078. https://doi.org/10.1136/bmj.c4078

Trenholm, S., & Ferlie, E. (2013). Using complexity theory to analyse the organisational response to resurgent tuberculosis across London. *Social Science & Medicine*, *93*, 229–237. https://doi.org/10.1016/j.socscimed.2012.08.001

Turner, J. H. (1991). Developing Cumulative and Practical Knowledge through Metatheorizing. *Sociological Perspectives*, *34*(3), 249–268. https://doi.org/10.2307/1389510

Turner, J. R., & Baker, R. M. (2019). Complexity Theory: An Overview with Potential Applications for the Social Sciences. *Systems*, *7*(1), 4. https://doi.org/10.3390/systems7010004

van Dijk, L. J., Nelen, W. L., D'Hooghe, T. M., Dunselman, G. A., Hermens, R. P., Bergh, C., … Kremer, J. A. (2011). The European Society of Human Reproduction and Embryology guideline for the diagnosis and treatment of endometriosis: An electronic guideline implementability appraisal. *Implementation Science*, *6*(1). https://doi.org/10.1186/1748-5908-6-7

Vandenbroucke, J. P. (2008). Observational Research, Randomised Trials, and Two Views of Medical Science. *PLoS Medicine*, *5*(3), e67. https://doi.org/10.1371/journal.pmed.0050067

Vandenbroucke, J. P., von Elm, E., Altman, D. G., Gøtzsche, P. C., Mulrow, C. D., Pocock, S. J., … Egger, M. (2007). Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): Explanation and Elaboration. *Epidemiology*, *18*(6), 805–835. https://doi.org/10.1097/EDE.0b013e3181577511

Veríssimo, J. M. C. (2018). Usage intensity of mobile medical apps: A tale of two methods. *Journal of Business Research*, *89*, 442–447. https://doi.org/10.1016/j.jbusres.2017.12.026

Vickery, K. D., Shippee, N. D., Guzman-Corrales, L. M., Cain, C., Turcotte Manser, S., Walton, T., … Linzer, M. (2018). Changes in Quality of Life Among Enrollees in Hennepin Health: A Medicaid Expansion ACO. *Medical Care Research and Review*, 107755871876945. https://doi.org/10.1177/1077558718769457

Vos, L., Chalmers, S. E., Dückers, M. L., Groenewegen, P. P., Wagner, C., & van Merode, G. G. (2011). Towards an organisation-wide process-oriented organisation of care: A literature review. *Implementation Science*, *6*(1). https://doi.org/10.1186/1748-5908-6-8

Wagemann, C., & Schneider, C. Q. (2010). Standards of Good Practice in Qualitative Comparative Analysis (QCA) and Fuzzy-Sets. *Comparative Sociology*, 397–418.

Warren, J., Wistow, J., & Bambra, C. (2014). Applying qualitative comparative analysis (QCA) in public health: A case study of a health improvement service for long-term incapacity benefit recipients. *Journal of Public Health*, *36*(1), 126–133. https://doi.org/10.1093/pubmed/fdt047

Weiner, B. J., Jacobs, S. R., Minasian, L. M., & Good, M. J. (2012). Organizational Designs for Achieving High Treatment Trial Enrollment: A Fuzzy-Set Analysis of the Community Clinical Oncology Program. *Journal of Oncology Practice*, *8*(5), 287–291. https://doi.org/10.1200/JOP.2011.000507

Westby, M., & Royal College of Nursing. (2005). *Perioperative fasting in adults and children: An RCN guideline for the multidisciplinary team*. London: Royal College of Nursing.

Westhorp, G. (2012). Using complexity-consistent theory for evaluating complex systems. *Evaluation*, *18*(4), 405–420. https://doi.org/10.1177/1356389012460963

Williams, L., Rycroft-Malone, J., & Burton, C. R. (2017). Bringing critical realism to nursing practice: Roy Bhaskar's contribution. *Nursing Philosophy*, *18*(2), e12130. https://doi.org/10.1111/nup.12130

Williamson, J. (2010). *Probabilistic Theories* (Vol. 1; H. Beebee, C. Hitchcock, & P. Menzies, Eds.). https://doi.org/10.1093/oxfordhb/9780199279739.003.0010

Wilson, T., Holt, T., & Greenhalgh, T. (2001). Complexity science: Complexity and clinical care. *BMJ*, *323*(7314), 685–688. https://doi.org/10.1136/bmj.323.7314.685

Wiltsey Stirman, S., Kimberly, J., Cook, N., Calloway, A., Castro, F., & Charns, M. (2012). The sustainability of new programs and innovations: A review of the empirical literature and recommendations for future research. *Implementation Science*, *7*(1). https://doi.org/10.1186/1748-5908-7-17

Wong, G., Greenhalgh, T., Westhorp, G., Buckingham, J., & Pawson, R. (2013). RAMESES publication standards: Realist syntheses. *BMC Medicine*, *11*(1), 21. https://doi.org/10.1186/1741-7015-11-21

Worrall, J. (1989). Structural Realism: The Best of Both Worlds? *Dialectica*, *43*(1–2), 99–124. https://doi.org/10.1111/j.1746-8361.1989.tb00933.x

Worrall, J. (2011). Causality in medicine: Getting back to the Hill top. *Preventive Medicine*, *53*(4–5), 235–238. https://doi.org/10.1016/j.ypmed.2011.08.009

Glossary

Term	Definition
Asymmetry	From a set theoretic perspective causal conditions that obtain an outcome do not mirror those conditions not obtaining the outcome. The presence and absence of an outcome are therefore two different states.
Case	A well-defined real subject with boundaries, description and characteristics defined for study purposes and is not an instance of an event or a set of variables.
Case orientated	A study orientated to examining cases comparatively to explore patterns of commonality and difference.
Causation	A philosophical term that explains an event preceded by another event which brought it about and requires further explanation of how the first event connected to bring about the second event.
Causal complexity	Defined in set theory as the states of equifinality, conjunctural causation and asymmetric causation.
Complex causality	The opposite of simple cause and effect relationships, where the scope of interest is to understand multiple causal relationships that are non-linear in their causal arrangement.
Complex Adaptive System	An organism (biological) or organisation (social) that exhibits self-organising adaptive behaviour to evolve into increasing higher level emergent structures with their own properties.
Complex Physical Systems	Refers to natural physical systems or simple rules in game theory that create increasing complex yet deterministic structures without emergent properties.
Complex realism	A form of realism that incorporates explicitly the view that social reality is composed of nested complex adaptive systems.
Complexity Theory	A transdisciplinary theory that describes and explains the behaviour of reality across the spectrum of physical, natural, biological and social systems through the process of higher order emergence and increasing organisational complexity.
Condition	A factor implied to connect a cause to an effect (outcome).
Configuration	Factors or conditions that combine in a series of different arrangements.
Context	Defines the wider field that surrounds the focus of interest in the research setting.
Counterfactual	Another possible explanation to explain study output or findings.
Critical realist	A form of realism that supports a view of reality that exists beyond the human mind but also a reality interpreted by the human mind.
Ecosystem	An integrated structure that organises internally to maintain and evolve its self-regulating state.
Emergence	A process by which structure evolves from a set of lower order structures to create a higher order structure with different properties and description.
Pluralism	Describes separate sets of entities or theories as having a meaningful connection rather than opposing positions, but equally retaining their individual identity.
Equifinality	Different condition configurations can obtain the outcome.
Equilibrium	A system reaches an optimal steady state.
Explanatory inference	Once an effect is known an explanation is inferred.
Feedback loops	Transfer of information between agents in a dynamic system. This feedback mechanism can affect the recipient agent by either amplifying or dampening the effect from that agent. This feedback is

	repetitive in dynamic systems and allows regulation of systems aspects and evolution to higher order states.
Framework	A structure of integrated concepts that describe and explain phenomenon.
General complexity	The general behaviour of a complex system, the collective phenomenon rather than the behaviour of individual elements.
Generalisability	The capacity to make general statements to a wider population based on specific statements drawn from findings gained in a specific time and place.
Generative mechanism	Underlying all levels of organisation there are mechanisms, real entities, that have power or capacity to generate the seen organisation. Mechanisms may remain unseen but can be inferred by observation of the effect.
Implementation	The deliberate process of enabling an act, event or intervention to occur within a setting or context.
Logical remainder	Combinations of conditions in a truth table of a set cases where all cells are empty because no cases were observed.
Mechanism	To obtain an effect causes need a mechanism. Described as the power, capacity or propensity that follows through a process of steps transmits cause to effect. Multiple mechanisms may coalesce to enable the cause to produce the effect.
Microsystem	Describes a level of organisational abstraction within a system under observation, a lower level description as oppose to the higher level or macrosystem.
Model	Provides an abstracted representation of a real entity describing the relationships between elements of that entity.
Multiple conjunctural causation	Multiple factors or conditions come together to bring about an effect.
Necessity	Whenever an outcome or effect is present a specific condition or factor is always also present. The outcome does not occur in the absence of the condition.
Net effects	Determines the quantitative assessment of individual independent variables producing an aggregated result (e.g. a mean).
Nonlinearity	The opposite state to simple and direct, linear cause and effect relationships whereby the input is not proportional to the output and the result not predictable.
Phase transition	A transformation point in system activity based on a small parameter (input) change that leads to a disproportionately larger effect and system change.
Power capacity and propensity	For causes to obtain their effects other factors are needed to enable the transmission, process or mechanism to result in the effect.
Pre-operative fasting	The preparation for a medical procedure that requires a general anaesthetic and needs the patient to starve to have an empty stomach to ensure stomach contents are not inhaled into the lungs.
Probability	Probability theory identifies how likely a cause leads to an effect. The increase or decrease of the cause will raise or lower the likelihood of the effect occurrence.
Process	A sequence of events that leads from one event to another and maybe causal, when the series of steps or mechanisms can trace the sequence from a causal agent to an effect.
Process evaluation	A separate study, typically undertaken alongside RCTs, of event sequences and mechanisms that occur between intervention and outcome.
Qualitative Comparative Analysis	A set theoretic method that analyses complex causation in social systems and assumes heterogeneity between cases studied with a common outcome. Outcome is achieved by different combinations of conditions.

Randomised controlled trials	An experimental method that compares 2 or more groups to establish whether if all things are equal an intervention makes a difference or not.
Regularity	Repetition of the same cause and effect event. Deterministic physical laws follow rules that ensure the cause will result in the effect, a constant conjunction. These constant conjunctions are assumed based on observations of their repetition.
Restricted complexity	Complex structures derived from repeating rules within physical deterministic systems that do not adapt and generate higher order levels of organisation.
Self-organisation	The notion of a state that brings about order and evolution within natural and social systems through internal organisation responding to external environments There is no external control.
Set relation	Set theory does not count events but determines whether a ‘thing’ belongs to one set or another, or several sets. Sets are based on superset and subset relations.
Sufficiency	Whenever, a condition is observed an outcome is observed, indicating the condition is sufficient to derive the outcome, however the outcome might also be observed in the presence of other conditions.
Theory	Describes, explains or predicts phenomena providing an interconnected narrative that structures and explains the reality of that phenomena.
Truth table	The principle analytical stage in Qualitative Comparative Analysis that presents, based on the number of conditions included, all possible logical combinations of those conditions whether cases in the study cover those combinations or not.
Variable orientated	A study that is orientated to variables across homogenous cases capturing the frequency of variable occurrence to establish a pattern of effect across a population of cases.

Appendices

Appendix 2.1

An overview of typical QCA procedures and steps undertaken

Analytic step	**Elaboration**	**QCA Stage**
Formulate question or hypotheses of interest	Based on qualitative and theoretical concepts which are of interest ensuring that substantive knowledge is obtainable to ‘qualify’ and calibrate the conditions and outcome. QCA strategy chosen.	*Pre QCA*
Define cases of interest relevant to an outcome of interest	Case specification is key to the underlying assumptions and inference typical within social contexts. Cases are selected on the basis that they exhibit the outcome or not. Variability across cases is an important criterion. Cases can be individuals, treatments, services, units or pathways of care.	*Pre-define*
Specify outcome of interest	The relation between the cases and the outcome (whether present or not) needs to be well articulated and grounded in theory and observation.	*Pre-define*
Identify conditions of interest	Provide well-articulated hypotheses as to why a given factor is understood to be part of the causal pathway. Further consideration is required as to the number of factors that can be managed in a single Truth table and so procedures will be required to limit causal condition sets by clustering, for example. This is typically between 4-7 conditions but will relate to the ratio of cases to conditions to ensure a level of diversity.	*Pre-define*

Consider QCA approach and plan (strategies that might be required)	Set out methods to be applied such as calibration, thresholds for consistency and coverage, type of QCA method and software.	*Analysis plan*
Identify source data required	The data source that will provide the knowledge or evidence to support the specification of cases, outcome (positive and negative for comparison) and the causally relevant conditions.	*Data collection and development of raw data matrix*
Raw data table (un-calibrated data)	Different data sources from each case will inform the cases membership in the condition and outcome sets. This data may either be numerical or textual.	*Preparation of data for calibration*
Calibrate (fuzzy/dichotomisation) conditions and outcome and put into a data matrix – that is assigning set membership scores	Raw data will need to be transformed into the language of sets, whether present or absent (crisp set) or by degree (fuzzy set). Discerning where the cut points are between fully in and fully out of the set, that is deciding on the thresholds. These should be grounded in theoretical or substantive knowledge and reasoning provided. Processes for fuzzy sets see Schneider and Wagemann, (2012), page 41.	*Transformation of raw data into set membership relations*
Truth tables for both negative and positive outcomes separately	Based on the number of cases and the logical possible configurations build a table that allocates cases to configurations. Positive and negative outcomes should be separate tables (or separated within the same table).	*QCA (use of software)* *Analysis*
Visual (Venn, 2x2 table, XY plot)	Use one or more graphical presentation of the data.	*View and examine data*
Necessity assessment	Identifying necessary conditions	*Analysis*
Sufficiency assessment	Identifying sufficient conditions	*Analysis*
Contradictions	Same configurations leading to positive and negative outcome. Identify strategies to manage these contradictions – e.g.	*Analysis*

	redefine conditions – add or remove a condition or combine etc. These need to be addressed before minimization procedures	
Logical remainders	A logical remainder is when logically possible configurations of conditions do not have any observed cases. Consider the plausibility or not of any logical remainders and the problem of limited diversity and how this might impact on the field of study. Use remainders for counter factual analysis. Strategies: -consider issue of the ratio of cases to conditions. -Increase cases and reduce conditions. -Assess plausibility of the logical remainders and their relevance and remove before minimisation.	*Analysis*
Robustness checks	Conduct checks on the data and set acceptance levels for:	*Evaluation of results*
	Coverage measure	
	Consistency measure	
Note limitations	Cases to conditions ratio	
Refinements/iterations	Undertake adjustments and redo analysis as required	
If appropriate conduct minimization procedure	Use software to establish the 'primary implicants' that arise in Boolean reduction of the across case minimization conducted in the software.	*Synthesis moment*
Solutions: Complex, intermediate and parsimonious	Decide on appropriateness of results and report the solutions using the language of sets and Boolean algebra.	*Interpret solutions within the study theoretical perspective and back to the original cases and the context the study e.g. large N or substantive case study design.*

Interpretation of conjunctual relationships	Based on theoretical premise of the study and substantive knowledge of cases deduce whether the results 'make sense', providing a justification.	*Interpretation and justification*

Appendix 3.1

Leading scholars in the interdisciplinary field of Complex Systems from the 1950's to 2013

(Adapted from *Map of the Complexity Sciences* http://www.art-sciencefactory.com/complexity-map_feb09.html, accessed 8 December 2013 with author permission)

Timeline	Scholars	Field of science	Trajectory of the development of the field of Complex Systems				
1950's	von Bertalanffy L	Systems theory founder & systems biology	**Systems Science**			**Cybernetics**	
	Weiner N	Cybernetics mathematics					
	Ashby WR	Cybernetics of mind					
	von Neumann J	Cybernetics/artificial intelligence/connectionism					
	Poincaré H Weaver W	Algebraic Topology Organised and disorganised complexity/machine translation	Complex systems theory	Dynamical systems theory	General systems theory		Artificial Intelligence and Cognitive Science
1970's	Odium HT Prigogine I	Ecological systems theory Dissipative Structure, time and matter	Self organisation		Ecological Systems Theory		Connectionism
	Bak P	Self organised Criticality	Autopoiesis and Adaptation		Complex living systems	2nd order cybernetics	Cellular Automata
	Haken H Mandlebrot B	Self organisation and synergetics Founder Fractal Geometry	Complex Adaptive Systems	Fractal Geometry			
1980's	Yorke J Feigenbaum M Lorenz E	Coined mathematical term 'Chaos' Chaos constant Lorenz attractor/butterfly effect		Chaos Theory			
	Crutchfield J Kolomogorov A Gell-mann M	Computational dynamics/Nonlinear dynamics Complexity & information Effective Complexity		Non linear systems		Systems science engineering	Computational Complexity Theory
	Holland J	Genetic Algorthims					Genetic Algorithms
	Langton C	Founder Artificial Life					Artificial Life
	Lotfi Zadeh & Kosko B	Fuzzy Logic					Fuzzy logic
	Kauffman S	Biology/Evolution Autonomous agents					
1990's	Goldstein J Sawyer K	Emergence in complex systems Social Emergence Theory	Emergence			Social Systems Theory	Agent based modelling

	Luhmann N Axelrod R Schelling T	Sociology Evolution of co-operation Micromotives and macrobehaviour					
	Deneubourg J-L	Swarm intelligence, non-linear dynamics. Biological computation	Swarm behaviour			Socio Cybernetics	Data mining
	Cilliers P Moran E Stacey R	Philosophy of complexity Philosophy of complexity Strategic Management & Organisational dynamics	Scaling and self similarity		Managerial Organisational Complexity	Complexity Theory/ Epistemology	
2000's	Gilbert N Byrne D Bar-Yam Y	Computational Social systems Complex realism Dynamics of Complex Systems	Dynamics in systems	Physics and computation in complex systems	Systems Biology	Social Complexity	
	Mitchell M Hofstadter D	Computation in complex systems Cognitive Science			Computational Biology	Economics and Behavioural dynamics	Computational modelling
	Watts D	Small worlds	Network Science			E-science	
	Ragin C	Causal Complexity/Fuzzy set theory					Case based modelling
	Barabasi A-L Wallerstein I Castellini B	Scale free networks World Systems Theory Sociology and Complexity Science tool kit	Global Network Society	Multi-level Complex Systems		Visual Complexity	
	Börner K	Visual complexity and data science				Data Science	
	Urry J	Globalisation and social mobility's	Spatial Graphical complexity				

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Appendix 3.2

Summary of selected social complexity theorists' perspectives (adapted from Chandler et al 2016)

Author, year and field	Brief summary of perspective
Kernick 2004 Organizational – healthcare specific	Kernick describes 'CAS' as a system that acquires information from its environment creating a schema from which it acts upon the external environment continually adapting to engage with the environment. Current scientific methods are limited in their ability to predict and control human organisational behaviour and that a model of a network of co-evolving elements inter-dependently connected resulting in changes to all elements from changes to one is applied as a metaphor to health organizations. This challenge's common assumptions in some organizational theory that organisations function in linear, reductionist, deterministic ways allowing for political and managerial control. Kernick sees Complexity Theory as providing a complementary approach to current scientific methods and that it provides an explanatory model of metaphor, for example from the machine to the ecosystem. He refutes the use of mathematical approaches used to describe complex physical systems (CPS) and that descriptions should be qualitative. He illustrates this in later work and introduces the view that researchers in their research can use the theory as a lens (Kernick and Mitchell 2010).
Cilliers 1998 Philosophy	Cilliers a philosopher, adopts complexity theory to explain complex developments such as the development of language, neural networks, the cognitive processes of the brain. He adopts a connectionist rather than a representational model and argues for the application of Complexity theory to social systems, whereby individuals interact and are therefore constituted by their relationships with each other. Non-linearity, asymmetry, power and competition are the components that ensure continuance of human systems. He espouses a 'distributed' model of a complex social human-based system not one that is rule based. Connectionism, in this context, refers to a method of information processing like that of the function of the brain. Information is distributed across neurons rather than localised to one specific neurone or cluster of neurones. Cilliers' view is one of adaption rather deterministic algorithms to describe systems. Humans use language

	collectively to organise themselves. The system history is important. It leaves traces distributed throughout the system but cannot be re-constructed.
Byrne 1998, 2013 **Social sciences**	Byrne presents in his early work a view of obtaining outcomes in the social world that are not determined by single causes but by multiple causes that usually interact in a non-additive way because the combined effect maybe more or less than the sum of the separate effects because other factors may inhibit or amplify those effects (through feedback). He conjectures with a complex system you will have a range of outcomes (alternatives) these will be limited and therefore will allow some potential for prediction and identification of this array of possibilities and therefore, researchers should consider the possible trajectories a system might travel.
Castellani and Hafferty 2010 **Sociology and complexity science**	Castellani and Hafferty, first develop an historical account of Complexity Theory across a diverse of set of disciplines (See table from paper [appendix or in thesis). Their Social Complexity Theory provides a set of tools and as a scientific framework allows system specific descriptions. The framework seeks to describe the field of relations operating within the system, the structure of sub systems, system dynamics and they include CPS terminology of attractor *clusters,* that guide the trajectory of the system*. S*ocial practice is defined as "any pattern of social organisation that emerges out of, and allows for, the intersection of symbolic interaction and social agency" p.38.
Stacey 2004 **Organizational – strategic management**	Stacey applies Complexity Theory principles to the understanding of the organisational dynamics and processes of change in organisations to address strategies for change in managing organisations. He challenges organisational management assumptions of individual autonomy, organisation wide intention and control as central to understanding organisations. Stacey from a process perspective proposes a theory focusing on the self-organizing and constructive nature of conversation and their attributed power relations in organizations. Conversation in organisations is described as a complex responsive process of relating between individuals and groups of individuals overtime evolves the organisation. Strategy in organisations is continually emerging through conversing in relationships and so Stacey does not see an organisation as having distinct 'inside', 'outside', 'whole' or 'boundary'.

Sawyer 2005 **Social theory**	Sawyer presents his emergence paradigm for the existence of social entities as an evolutionary development from the individual to the macro social structures and explains complex social phenomena as the "successive symbolic interactions among autonomous individuals that result in the emergence of collective phenomena" (Sawyer, 2005 p. 22). Social science is split between those that study macro-level social systems for example societies and those that study the micro-level social dynamics of individuals. Sawyer takes the complexity principle of emergence to explain the development of macro social phenomena from the micro social phenomena and how macro social properties emerge from communicative interactions among thousands of independent human agents. Human societies are unique complex systems because of the complex properties of human language and the '*sophistication of human symbolic communication'.* In other words, the meaning and interpretation humans give the observed world. Sawyer asks, '*How do social facts have causal powers independent of individual agency*?'

Appendix 3.3

Refinement of original process evaluation findings into overarching topic areas for theory application

This table summarises the study process findings used to illustrate theory application. This shows how the overarching topic areas were derived for the purpose of simplifying the findings to apply the core concepts.

Study key findings extracted from the process evaluation[44]	Summary of key points	Overarching topic area for theory application
Limiting factors identified were: • The UK NHS Trust capacity at senior and local level to conduct the trial and the capacity of individual members of NHS staff identified to collect data. • Resources available for practice change e.g. staff time, workloads, support structures. • Level of priority and importance given to the guideline recommendations. Tweaking fasting times was not a surgical department priority. • The final outcome of a significant decrease in mean fasting duration at six surgical departments plus one with a significant increase in mean fasting time and the additional variability in other surgical departments with non-significant results suggested a multi-factorial nature to the implementation of the fasting guideline. • The size and scale of the implementation task could be a factor, the weight of the operation to manage surgical operations in the light of 18-week targets applied pressure on theatres to maximise efficiency. • The variable capacity, commitment and interpretation of interventions at local implementation level compromised the implementation fidelity of the strategies across surgical departments. • The limits of the study interventions prescribed (guideline strategies) to facilitate guideline implementation. However, the level of 'activity' observed suggested the importance of 'doing something' to change practice that was locally relevant indicating adaptation and innovation. • Practice was observed embedded into most surgical departments' policy but not actually into practice. • Prescriptive interventions did not function well, hence intervention fidelity was compromised • Degree of motivation/push in the system	Factors hindering evaluation and implementation of guideline recommendations were based on the individual surgical department's capacity to conduct the trial and support the intervention implementation strategies. This was illustrated by the limited resources available, lack of priority given and the motivation and push in the system. Prescriptive top down interventions were limited in the face of local adaptations and innovation activities. Fasting as a context specific embedded practice illustrated by variability across sites suggested attention to multiple factors was required.	The impact of system factors to limit (inhibit) evaluation and implementation of the proposed guideline recommendations
Communication as a factor was identified by: The process of changing fasting practice required the co-operation and communicative feedback looping of nurses (pre-admission, ward, theatre, recovery), doctors (surgeons and anaesthetists), managers and patients. Central to	Strong credible evidence accepted by key professionals was however inhibited by risk averse attitudes to protect the 'operation list management	The impact of communication and interaction between individuals, teams, departments and professions on the

this involved the management of the operating list. Fasting practice could not be separated from this process. • The guideline had provided strong credible evidence for shortening current fasting practice. Nurses and anaesthetists had overall accepted the evidence base of the guideline. • Some anaesthetists showed conservative and risk aversive attitudes with the priority given to managing the operation lists. • Influential mediators of practice change observed were inter-professional issues (e.g. tense communications) and a lack of clarity for the authority and responsibility for local fasting decisions (e.g. when operating lists changed). • Rule based and rigidity of structures e.g. levels of hierarchy, formal rules and procedures, committee structures to agree policies etc. Levels of authority, therefore a lack of enabling structures for practice change facilitation. • Individual belief systems, emotional responses (anger and anxiety), power struggles around whose responsibility and authority for fasting practice change. • Poor communication between healthcare professionals at the local level and between departments was identified as a barrier to practice change.	system'. Authority and responsibility for policy development and management of the patient's fast was not clear (at times antagonistic) and was further hindered by rigid procedures. These set the scene for a restricted level of communication required to facilitate practice change.	evaluation and implementation of the proposed guideline recommendations
History as a factor was identified by: • The importance of history in practice change • Although patients are suffering discomfort many would actually rather be cautious and starve longer even though most did not clearly understand why they fasted. It has historically become understood patients fast before operations and the practice is a cornerstone of surgical care. • Reluctance, resistance and caution in response to a push for practice change were observed of many healthcare professional staff, irrespective of the acceptance for the evidence. • The individual starting point of each NHS Trust within fasting practice by the variability of baseline mean fasting times. • Impacts on aspects of practice and service delivery that did not translate into changes to the primary outcome mean duration of fasting in the trial timeframe, however change had begun to be negotiated. • The ability of individuals to change the parameters of an entrenched practice with a long history.	Fasting is the cornerstone of surgical practice with a long history and is so well established that patients fully expect to fast even though many do not clearly understand why. Professionals are resistance to change a well-established practice. Changes observed through the process evaluation did not impact on the primary outcome mean duration of fast, indicating the necessity for 'time' to change entrenched practice.	The impact of the longevity of fasting practice in the face of accepted credible evidence to change the practice

Appendix 3.4

Full definition of simplified social complex adaptive concepts

Summary of the five simplified concepts for Complexity Theory as applied to social systems (adapted from Chandler et al 2016)

CT simplified concept	Abbreviated elaboration
Self-organisation	Self-organisation describes how systems evolve without an 'external controller' and organises from within itself in response to its external environment, making decisions leading to adaptation. Smaller complex systems are nested in larger systems in which they interact and respond to the influence of the behaviour of either the larger or smaller system.
Interaction	Interaction in a complex system is the bidirectional transfer (feedback) of information from one decision-making agent (individual human) to another and represents the inter-play of micro-agency at varying levels within a social system. This interplay of information transfer can be enhanced, suppressed or altered leading to effects on the system. These interactions will be non-linear (asymmetric) and paradoxically, large changes can have a small effect, whereas small changes can have a large effect. In human systems communication through language and behaviour of human individuals is the principle structure of social interactions and organization of social systems. However, human systems have broadened this to include technological interfaces that might be automated.
Emergence	Through interaction and self-organization of the system in response to environmental stimuli and internal requirements to maintain the system, ongoing adaptation results through the characteristic of emergence. The phenomenon of emergence leads to greater system complexity that is not equal to the systems constituent parts. Also, organisation such as social structures and systems result in multiple hierarchical structures. Individuals do not have a complete schema of the 'whole' system for which they are a part system information is 'distributed' among the individuals. The emergent property cannot be dismantled to its constituent parts.
System history	System history maintains although the system continually transforms overtime its origins suggest a 'boundary' within which the system responds, maintaining an adherence to trace 'behaviour's' (Cilliers 1998), such as 'habits'. This could involve in social systems organisational culture as an evolving history that presents a boundary in which the system will behave.
Temporality	Complex systems are always in a constant state of flux between stable and unstable system states, emergence and transformation of the system, with increasing complexity and reactivity through feedback processes overtime, hence the importance of temporality. Systems also have periods of 'stability' and create stable structures. This is logically obvious within social structures. Social systems could follow certain trajectories based on decisions made and are not pre-determined.

Appendix 3.5

Illustration of the 'Organising Principle' using the case of health care acquired infections and handwashing

I use findings and other information provided by two reviews published in the same year that address the problem of hand hygiene compliance to illustrate my conception of an *organising principle*.

One of the most enduring infection control interventions is the simple and cost-effective behavioural intervention of getting healthcare workers to wash their hands. This fundamental practice in healthcare remains an issue within developed, as well as a significant issue, in developing countries. The World Health Organisation's "Cleaner Care is Safer Care" programme makes recommendations to tackle the problem of health care acquired infections (HCAI). The story of hand hygiene has a long history starting with the well-known case of Semmelweis identifying the aetiology of puerperal sepsis in 1847 caused by physicians not washing their hands between visiting the morgue and subsequently performing examinations on pregnant women. Noakes and colleagues (2008) review his data and establish within current epidemiological and statistical approaches his findings remain valid. This is before the role of bacteria had been established and the subsequent pursuit of antisepsis pushed in hospitals by Joseph Lister (Loudon, 2013). See Fig 3.1 below:

> he entered upon his office, though convinced of the truth of the theory of the antiseptic treatment, he by no means felt the confidence in carrying it out which he has since acquired; and if an able man like Mr. Coats, imbued with the principles which I have striven to establish, required some practical initiation into the subject before he could be regarded as trustworthy, still more must such be the case with those who, educated in the old system, and long habituated to its practice, have to unlearn cherished ideas and instinctive habits.

The struggle to change behaviour is revealed in this early era to establish good hand hygiene practice in healthcare and invokes often repeated observations of the problem to change habituated behaviour (Nilson et al 2012). Throughout the years with major developments in the production of guidelines in the 1980's and the introduction of antiseptic alcohol based hand rubs (ABHR) in the early 2000's (WHO, 2009), the issue of establishing and maintaining hand hygiene practices remains a concern A Cochrane Review updated in 2017 assesses the short- and long-term success of strategies to improve compliance to recommendations for hand hygiene, and to determine whether an increase in hand hygiene compliance can reduce rates of HCAI. They identify studies that compare single and multimodal approaches as recommended by the 2009 WHO guidelines and conclude "With the identified variability in certainty of evidence, interventions, and methods, there remains an urgent need to undertake methodologically robust research to explore the effectiveness of multimodal versus simpler interventions to increase hand hygiene compliance, and to identify which components of multimodal interventions or combinations of strategies are most effective in a particular context." (Gould et al p. 2) The particular result for the multimodal approach, Gould and colleagues found: "Multimodal interventions that include all strategies recommended in the WHO guidelines may slightly reduce colonisation rates (one study; 167 centres; low certainty of evidence). It is unclear whether the intervention improves hand hygiene compliance (five studies; 184 centres) or reduces infection (two studies; 16 centres) because the certainty of this evidence is very low. For EBM, this presents an interesting case of a long history for a clearly effective intervention that remains an issue in 2017, although practice has greatly improved since the 1800's. The WHO guidelines are highly detailed and address different country contexts, health settings, etc. but the Cochrane Review indicates that data and studies remain inadequate (high risk of bias) to determine the most effective approach to ensure and maintain this simple effective practice, why?

The Cochrane Review includes both randomised and nonrandomised quantitative designs and multiple interventions to include single and multimodal strategies. For example, the WHO's five moments strategy (WHO, 2009) and single strategies such as cues, education, placement of alcohol-based hand rub (ABHR), all aimed at behavioural change. Outcomes are based on either observed handwashing rates or colonisation rates. Standard Cochrane methods as applied by the Effectiveness of Practice and Organisation of Care Review Group and includes using the GRADE approach and produces 'Summary of findings' tables. A meta summary of qualitative studies on hand hygiene compliance that applied the GRADE-CERQual tool (Lewin 2017) asks also for further investigation, specifically, into healthcare cultures that are perceived as supportive for infection control (Chatfield, 2017). A summary table 3.5.a presents both these reviews, utilising different methodologies:

Table 3.5 Hand hygiene reviews

	Cochrane Review (Gould)	**Qualitative Meta summary (Chatfield)**
Year of publication	2017	2017
No. of included studies	26 studies	36 study reports
Study designs	14 randomised trials, 2 non-randomised trials and 10 interrupted time series designs.	5 letters or conference abstracts and 31 empirical research reports. These included use of mixed methods, specific qualitative approaches e.g. grounded theory and most 27, refer to the type of data collection as the research design (interview or focus groups).
Publication dates of studies	2009-2016 (initiation of WHO Guidance in 2009)	2008-2015 (limited to post 2000 after the introduction of hand sanitisers and ABHRs)
Countries of study origin/settings	South East Asia, Europe, Canada, Australia, Middle East, South America, US. Mixed health care settings	Europe (incl. UK), Canada, US, Central & South America, Africa, Asia, Australia, Middle East. Mixed health care settings
Interventions	Multimodal campaigns (WHO=ABHR, education, reminders, performance feedback	Observation of behaviour and perceptions obtained by interview.

	and managerial support), performance feedback, education, cues, placement of ABHR.	(training, monitoring, supplies and types of products)
Study quality issues	GRADE tool reports certainty of the evidence. Overall, was found to be low or very low, with only certainty of the evidence for placement of ABHR being moderate. Issues arose in this synthesis due to heterogeneity across the PICO and meta-analysis was not conducted. Risk of Bias across included studies contained two or more sources of risk. Multiple design issues in the primary studies are discussed, e.g. introducing interventions at multiple different stages, lack of adequate controls across all study designs and blinding observers.	GRADE-CERQual tool as applied in this reports High, moderate and low confidence findings based on their methodological assessment, relevance, coherence, adequacy resulting in an overall rating of confidence in findings. Most individual studies were relevant most presented moderate to substantial concerns with coherence.
Key findings	Performance feedback may improve compliance (low certainty) and probably slightly reduces infection and colonisation rates (moderate certainty). Education may improve compliance (low certainty). Cues may slightly improve compliance (low certainty of evidence). ABHR close to point of use probably slightly improves compliance (moderate certainty of evidence). Multimodal strategies that either include all or some WHO guidance strategies, or additional strategies either slightly improve compliance (low certainty of evidence). Impact on infection rates ranged from slight to unclear due to low and very low certainty of the evidence.	There is high confidence for the view that there is adequate handwashing training for health care workers. Further training directed towards nonprofessional staff and patients, etc. could potentially help reduce HCAI rates. A moderate confidence finding suggests individuals have different perceptions of clean and dirty and that this is influenced in some cultures by the status of the patient and the need not to offend by washing hands. In addition, lack of time is a factor in busy health care scenarios and inhibits frequent hand hygiene. Low confidence findings not reported here.
Authors' conclusions	Variability across certainty of evidence, interventions and methods indicates methodologically robust research is required to compare multimodal and simpler interventions or combinations that are most effective in particular contexts.	First integrated qualitative review on this topic. Studies presented particular problems with coherence and require greater justification in their methods for design decisions.
Recommendations for practice and future research	WHO guidance is the most comprehensive. The review does not provide sufficient evidence to justify taking actions to improve hand hygiene. For practice, organisations need to evaluate their own results and revise interventions as well as consider their audit approach. Presence of observers improves handwashing frequency	1. Rather than further instructional material facility management needs to demonstrate support for hand hygiene, and where possible improve hand hygiene supplies. 2. Using multiple methods identify optimal hospital cultures and develop methods for their implementation elsewhere.

	and overestimates compliance and needs to be considered. Outcome measures of product uptake and electronic counting do not provide contextual information. Future research studies need to provide adequate controls, blind data collectors, and analysis to group allocation, and better reporting. ITS studies need to include sufficient data collection points pre- and post-intervention.	3. Tracking and reporting needs to be meaningful to HCWs. 4. Use of qualitative approaches that can assess “nuance in perceptions and priorities”. In addition, theorise and interpret findings rather than provide descriptions.

Following the findings of these reviews that overlap although using different methods they provide an up to date overview of a fundamental practice expected in healthcare and given the problem of hospital acquired infections suggest it remains a challenge to instil good hand hygiene behaviour. I took these review findings and re-interpreted them using the core simplified Complexity Theory concepts for social systems, see table below.

CT simplified concept	Elaboration (Chandler et al 2016)	Interpretation of data in Gould and Chadwick reviews
Self-organization	The phenomenon of self-organization is central to the understanding of the behaviour of complex systems. Self-organization means that there is no 'external controller' and that the system organises from within itself in response to its external environment. However, complex systems are open systems and therefore the observer defines the boundaries of any system. Smaller complex systems are nested in larger systems in which they interact and respond to the influence of the behaviour of either the larger or smaller system.	Cultural practices, individual attitudes to cleanliness of themselves, the patient etc. Practices become self-sustaining and therefore seem persistent against interference from outside the system. System priorities are likely to be around managing time and attending to patients and those in direct patient contact will ensure these priorities are met potentially at the sacrifice of certain practices such as hand hygiene.
Interaction	Interaction (feedback) in a complex system is the bidirectional transfer of information from one decision-making agent (individual human) to another. This information can be enhanced, suppressed or altered leading to an impact of this effect overall on the system. These interactions will be non-linear (asymmetric) and paradoxically, large changes can have a small effect, whereas small changes can have a large effect. However, greater interaction creates greater system complexity. The transformative process of human communication and relations (use of language conveying thought processes resulting in behaviour) underlies social interactions and organization of social systems. Furthermore, Johnson (2011) and Mitchell (2009), qualify that this system interaction is incentivised.	System and individual agent behaviour was driven by incentives and priorities at any given moment. If management support is not promoting and managing system components to enable good hygiene practice, then it falls to the single individual to push against the system. Likewise, interventions supporting management enablement of good practice (part of WHO guidance) and a finding in the Meta summary indicates the importance of this factor. Although, evidence for its success is lacking.
Emergence	The self-organization of the system through interaction leads to greater complexity and a primary characteristic referred to as emergence of behaviour or phenomena that is distinguishable from the interactions of individuals. Individuals do not have a complete schema of the 'whole' system for which they are a part. The system collectively functions on the information 'distributed' among the	The emergent system or emergent practice could be "hand washing" the studies indicate it was done, however, the Five Moments Strategy requires more attention by the individual to different contact points. To create a handwashing system that attends to the Five Moments strategy and does not require individual attention (somehow

	individuals. This constant process of feedback, interaction and emergence results in the evolution of the system and its adaptation. The emergent property cannot be dismantled to its constituent parts.	automated). Hence the suggestion for reminders or cues or placement of ABHR. I imagine that the initial surgical scrub in is never missed.
System history	System history refers to system sensitivity to its starting point. The key to system history is that although the system continually transforms overtime its origins suggest a 'boundary' within which the system responds, maintaining an adherence to trace 'behaviour's' (Cilliers 1998), such as 'habits'.	Health care systems are set up to treat and manage the throughput of patients from admission to discharge. Infection is a consequence of transmission of infective agents between patients. Infection control could be seen to compete with the pressure of maintaining the patient system. Efficiencies to move between patients and distractions to be reactive may inhibit the establishment of good hygiene across the health system.
Temporality	Complex systems are always in a constant state of flux between stable and unstable system states, emergence and transformation of the system, with increasing complexity and reactivity through feedback processes overtime, hence the importance of temporality. Systems also have periods of 'stability' and create stable structures. Therefore, observation of the system is temporally located. Complex systems do not reach or maintain a state of equilibrium (fixed point).	Understanding key drivers or organising principles of either the specific system or types of health care system more broadly how they are coping and reacting to different pressures and that this is constant flux is a key point to make. Gould makes the comment that study participants aware of the observer may lead to overestimation of true compliance rates if the observer was not observing. The objective is to build the required behaviour as an adaptive component into the system that becomes automated.

The above studies indicate that we struggle to achieve evidence that the system has changed or responded to a specific intervention. The most obvious observation is the perpetual struggle for those reviewing primary studies of their methodological limitations and the inevitable limits to aggregating heterogeneous data. This may also indicate the constraints of these evidence gathering approaches to understand and intervene and address the problem. Both authors raised the issue of the need for theory to underpin the interventions and expected mechanisms, that was missing in many primary studies. What the re-interpretation seems to indicate is that there are imperatives that override good practice in hand hygiene, the availability of alcohol hand rubs may be providing some effect to ensure good hand hygiene, perhaps they are close to hand and do not require moving towards water and a sink. The reviews remain uncertain in their findings to establish effect of a strategy to ensure hand hygiene compliance. Practice imperative was explored in the QCA study, Chapters 6 and 7.

Appendix 4.1

Current search (2015-2018) – Initial included articles

Lead author, year and title	**Rationale for inclusion in synthesis (N=16)**
Ellen 2017 A knowledge translation **framework** on aging and health (WHO) –	Conducts review and includes five well known frameworks (PARIHS, OMRU, KTA, Dobbins Framework, CFIR and four others, which included SUPPORT tools for evidence informed health policy making (Lavis 2009). This work is seen as comprehensively including components for the current framework result provides model (fig.1 and Table 2) with seven elements with a series of questions for each element. Authors provide a four-step process to apply the framework in practice. Elements are conceptualised and provide framing for 'push', 'pull', 'climate' and may assist synthesis with cross matching with other concepts.
Guerrero 2017 The leadership-climate relationship as a mechanism of the implementation of cultural competence. **Single concept**	Empirical research surveys for views on leadership n=427 employees in 112 addiction treatment programmes in the US. Concepts of transformation leadership and implementation climate intersects with other work. Paper presents hypotheses in which they found support for all three presented and provide theoretical implications.
Sarkies 2017 Effectiveness of research strategies for promoting evidence-informed policy and management decisions in healthcare. **Model**	Systematic Review of research strategies, thematic synthesis conceptualised inter-relating factors perceived to be associated with effective research implementation strategies. New element of establishing the "imperative" for practice change. Presents a model for implementation strategy design.
Greenhalgh 2017 Beyond adoption: A new framework for theorizing and evaluating non-adoption, abandonment and challenges to the scale up, spread and sustainability of health and care technologies. **Framework**	Targeting technological innovations with a focus on scale up, spread and sustainability. Framework developed using Empirical case studies, conduct hermeneutic literature review, conduct synthesis and develop framework. Applied and tested and refined. Table 2 provides domains and questions structured around condition, the technology, value proposition, adopter system and organisation.
McWilliam 2016 The Triple P implementation **framework**	The Triple P (Positive Parenting Program) system focuses on two core principles minimal sufficiency and self-regulation and is taken from the purveyor organisation perspective. Purveyor is defined as individual or group who seek to actively implement a practice or programme with fidelity and good effect. Triple P is an extensively used programme supported by the WHO. It is included because of its underpinning theoretical premise and implicit hypothesis is relevant to the SCAS framework. It reports on several frameworks and models identified in this review and indicates formal evaluation required.

Moore 2015 Evidence informed decision making through engagement **model**.	Utilises the OMRU model reported in Rycroft-Malone & Bucknell modified to include decision making and patient activation and so addresses the gap to focus on engagement in this case women's engagement in decisions for induction of labour as case example. included as articulates the importance of patient engagement a key element in the study data to be used for the QCA to which the SCAS framework will be applied.
Bertram 2015 (based on Fixen 2005 monograph) NIRN Implementation **framework** (Active Implementation Frameworks)	A large programme to support this model developed by its authors in 2005 based on a systematic review covering three decades of implementation studies. Implementation stages similar to EPIS also addresses implementation drivers.
Scaccia 2015 Practical implementation science heuristic for organisational readiness – **Single concept**	Seeks to develop organisational readiness as a construct based on the concept of practical implementation science (Meyers 2012). This links to the Quality Implementation Framework. Authors then describe how this fits' in with ISF excluded below. However, given the importance of the construct it is retained here. Authors are connected through the substance abuse field.
Moore 2017 Developing a comprehensive definition of sustainability **Single concept**	To standardise "Sustainability" for the purpose of effective operationalisation and measurement. Review of reviews to seek broader scope and constructs of sustainability. Nine new constructs emerged from 24 existing definitions identified and were mapped with the author's original three. Conceptualised sustainability, an important aspect to implementation.
Atkins 2017 Theoretical Domains **Framework** (TDF) to investigate implementation problems.	Guidance on use of TDF to investigate implementation problems. 2015 paper integrated theoretical framework that synthesises 128 theoretical constructs from 33 theories judged most relevant to implementation questions was developed using consensus techniques. Table 1 provides 14 domains and accompanying constructs 2 versions. Version 2 are: Knowledge, Skills, Social/professional role and identity, beliefs about capabilities, Optimism, Beliefs about consequences, Reinforcement, intentions, Goals, memory attention & decision process, environmental context and resources, social influences, emotion, behavioural regulation. This work needs to connect with COM-B and the Behaviour Wheel.
Dearing (2017) Pathways for best practice diffusion. **Single concept**	Empirical research mapping opinion leaders in a wide organisational network in Canada of long-term care institutions. Concept of "informal advice-seeking networks" is hypothesised as facilitating adoption and implementation of practice.
Aarons (2017, 2015) Leadership and organisational change for implementation (LOCI) (Protocol) *Linked with below* **Single concept**	Protocol to evaluate the Leadership and Organisational for Implementation Tool (LOCI) tool (Arrons et al 2015) for motivational interviewing in 60 substance abuse units in the US. The leadership model presented uses the full range leadership model and implementation leadership and is part of the EPIS framework. Leadership and concepts of leadership (transformational and transactional) are important implementation and the work here is

	part of previous work. LOCI is an implementation strategy involving training for leadership.
Arron (2011) Four phase **model** of Evidence Based Practice implementation in public service sectors: Exploration, Preparation Implementation and Sustainment (EPIS), **framework** *Linked with below and above*	This paper links to work undertaken within the substance abuse field and links with other studies included (LOCI). It seems extensively used in that sector and is advanced into public health more widely. Presents four stages with comprehensive set of domains, https://episframework.com/
Richter (2016) iLead- transformational leadership intervention – Protocol *Linked with above* **Single concept**	Links with Aarons (2011) and EPIS regarding transformational leadership and is a protocol to evaluate an intervention based on this model of leadership.
Kaplan (2012) The **model** for understanding success in quality –identified from a conference abstract.	Using a systematic literature review and consensus approach with the QI experts and identifies 25 contextual factors which are hypothesised to likely influence QI success. Using Google search on MUSIQ one study SR of QI strategies uses the tool as a framework
Pfadenhauer 2017 Context and implementation of complex interventions (CICI) **framework.**	Developed by a scoping review and pragmatic utility concept analysis to advance concepts of context and implementation, along with setting and tested in systematic reviews. Framework developed graphically and provides tools for its implementation seeks to simplify and structure complexity in order to advance understanding of whether and how interventions work. Authors provide definitions for context and implementation, useful for the synthesis. Worked example compared with CFIR and PARIHS frameworks

Appendix 4.2

Current search (2015-2018) – Initial excluded articles

Reference	Reason for exclusion (N=9)
Scaling-out evidence-based interventions to new populations or new health care delivery systems – Aarons 2017	Discusses the concept of scaling out for applying interventions beyond their scope in either a different delivery system or different population. Useful background but beyond scope of implementation covered here.
Integrated technology implementation model – Schoville 2015	This article refers to authors review of 51 theories (not reported) for technological research and implementation science. Theories translated into models with implementation strategies attached were utilised with the most widely used to conceptualise the ITI model. Authors integrate technological adoption with implementation science in their model which is undergoing testing. Overlaps with another novel more recent technological review Greenhalgh. Preference is given to that one based on approach. It provides a richer theoretical premise with more detailed description based on case studies of innovations of the type this paper also covers within healthcare.
Evidence informed decision making through engagement model- Moore 2015	Utilises the OMRU model reported in RM & Bucknell modified to include decision making and patient activation and so addresses the gap to focus on engagement in this case women's engagement in decisions for induction of labour as case example. included as articulates the importance of patient engagement a key element in the study data to be used for the QCA to which the SCAS framework will be applied.
Interactive Systems Framework (Moullin review) reference link paper 2008.	The framework is developed specifically as a heuristic to manage the implementation of prevention within the field of child maltreatment and youth violence to bridge the implementation gap and is an extension to the IOM prevention research cycle. Fig 2 does not provide any new or novel approach for consideration in this synthesis. And seems very prevention specific.
Hitting the moving target framework Højberg 2018	An implementation framework developed for sustainable working environment to optimise implementation of workplace improve initiatives. Interviews, workshops, and email survey methods were used to develop model. Resulted in 11 practice-based implementation components clustered into four overall domains. They counter the PDSA model and propose a whole of organisation approach. The model is seen as bridge between CFIR for large scale implementation project and is more appropriate when addressing "everyday work routines" and described as sector specific. Table 2 presents a checklist within domains. Given authors see a strong relationship with CFIR adding this content to synthesis did not seem necessary.

Complex innovation implementation framework (modification) Helfrich 2007 original work Scheck Maclearney 2016	Original (Helfrich 2007) not picked up as a key paper but is utilised to inform other work (Moullin). This article informs the addition of working with unanticipated outcomes or barriers to implementation within the framework most notably external factors. Identifying barriers is very common approach within implementation science. The revised model indicates challenges for each of the framework components as feedback on an implementation study. Did not provide enough conceptual information for the synthesis here. Very descriptive in approach.
Iowa model of EBP – revisions and validation	Revision of the Iowa model through literature search for evaluations of model, user feedback through survey and live work groups. Results in major changes to model with expansion to piloting, implementation, patient engagement and sustaining change. Based on planned action process (working as a group or team, is a process and requires evaluation of implementation), Rogers diffusion theory, and a development from the Quality Assurance model. For use at point of care by clinicians. Widespread usage since in 1994 (Titler 1994, 2001, 2009, 2010). Tool provides triggers and is set out as a flowchart and decision model. Although utilising prior theories it does not propose conceptual or theoretical approaches for synthesis.
Multi-level Implementation framework (Protocol) Chuang 2015	The MIF is a conceptual model developed specifically for identifying factors affecting implementation of multilevel, multisector interventions, for example, obesity prevention and control initiatives that utilise a social ecological approach. Model is informed by theoretical constructs from previous research from the Interactive Systems Framework, the organizational model of innovation implementation, and the Consolidated Framework for Implementation Research. Overlaps and builds on other models and is a demonstration that might produce new content.
Replicating effective programs Framework Killborne 2007 (picked up in Moullin)	Describes a four-stage development programme in figure 1 with 2 pre-implementation, implementation and maintenance and evolution stages. It is based on action anthropology, where a neutral party mediates interaction and exchange between two cultures: research and practice. In addition, diffusion of innovation and Social Learning Theory. This work comes from the US Centers for Disease Control and Prevention and targets intervention implementation in community-based organisations. Focus is on the development of the intervention package (for widespread dissemination) and meets the prescriptive process category. It is highly detailed and specific to its field.

Appendix 4.3

References used to identify pre-2015 implementation frameworks, models and theories

	Rycroft Malone & Bucknell 2010	Nilsen 2015 (Review)	Moulin 2015 (Review)	McKillop 2017 (Review)
Description and aim of reference	Book sets out to address the limits in Evidence based practice resources attending to implementation issues and provides the reader with a resource that reports on several internationally accepted approaches aiding decision making about their use in implementation efforts.	Nilsen provides a narrative review of theories, models and frameworks applied in the research field.	This review was identified by subsequent searches and sought to develop a “generic implementation framework”	This meta-narrative review was identified by subsequent search. Authors set out to conduct a meta-narrative review to understand the attributes of relevant implementation frameworks to address what are the key dimensions and gaps in existing frameworks relevant to the implementation of person-focused community based integrated primary health care for older adults with multi-morbidities.
Search and inclusion criteria	Selection for inclusion: Recognised internationally and published in international journals, subject to evaluation and testing, transferable across different settings, sample includes cross section of settings, include well established and newer models and frameworks, authors willing	Selection for inclusion: Selective literature review included 6 textbooks including RM & Bucknell 2010 that provided an overview of implementation research and implementation. Other five were: Nutley 2007, Greenhalgh 2005, Grol 2005, Straus 2009, and Brownson 2012. Overview papers identified were	Conducts a broad systematic search with a clearly specified search strategy to identify implementation frameworks of innovations in healthcare from 2004 to May 2013. Reviewed titles and abstracts from Implementation Science. Inclusion and exclusion criteria specified: Implementation, Framework, Innovation in	Selection inclusion: Systematic reviews (a review of reviews). Three phase approach: seminal works, frameworks developed from reviews and iterative snowballing through citation searches and finally checked by specialist librarian (medline, Pubmed, CINHAL and cochrane Library between 2003-16) to pick up anything

	Rycroft Malone & Bucknell 2010	Nilsen 2015 (Review)	Moulin 2015 (Review)	McKillop 2017 (Review)
	to submit details of model on a standard template.	Estabrooks 2006, Sales 2006, Graham & Tetroe 2007, Mitchell 2010, Flottorp 2013, Meyers 2012, Tabak 2012. Implementation Science established 2006) was searched using "theory", "model" and "framework".	healthcare – exclude single domains, single studies, QI, fields of implementation science or knowledge translation, educational, patient care models, implementation of a culture.	missed. Exclusions specified e.g. areas specific to aspects of care not relevant to community-based health care.
Models included	Stetler model Ottawa Model of Research Use (OMRU) Promoting Action on Research Implementation in Health Services (PARIHS) framework Iowa model of evidence-based practice Advancing Research and Clinical practice through close Collaboration (ARCC) model Dobbins' dissemination and use of research evidence for policy and practice framework Joanna Briggs Institute model Knowledge to Action framework	Table 1 provides the following examples: *Process models*: Huberman 1994, Landry 2001, Davies 2007, Majdzadeh 2008, CIHR 2014, Wilson 2011 (K2A), Stetler Model, Stetler 2010, ACE star model of transformation Stevens 2013, Knowledge To Action model Graham 2006, Iowa model Titler 1995, 2001, Ottawa Model Logan 1998, 2010, Model by Grol & Wensing 2004, Model by Pronovost 2008, Quality implementation Framework Meyers 2012. *Determinant frameworks*: PARIHS Kitson 1998, Rycroft-Malone 2010, Active Implementation Frameworks Blasé 2012, Holmes 2012, Understanding user-context Framework Jacobson 2003,	Inclusion of 49 frameworks into the systematic analysis. Summary authors found a larger number of descriptive and explanatory frameworks compared to prescriptive and predictive. Present frameworks by type (table 1), framework stage by innovation group (table 2), framework domain by innovation group (table 3). Describe limits and overlaps between frameworks for both different and similar healthcare innovation. Leads to the assumption that multiple frameworks might be needed and the emergence of a composite generic implementation framework fig 2. Key points non-linear, recursive nature of the implementation process, series of steps and stages (process), throughout there are factors, strategies and	These meta narratives across reviews and their sources were synthesised into four themes: 1.Purpose and scope – key point Shaped by nature and complexity context and frameworks attempted represent this complexity for a wide set of interventions. Both effectiveness of intervention and process of implementation were clear purposes. Conclusion: "Careful assessment of the context of implementation from multiple disciplinary perspectives in order to fully appreciate the barriers and enablers." 2.Theory and mechanisms Implementation based on theoretical research improves health outcomes and advances

	Rycroft Malone & Bucknell 2010	Nilsen 2015 (Review)	Moulin 2015 (Review)	McKillop 2017 (Review)
		Conceptual model Greenhalgh 2005, Grol 2005, Cochrane framework 2007, Nutley framework 2007, Ecological framework by Durlak and Dupre 2008, CFIR Damschroder 2009, Gurse 2010, Ferlie & Shortall 2001, Theoretical Domains Framework Michie 2014. *Classic theories*: Theory of diffusion Rogers, social cognitive theories, theories concerning cognitive processes and decision making, social network theories, social capital theories, communities of practice, professional theories, organisational theories *Implementation theories*: Implementation climate Klein 1996, Absorptive Capacity Zahra 2002, organisational readiness Weiner 2009, COM-B Michie 2011, Normalisation Process Theory May 2009. *Evaluation frameworks*: RE_AIM Glasgow 1999, PRECEDE-PROCEED Green 2005, Proctor 2011.	evaluation. Frameworks evaluated can be used based on the attributes of the innovation broadly speaking interventions, guidelines, knowledge, evidence-based practice model or implementation programme. Table of analysis suggested as a decision-support tool. Table includes 17 frameworks or versions of those reported in Nilsen and Rycroft-Malone & Bucknell.	implementation science. A single theory of implementation does not seem feasible given the multitude of influences involved in implementation. Context and the interplay of contextual factors specifically influences theory application. Conclusion: Authors found that the frameworks were particularly weak on person centred care, relationship centred care and culturally safe care. 3.Context, complexity and process There is across framework agreement that the context is shaped by many influencing factors that are in turn impacted by the change process and the outcomes sought. There is reference to complex adaptive systems (Wong 2013) understood to impact on different determinants that “deny confident prediction of outcomes. Levels within the context are addressed within the frameworks from individual to organisation. Management of complexity that involves working with different stakeholders that accounts for

	Rycroft Malone & Bucknell 2010	Nilsen 2015 (Review)	Moulin 2015 (Review)	McKillop 2017 (Review)
				adaption to local contexts as well as engagement in knowledge exchange and participatory relationships. Conclusion: To include a wide variety of stakeholders from decision makers, clinicians and most importantly health consumers in “all phases of planning and delivery of the implementation”. 4.Outcomes and success Focus was on process rather than outcome measures and few include cost. Certain strategies were found to be effective on individual factors e.g. decision support and reminder systems. Again, context was considered important for success and includes taking account of health professional knowledge, motivation, and perceived benefits in designing interventions. However, measuring and determining success is not a one size fits all but needs to be part of any implementation effort. Conclusion: Implementation effort requires careful evaluation from multiple

	Rycroft Malone & Bucknell 2010	Nilsen 2015 (Review)	Moulin 2015 (Review)	McKillop 2017 (Review)
				perspectives of both process and summative outcomes.
Assessment undertaken	Assessed models and frameworks by type (model/framework), purpose (Descriptive, Explanatory, predictive), development (inductive/deductive, empirical or collective insights, evidence for support or refutation) theoretical underpinnings, conceptual clarity, levels, situation (hypothetical or real), function (assess barriers and facilitators, intervention development, Outcome measurement and variable selection, evaluation processes), testable. See Tables 11.3, 11.4.in reference.	Develops five categories of theories, models and frameworks – Table 1 description and examples. A narrative summary of examples found in the sources used is given that takes account of how the frameworks and models were developed through concept building, observation or experience, or by synthesizing empirical research.	Data extraction and assessment (definitions provided by authors in additional table 1 see reference): • orientation: purpose and aim • type of framework: descriptive, prescriptive, explanatory, predictive • implementation stages based on Greenhalgh conceptual framework 2004. • Domains addressed in the framework based on CFIR. • Degree of inclusion of elements: influencing factors, strategies and evaluations + ++ +++ • Depth of analysis of these three elements classified into three levels ^ ^^ ^^^	Reviews identified were appraised independently by three people and discussion to reach consensus on categorisation. Used Greenhalgh's work to pose questions to understand bodies of knowledge or research tradition, key premises, theories and methodological approaches and main findings etc. present five meta-narratives (table 4 see paper). These narratives were based on 34 references that included over 2000 sources which may well overlap between reviews. Article cites Moullin 2017 and the PARIHS framework.

Appendix 4-4

Synthesis of included implementation models, frameworks and theories

Author & Year (& plus related articles viewed)	Title of model, framework or theory	Abstraction of key theoretical assumptions, propositions or underlying theory used (e.g. classical) (how is the underlying function of the construct/concepted expected to operate – its causal assumption)	Key domains, concepts, constructs etc. (separate files for listed domains and figures of models)
Pfadenhauer 2017 **Rohwer 2017**	Context and Implementation of Complex Interventions framework	Based on logic model approaches developed the system-based logic model, describing the system in which the interaction between participants, intervention, and context takes place; and the process-orientated logic model, which displays the processes and causal pathways that lead from the intervention to multiple outcomes. This paper develops the framework and defines implementation, setting and context as dimensions. Table 2 Context: Reflects a set of characteristics and circumstances that consist of active and unique factors, within which the implementation is embedded. As such, context is not a backdrop for implementation, but interacts, influences, modifies and facilitates or constrains the intervention and its implementation. Context is usually considered in relations to an intervention with which it actively interacts. It is an overarching concept, comprising not only a physical location but also roles, interactions and relationships at multiple levels. Implementation: is an actively planned and deliberately initiated effort with the intention to bring a given intervention into policy and practise within a particular setting. These actions are undertaken by agents who either actively promote the use og the intervention or adopt the newly appraised practices. Usually a structured implementation process consisting of specific implementation strategies is used and underpinned by an implementation theory. Setting: refers to the specific physical location in which the intervention is put into practise and interacts with context and implementation. “we refer to a logic model as “. a graphic description of a system. designed to identify important elements and relationships	Context: Geographical Epidemiological Socio-cultural Socio-economic Ethical Political Legal Implementation: Theory Process Strategies Agents Outcomes Setting: Physical location in which intervention is put into practice.

		within that system''. Logic models can help conceptualise complexity by depicting intervention components and the relationships between them, making underlying theories of change and assumptions about causal pathways between the intervention and multiple outcomes explicit, and (3) displaying interactions between the intervention and the system within which it is implemented. A *system-based logic model* (also described as a conceptual framework by some authors) depicts the system in which the interaction between the participants, the intervention, and the context takes place. This perspective is mostly static: although it recognises that interactions between different elements of the model take place, these are not investigated in detail. A *process-orientated logic model* graphically displays the processes and causal pathways that lead from the intervention to its outcomes. Unlike the system-based logic model, it recognises a temporal sequence of events and aims to explain how an intervention exerts its effect. It can also be described as an analytical framework or theory of change. Rohwer	
Summary	Builds core concepts of implementation and context and subsequently setting. Context already exists and implementation is a deliberate action operating upon the context. Context can constrain implementation processes and the implementation object (intervention, programme etc.). Focus on using causal mapping of pathways using logic models either to describe (system/context) and process (sequencing and implementation). Contexts are contingent and unique. Process acknowledges temporal sequencing. Describes interactive feedback processes between the human agents (interaction and feedback), intervention and processes of implementation. Agency is clearly a key component in responding to the act of implementation. As with other models the 'whole system' is considered with regard to the geographical, socio-cultural, socio-economic, ethical, political and legal and its physical setting etc. Agents require multiple theories of change for both their strategies and interventions. Hence a broad and pluralistic account of implementation of interventions specifically those described as complex interventions. **Key concepts:** Whole system, human agency and their interactions relationships, feedback loops, strategies to manage the event, implementation, its processes and object. Includes time. Prior existence of systems involves an historical account for context as well as current status.		

Ellen 2017	Knowledge translation framework on aging and health WHO definition of KT	KT: “the synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of global and local innovation in strengthening health systems and improving people’s health” Climate and context foundational elements Climate: localise manifestation of the overarching culture and is typically less stable over time compared to culture. Includes: political will and desire to use knowledge by knowledge users. Context: characteristics, circumstances and conditions. Social, political e.g. response to trends in aging across societies.	Seven elements; Climate/context for research use, Linkage and exchange efforts Knowledge creation Push efforts Facilitating pull efforts Pull efforts Evaluation efforts Delivered through 4 practical steps(prescriptive) to implement framework.
Summary	Climate and Context are key concepts for knowledge translation in aging. Climate is the local manifestation of the culture, political will and motivation of agents and that these are not stable over time. Strategies involve push, pull and facilitation and provide a prescriptive implementation process. Context refers to the characteristics, circumstances and conditions such as political, social and response to trends in aging. **Key concepts:** looser description of ‘whole system’ that includes global trends with their social and political forces, agency and its motivation. The implementation context as described fluctuates over time. Structured, simplified mechanical process to manage implementation. History and present and future status of system important components.		
Kaplan 2018	Model for understanding success in quality	Contextual factors within micro-systems and related to the QI team are articulated into hypotheses for “QI success implementation of system and process changes and associated outcome improvements) is influenced directly by microsystem and QI team factors which are interdependent and mutually reinforcing.” Identified causal relationships believed to exist among factors included in logic model to explain mechanism of action. Leadership pervasive and important theme throughout. • Support and capacity hypothesised for QI success. • External Incentives and project sponsorship by outside entities encourage organisational QI leadership to support particular QI initiatives. • A triggering event exerts influence by encouraging QI leadership to support a specific improvement focus, motivating staff and alignment of the QI project goals with the organisations overall	25 contextual factors grouped into: External environment Organisation, QI support and capacity, microsystem, QI team and miscellaneous. Provides fig of model

		strategic plan was hypothesised to influence organisational leadership to champion specific QI projects. • Note but do not include in model: moderating relationships e.g. project complexity and scope, interaction effects, feedback and reciprocal relationships	
Summary	Stresses the importance of the micro-system in bringing about change for quality improvement implementation. Refers to both system and process changes for successful outcomes. Team factors important and are interdependent and mutually reinforcing. Clarity regarding mechanism of action required. Key theme that pervades approach is leadership. Refers to the influences of the external environment, support and capacity. Motivation through leadership of a triggering event presents the opportunity as well as aligning QI goals with that of the organisations strategic objectives, in other words to find a fit. Also noted are the moderating factors of project complexity and scope, interaction effects, feedback and reciprocal relationships. **Key concepts:** Bridges a mechanistic view with leadership as the central driver and the moderating effects of the dynamic feedback and interaction.		
Scaccia 2015	$R=MC^2$	Three dynamic core components: Motivation, General Capacity and Innovation Specific Capacity Organisational readiness is dimensional and a matter of degree. The type and degree of deficit can be identified and this can alter overtime and fluctuate as capacity and motivational factors fluctuate. Components are interactive rather than additive	Table 1 factors for motivation Table 2 General capacity Table 3 Innovation Specific Capacity linked to citations.
Summary	Conceptualises organisational readiness as requiring motivation, general capacity and innovation specific capacity. Components are interactive, not additive and are a matter of degree rather than binary. They note that readiness can fluctuate and alter overtime. **Key concept:** Gaining a historical as well as current status of the system to garner ability to embark on implementation activity.		
Dearing 2017	Informal advice seeking relationships	Shows network models of informal support relationships and that physical proximity remains key even when communicating through email etc.	-
Summary	Illustrates the important of informal advice seeking networks and given the digital age the proximity of agents in different settings is an important factor. **Key concepts:** Networking between agents operates better when they are in proximity – here illustrated between organisations rather than within organisations.		
Sarkies 2017	Model of implementation strategy design	Thematic analysis conceptualised factors perceived to be associated with effective strategies and the inter-relationships between these factors. Five broad inter-related themes emerged;	Fig 2

		Establish imperative Personal gain Organisational and societal gain *Build trust* Relationships Leadership authority *Develop shared vision* Stakeholder understanding Influence change Characteristics of organisation *Provide resources to support change* *Employ effective communication strategies* Active change mechanism	
Summary	Conceptualised factors for effective implementation strategies. These were to establish the imperative (personal gain, organisational and societal gain), build trust (relationships and leadership authority), develop a shared vision (stakeholder, influence, characteristics of organisation), provide resources to support change and employ effective communication strategies. **Key concepts:** Imperative for both system and individual involving trust and shared vision with the capacity and resources to respond. Current status or history of organisation required.		
Moore 2017	Definition of sustainability	Identified five key constructs that describe individual and organisational sustainability: "1. After a period of time 2. the program, clinical intervention, and/or implementation strategies continue to be delivered and/or 3. individual behaviour change (i.e. clinician, patient) is maintained, 4. the program and individual behaviour change may evolve or adapt while 5. continuing to produce benefits for individual/systems. "	-
Summary	Defining sustainability as involving over time to embed implementation object and the response by agents of change continues and includes the capacity to adapt and evolve producing ongoing benefits. **Key concept:** To sustain an intervention over time in which it becomes integral to the system through adaption and evolution.		
Greenhalgh 2004	Conceptual model for considering the determinants of diffusion,	Puts forward a "whole systems" approach that assumes interaction between components of the system.	Figure 10.1

	dissemination and sustainability of innovations in health service delivery and organisation.	Dimension of controllability = 'make it happen', 'let it happen', to 'help it happen' Spread and sustainability should focus on the 'would it work here?' framework. Wholes systems approach – • Theory driven • Process- rather than 'package'- orientated • Participatory • Collaborative and co-ordinated • Address using common definitions, measures and tools • Multi-disciplinary and multi method • Meticulously detailed • Ecological	Box 11.1 A whole systems approach to implementation research Core components are: Innovations Adopters and adoption Communication and influence The inner context The outer context Implementation and sustainability Linkage between components.
Greenhalgh 2017	Non-adoption, Abandonment, and Challenges to the Scale up, Spread, and Sustainability of Health and Care technologies	The framework domains are structured in simple, complicated and complex definitions. These are defined as: SIMPLE: straightforward, predictable, few components COMPLICATED: multiple interacting components or issues COMPLEX: dynamic, unpredictable, not easily disaggregated into constituent components. Complexity in multiple domains poses the greatest challenge to scale-up, spread and sustainability. This was shown by: - Technology designed based on Oversimplification of the condition. - Technology design, development did not meet expectations or needs within the care context. - Value proposition of the technology unclear for both developer and recipient. - Resistance of intended users of the technology for justifiable personal and professional reasons. - Organisation were not ready or set up to adopt technology. - External complexity (financial, regulatory, legal, policy) stalled spread of the technology. - Intended technology was unable to adapt over time to its originally objective for its users.	Fig 2, Table 2 Thirteen questions in 6 domains: the condition, the technology, the value proposition, the adopter system (staff, patient, and lay caregiver), the health care organisation (s) (including attention to the work of implementation and adaption), and the wider (institutional and societal) context. It also includes a seventh domain that considers interactions and adaptions overtime.

Summary	2004 – Seminal work on the diffusion of innovations that others use as a basis for their work. Authors investigated a broad set of literature across research traditions beyond the health sector. The final model set out the whole systems approach to diffusing innovations across organisations in health care. The components of inner and outer context and sustainability have undergone further work. The particular features of this work were the collaborative, participatory approach required to ensure adoption and the multiplicity of the organisational dynamics, thus the whole system. This work did include complexity theory as one of the research traditions. 2017 - To integrate innovative technological interventions into health systems requires a realistic appreciation of the technology and the degree of complexity of the innovation itself (and capacity to meet condition (illness, disease) requirements, recipients, organisation as well as the wider institutional and societal influences. Key questions involve why do it (value perceived), do not want to do it (resistance), can't do it (organisation not ready) and becoming unable to use it overtime as it lacks capacity to adapt. Complexity in multiple domains poses the greatest challenge to scale up, spread and sustainability. Complexity is dynamic, unpredictable, not easily disaggregated into constituent components and requires adaptation overtime to be sustained. Systems are layered, diffusion of innovation into system requires theory of change, focus on process, agents need to operate collaboratively to understand whether 'it would work here' **Key concept:** Whole system approach with a need to understand the nature of the intervention and its intended target and how it will intersect within the wider system. Notion of complexity, assemblage and dis-assemblage and adaption overtime shifting the focus onto the acceptability and capacity for the intervention to work where required.		
Richter 2016	iLead-transformational leadership intervention to train healthcare managers' implementation leadership	Testing the combination of transformational leadership with contingent reward (effective subcategory of transactional leadership) and refers to managers being specific, providing feedback, and evaluating the change process. Transformational leadership defines the difference between active (transformational) and passive leadership. This provides a general model for leadership; however, specific leadership operationalises the general leadership focus and is measurable. Furthermore, managers need to focus their actions on the specific practice that is implemented "domain specific leadership, (implementation leadership)".	-
Aarons 2017	Leadership and Organisational Change for Implementation (LOCI)	Development seeks to create positive climate and fertile context for EBP implementation. Full range leadership (FRL) and implementation leadership (Aarons 2014). FRL -transformational (inspires, motivates and transactional (manage and motivates through interactions and rewards) leadership. Implementation leadership: Knowledgeable on EBP implemented, proactive and anticipatory in problem solving, supporting others and perseverance during implementation process. Implementation climate: strategic climate defined as "employees" shared perceptions of the importance of the innovation implementation within the organisation. Cross level relationships between executive management, mid management, and first level leadership develop and support congruence of EBP support structures and processes in a targeted and concerted strategy to improve implementation climate. 4 aims with related hypotheses reported.	Fig 1 sets out study hypothesis that improved leadership in combination with targeted and multi-level organizational strategies, is hypothesised to lead to improved leadership and implementation climate…. This component sits within the EPIS framework Aarons 2011.

Aarons 2011	Exploration, Adoption/Preparation, Implementation, Sustainment (EPIS)	Four components are each articulated by the relevance for the outer and inner contexts. Identification of anticipated challenges present at different implementation phases should help multiple stakeholders more effectively navigate the complex process of EBP.	Fig 2
Guerrero 2017	Leadership-climate relationship as a mechanism of the implementation cultural competence	Cultural competence: employees' shared perceptions of middle managers (e.g. clinical supervisors) priorities, expectations and rewards to implement cultural competence). Hypotheses: 1. Transformational leadership will be positively and indirectly related to the implementation of culturally competent knowledge through climate for implementation of cultural competence. 2. Transformational leadership will be positively and indirectly related to the implementation of culturally competent services practices through climate for implementation of cultural competence. 3. Transformational leadership will be positively and indirectly related to the implementation of culturally competent personnel practices through climate for implementation of cultural competence. Authors found support for all three hypotheses and conclude that findings contribute to "leadership theory on the embedded mechanisms that explain leadership influence on climate and practice implementation……..At the core of the leadership process related to influencing followers' attitudes and behaviour is the role of social exchange explained by social learning theory" (role modelling). In addition, this role modelling trickles down and authors imply that middle managers are key in translating this cultural competence into training and culturally tailored practices. However, additional embedded mechanisms play a role in influencing followers' attitudes and behaviour.	-
Summary	Leadership notions are important to implementation such as Transformational leadership (full range leadership) and transactional leadership (manage and motivate through interaction and reward). Improvements to leadership combined targeted and multi-level organisational strategies. Levels of leadership executive and supervisory have different roles one of creating a general climate for implementation and setting the culture for change and the other working more closely with the implementers focusing on specific activities/strategies for implementation. Combining these key aspects for implementation leadership involve the ability influence 'followers' through role modelling, being pro-active and anticipatory and knowledgeable about the intervention.		

	Key concept: implementation effort requires leadership that can create the climate and conditions for implementation. Leaders need feed into the system and interact to gain impact.		
Bertram 2015	Refinement to the National Implementation Research Network frameworks for application in diverse endeavours	"If an organisation carefully considers the intervention components of its program models, then thinks through the activities of each stage of implementation and the model-pertinent adjustments that must be made to implementation drivers, then benchmarks for model fidelity, implementation outcomes, and outcomes for the program's target population will more likely be achieved.	NIRN frameworks comprise: Intervention components: Implementation drivers: *Competency drivers, leadership drivers, organisation drivers* Stages of implementation fig 2: Exploration, installation, initial implementation, full implementation.
Summary	**Key concept:** Mechanistic approach that provides steps for implementation and identification of 'drivers' and careful consideration of intervention components provides the implementation approach. Large programme effort that provides tools.		
Glasgow 1999	Reach, Efficacy, Adoption, Implementation, Maintenance, RE-AIM	Public health impact of an intervention is conceptualised as a function of 5 factors each placed on a scale 0-1 (0%-100%) Framework fits with systems based and social-ecological thinking. The central tenet is that the ultimate impact of an intervention is due to its combined effects on 5 evaluative dimensions. REACH: individual level measure receiving the intervention. Includes their characteristics, details of nonparticipants, socio-economic status – the key principle is to ensure that the intervention reaches those that need it. EFFICACY: Both benefits and harms require assessment as well as other outcomes behavioural, quality of life and participant satisfaction. -The key principle is measuring the impact of the intervention on the recipient. ADOPTION: Refers to settings, places, departments communities that adopt intervention and should include time and barriers to adoption. IMPLEMENTATION: Delivered as intended, Interacts with efficacy. Adherence, delivery. MAINTENANCE: measuring routinisation of practice that becomes the norm and measuring individual relapse of behaviour change. Includes issues of enforcement success and stability of change.	Table 1 that achieves a public health impact score

		Temporality with data collection follow up taken of at least 2 years to determine maintenance. Items are seen as interacting multiplicatively rather than additively.	
Summary	Five factors that fit into systems based social-ecological approach are central to the impact of an intervention and involve the ability to reach intended recipients, knowing the benefit and harm on a recipient, assessment of barriers within the context and/or setting, fidelity and adherence, and how the implementation object becomes embedded and routinised. These elements interact multiplicatively and not additively. **Key concept:** Adopts a systems' based social-ecological approach of components that interact non-linearly to explain the impact of an intervention in situ on recipients and its ability to become embedded.		
Harvey 2015 (i-PARIHS) **Rycroft-Malone 2010, 2013** **Kitson 2008, 1998**	Prompting Action on Research Implementation in Health Services PARIHS	Successful implementation is represented as a function of the nature of evidence, the quality of the context of implementation, and appropriate approaches to facilitation. Informed by Diffusion of Innovations theory, organisational theories and humanism. EVIDENCE: Broad and includes research, clinical experience, patients and carers experience. Needs to be robust and credible and needs to attend to different beliefs about the evidence. CONTEXT: environment or setting for implementation and covers culture, leadership and evaluation. Described as complex and dynamic and conducive where there is clarity of roles, decentralised decision making, staff are valued, transformational leadership and a reliance on multiple sources of information on performance. FACILITATION: process of enabling or making easier the implementation of evidence into practice. It is achieved by a facilitator with appropriate skills and designated to the task. Facilitators can help to make sense of an intervention. Role may be task oriented or enabling. Further develops identify the role of individuals in the interplay between evidence and context and i-PARIHS expands to address the innovation, recipients and context re-structured into levels of organisation from the local to the external health system.	Elements and sub-elements measured on a low to high continuum. Table 5.2 (Rycroft-Malone, 2010, p. 115) Elements are conceptualised at the high and the low continuum
Summary	Successful implementation is a function of the nature of evidence, the quality of the implementation context and the appropriate approach to facilitation. Robust evidence needs to be credible and address different beliefs held. Context defined as the environment or setting for implementation and covers transformational leadership, decentralised decision making, and relies upon multiple sources of information. Considered dynamic and conducive when agent roles are clarified. Facilitation a key process to enable implementation of evidence.		

	Facilitator needs to be knowledgeable and able to facilitate intervention. Subsequent research covers multiple organisational levels and from the local to the wider health system as well as the impact of individuals on implementation within the system. **Key concepts:** Involves the implementation object (evidence) and its successful implementation into the implementation context with the key being its deliberate facilitation. The implementation into health care systems.		
Damschroeder 2009	Consolidated Framework for Implementation Research (CFIR)	Meta-theoretical framework that synthesises theories' constructs. Does not specify interaction between constructs and expects framework users to use the constructs to hypothesise mechanisms of change and test empirically. Define context, implementation and setting Implementation is the constellation of processes intended to get an intervention into use within an organisation…..it is a social process. Context consists of a constellation of active interacting variables and is not just a backdrop to implementation. It is a set of circumstances or unique factors that surround a particular implementation effort. Theories underpinning the intervention and implementation also contribute to context. Setting includes environmental characteristics in which implementation occurs. Constructs are: INTERVENTION source, evidence strength and quality, relative advantage, adaptability, trialability, complexity, design, quality and packaging, cost. OUTER SETTING, patients' needs and resources, cosmopolitanism (boundary spanning other orgs), peer pressure, external polices and incentives. INNER SETTING structural characteristics, networks and communications, culture, implementation climate. INDIVIDUALS knowledge and beliefs about intervention, self-efficacy, individual stage of change, individual identification with organisation, other personal attributes. PROCESS planning, engaging, executing, reflecting and evaluating.	Five major domains: Intervention, inner and outer setting, the individuals involved, and the process by which the implementation is accomplished. Fig in additional file 1.
Summary	Implementation is a social process of a constellation of interacting processes intended to get an intervention into use. Context is a set of unique circumstances and factors. Setting is the environment in which implementation occurs. These involve the intervention (e.g. source, evidence strength, adaptability, trialability, complexity), the outer setting (e.g. patient needs and resources, external policies and incentives), the inner setting (e.g. networks and communications, culture, implementation climate), individuals (e.g. beliefs, knowledge, personal attributes) and the process (planning, engaging, executing, reflecting and evaluating). **Key concepts**: Social system of processes in which the intervention is introduced and requires consideration of multiple interacting elements.		
Moullin 2015	A Generic Implementation Framework	Generic Implementation framework depicts the core elements for any implementation effort that researchers, policymakers, health administrators and practitioners require.	Fig. 2 p. 8

		Key points observed and reflected in framework: Non-linear, recursive nature of the implementation process, however, implementation follows a series of stages or steps focussed around the innovation/intervention. Core components are: Context domains in which strategies, factors and evaluations operate as the implementation process. The diagram includes a pre-implementation and post implementation stage.	
Summary	**Key concept:** Implementation is a non-linear, recursive process that follows temporally a number of stages that centre on a series of context domains that involve strategies, factors and evaluations required to support the intervention.		
McKillop 2017	Understanding the attributes of implementation frameworks	Conducting a review of articles using multiple research traditions – Greenhalgh categories is used (2009) categories. The narratives are based on sources that mix these traditions. The five meta-narratives are: 1. Implementation should be informed by theoretical constructs. iv. *Seeks an understanding of evidence use through theory-based reasoning and decisions* *vi. Is complex and is potent influence on how a theory may operate with a particular project or programme* 2. The relationships between theoretical constructs and the ways in which they impact implementation. iv. *Captures the factors impacting on achievement, accomplishment and execution of translating research findings effectively and rapidly into policy and practice.* *vi. the context, the nature of innovation/s and the capacity to sustain are interacting dynamics of a complex and unstable phenomenon.* 3. Developing new frameworks from theories, constructs and key factors iv. *A collection of activities designed to alter the behaviour of health care providers, under the influence of a variety of contextual factors.* *vi. context, exists within and outside an organisation and fundamentally influences implementation* 4. Applying existing frameworks in many ways iv. *A process which occurs within a particular context involving barriers and facilitators.*	Table 4 p. 6 gives the following key features of the meta-narratives based on their: i. disciplinary and philosophical roots. ii. definition and scope of implementation. iii. general format of review questions. iv. implementation conceptualised as…. iv. end users/beneficiaries conceptualised as…., and vi. implementation context conceptualised as….

		vi. *Related to the type of evidence/intervention being implemented, and micro, meso, and macro level factors that can support implementation.* 5. Evaluating effectiveness of interventions with frameworks and models. iv. use of research evidence involves employing strategies to implement improvements in patient care. vi. context determines important factors and directs the approaches used to select interventions. These are then sifted in to 4 themes, Purpose and scope, theory and mechanisms, context, complexity and process, outcomes and success. From this body of work authors add the need for "collaborative adaption with stakeholders" in particularly for their sector patients and their families. Finally, the importance of robust evaluation in such programmes of work to ensure consideration of what works, for whom, and what circumstances.	
Summary	Implementation seeks an understanding of evidence use through theory-based reasoning and decisions. It is complex and a potent influence on how theory may operate with a particular intervention or programme. Factors impact on achievement, accomplishment and execution of getting evidence into practice. The context, the innovation and capacity to sustain are interacting dynamics of complex unstable phenomena. Implementation is a collection of activities designed to alter behaviour of health care providers under the influence of a variety of contextual factors. Context fundamentally influences implementation and involves barriers and facilitators. Based on the implementation object it may involve multiple levels of organisation (micro, meso, macro level factors). Implementation can be characterised by its purpose and scope, theory and mechanisms, context, complexity and process, outcomes and success. Overarching is the need for collaborative adaption with stakeholders and to ascertain what works, for whom and in what circumstances. **Key concept:** Implementation requires understanding of the factors that influence its achievement, accomplishment and execution. The interacting dynamics of complex unstable phenomena of the context, the innovation and capacity impacting on sustaining the intervention. Context is a fundamental influence in implementation and its success and requires collaborative adaptation.		
May 2006 (2007)	Normalisation Process Model	Normalisation – is the embedding of a technique, technology or organisational change as a routine and taken-for-granted element of clinical practice. Shift from diffusion approaches that focus on special champions and early adopters to the conditions of use and the behaviour of everyday users. And the focus is micro level of clinical practice rather than a 'whole systems' approach (e.g. CAS, actor network theory). NPM/theory: Group of related propositions: Process (endogenous and exogenous) defined as patterns of organised, dynamic and contingent interaction between agents, objects and contexts.	Four constructs defined with a series dimensions related to the propositions. endogenous 1. Interactional workability 2. Relational integration exogenous 3. Skill set workability 4. contextual integration

		P_1 A complex intervention is disposed to normalisation if it confers an interactional advantage in flexibly accomplishing congruence and disposal. P_2 A complex intervention is disposed to normalisation if it equals or improves accountability and confidence within networks P_3 A complex intervention is disposed to normalisation if it calibrated to an agreed skill-set at a recognizable location in the division of labour P_4 A complex intervention is disposed to normalisation if it confers an advantage on an organisation in flexibly executing and realizing work.	
May 2013	A general theory of implementation	Author subscribes the theory is based on social mechanisms and agency leading to an emergent social process. The model is not linear or sequential. Each of the constructs of the General Implementation Theory are reduced to a "single context-independent proposition" P_1 the capability of agents to operationalise a complex intervention depends on its workability. P_2 the incorporation of a complex intervention within a social system depends on agents' capacity to co-operate and co-ordinate their actions. P_3 The translation of capacity into collective action depends on agents' potential to enact the complex intervention. P_4 The implementation of a complex intervention depends on the agents' continuous contributions that carry forward in time and space. Explanation for implementation processes is given as: 1. An implementation process involves agents in the intentional modification of the social systems that occupy a field, or fields, of action 2. Within social systems, emergent expressions of agency both shape and are shaped by, dynamic elements of their contexts. They continuously interact to form an emergent social process. 3. Emergent expressions of agency and dynamic elements of context continuously interact with both endogenous and exogenous contingencies and confounders. 4. Agents work to negotiate the effects of interactions, contingencies and confounders. They seek to make these plastic and shape them through their	Four constructs: Capability Capacity Potential Contribution Fig. 1 p. 2 Fig 2 p. 3 Fig 3 p. 4

		agentic contributions, and thus to govern the conduct of an implementation process and its outcomes.	
May 2016	Implementation, context and complexity	General theoretical argument – the generative mechanisms characterised by NPT are examples of self-organising mechanisms in complex adaptive social systems. Their operation explains differences in implementation processes over time and between settings, and they play an important part in determining intervention fidelity. Propositions: 1a Differences in participants' resource mobilisation and actors' contributions explain variations in process and negotiation outcomes over time. 1b. Differences in normative and relational restructuring processes explain variations in process and negotiation outcomes between settings. 2a. the greater the degree of plasticity possessed by a set of intervention components, the less strain that actors enacting them place on the normative and relational structure of host contexts, 2b. The greater the degree of elasticity possessed by the normative and relational structure of host contexts, the less strain they place on actors enacting a set of intervention components. 3a. the more tightly coupled intervention components are, the less discretion participants have in resource mobilisation and collective action, and the more they must do adaptive work to ensure intervention integration 3b. The more loosely coupled intervention components are, the more discretion participants have in resource mobilisation and collective action, and the more they must do adaptive work to ensure intervention workability. "Implementation processes as non-linear, emergent and dynamic events within systems"	Fig 1 p. 8
Summary	May and colleagues build from Normalisation Process Theory to a general theory of implementation developed further by understanding the complexity within implementation and context. Firstly, normalisation is the process of embedding a technique, technology or organisational change as a routine and taken-for granted element. This involves working at the micro level of clinical practice rather than taking a system wide approach. The process involves patterns of organised, dynamic and contingent interaction between agents, objects and contexts. A complex intervention will become normalised within clinical practice if it confers an interactional advantage in flexibly accomplishing congruence and disposal, equals or improves accountability and confidence within networks, is calibrated to an agreed skill set at a recognisable location in the division of labour and confers an advantage on the organisation in flexibly executing and realising work. The General theory of implementation develops the social system involving the social processes of agents in enabling the implementation of a complex intervention through their capacity, capability and the resources available to the agents. The theory also includes the ability to sustain change overtime. The social process is viewed as a negotiation through continuous interaction managing various contingencies and		

	confounders. The agents seek to manipulate (make plastic) these processes to enable implementation outcomes to be achieved. NPT characterises its generative mechanisms based on self-organising mechanisms in complex adaptive social systems, which explains why implementation and the fidelity of complex interventions is different over time and across settings. Thus, implementation is a non-linear, emergent and dynamic event occurring with a system. Therefore, as a unique event explains variation of implementation of a given complex intervention in different settings given their different normative and relational restructuring processes, agents resources and contributions, degree of adaptation of the intervention and the agents ability to normalise within the system. The interventions components and how they can be flexibly tailored to meet both the agent's capacity and the ease of working within a system is also important to routinizing the intervention. **Key concepts:** Intervention adaptability and malleability, along with the capability, capacity of, and available resources to human agents operating in social systems permits their ability to negotiate the local restructuring required to embed the complex intervention.		
Atkins 2017 **Michie 2017** **Michie 2011** **Michie 2005**	Large programme of work to promote the influence of psychological theories to understand human behaviour change in the implementation of evidence-based practice	COM-B central tenet is that "capability, opportunity and motivation interact to produce behaviour. Simpler than the TDF which provides greater granularity of psychological capability and reflective motivational processes and refers researchers to other relevant theories and frameworks including normalisation process theory, CFIR (both include here) and the Yorkshire Contributory Factors framework. TDF (v2) – is a theoretical framework rather than a single theory and therefore does "not propose testable relationships but provides a theoretical lens through which to view the cognitive, affective, social and environment influences on behaviour". Synthesis using expert consensus resulted in fourteen domains with constructs. Behaviour change wheel- Table 1definitions of interventions and policies – provides a three layers fig 2 in the BCW. Model not linear, Functions in intervention layer, categories in policy layer and the COM-B components are linked by authors in tables 2 and 3. Authors suggest a pluralistic approach to behaviour change. BCW is underpinned by a single unifying theory of motivation in context that predicts what aspects of the motivational system will need to be influenced in what ways to achieve a behavioural target. Key points are: - Identified intervention functions are likely to need a number of behaviour change theories. - Behaviour change theories may support a number of intervention functions. - Context is represented by opportunity and behaviour can only be understood within context and is the starting point for intervention design. - Automatic processing is at the heart of BCW	2011.Table 1 provides 14 domains and accompanying constructs 2 versions. Version 2 are: Knowledge, Skills, Social/professional role and identity, beliefs about capabilities, Optimism, Beliefs about consequences, Reinforcement, intentions, Goals, memory attention & decision process, environmental context and resources, social influences, emotion, behavioural regulation. Fig 1 builds on the behaviour wheel Fig 2. (Michie 2011, p. 8)

		- BCW recognises target behaviour can in principle arise from combinations of any of the components of the behaviour system. - BCW is based on comprehensive causal analysis of behaviour and starts with the question 'what conditions internal to individuals and in their social and physical environment need to be in place for a specified behavioural target to be achieved?'	
Summary	Interventions whether the recipient or the deliverer requires changes to human behaviour. Multiple psychological theories explain aspects of human behaviour change. Authors work conceptualises the need for behaviour change in the implementation of evidenced based practice as focusing on human agents' capability, opportunity and motivation to produce required behaviour. A Theoretical Domains Framework supports a greater granularity of psychological capability and reflective motivational processes and refers to multiple theories including NPT. The purpose is to provide a pluralistic theoretical lens through which to view the cognitive, affective, social and environment influences on behaviour. Further work develops both the COM-B and the TDF into a Behaviour Change Wheel which is underpinned by a single unifying theory of motivation in context that predicts what aspects of the motivational system will need to be influenced in what ways to achieve a behavioural target. Implementation of interventions require for human behaviour modification, multiple theories to explain the behavioural change mechanisms. Context is characterised by opportunity and behaviour change in context is key to intervention design. Automatic processing is central to the BCW, that results in the behaviour not warranting processing effort and attention that distracts from other processing needs following May's routinization (and Nilsen's habit). The BCW seeks to provide a comprehensive causal analysis of the target behaviour change and starts with the question, 'what conditions internal to individuals and in their social and physical environment need to be in place for a specified behavioural target to be achieved?'. The wheel layers the policy categories (e.g. guidelines, legislation, fiscal measures, environmental/social planning), intervention functions (e.g. education, incentivisation, persuasion, modelling, restrictions) and sources of behaviour (capability, motivation and opportunity. **Key concepts:** Specific theories are available to explain different aspects of human behaviour change when designing interventions. The BCW enables a process to articulate using theory the identification of the motivation for change within the context that change needs to take place. This involves intervention functions, policy type and sources of behaviour, that is the opportunity motivation and capability to change.		

Appendix 4.5

Key concept summaries of included implementation models, frameworks and theories

Author & Year	Title of model, framework or theory	Key concept summaries
Pfadenhauer 2017 **Rohwer 2017**	Context and Implementation of Complex Interventions framework (CICI)	Whole systems, that involve human agency and their interactions relationships, feedback loops, strategies to manage the event, implementation, its processes and object overtime. Prior existence of systems involves an historical account for context as well as current status.
Ellen 2017	Knowledge translation framework on aging and health (Using WHO definition of KT)	Looser description of 'whole system' that includes global trends with their social and political forces, agency and its motivation. These influences within the implementation context fluctuate over time. Takes a structured, simplified mechanical process to manage implementation. History, present and future status of system are important aspects for knowledge translation.
Kaplan 2018	Model for understanding success in quality	Bridges a mechanistic view with leadership as the central driver against the moderating effects of the contexts dynamic feedback and interaction.
Scaccia 2015	Organisational Readiness requires Motivation, general and innovation specific Capacity ($R=MC^2$)	Gaining a historical as well as current status of the system to garner ability to embark on implementation activity.
Dearing 2017	Informal advice seeking relationships	Networking between agents operates better when they are in close proximity as illustrated between organisations geographically located rather than within organisations.
Sarkies 2017	Model of implementation strategy design	Imperative for both system and individual involving trust and shared vision with the capacity and resources to respond. Current status or history of organisation is required.

Moore 2017	Definition of sustainability	To sustain an intervention over time in which it becomes integral to the system through adaption and evolution.
Greenhalgh 2017 **Greenhalgh 2004**	Conceptual model for considering the determinants of diffusion, dissemination and sustainability of innovations in health service delivery and organisation. Non-adoption, Abandonment, and Challenges to the Scale up, Spread, and Sustainability of Health and Care technologies	Whole system approach with a need to understand the nature of the intervention and its intended target and how it will intersect within the wider system. Notion of complexity, assemblage and dis-assemblage and adaption overtime shifting the focus onto the acceptability and capacity for the intervention to work where required.
Guerrero 2017 **Aarons 2017** **Richter 2016** **Aarons 2011**	iLead-transformational leadership intervention to train healthcare managers' implementation leadership Leadership and Organisational Change for Implementation (LOCI) Exploration, Adoption/Preparation, Implementation, Sustainment (EPIS) Leadership-climate relationship as a mechanism of the implementation cultural competence	Implementation effort requires leadership that can create the climate and conditions for implementation. Leaders need to feed into the system and actively interact to gain impact for implementation.
Bertram 2015	Refinement to the National Implementation Research Network frameworks for	Mechanistic and process orientated approach that provides tools with steps for implementation and identification of 'drivers' with careful consideration of intervention components.

	application in diverse endeavours	
Glasgow 1999	Reach, Efficacy, Adoption, Implementation, Maintenance, RE-AIM	Adopts a systems' based social-ecological approach of components that interact non-linearly to explain the impact of an intervention in situ on recipients and its ability to become embedded.
Harvey 2015 (i-PARIHS) **Rycroft-Malone 2010, 2013** **Kitson 2008, 1998**	Prompting Action on Research Implementation in Health Services PARIHS	Key concepts involve the implementation of evidence-based support intervention or knowledge into health care systems and its successful implementation into the context with the key being its purposeful facilitation.
Damschroeder 2009	Consolidated Framework for Implementation Research (CFIR)	Social system of processes to plan and execute implementation within the context and setting in which the intervention is introduced requiring consideration of multiple interacting elements between inner and outer layers of the setting from patients' needs and health professional beliefs and personal attributes to resources and external policies.
Moulin 2015	A Generic Implementation Framework	Implementation is a non-linear, recursive process that follows temporally several stages that centre on a series of context domains that involve strategies, factors and evaluations required to support the intervention's implementation.
McKillop 2017	Understanding the attributes of implementation frameworks	Implementation requires understanding of the factors that influence execution and realisation. The interacting dynamics of complex unstable phenomena of the context, the innovation and system capacity impact on sustaining the intervention following initial implementation. Context is a fundamental influence in implementation and its success and requires collaborative adaptation.
May 2016 **May 2013** **May 2006 (2007)**	Normalisation Process Model A general theory of implementation Implementation, context and complexity	Intervention adaptability and malleability, along with the capability, capacity of, and availability of resources to human agents operating in social systems influences their ability to negotiate the local restructuring required to embed the complex intervention.

Atkins 2017 **Michie 2017** **Michie 2011** **Michie 2005**	Large programme of work to promote the influence of psychological theories to understand human behaviour change in the implementation of evidence-based practice	Specific theories are available to explain different aspects of human behaviour change when designing interventions. The Behaviour Change Wheel enables a process to articulate, using theory, the identification of the motivation for change within the context where change needs to take place. This involves intervention functions, policy type and sources of behaviour, that provides the opportunity, motivation and capability to change.

Appendix 4.6

Convergence between implementation concepts and social complex adaptive system concepts

Social complex adaptive systems concepts	**Framework, model or theory extracted examples**	**Author year and title**
Interaction and system history	• Describes interactive feedback processes between the human agents (interaction and feedback), intervention and processes of implementation. Agency is clearly a key component in responding to the act of implementation. Focus on using causal mapping of pathways using logic models either to describe (system/context) and process (sequencing and implementation). Agents require multiple theories of change for both their strategies and interventions. • Context already exists and implementation is a deliberate action operating upon the context. The 'whole system' is considered with regard to the geographical, socio-cultural, socio-economic, ethical, political and legal and its physical setting etc. Contexts are contingent and unique	Context and Implementation of Complex Interventions framework Pfadenhauer 2017, Rohwer 2017
Self-organisation and emergence	• Collaborative, participatory approach required to ensure adoption and the multiplicity of the organisational dynamics, thus the whole system. Complexity in multiple domains poses the greatest challenge to scale up, spread and sustainability • Complexity is dynamic, unpredictable, not easily disaggregated into constituent components and requires adaptation overtime to be sustained. Systems are layered, diffusion of innovation into system requires theory of change, focus on process, agents	Conceptual model for considering the determinants of diffusion, dissemination and sustainability of innovations in health service delivery and organisation. Greenhalgh 2004 Non-adoption, Abandonment, and Challenges to the Scale up, Spread, and Sustainability of Health and Care technologies Greenhalgh 2017

	need to operate collaboratively to understand whether 'it would work here'	
Interaction	Implementation is a social process of a constellation of interacting processes intended to get an intervention into use.	Consolidated Framework for Implementation Research (CFIR) Damschroeder 2009
Interaction	The context, the innovation and capacity to sustain are interacting dynamics of complex unstable phenomena.	Understanding the attributes of implementation frameworks McKillop 2017
System history	CONTEXT: environment or setting for implementation and covers culture, leadership and evaluation. Described as complex and dynamic and conducive where there is clarity of roles, decentralised decision making, staff are valued, transformational leadership and a reliance on multiple sources of information on performance. i-PARIHS expands to address the innovation, recipients and context re-structured into levels of organisation from the local to the external health system.	Promoting Action on Research in Health Services (PARIHS) Harvey 2015 (i-PARIHS) Rycroft-Malone 2010, 2013 Kitson 2008, 1998
Interaction and **Self-organisation**	• Firstly, normalisation is the process of embedding a technique, technology or organisational change as a routine and taken-for granted element. This involves working at the micro level of clinical practice rather than taking a system wide approach. The process involves patterns of organised, dynamic and contingent interaction between agents, objects and contexts. A complex intervention will become normalised within clinical practice if it confers an interactional advantage in flexibly accomplishing congruence and disposal, equals or improves accountability and confidence within networks, is calibrated to an agreed skill set at a recognisable location in the division of labour and confers an advantage on the organisation in flexibly executing and realising work. The social process is viewed as a	Normalisation Process Model Implementation, context and complexity May 2016 A general theory of implementation May 2013 May 2006, 2007

	negotiation through continuous interaction managing various contingencies and confounders. • The NPT characterises its generative mechanisms based on self-organising mechanisms in complex adaptive social systems, which explains why implementation and the fidelity of complex interventions is different over time and across settings. • General theory of implementation develops the social system involving the social processes of agents in enabling the implementation of a complex intervention through their capacity, capability and the resources available to the agents.	
Interaction	Multiple psychological theories explain aspects of human behaviour change. Authors work conceptualises the need for behaviour change in the implementation of evidenced based practice as focusing on human agents' capability, opportunity and motivation to produce required behaviour. A Theoretical Domains Framework supports a greater granularity of psychological capability and reflective motivational processes and refers to multiple theories including NPT. The purpose is to provide a pluristic theoretical lens through which to view the cognitive, affective, social and environment influences on behaviour. Further work develops both the COM-B and the TDF into a Behaviour Change Wheel (BCW) which is underpinned by a single unifying theory of motivation in context that predicts what aspects of the motivational system will need to be influenced in what ways to achieve a behavioural target. Implementation of interventions require for human behaviour modification, multiple theories to explain the behavioural change mechanisms. Automatic processing is central to the BCW, that results in the behaviour not warranting processing effort and attention that distracts from other processing needs following May's routinization (and Nilsen's habit).	Large programme of work to promote the influence of psychological theories to understand human behaviour change in the implementation of evidence-based practice Atkins 2017 Michie 2011 Michie 2005

Appendix 4.7

Mapping separate implementation concepts across social complex adaptive system domains

Mapping of key implementation concepts (constructs and components) across social CAS (SCAS) concepts							
Social complex adaptive system concepts							
Individual agent	**SCAS-Interaction** **(Microsystem-** (NP) (KAP)**)**	**SCAS-Self organisation**	**SCAS-Emergence**	**SCAS-History**	**SCAS-Temporality**	**SCAS-System Organising Principle (SOP)**	**Innovation (intervention or technology, evidence-based practice, research guideline etc.)**
System Micro Level		***System Meso/Macro Level***		***System state***	***System fluctuations and change, adaption and evolution***	***System imperative: key determinant for system existence***	***Disruptor, event or trigger to system***
Implementation concepts							
Implementation agents/actors	Implementation process (exploration, decision to adopt, planning preparation, implementation steps (CICI)) climate, setting, strategies			Implementation context	Implementation process (CICI) dynamic, recursive,	Implementation drivers ((Implementation drivers: Competency drivers, leadership drivers, organisation drivers) NIRN)	Implementation object (or event)

Opinion leaders/change agents, champions, implementation leads (CFIR)	COM-B sources of behaviour: capability (physical and psychological), opportunity (social and physical), motivation (automatic and reflective). (BCW)	Informal advice seeking networks (DER)					Understanding innovation target condition and related factors e.g. co-morbidities (NAS)
Coherence(NP)	Coherence, cognitive participation(NP)	Cognitive participation, collective action, reflexive monitoring(NP)	Collective action, reflexive monitoring(NP)	Inner and outer context/setting (CICI) (NAS) (CFIR), external Wider system (political, policy, regulatory, professional, socio-cultural) (NAS)	Sustainability (McK) Sustainment needs adaption and evolution of innovation overtime (MRE) (NAS)(MAY)) (CICI)	Establish imperative (SAR)	Intervention Characteristics: source and stakeholder perception, strength and quality of evidence, relative advantage, adaptability, trialability, complexity (difficult, disruptive, radical, intricacy, number of steps to implement), design , cost (CFIR)
Knowledge(TDF)	Evidence (clinical experience,	Resources for implementation (CFIR)		Organisational capacity (NAS) /readiness	Embedding and adaption over time:	Tension for change (CFIR)	Evidence (research), Context

	patient, local data information) (PAR)			(motivation, general and innovation specific capacity) to innovate (SCA) Organisational commitment (CFIR)	scope and resilience for innovation (NAS)	Incentives and rewards (CFIR)	(evaluation) (PAR) (CICI)
Skills: competence, ability, interpersonal skills (TDF)	Facilitation (purpose, role, skills, attributes) (PAR)	Strategies (push, pull, facilitation) (KT)		Context (culture) (PAR)			Implementation outcomes (fidelity, uptake, acceptability, cost, penetration (CICI) spread, scale up (NAS)
Professional role & Identity: social identity, boundaries, confidence, leadership(TDF)	Leadership – Transactional (operational - strategies) (RTAR)	Leadership Transformational (active and show cultural competence) (PAR) (RTAR) Leadership engagement: commitment, involvement, accountability (CFIR)		Context (Geographical, epidemiological, socio-cultural, socio-economic, political, system and securing its accessibility, legal, ethical,) (CICI)			Compatibility, relative priority for implementation of intervention (CFIR)
Beliefs about capabilities: empowerment, self-esteem, beliefs, self-confidence(TDF)	Setting: physical location (CICI)	Embedding and adaption over time: scope and resilience for innovation (NAS)		Outer setting: Accuracy of knowledge of patients' needs and resources by org, org networked with other orgs, peer			Intervention functions: Restrictions, education, environmental re-structuring, modelling, enablement,

				pressure with competing orgs, policy/regulations, external mandates) (CFIR)			training coercion, incentivization, persuasion (BCW)
Optimism: Pessimism, unrealistic(TDF)	Implementation climate localised culture less stable (KT)			Inner setting: Social architecture, age, maturity, size of org, social networks within org, absorptive capacity of org, (CFIR)			Workability (MAY)
Beliefs about consequences: outcome expectations, anticipated regret, consequents(TDF)	Learning climate (CFIR) and learning style of individuals (CFIR)			Policy: guidelines, fiscal measures, regulation, service provision, legislation, communication and marketing, environmental and social planning (BCW)			Dependency on other systems or free standing(NAS)
Reinforcement: incentives, punishment, consequents, sanctions, contingencies(TDF)	Changes in staff roles, practices and identities (NAS)						Evaluation- (RE-AIM)
Intentions: Stability of, at stages of change model	Build trust and shared version (SAR)						
Goals: priority, distal, proximal, target setting, action	**<u>Legend</u>** **NP –** Normalisation Process model						

<table>
<tr><td>planning, implementation intention[TDF]</td><td rowspan="7">KAP – Model for Understanding Success in Quality
CICI – Context and Implementation of Complex Interventions framework
NIRN – National Implementation Research Network
CFIR - Consolidated Framework for Implementation Research
DER – Informal advice seeking relationships
BCW - Behaviour Change Wheel
NAS – Non-adoption, Abandonment and Challenges to the Scale up, Spread and Sustainability of Health and Care Technologies
McK – Understanding the attributes of implementation frameworks
MRE - Definition of sustainability
MAY – Implementation, Context and Complexity
PAR – PARIHS (Promoting Action on Research Implementation in Health Services)
TDF – Theoretical Domains Framework
KT – Knowledge Translation framework on aging and health
RTAR – iLead- Transformational leadership
SAR – Model of Implementation Strategy design
RE-AIM – Reach, Efficacy, Adoption, Maintenance</td></tr>
<tr><td>Memory: attention, attention control, decision-making, cognitive overload/tiredness[TDF]</td></tr>
<tr><td>Environmental context & resources: resources, stressors, barriers/facilitators, person and environment interaction[TDF]</td></tr>
<tr><td>Social influences: Social pressure, social norms, group conformity-norms-identity, social comparisons, group, social support, modelling, power, inter-group conflict, alienation[TDF]</td></tr>
<tr><td>Emotion: Fear, anxiety, affect, stress[TDF]</td></tr>
<tr><td>Behavioural regulation: self-monitoring, breaking habit, action planning[TDF]</td></tr>
<tr><td>Assessing patient & caregiver</td></tr>
</table>

expectations for innovation (NAS)	
Incentives and rewards: promotion, respect, performance review and salary raise. (CFIR)	

Appendix 5.1

Data extraction templates for the review of QCA studies

STUDY SUMMARY

Study demographics and health focus	Study objective and research question	Cases defined	Conditions defined	Outcomes defined	Results and interpretation
Other information					

STUDY QUALITY APPARISAL: METHODS AND DATA SOURCES USED IN THE PRE-QCA PHASE AND CORE COMPONENTS OF THE QCA

Study and QCA technique	Pre-QCA Methods and Data sources	QCA: case, condition selection and calibration of set membership	QCA: Use of software, truth table and minimization process	Terminology use and reporting	Coherence of interpretation

Narrative summary and judgement on quality

STUDY RATIONALE FOR QCA APPLICATION AND RECORD OF CAUSAL ASSUMPTIONS TABLE

Lead author year and health focus
Rationale for use of QCA (the problem):
Casual assumption statements made:

Qualitative Comparative Analysis method *step by step*		**Review author judgement**	
QCA step Item	**Criteria**	**Criterion met** **(Y-Yes, N-No, PM-Partially met, UC-unclear)**	**Review author explanation**
QCA 1. The phenomenon of interest is best understood in terms of set relations.	Do authors articulate a rationale or hypothesis for applying a set theoretic approach? 1. Equifinality (different, mutually nonexclusive paths) 2. Conjunctual causation (the effect of a single condition unfolds in combination with precisely specified other conditions 3. Exploration of asymmetric relations. 4. Explicit that interested is in relations between sets not correlations.		
QCA 2. Case selection	Is there familiarity with cases before, during and after (interpretation) analysis.		
	Are cases clearly defined with an explicit rationale and share background characteristics and clearly state non-selection of cases?		
	Is there a clearly defined outcome that is relevant to the cases?		

	Are positive and negative cases included (i.e. with the outcome or not)? If so, are they conducted as two separate analyses?		
QCA 3. Condition selection and calibration should be documented in detail	Does the condition vary across the cases?		
	Does each condition have a clear hypothesis regarding its connection to the outcome?		
	Are the parameters of the conditions for necessity or sufficiency specified?		
	Is the case to condition ratio (logical/reasonable) 10-40 cases will have 4-7 conditions?		
	Does the study discuss the theoretical 'qualitative anchors' for the cut-off points: dichotomization, trichotomization, fuzzy sets etc.?		
	What is the theoretical reasoning for these anchors?		
	What empirical evidence underpins this reasoning?		
QCA 4. Outcome selection and calibration should be documented in detail	Is the basis of the selected outcome specified? Does the study discuss the theoretical 'qualitative anchors' for the cut-off points: dichotomization, trichotomization, fuzzy sets etc.?		

	What is the theoretical reasoning for these anchors?		
	What empirical evidence underpins this reasoning?		
QCA 5. Raw data matrix	Reported		
QCA 6. Application of software	Reported and referenced		
QCA 7. Truth table	Reported Does the table Identify all logical remainders? Are all cases assigned to a truth table row? Is the outcome clearly defined for each row?		
QCA 8. Assessment of necessary conditions	Is this conducted as a separate analysis before analysis of sufficient conditions? Must not be inferred from sufficiency analysis. Consistency value 0.9 or higher		
QCA 9. Assessment of sufficiency	Is the level of consistency for a sufficient condition pre-specified and justified? > 0.75		
QCA 10. Logical remainders **(understanding limited diversity)**	Are logical reminders addressed (configurations with no observed cases)? Do authors differentiate between plausible and non-plausible logical remainders, and provide a strategy or explanation for approach?		

QCA 11. Treatment of contradictory rows	Do authors identify contradictory rows that are present? Do authors undertake to resolve these contradictions?		
QCA 12. Consistency (raw)	Do authors measure consistency of individual rows?		
QCA 13. Coverage	Do authors measure coverage?		
QCA 14. Analysis of the negative outcome	Analysis of outcome occurrence and its non-occurrence using the same conditions should not include the same truth table rows in both minimizations.		
QCA 15. Presentation of results	Do authors provide a Venn diagram or other visual (XY plot) to show the results of the truth table and the configurations? Graphical or tabular (truth tables)		
QCA 16. Boolean minimization and appropriate notation	Do authors (using software) undertake minimization procedures? Is appropriate notation used for solution terms?		
QCA 17. Overall robustness check (S&W. P286)	Do authors report that they check the robustness of their results and clearly explain the procedures (and decisions) used to do so with an explanation of the results? Such as the differences in parameters of fit (consistency and coverage) and set relational status of the different formulas. Effects of: - Dropping or adding cases		

	- Changing consistency levels - Changing calibration - Importance of determining the 0.5 anchor.		
QCA 18. Coherence of interpretation of solutions/minimal formula	Do authors produce solutions with clear explanation as to whether they are intermediate, complex or parsimonious? Are solutions interpreted as multiple conjunctural configurations and coherently related back to the individual cases? Only solution paths that have reached a pre-specified consistency threshold should be interpreted. Theoretical importance is greater than empirical importance (coverage). “In a causally complex solution, single conditions are INUS conditions which possess causal relevance only in combination with other conditions.” P 281		

Appendix 5.2

QCA step criterion, identifying signals and elaboration (Rhioux & Ragin, 2009, Schneider and Wagemann, 2012)

QCA step	Criterion	Identifying signals	Elaboration of criterion
1	**The phenomenon of interest is best understood in terms of set relations.**	Do authors articulate a rationale or hypothesis for applying a set theoretic approach? 1. Equifinality (different, mutually nonexclusive paths) 2. Conjunctual causation (the effect of a single condition unfolds in combination with precisely specified other conditions 3. Exploration of asymmetric relations. 4. Explicit that interested is in relations between sets not correlations.	This item identifies the authors' comprehension and understanding of the underlying key concepts of the method. 1. This allows for different, mutually nonexclusive sufficient conditions for the outcome. 2. Independent conditions combine in different patterns in relation to a common outcome. 3. There is most likely to be qualitative differences in the paths to the occurrence of an outcome and the non-occurrence. One is not a mirror of the other. 4. The logic is one of set relations not correlations. There is a tendency to blur these different concepts, particularly when employing quantitative techniques. See further notes on set relations logic in the technical appendix.
2	**Case selection**	Is there familiarity with cases before, during and after (interpretation) analysis: Are cases clearly defined with an explicit rationale and share background characteristics and clearly state non-selection of cases? Is there a clearly defined outcome that is relevant to the cases? Are positive and negative cases included (i.e. with the outcome or not)?	This is a case-based approach and cases need to continue beyond the analytic moment of Boolean minimization. The solutions require testing on the individual cases in terms of plausibility and theoretical constructs. Selection of cases is more informative (comparative) if cases with and without the occurrence of the outcome are identified. They should be based on the concept of asymmetry above and be conducted as separate analyses. Because qualitatively the configurations and

		If so, are they conducted as two separate analyses?	conditions for non-occurrence may be very different from those related to the occurrence of the outcome (i.e. not a mirror image).
3	**Condition selection and calibration should be documented in detail**	Does the condition vary across the cases? Does each condition have a clear hypothesis regarding its connection to the outcome? Are the parameters of the conditions for necessity or sufficiency specified? Is the case to condition ratio (logical/reasonable) 10-40 cases will have 4-7 conditions? Does the study discuss the theoretical 'qualitative anchors' for the cut-off points: dichotomization, trichotomization, fuzzy sets etc.? What is the theoretical reasoning for these anchors? What empirical evidence underpins this reasoning?	A condition is a factor that explains the outcome of interest. The condition needs to vary across the cases. The property space expands exponentially with increasing conditions (2^k) that can leave a high number of logical remainders requiring an explanation. Calibration of each condition should 'qualitatively' specify when it is deemed present or absent, or where there is a crossover point (greatest point of ambiguity). The basis of decision making should be articulated.
4	**Outcome selection and calibration should be documented in detail**	Is the basis of the selected outcome specified? Does the study discuss the theoretical 'qualitative anchors' for the cut-off points: dichotomization, trichotomization, fuzzy sets etc.? What is the theoretical reasoning for these anchors? What empirical evidence underpins this reasoning?	All research expects a clear rationale for the choice of the phenomenon of interest and its understood relationship with the cases. Calibration of the outcome should 'qualitatively' specify when it is deemed present or absent, or where there is a crossover point (greatest point of ambiguity). The basis of decision making should be articulated.
5	**Raw data matrix**	Reported	The building up of the approach and data tables in preparation for the analysis requires the transparency of the data matrix table that identifies all cases and the condition set relations and includes calibration values for these set relations.
6	**Application of software**	Reported and referenced	Use of QCA software is highly recommended
7	**Truth table**	Reported Does the table Identify all logical remainders? Are all cases assigned to a truth table row?	The Truth table is a core component of QCA methods. It is an output of the software when used. It reports all logically possible configurations with observed and unobserved cases. Both the

		Is the outcome clearly defined for each row?	presence and absence of the outcome of interest is provided, preferably in a separate table.
8	**Assessment of necessary conditions**	Is this conducted as a separate analysis before analysis of sufficient conditions? Must not be inferred from sufficiency analysis. Consistency value 0.9 or higher	A condition is necessary if, whenever the outcome is present, the condition is also present. However, some with the condition do not have the outcome. This will be defined further in fuzzy set analysis to determine the cut point for presence of the condition in relation to the outcome. Authors should report a separate first step analysis to determine necessary conditions (not sufficiency) and the consistency value set at 0.9 or higher. In addition, this should be articulated in relation to any assumptions about logical remainders. This is to guard against making false inferences.
9	**Assessment of sufficiency**	Is the level of consistency for a sufficient condition pre-specified and justified? > 0.75	A condition is sufficient if, whenever the condition is present, the outcome is also present. However, some cases with the outcome do not have the condition. This will be defined further in fuzzy set analysis to determine the cut point for presence of the condition in relation to the outcome. The level of consistency should be pre-specified and justified and should be above 0.75.
10	**Logical remainders** **(understanding limited diversity)**	Are logical reminders addressed (configurations with no observed cases)? Do authors differentiate between plausible and non-plausible logical remainders, and provide a strategy or explanation for approach?	Whether authors *treat* the logical remainders or not, and whether there is a clear acknowledgement that they are identified in the Truth table (if present) and a justification for no treatment or a plan provided to address these remainders is expected.
11	**Treatment of contradictory rows**	Do authors identify contradictory rows that are present? Do authors undertake to resolve these contradictions?	Contradictory rows in the truth table are those configurations that lead to either presence or absence of the outcome. Fuzzy set analysis rows maybe inconsistent but necessarily contradictory. This will be relevant at the crossover qualitative anchor of 0.5 and these results will require careful examination.
12	**Consistency (raw)**	Do authors measure consistency of individual rows?	This expresses the % of cases set membership scores are in line with the statement that one of two sets is a subset (or superset) of the other. Typically conducted by the software.

13	**Coverage**	Do authors measure coverage?	Either for sufficiency or necessity. Coverage sufficiency expresses how much of the outcome is covered by the sufficient condition. Coverage necessity refers to whether the necessary condition is trivial or relevant.
14	**Analysis of the negative outcome**	Analysis of outcome occurrence and its non-occurrence using the same conditions should not include the same truth table rows in both minimizations.	The Truth table should be two separate tables for the present and absent outcome. Or one table which splits the outcome present and absent.
15	**Presentation of results**	Do authors provide a Venn diagram or other visual (XY plot) to show the results of the truth table and the configurations? Graphical or tabular (truth tables)	Presentation of results refers in particular to graphical results here. Visualisation of results as with statistical techniques is considered an important step to assessing the results.
16	**Boolean minimization and appropriate notation**	Do authors (using software) undertake minimization procedures? Is appropriate notation used for solution terms?	Another presentational form is the reporting of the solution terms using appropriate notation. This notation ensures the maintenance of the underlying logic and Boolean algebraic expressions. E.g. Upper (present) and lower case (not present) letters.
17	**Overall robustness check**	Do authors report that they check the robustness of their results and clearly explain the procedures (and decisions) used to do so with an explanation of the results? Such as the differences in parameters of fit (consistency and coverage) and set relational status of the different formulas. Effects of: - Dropping or adding cases - Changing consistency levels - Changing calibration Importance of determining the 0.5 anchor.	There are two key dimensions to assess robustness in QCA. 1. Parameters of fit: If adjustments result in meaningful differences in consistency (case selection/calibration) and coverage this suggests results are not robust. If these checks do not change (or marginally) consistency and coverage this suggests the check are robust. 2. Set relational status of the different solutions (or formula). Different solution terms should share a clear subset relation. Any change that results in solutions not sharing a subset relation then the results are not robust. Any discussion or attempt at examining the complexity of these checks. Coverage and consistency are produced by the software.

18	**Coherence of interpretation of solutions/minimal formula**	Do authors produce solutions with clear explanation as to whether they are intermediate, complex or parsimonious? Are solutions interpreted as multiple conjunctural configurations and coherently related back to the individual cases? Only solution paths that have reached a pre-specified consistency threshold should be interpreted. Theoretical importance is greater than empirical importance (coverage). "In a causally complex solution, single conditions are INUS conditions which possess causal relevance only in combination with other conditions." (Schneider and Wagemann, 2012, p. 281)	Procedures that result in a series of 'solutions' require a comprehensive explanation that makes sense of these solutions in the context of the cases and the outcome. The solutions should be redirected back to the cases and the substantive knowledge or theory used to explain cases covered by solutions and deviant cases, uncovering the multiple conjunction of the conditions. For example, INUS[1] conditions that are only causally relevant when in conjunction with other conditions.

[1] Refers to Mackie's INUS condition which is a condition that is insufficient but necessary part of a condition which is itself unnecessary but sufficient for the result (P.79 S&W).

Appendix 5.3

Full papers reviewed and excluded (N=15)

Lead author and year	**Title**	**Reason**
Berry 2011	Historical review of the commissioning of health care disciplines in the USPHS	Uses the term Qualitative Comparative Analysis in abstract – but is not the Ragin inspired QCA method
Castellani 2019	Case-based methods and agent-based modelling: Bridging the divide to leverage their combined strengths	Methodological illustration of comparing and combining approaches.
Chiu 2017	Visualization of dietary Patterns and their associations with age-related macular degeneration.	Diagnostic application was beyond scope of health context in the review.
Donnelly 2013	An example of qualitative comparative analysis in nursing research	A demonstration rather than a full QCA although produces key components as steps for illustration – the paper specifies the results need to be defined in a broader report
Farrell 2007	A replication study of priorities and attitudes of two nursing programs' communities of interest: An appreciative inquiry	Uses the term Qualitative, Comparative Analysis in abstract – but is not the Ragin inspired QCA method
Haynes 2017	The Effect of Sleep Disorders, Sedating Medications, and Depression on Cognitive Processing Therapy Outcomes: A Fuzzy Set Qualitative Comparative Analysis.	Diagnostic application was beyond scope of health context in the review.
Hollingsworth 1996	Assessing capital investment in health systems	Seemed too far from the range of health care and health system studies included.
Kane 2014	Using qualitative comparative analysis to understand and quantify translation and implementation	Abstract unclear reporting technique not QCA process and findings.
Marx 2007	Comparative configurational analysis of ergonomic injuries	Beyond the scope of the health context in the review.
Melendez-Torres 2019	Developing and testing intervention theory by incorporating a views synthesis into a qualitative comparative analysis of intervention effectiveness.	Methodological paper.
Peddle 2018	What non-technical skills competencies are addressed by Australian standards documents for health professionals who work in secondary and tertiary clinical settings? A qualitative comparative analysis.	Workforce issues beyond the scope of the review.

Price 2014	Behaviour change pathways to voluntary medical male circumcision: narrative interviews with circumcision clients in Zambia	Although, there were indicators in language use this was not a Ragin inspired QCA method
Seror 2002	Internet infrastructures and healthcare systems: a Qualitative Comparative analysis on networks and markets in the British National Health Service and Kaiser Permanente	Title suggests QCA but it is a comparative case study
Staton 2017	A prospective registry evaluating the epidemiology and clinical care of traumatic brain injury patients presenting to a regional referral hospital in Moshi, Tanzania: challenges and the way forward	Not using QCA although refers to qualitative comparative analysis.
Villanveva 2017	The importance of trait emotional intelligence and feelings in the prediction of perceived and biological stress in adolescents: hierarchical regressions and fsQCA models.	Psychological study beyond the scope of the review.

Appendix 5.4

Study Characteristics of included studies for both the initial and updated review

Initial review January 1999-September 2015

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
1	**Bell 2012**	Not reported	Tasmani a, Australia	Services for chronic disease prevention and treatment	Health Policy – implementati on in health systems	Benchmarking in chronic disease	To use QCA to develop indicators and understand how policy goals such as chronic disease benchmark health service achievement of policy goals	Manager and clinician survey respondents from 17 services N=24	Eight conditions - policy goals: 1. Inequity, 2. Whole patient, 3. Health promotion, 4. Integration of self-management, 5. Adoption of evidence base practice, 6. Coordinated and integrated care, 7. Partnership links, 8. Quality improvement monitoring.	Perceptions of state health contribution and improvement in the sentinel services of evidence-based practice

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
2	**Blackman 2008**	2001-2003	Middles-borough, UK	Smoking cessation services in area of high depravat-ion	Health inequalities	Health prevention	To investigate how smoking cessation services could be more effectively targeted to tackle socioeconomic inequalities in health.	Smokers in a socioecono mic deprived area N=2882 Large N*	Five conditions -Indicators of deprivation: 1. worklessness, 2. Unhelpful neighbours, 3.No further education, 4. Low liveability 5. Low income	Smoking prevalence as % of sample
3	**Blackman 2011**	2005-07	Spearhe ad areas (worst health and deprivati on indicators) England UK	Life expectancy of individuals with cancer and CVD	Health inequalities	Life expectancy	What local conditions may be behind substantial variation to close the life expectancy gap across Spearhead areas examining the cancer and CVD outcomes, which account for much of the variation in life expectancy?	Spearhead areas N=27	Ten organisational attributes and contextual features that might affect outcome.	Narrowing or not narrowing of the life expectancy gap for cancer and CVD
4	**Blackman 2013**	2005-09	Spearhe ad areas (worst health and deprivati on indicators)	Teenage pregnancy rates in deprived local authority areas	Health inequalities	Pregnancy rates	To identify the conditions associated with the presence or absence of a narrowing gap in teenage pregnancy rates as measured by the differences between deprived local authority areas and the national average.	Spearhead areas N=27	Nine conditions: 1. Higher BME, 2. Lower numbers in drug treatment, 3. higher under 18’s in population, 4. Good commissioning	Narrowing or not narrowing of the teenage rate of pregnancy

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
			England, UK						5. fair leadership, 6. Interventions mostly in community settings, 7. Major programmes, 8. lower deprivations, 9. higher GSCE achievement	
5	**Blake 2001**	1945-94	Global	Advanced industrial Countries	Health Policy	National Health Insurance	Why has the United States failed to adopt National Health Insurance when other advanced industrial democracies have done so?	Advanced industrial democracie s N=20	Five conditions: 1. societal culture amenable to the emergence of NHI, 2. unitary state, executive 3. dominance of policy making, 4. leftist party capable of capturing the office of chief executive 5. corporatist interest-group setting.	Presence of a National Health Insurance scheme
6	**Britt 2000**	9/1989 - 10/1998	Wayne State, US	University reproductiv	Decision context for terminations	Genetic abnormalities	Seek to address contextual and social factors that relate to a decision to	All case logged in one clinic for	Four conditions - factors of the	Decision to terminate pregnancy

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
				e genetics clinic			terminate a pregnancy following a positive trisomy 21 anomaly.	specified period. N=142 Large N*	decision context reflecting past experiences, 1. current situation: 2. Maternal age, 3. Gestational age, 4. existing children 5. prior voluntary abortions.	when trisomy 21 anomaly detected
7	**Britt 2006**	Not reported	Arkansas, US.	Neonatal care	Telemedicine	Video consultations with high-risk pregnancy specialists	Investigates how combinations of resources affect the nature of maternal transfer patterns.	Birth related transfers – pre and post telemedicine programme period 1 N= 174 Period 2 N=152 Large N*	1. Period 1 or 2 2. Level 2 or 3 hospital 3. Access to telemedicine.	Very early gestational age transfer (<33 weeks) or Not very early gestational age transfer (33+ weeks).
8	**Britt 2007**	Not reported	US	Multiple pregnancy	Multi-foetal reduction decisions	Impacts on decision difficulty	Do different combinations of medical, conceptual and lifestyle frames have an impact on the difficulty and attendant emotional turmoil surrounding these decisions?	Women and partners during and following counselling at a single facility specialising in multifetal	Three conditions - decision making frames: 1. Medical, 2. conceptual 3. lifestyle	Decision difficulty (emotional turmoil) undertaken at 8-12 weeks gestation.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								pregnancy reduction (carrying at least 3 foetuses). N=54 Large N		
9	**Brunton 2014**	January – September 2013	Global	Community engagement	Public health interventions	Disadvantaged pregnant women and new mothers: breastfeeding, immunization, antenatal care and early intervention	To explore which conditions of community engagement are implicated in effective interventions targeting disadvantaged pregnant women	Disadvantaged pregnant women and new mothers in a subset of trials N=29	Four conditions - mechanisms of engagement: 1. Empowerment 2. Lay delivered 3. Collaborated on delivery 4. Consulted on design	Effectiveness of interventions
10	**Candy 2013**	From 2009	Global	Chronic conditions	Complex interventions	Adherence to treatments (drug therapy) in chronic conditions	To identify matches between patient's views and components of interventions and see whether these matches were associated with the effectiveness of interventions. Uses qualitative evidence synthesis (QES) to explain variability in effectiveness in complex interventions.	Trials (RCTs) within a Cochrane Review evaluating interventions for enhancing medication adherence cross a range of disease	Nine conditions: 1. Discuss circumstances that lead to forgetting to take treatment. 2. Emphasise that experiencing no symptoms does not mean	Intervention effective or not effective by each trial based on *P* value cut off 0.05

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								specific areas. N=21	to stop taking the drug. 3. Enhance convenience of taking the drug. 4. Information on side effects. 5. A focus on personal risk factors. 6. An exploration of attitudes to drug and/or disease. 7. Emphasis on the value of adherence. 8. Clear or appropriate information. 9. A focus on improving social support.	
11	**Chang 2013**	Jan – Mar 2009	Taiwan	Acute care	Patient loyalty to a hospital	Surgical patients – because they have several treatment options available to them.	To explore sufficiency conditions for patient loyalty to a hospital.	600 completed patient questionnaires	Three antecedent conditions: 1. Patient satisfaction	Patient loyalty

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								Large N*	2. Patient participation 3. Patient decision making	
12	**Chuang 2011** (overlap with Dill 2014)	2007-2008	US	Health care systems	Workforce management	Key worker practices impact on health care	To identify different configurations or “bundles” of High-Performance Work Practices (HPWP) associated with high job satisfaction and perceived quality of care among Front Line Workers (FLW).	FLW from 13 large healthcare employers – ten unique hospitals or health care systems and three community centres. N=661 Large N*	Six conditions 1. Creative input 2. Supervisor support 3. Incentive pay 4. Team based work 5. Flexible work 6. Job rotation	1. High job satisfaction 2. Perceived high quality of care
13	**Cragun 2015**	Oct-Dec 2012	US	US institutions providing genetic counselling and testing	Tumour screening Programme	Programme implementation	To identify institutional level conditions that might contribute to the wide variability of patient follow through (PF).	Lynch Syndrome Screen network representati ves working in various institutions performing universal tumour screening from all newly	Four conditions: 1. Genetics professional discloses abnormal screening results to patients (gen_prof_disc lose _Screen)	High patient follow-through

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								diagnosed CRC patients for at least 6 months and had access to institutional data on patient follow through (PF). N=15	2. Obtaining a referral from a health worker provider was the primary mechanism for genetic counselling (referral_barrier) 3. Difficulty in contacting patients (difficulty_contact_pt) 4. Genetic professional sets counselling and testing (gen_directly_contacts_pt)	
14	**de Andrade 2014**	2011-2012	Brazil	Treatment delays to patients with ST-segment elevation Myocardial Infarction (STEMI)	Acute care	Service delivery (guideline implementation)	To evaluate the factors related with delays in the treatment of STEMI patients to support a strategic plan toward structural and personnel modifications in a primary hospital aligning its process	STEMI patients, identified through patient records who were admitted to the emergency	Four conditions (described as variables) taken from patients notes 1. First medical contact (FMC) at admission	1. Ejection fraction < 50% [EF] 2. Length of stay (LOS)

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
							with international guidelines.	department, diagnosed and transferred to a Primary percutaneous coronary intervention (PCI) center. N=29	2. electrocardiogram acquisition (ECG) 3. ECG transmission and PCI centre team feedback time (TXF) 4. patients transfer waiting time (TWT)	
15	**Dy 2005**	1990-1996	Surgery, hospitals, US	Emergency and acute care	Critical care pathways	Service delivery	To qualitatively describe patient, hospital care, and critical pathway characteristics that may be associated with pathway effectiveness in reducing length of stay	Surgical pathways in a tertiary care department of surgery. N=26	These are couche under 4 hypotheses, so associated characteristics are 1. Length of stay not already decreasing at the time of implementation 2. First pathway implemented in a service 3. Lower severity illness 4. Successful pathway implementation.	Effective pathway effect was statistically significant on decreasing post-operative length of stay or ineffective pathway effect was not statistically significant.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
16	**Eng 2012**	1997 and 1998	Lifestyle survey, US	Social drinking patterns	Characteristics of male heavy alcohol drinkers	Addiction behaviour	To examine the underlying characteristics of heavy-alcohol drinking behaviours by taking into account all three macro sets of variables in configural recipes: conjunctive statements that include demographics, lifestyle and beliefs and opinions	Survey consumers who heavily frequent bars and taverns of 60 or more times per year. N=26	11 antecedent conditions for heavy drinking males. 1.gambled in a casino frequency last 12 months. 2.Statements of fun, parties etc. 3. Statements 'I dread the future'. 4. Statements re: lack of control over life. 5. More self-confidence than friends 6.most welfare recipients are cheats 7. I would do better than average in a fist fight 8. Statement attended a professional athletic event – frequency last 12 months	Visit frequency to a bar or tavern within the last 12 months.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
									9. Attended Church or other place of worship frequency in the last 12 months. 10. Sex 11. Race 12. Marital-status	
17	**Ford 2006**	5-year period/10 years 1990-2000	State level Health agencies, US	Data obtained from budgets agency plans and annual reports	Adherence to Institute of Medicine guidance	Public Health	To investigate the relationship between state health agencies' adherence to the recommendations of the United States Institute of Medicine (IOM) Report, the future of public health, and changes in their population's health.	US states, that is the cabinet level leader that can inform on public health in that state. N=41	Five conditions - Public health core functions: 1.Assessment Assurance 2. Policy development 3. Strategi c characte ristic variable 4. Resource availability 5.Adaptability/ proactivity	Superior progress (or improvement)
18	**Gillighan 2010**	Not reported	Australia	Forensic Psychiatric	Pathways to homicide	Forensic mental Health	To examine if the Harris (2001) two-path model	Purposive sample of	Three conditions:	Head injury

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
				patients in one institution			accounts for the heterogeneity observed in a sample of homicide offenders.	offenders charged with murder or attempted murder and were found not guilty due to mental illness in their subsequent trials. N=26	1. Impaired executive 2. functioning Impaired 3. temporal lobe functioning.	Substance abuse Anti-social parenting: Negative role modelling, instability, lack of safety and overall instability.
19	**Glatman-Freedman 2010**	Not reported	African Region	'Poor nations' – GAVI (Global Alliance for Vaccines and Immunisations) eligible	Vaccine implementation	Public Health	To investigate the conditions which have been conducive to the successful introduction of the Hib and HepB vaccines by the GAVI into lower income countries during its first phase of operations.	African countries with a population of 0.5 million or more. N=35	Three conditions: 1. Total health expenditure as a percent of the GDP 2. Government healthcare expenditure per capita 3. Combined Governance indicator	Success in the introduction of at least one new vaccine
20	**Goicolea 2015**	Jan 2013-March 2014	Spain	Primary health care centers in four	Primary Health care response	Intimate Partner Violence	To test previously described programme theory in Primary Health care centre (PHCC) teams located in four different	15 PHCC in 4 Spanish regions of different size, socio-	Ten conditions 1. Self-efficacy 2. Victim understanding-	A good response to IPV **(Pract)**

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
				regions of Spain			Spanish regions with the aim of identifying the key combinations of contextual factors and mechanisms that trigger a good primary health care center team response to IPV. N=15	demographic indicators and implementation of IPV interventions.	Woman centeredness 3. Knowledge 4. Perceived preparation 5. Team workings on IPV (Interventions & contextual) 6. Protocol use 7.Training received 8.Experience with PHC 9. Team climate/organisation 10. Champion social worker	
21	**Hark-reader 1999**	1965-1990's	Political policy, Florida, US	Legislation history	Legislation that regulates hospitals and the market arrangements that are at the centre of political decisions.	Health system/ policy	To provide an in-depth description of the factors affecting healthcare and an analysis of the conditions for a state that has been innovative in health care policies.	Policy legislative groups covering Hospital licensing and regulation, state planning of healthcare facilities and services, -	Seven conditions 1. Federal financial incentives promoting policy 2. Unified healthcare provider policy position in opposition to state policy	Enactment of legislation or not

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								hospital indigent care and medical assistance for the needy. N=27	3. state agency supporting policy position 4. Legislative leadership supporting policy position 5.Governor not opposing policy position 6. Legitimation of unified health care provider position 7. Legitimation of state policy position undermined by fiscal condition	
22	**Haworth-Hoeppner 2000**	Not reported	Michigan, US	Not described or elaborated	Eating disorders	Mental Health	To identify combinations of family characteristics that are especially important in generating conditions associated with the development of eating disorders.	White middle-class women with or without anorexia or bulimia from 21-44 years old. N=30	Four conditions: 1. a critical family environment, 2. coercive parental control, 3. unloving parent-child relationship 4. main discourse on weight.	Eating disorder occurrence

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
23	**Kahwaiti 2011**	2009-2010	US	Veteran medical facilities	Weight care management	Programme implementation	To explore variation in MOVE! Program implementation to identify facility structure, policies and processes associated with larger patient weight loss outcomes	30 patients at Veteran Medical facilities providing the program MOVE! 239 N=22	17 (*potential causal*) conditions were: 1. high interface between screening and treatment 2. Use of standard program curriculum 3. Use of multidisciplinary team approach. 4. High program complexity. 5. Use of weight loss component. 6. Use of group care format. 7. High use of tailored and structured dietary plans. 8. High use of tailored and structured physical.	Weight loss outcomes highest and lowest that is proportion of patients achieving > 5% weight loss at 6 months follow up.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
									activity plans. 9. High use of multiple behavioral strategies. 10. High staff involvement. 11. No use of waiting list. 12. High facility complexity. 13. High data tracking and analysis capacity. 14. Active physician champion involvement. 15. Use QI enhancing program and resolve challenges. 16. High program accountability to facility leadership and internal reporting requirements.	

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
									17. High program accountability to regional leadership and external reporting requirements.	
24	**Leykum 2014**	Over 11 months	Various health care US	Facilitation of care	Effective conditions and contexts to improve processes of care delivery and outcomes	Health care system delivery	Theory development Seeking to understand better the conditions or contexts across which approaches of improving the relational aspects of care delivery as a strategy to improve processes and outcomes that would be most effective.	Studies (observational and interventional) with a common team of investigators to investigate patterns to provide insights using a complexity theory lens. N=8	Five conditions (*theoretical variables)* Disease related: 1. Pace 2. Patient control Task related 3. Standard/ custom, 4. interdepend-ency 5. Routine/non routine.	Reported outcomes (from studies) 1. Process outcomes 2. Other outcomes
25	**Longest 2012**	1988-1990	US	Public Health	Gender differences in managing stress	Mental health	Aims to compare the workings of the stress process for women and men who suffer two types of internalising problems (psychological distress and poor physical health).	Divorced or married adults randomly sampled in the Indianapolis area US.	Five conditions: 1. Stress events 2. Strain 3. Mastery and self-esteem 4. Coping	1. High psychological distress 2. Poor health

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								N=528 (males=204, females=324) Large N*	5. Social support	
26	**Melinder 2001**	1990	Sweden	Socioeconomic and cultural factors within European countries	Examining the social and environmental genesis of injuries (traffic accidents and suicides)	Public health	To analyse how socio-economic factors – such as education and religion – relate to kinds of injuries Seeking to investigate the impact of various factors on environmentally and socially related injuries	European countries N=12	Five conditions 1. Gross national product (GNP) in US dollars per capita 2. Unemployment rate in %, 3. years of schooling 4. Annual pure alcohol consumption (litres per person aged 15 above) 5. Religion by country	Death due to injury: Standardised death rates per 100.000 inhabitants for motor vehicle fatalities and suicides/fate self-inflicted injuries
27	**Sheehy 2014**	Not reported	California US	Physician organisation medical manageme	Length of stay (bed days)	Care management practice	To investigate which Physician Organisation medical management practices are linked to effective inpatient utilization management, as	Physician organisations (PO) in the US state of California that met	Four conditions: 1. Medical	Bed days per 1000.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
				nt practices			manifested by low inpatient bed-days per thousand members per year (bed days)	criteria and responded to interview request. N=14 and 16	2. length of stay 3. Surgical admissions 4. Medical admissions (two-step process) each of these was an outcome for a number of conditions	
28	**Thomas 2014**	Not reported	Global	Interventions to promote breastfeeding	Complex interventions	Research synthesis of policy and practice in health	Identifying intervention components that are effective within the complex intervention based previously on identified 'theories of change'.	Subset of studies from previous large multi method systematic review of interventions to modify smoking, alcohol abuse, substance abuse and obesity that incorporate community engagement in disadvantaged	Five conditions 1. Empowerment 2. Involvement in intervention design, and 3.Lay led intervention 4. Quality 5. intensity.	Highly effective outcome based on previous review effect estimates for each study.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
								populations. Subset investigates breastfeeding interventions N=12 primary studies.		
29	**Thygeson 2011**	Not reported	Upper mid-west integrat-ed delivery system US	Patient centred medical homes (Primary care practices – level 111)	Service delivery Quality of medical home care	Primary care service delivery	To evaluate the connection between medical home system capabilities and quality outcomes.	Clinics that are recognised as Level lll NCQA Medical Homes using the PPC (Physician Practice Connections _PCMH) 2008 N=21	Nine conditions: 1. Provider reporting 2. Preventative services 3. Systems 4. Women or seniors 5. Low socio-economic 6. team care diabetes 7. BMI 8. Not enough information, 9.Communicat-ion problems. 3-5 conditions per model. Seven models	Three main outcomes: low ODC (optimal diabetes care, low PSUTD (preventative services up to date) and NOTRECOMMED These outcomes are then further defined based on the PPC-RS domains There are 7 models for each outcome (dependent variable)

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
30	**Warren 2013**	2009-2010	Primary Care Trust, North East England UK	Long term incapacity benefit recipients	Case management	Public health – health improvement	Exploration of how the health improvement effects of the intervention (case management) varied by 1. Individual participant characteristics and 2. Service characteristics.	Individuals referred onto the pilot case manage-ment programme (average duration 6 months) provide data via series of question-naires N=130 Large N	Five conditions: characteristics of individuals 1. age, 2. sex, 3.primary health problem (musculoskeletal or not), 4. Skill (skilled or unskilled) in last paid job 5. Whether they talk to neighbours on a weekly basis or not. Service characteristics not reported	Health improvement – as the movement towards the UK population norm EQ-VAS score of 82.48
31	**Weiner 2012**	2010	National Cancer Institute, Community Clinical Oncology Programme, US	Oncology practice and community hospital networks	Trial enrolment	Health Research	To examine the organizational design features that were consistently associated in 2010 with high levels of patient enrolment onto the National Institute (NCI) cancer treatment trials among the oncology practices and hospitals participating in the NCI	Community clinical Oncology Programme (CCOP's) operating in 28 US states, which covers 400 hospitals and 3, 520	Four conditions-organizational design features 1. Treatment trials (accrued at least one patient) 2. Patients with newly	12-month patient enrolment onto NCI treatment trials. Treatment accrual.

	Study (First author and year)	Study period (data collect-ion)	Study setting	Contexts	Health Focus	Health Field	Objective or research question	Cases	Conditions	Outcome(s)
							Community Clinical oncology program.	community physicians. N=47	diagnosed cancer seen 3. CCOP number of Physicians affiliated to the CCOP 4. CCOP components for enrolment	

- Large N refers to a case sample size number greater than 50

Update review study characteristics September 2015- February 2019

	Study (First author and year)	Study period (data collectio n)	Study setting	Contexts	Health Focus	Health Field	Objective/RQ	Cases	Conditions	Outcome (s)
1	Beifus 2017	To be identified (Protocol)	Various – systemati c review	Whole population People at risk Age specific perspectiv e	Skin cancer prevention	Cancer	To establish through the available literature, the effects and conditions that prove the effectiveness of prevention strategies in skin cancer	Each included study	To be identified	Effectiveness or not of prevention strategies for skin cancer

2	Bianchi 2018	Search August 2017	Various – systematic review	Education on meat consumption and lifestyle changes to behaviour	Reducing meat consumption	Environmental health	To evaluate the effectiveness of interventions targeting conscious determinants of human behaviour to reduce the demand for meat.	N=24 comparisons between interventions and no-intervention controls or pre-intervention baselines.	Non-tailored environmental information Non tailored health information with practical strategies Self-monitoring and goal setting Lifestyle counselling with people at increased risk of ill health Animal suffering Tailored information Information about multiple issues Non tailored education on the environment and health When actual behaviour the outcome	Statistically significant reduction in meat consumption or purchase in both actual and virtual environments
3	Bicknell 2017	2009-2012	Hospital and community settings	Facilities serving women predominately from Black and	Health system failures resulting in underuse of treatment for	Cancer	To identify key organisational characteristics associated with low underuse cancer care.	N=9 inner city, hospitals	Information sharing Follow up System support	High quality hospital

			New York US	Hispanic ethnic groups	breast cancer				Patient centred Private practice Flexibility	
4	Breuer 2018	October to December 2013, March 2014-November 2016	Health facilities in Nepal	Mental health provision in primary care	Utilisation of mental health services	Mental Health	To determine what combination (s) of conditions identified by the PRIME theory of change at facility and community level influenced the mental health service utilisation in the PRIME implementation facilities in West Chitwan.	N=10 primary care and outpatient posts	Medication Community Level activities Services available	High mental utilisation vs low mental utilisation
5	Burchett 2017 Linked to Melendez-Torres)	Search	Various – systematic review	Children 0-11	Weight management	Public Health	To identify critical features of successful lifestyle management interventions for overweight children	Types of interventions N=20	Physical activity, Practical behaviour change, calorie intake advice Child friendly sessions, aim to change behaviour, education/discussion	Most and least effective interventions
6	Castellano Rioja 2019	2015-2017	Patients from the Valencian Association of Lupus Sufferers Spain	Lupus erythematosus	Quality of life	Autoimmune disease	To analyse the influence that socio-demographic variables and medical variable have on the quality of life of patients with Lupus.	N=161 patients suffering from Lupus erythematosus	Age Sex Type of lupus Time with lupus Time to diagnosis	Quality of life

7	Chiappone 2018	2015-2016	Two states in the US	Early care and education programmes in receipt of technical assistance	Breast feeding and infant feeding, child nutrition, infant and child physical activity, screen time, and outdoor play and learning	Early care education	To identify and compare characteristics of technical assistance associated with high-performing programs and low performing programmes explore associations with nutritional and physical activity practices in the National Early Care and Education Learning collaboratives Project	Early care Educational programmes N=84	Mode of technical assistance e.g. email Method of technical assistance e.g .resource sharing	Receipt of technical assistance (hours received)
8	Dill 2014 Missed in previous (overlap Chuang 2012)	2007-2010	Hospitals health-care systems and commun-ity health centers US	Low skilled workers	Career ladder development	Front line healthcare workers	To examine how healthcare organization-education partnership dynamics are related to worker outcomes in career ladder programs	N=291 Frontline workers	Education leader Supportive frontline management Educational policies Partner history Community need	Career self-efficacy Program satisfaction Wage and/or promotion Credit and/or credential
9	Eicher 2016	November 2014 - February 2015	Acute care hospitals Switzerland	Asset investment models used by hospitals	Expenditure for investment in hospital assets	Health expenditure (Transaction cost economics)	To identify influencing factors for hospital asset investment decision	Hospitals N=19	1. (Context) Human asset specificity Physical asset specificity Uncertainty 2. (Proximate) Bargaining power	Degree of outsourcing

									Privacy of ownership	
10	Forman Hoffman 2017	Search February 2017	Various – system-atic review	Child and adolescent mental health care	Quality improvement, implementation and dissemination strategies to improve care	Mental Health	To determine whether effectiveness or harms differ for subgroups based on system, organisational, practitioner or patient characteristics	19 studies	Educational materials, Meetings and outreach, Patient mediated intervention components, Reminder components, Financial and organisational components	Statistically significant improvement practitioner, system and patient intermediate outcomes
11	Gimenez-Espert 2018	September 2015-February 2016	Nurses based in hospitals Spain	Attitudes towards communication of nurses (ACO)	Empathy and emotional intelligence	Communication behaviour with patients	To analyse link between empathy and emotional intelligence as a predictor of nurses' attitudes towards communication while comparing the contribution of emotional aspects and attitudinal elements on potential behaviour.	Nurses completion of questionnaire (N=460)	Perspective-taking Compassionate care Thinking as the patient Emotional attention Emotional clarity Emotional reparation, affective, cognitive	Affective, cognitive and Behavioural dimensions
12	Goicolea 2018	September 2016	Municipalities in four Norther	Youth Health Centers	Utilisation of mental	Mental Health	To analyse the various conditions that are sufficient and/or necessary to make Swedish youth health	Youth Health Centers N=18	Trust in Center	Access to mental health

		to April 2017	counties of Sweden		health services		centers accessible for mental and psychosocial health		Consists of a multi-disciplinary team Expertise in mental health Easy to contact	
13	Harris 2018	Search August 2018	Various – systematic review	School based self-management Asthma interventions	Self-care	Public health	To identify the intervention components and processes that are aligned with successful school-based asthma self-management intervention implementation	27 studies (process evaluations)	Theory driven, Child satisfaction, Running intervention outside child's own time, Good engagement with parents, Whether high school or not	Successful implementation of intervention
14	Harting 2017 (overlap with Peters)	2009-2014	Netherlands public health policy networks	Active participation of actors in the networks to provide a 'mix of interventions'	Multi sectoral policy networks (Overweight or drug and alcohol abuse)	Public health	(i) Is a multi-sectorial policy network indeed necessary for the implementation of an intervention mix that include multiple intervention strategies (ii) Which other conditions or combinations of conditions are necessary for a multi-sectorial policy network to achieve this kind of network performance	Dutch public health policy networks N=29	A multi-sectorial network. Active participation of network actors Trust among network actors Active networking by the project leader No. of actors	Intervention mix – educational and non-educational

15	Hartmann-Boyce 2018	Search June 2017	Various – systematic review	Interventions involved in food purchasing	Diet and nutrition choices	Public health	To evaluate the effectiveness of grocery store interventions to change food purchasing and to examine whether effectiveness varied based on intervention components, setting or socio-economic status	Interventions N=89	Whether or not the intervention involved an economic component Changes to store environment Consumer education, food swaps, whether or not the intervention was based in a real grocery store	Effectiveness of interventions to change food purchasing behaviour
16	Kahwati 2016	Studies from previous search cover 1995-2012	Various – systematic review	Medication adherence	Behaviour change interventions	Chronic condition care	To identify necessary or sufficient configurations of behaviour change techniques among effective interventions	60 studies (RCTs)	Knowledge Facilitation Awareness Self-efficacy Intention formation Action control Attitude Maintenance Motivational interviewing.	Improved adherence
17	Kien 2018	September 2010-April 2012	Primary schools, Austria	Lower Austria primary	Health of primary school age	Health promotion	To identify combinations of conditions that were associated with either and increase or no increase in	Classes assigned intervention (N=24) and control group	Dosage of the intervention	25% of children in class showed improvement in emotional

				schools (German)			the emotional and social school experience	(waiting list assignment) (N=27)	Quality of the implementation Relative advantage Perceived self-efficacy, knowledge about the intervention	and social experience
18	Kneale 2018	2012-2014, 2015-2017	Health and Social England	Health and Well-being Boards (HWB)	Health and well-being strategies (HWS)	Health and social care – public health	To understand: (i) the HWB characteristics overlapping with evidence use; (ii) exploring overlaps between evidence use patterns and HWB characteristics with local authority public health spending allocations.	HSWs published in 2015/16 N=28	Reflecting evidence use: Robust evidence sources, specific local research, reference to needs assessment and guidance from national stakeholders Reflecting local characteristics, most deprived and male expectancy.	Top quintile of public health allocations per person
19	Leas 2017	Search April 2017	Various – systematic review	Adults and children with asthma	Effectiveness of interventions to reduce or remove exposures to indoor inhalant	Respiratory disease	What allergen reduction intervention or combination of intervention components is present in studies demonstrating improved asthma outcomes?	N=49 RCT studies	Acaricide Air purification Carpet removal HEPA* vacuum	Improved asthma outcomes (any - asthma control, exacerbations, healthcare utilization,

					allergens on asthma control				Mattress covers Pet control *high-efficiency particulate air-filtration	pulmonary physiology, or quality of life)
20	Lubold 2017	2005	High income countries worldwide	Macro level factors (welfare and public health)	Breastfeeding initiation	Infant nutrition	To examine the effects of both public health initiatives and welfare state policies on breast feeding initiation among eighteen high income countries	High income countries N=18	%of baby friendly hospitals Weeks FTE paid maternity leave Female part time employment Caesarean section rate Public spending on family benefits	Breastfeeding initiation
21	Matheson 2017	Evaluation period 3.5 years 2013- (Protocol)	Aotearoa / New Zealand	Healthy families – community based interven-tion – Maori people	Prevention of chronic disease	Public health prevention	To evaluate a community based public health intervention assuming the social system is complex	N=10 sites in New Zealand	To be identified	To be identified

22	Melendez-Torres 2017	Search period of guideline	Various – systematic review	Adults	Diet, exercise and behaviour change	Weight management programmes (WMP)	To identify the factors on the pathways to the most and least effective WMPs using a patients' views synthesis	N=20 most effective and least effective WMPs identified in a clinical guideline using RCT's	Provider relationship emphasised High intensity of relationship Direct provision of exercise Graduated exit Population targeting and group work	Provider support Peer relationships
23	Mendel 2018	May-September 2013, October-December 2014	Centers for Medicare and Medicaid services in the US	Attainment of Patient-centered medical home (PCMH) status	Organisational -structural and cultural transformation	Primary care	To understand the process of practice transformation by identifying pathways for attaining patient-centered medical home recognition	Federally qualified health center N=20	PCMH culture context PCMH structural context Implementation process	PCMH transformation
24	Paykani 2018	2004-2015	Countries world-wide	Structural determinant of health inequality	Life expectancy at birth	Health inequality	What combinations of structural conditions is usually sufficient for high life expectancy? What combination of structural conditions is usually sufficient for low life expectancy?	Countries N=131	Governance Wealth Income equality Education Health systems	Life expectancy
25	Peters 2017 (overlap with Harting)	2009-2015	Municipalities in the Netherlands	Environmental determinants of health	Intersectoral policy networks for reducing overweight, and 'alcohol	Health behaviour	To what extent is network diversity a necessary condition for addressing environmental determinants of health amidst the conditions of network size,	Local public health-related networks N=25	Network diversity Network size Network management	Addressing environmental determinants of health behaviour

					and drugs abuse’		management strategies, and budget?		Additional budget	
26	Saltkjel	2008 and 2013	Europea n countries	Country austerity policy and crisis	Welfare macro-economics	Population health	How are configurations of crisis and austerity related to changes in population health across Europe?	European countries N=29	Austerity Crisis	Enhanced vs deteriorated health
27	Scott-Parrot 2018	Two searches for review 2013 and 2015	Various – system-atic review	Complex multicomp onent nutrition interven-tions	Weight management	Paediatrics	To examine the interplay of configurations of context characteristics can influence the outcomes of paediatric weight management	Number of arms in studies configuration characteris-tics N= 28	Context characteristic: Intensive medical nutrition or behavioural intervention Treatment > 6 months Clinic setting Family involvement Group sessions Teenager	BMI Waist circumstance and BMI percentile
28	Thygeson 2016 Abstract only	2012	Palliative hospitals in California US	Program reports to the California Statewide Health Planning and Developme nt	Medicare utilisation	End of life care	To determine whether self-reported California hospital program characteristics are associated with lower end of life Medicare utilisation	N=203 general medical care hospitals	Staffing levels of palliative care (PC) teams Presence of PC program No. of certified PC staff % of Medicare decedents, dying as inpatients	Improved program performance

									Physician visits in last 6 mths Ave. hospital stay and ICU* days *Intensive Care Unit	
29	Verissimo 2018	2015	6000-member medical social network who use mobile medical apps	Medical staff who use mobile apps in Portugal	Usage intensity of mobile medical apps	General and specialised medicine	To investigate factors associated with the adoption of new mobile technologies	N=199 survey respondents	Perceived ease of use Perceived usefulness Peer influence Seniority Age Gender	Positively associate with intensity of mobile medical apps
30	Vickery 2018	2011-2014	1 Medicaid Accountable integrated care organisation (ACO) US	Primary care, low income Medicaid enrolees	Quality of life benefits for integrated care	Integrated health (physical, social and behavioural)	Does the ACO care model address enrolees needs, shape their experience with healthcare and affect their quality of life?	N=35 patient enrolees in Medicaid ACO	Physical complexity Mental health complexity Substance abuse complexity Bond to primary care clinic Receipt of regular mental healthcare Receipt of clinic-based support	Improved quality of life

Appendix 5.5

QCA review framework synthesis: Stages 3 and 4

Study purpose, rationale, and underlying assumptions of causal complexity

Study			**Authors understanding, explanation and application key QCA concepts within the studies**		
Author and Year	**Purpose of study**	**Authors rationale for using QCA in research strategy**	**Causal complexity: core concepts of Equifinality, asymmetric causation and conjunction causation**	**Applications of core concepts of set relations: Necessary and Sufficient conditions** **(Tracer concepts for understanding of underlying epistemology) (N/A- not addressed)**	**Theory and underlying assumptions of causal processes expressed in study**
Bell 2012	Macro level – To identify the impact on service improvement of health system policy goals	To understand how parts of the state health system, by kind or degree, work together in concert.	Ways in which service improvements combine and work in relation to each other.	Concepts referenced only.	Sought explore data (health worker perceptions) for plausible reasoning for the implementation of policy goals for health system service improvements.
Blackman 2008	Macro – Targeting health services to improve health more effectively taking account of health inequalities.	Identifying the possible combination of conditions under which an outcome will occur.	To ensure an intervention outcome, other conditions (contributory stress factors) combine to facilitate outcome.	Concepts used to explain results, although not clearly defined.	To explore data and develop intervention theory.
Blackman 2011	Macro – Explain the local variation between areas of high deprivation on reducing premature mortality	Developing causal arguments (models) by creating a close correspondence between theory and data to explain	Provides causal pathways based on real cases and actual practice using theoretical reasoning	Sufficiency and necessity concepts used.	To identify factors based on concept of causal complexity and a systems approach.

		mechanisms for given outcome.			

Blackman 2013	Macro – Identifying factorial differences between different regions impact on reducing teenage pregnancy rates	Identifying explanations based on reasoning of complex realities not possible using multiple regression techniques. Identifying different causal models possible in a systematic and transparent approach a weakness in qualitative research.	Provides alternative causal pathways more useful for policy makers that determine the factors present for a given outcome.	Utilised in the findings section.	To identify causal 'associations' to explain local variation found teenage pregnancy rates.
Blake 2001	Macro – Explaining why an advanced national democracy (US) did not (at time of study) adopt a national health insurance scheme	Limitations of cross-sectional analyses that examine proportional relationships is unusable in the context of a explaining health policy decision dynamics	Use of QCA to manage small N and identify conjunction of factors that allows closer examination of a larger number of cases (case based) to achieve some generality and retain complexity.	N/A	Theory development to model the function of 5 independent variables that might be obstacles to the implementation of National Insurance Schemes, as examined by their configurations across the specific cases.
Britt 2000	Micro – What contextual factors impact on parental decisions to terminate a pregnancy following a positive trisomy 21 anomaly.	Identifying the complex layers of contextual factors that contribute to whether or not patients decide to terminate a pregnancy is not attainable through more typical sampling and statistical techniques.	To confront complexity of decision making by examining how certain factors interact to create decision contexts, which have different implications or work for different reasons.	N/A	Theory development hypothesizing alternative decision contexts for termination of pregnancy following positive trisomy 21 anomaly
Britt 2006	Meso – Resource factors that impact on service delivery to ensure most appropriate care for low weight babies.	Allows rigorous cross case analysis	Conditions that combine	N/A	Use of QCA as an adjunct to explain findings of logistic regression.

Britt 2007	Micro – parents decision context that influences their degree of difficulty in deciding to terminate a foetus.	To examine data related to concepts of interest in systematic way across cases.	Author addresses numerically the number of cases that do or do not lead to the outcome.	N/A	Hypothesis testing of the level of difficulty in making decisions to terminate one or more foetus
Brunton 2014	Macro – Identifying factors for effective community engagement of disadvantaged pregnant women.	To identify what works for disadvantage new and expectant mothers in using QCA to examine multiple routes of multi component interventions resulting in an effective outcome.	A descriptive approach that resists simplification holding on to complexity and allows examination of the 'active ingredients' to inform interventions for testing in a causal model of an RCT.	N/A	Hypothesis generation for aspects of community engagement aligned with effective interventions
Candy 2013	Micro – Explaining variability in effectiveness of interventions to address medication adherence by incorporating patient views.	Use of QCA as an integrated mixed method approach for small N studies (trials in a systematic review), to explain the outcome in terms of which intervention ingredients were '*essential or necessary*' (using patient views) for an effective outcome. Used QCA '*add information on interventions not available in a net effects statistical approach.*	Patterns observed in the data across the cases allow inference. This is unidirectional and combinatorial.	N/A	Hypothesis generation based on incorporating qualitative (patient's views) data in a systematic review of trials of effective or ineffective treatments for adherence to medication
Chang 2013	Micro – identifying the conditions for patient loyalty to a hospital	QCA is used to examine alternative propositions using set relations not correlations, which is not hampered by sampling, confounding and net effects issues.	Examines logical (patterns of relationships) rather than statistical relationships between variables in linear models. Such variable relationships are triangular and asymmetric.	Authors articulate throughout the sufficiency and necessity of conditions in relation to the outcome.	Proposition development

Chuang 2011	Meso – identification of high-performance work practice bundles that provide high job satisfaction and perceived quality of care among front line workers	QCA used due to limitations of regression approaches to accommodate interaction between three or more variables. Therefore, seek to test multiple interactions rather than isolating a single factor. Work practices are typically bundled their relative effectiveness of different bundle combinations not addressed.	Authors explain equifinality, asymmetry and conjunction without necessarily using these terms.	Authors utilise the set relation concepts of sufficiency and necessity.	Hypotheses tested with preliminary confirmation that a “bundled” approach to HPWP incorporating practices from multiple HPWP subsystems might be more effective than focussing on practices from just one HPWP subsystem.
Cragun 2015	Macro – Exploration of patient follow through in a colorectal tumour screening programme	Use of QCA to address complex real-world situations in a multi method approach to evaluate the effectiveness of universal colorectal tumour screening programmes to identify Lynch syndrome.	QCA uses logical mechanisms by which key conditions may act together to facilitate or impede outcomes and provide a causal theoretical model iteratively modified as further information is obtained.	Authors articulate the constructs of necessity and sufficiency further reported in their findings.	Testing underlying conceptual frameworks
de Andrede 2014	Meso – Service delivery to investigate delays to treatment of STEMI patients in tiered health system	Use of QCA to identify factors to explain system delays to STEMI treatment.	Reference to key terms but clear how these are embraced or interpreted.	Authors’ application of key constructs necessity and sufficiency is ambiguous.	Systematically identifying causal factors
Dy 2005	Meso – Investigates components of critical care pathways for surgical patients associated with patient length of stay.	Use of QCA to identify cross-commonalities	To test hypothesis using regression language rather than the language of sets.	Reference concepts but application and interpretation are unclear	Exploratory
Eng 2012	Micro – Investigates antecedent behaviour	Use of QCA to negate the net effects approach	Averages smooth out case (system) behaviour. QCA extends the concept of property space and	Concepts not reported although software is used,	Approach used to isolate antecedents for drinking behaviour in males.

	leading to heavy-alcohol drinking in males	to loss of information provided by outliers.	allows qualitative and quantitative measurements.	and robustness checks made.	
Ford 2006	Macro – Investigation of state health agencies adherence to National recommendations for public health	To explore results from a linear regression model by separating public health core functions and their relationship to health improvement	To separate individual factors and explore association with outcome	Condition sufficiency and necessity are used in this study.	Seek to test hypotheses on public health core functions and their impact on the health improvement status of the population.
Gillighan 2010	Micro – Examines heterogeneity in findings for homicide offenders	Provides a middle ground alternative between qualitative and quantitative techniques maintaining cases as wholes allowing examination of multiple factors building theory and testing fit of theory to data.	QCA cannot provide causal inference, however, within the data set cases inference is stronger but lacks generalisability. It is primarily used to dichotomise variables.	N/A	Multiple methods approach that includes a technique that uses statistical algorithms to identify patterns of variables that are predictive of a re-defined criterion (Answer tree program-SPSS).
Glatman-Freedman 2010	Macro – Identifying conducive factors for the successful introduction of vaccines into lower income countries	Identifying combinations of conditions leading to favourable outcomes and the alternative combinations for a failed outcome.	Suggests results identified key factor (necessary and sufficient) to determine the ability of successful vaccine introduction	N/A *See case example that assumption is not bore out by results.	Development of theory or hypothesis.
Goicolea 2015	Macro - identifying contextual factors and mechanisms that trigger a good primary health care response to intimate partner violence.	QCA allows in-depth exploration of individual cases balanced with the identification of patterns across cases related to different outcomes.	Provides evidence for the relationship between a factor and other factors in combination to ensure the outcome.	Authors make reference to conditions fulfilling necessity and sufficiency.	Multiple method approach employed using two techniques related to ascertaining context and mechanism factors to outcomes of interest.
Harkreader 1999	Macro - How US state level legislation for health care influences the distribution and financing of health care services in the market	To establish the minimum combination of factors necessary for the outcome of interest to occur.	The process of minimization provides a simpler causal combination statement.	N/A	Exploratory approach allowing the model to change on the addition or subtraction of cases.

Haworth-Hoeppner 2000	To identify associations of family characteristics that contribute to the development of eating disorders	QCA allows examination of patterns of similarity and difference (potentially competing factors) between a particular set of cases	Provides an approach that develops theory but is not empirical.	Partially executed	Theory development-based notion of complex patterns previously over simplified
Kahwaiti 2011	Meso - o identify the implementation factors for weight loss targeted at older people in care homes associated with patient weight loss outcomes	QCA addresses causal complexity therefore multiple factors related to the implementation of an evidenced programme for weight loss	Complex phenomena and complex causality allow configuration patterns of conditions rather than a single condition lead to certain outcomes. Maximum diversity enhances generalisabilty of findings.	Authors define necessity and sufficiency and interpret its meaning within the context of their study.	Programme evaluation to establish policies, structures and processes that lead to better outcomes.
Leykum 2014	Micro - To develop theory to understand individual behaviour within health care systems and the impact on outcomes	Using theoretical constructs to understand the inconsistency in the findings in studies to understand how individuals respond to improve healthcare settings	Inductive theory building approach developing theoretical insights that may be causal.	N/A	Theoretical development based on underlying assumptions of Complexity Theory
Longest 2012	Understanding gender differences to internalising stress when suffering psychological stress or poor health	Standard approaches in psychometrics does not allow the examination of possible contingent interplays among stressors and psychological resources and that particular patterns of predictors may have unique relationships with outcomes, therefore QCA used.	A configurational analysis as oppose to regression methods that identify factors that will maximise the outcome and its likelihood of occurring will produce novel conclusions. Thus, are complimentary but provide different information.	Partially executed (sufficiency tests)	Hypothesis testing of combination of predictors for the outcome of interest are different by gender.
Melinder 2001	Seeking to establish associations between socio economic factors and	QCA allows exploration of causal complexity to identify complicated	QCA results are intrinsically uncertain	N/A	Hypothesis testing that injuries are either predominantly related to

	different kinds of injuries (traffic accidents and suicides)	patterns across detailed cases taking account of context.			a social genesis or environmental hazards.
Sheehy 2014	Macro - To investigate which Physician Organisation medical management practices are linked to effective inpatient utilization management, as manifested by low inpatient bed-days per thousand members per year (bed days)	QCA allows the exploration and identification of important causal and constitutive relationships between factors of interest and outcomes. Provides a formal method for conceptualising and analysing qualitative information. Supports exploratory analysis and theory development.	QCA leads to equifinal sufficient configurations.	Partially executive (Necessity analysis not conducted but sufficiency undertaken with pre specified level)	Exploratory study to identify relevant factors for future research.
Thomas 2014	Identifying intervention components that are effective within a complex intervention in a systematic review context based previously on identified 'theories of change'.	Existing methods are inadequate to identify the critical intervention components in a systematic review. QCA provides a formal structure that could be akin to subgroup analysis in SRs but provides explanations using all available evidence in a systematic review context, unlike subgroup analysis.	Knowledge claims similar but more informative that subgroup analyses and that QCA can be best thought of an 'abductive' approach, which aims to provide an 'inference to the best explanation' based on the available evidence.	Sufficiency and necessity concepts used.	To disaggregate components of a complex intervention using data from a systematic review of studies for further theory development and causal pathway modelling.
Thygeson 2011	To evaluate the connection between medical home system capabilities and quality outcomes.	QCA used to address limited sample size in a previous survey and examine relationships not found statistically significant. And identify necessary but not sufficient or sufficient but not necessary set	Seeking to establish whether a causal relationship exists based on the number of cases within subset as proportion of a super set. Substantive theoretical reasoning or a bivariate set relationship equal to	Sufficiency and necessity concepts used.	Seeking to establish empirical relationships within complex systems.

		relationships not just necessary and sufficient correlations.	0.9 leads to causal relationship.		
Warren 2013	Exploration of how the health improvement effects of the intervention (case management) varied by 1. Individual participant characteristics and 2. Service characteristics.	QCA approach benefits public health evaluation because it provides a more contingent analysis of what underpins success and how different factors interact to produce outcomes.	Develop causal pathways leading to health improvement or not that addresses health inequalities, although not probabilistic causation.	Sufficiency and Necessity concepts used.	Conducting an additional detailed analysis to understand better headline findings.
Weiner 2012	Macro – Examination of organizational design features associated with high levels of patient enrolment into cancer treatment trials.	QCA can address the likely causal complexity of design features working in combination that lead to high performance in small to medium studies.	To identify the different complex causal combinations that might produce the same outcome of interest.	Sufficiency and Necessity concepts used.	An exploratory approach using routine collected data to examine the likely different combinations that could result in the outcome.

Study purpose, rationale, and underlying assumptions of causal complexity

Framework synthesis: Stage 4

Health domains covered using this research strategy (Studies were identified as either operating at the macro, meso of micro level – that is is from exploring implementation at system/organization wide level to the internal dynamics of individual behaviour and decision making.)	*Implementation into health systems*: Policy goals, National Health Insurance, workforce and physician management practices, screening programme, guidelines, critical care pathways, vaccines, service response to intimate partner violence, political decisions, weight management programme, improving care delivery and outcomes, primary care service delivery *Socio-economic issues*: Inequalities, environmental and social factors related to injuries sustained, case management to improve health of long-term incapacity benefit recipients *Decision making*: Individual patients – difficult decisions, hospital loyalty, Individual behaviour: addiction, homicide, eating disorders, gender differences in managing stress

	Complex interventions: telemedicine, public health – community engagement, adherence to treatments, identifying effective components, *Other*: trial enrolment
Key reasons for using QCA	1. Complexity of area of interest with multiple factors identified as relevant to the research question. Looking for a research strategy to manage multiple components or influences on the outcome of interest, context and mechanisms, recognition that multiple paths of factors might achieve outcome and the desire to understand factors combining in different ways to achieve outcome. 2. Complex factors are not well addressed in routine quantitative approaches. 3. Sample of cases of interest was too small for routine quantitative approaches. 4. Address heterogeneity and variation between cases providing explanation. 5. Integrate data and theory systematically. 6. Greater case detail and information maintained throughout analysis and synthesis. 7. Transparent and systematic approach. 8. Develops and tests hypotheses and is often used to explore data.
Understanding of key assumptions: Necessity and sufficiency of conditions in varying multiple conjunctual pathways to a given outcome. Using the basis of set theoretic logic decide whether a case is in a factor set or not (or partially in or out). QCA seeks to provide parsimonious explanations of the complex phenomenon of interest (typically of social systems).	This is variable across the study reports and improves with more recent papers. However, many study reports do not articulate well necessity and sufficiency. Sufficiency is more commonly used than necessity. Simplifying configurational patterns is taken on board by many studies, supported by the use of software to move from the complex expressions to the most parsimonious
Complex causality: Within the parameters of QCA methods consists of equifinality, conjunctural causation and asymmetric causation (Schneider & Wagemann, 2012) and specifically: 1. Permanent of causality is not assumed 2. Uniformity of causal effects in not assumed 3. Unit homogeneity is not assumed 4. Additivity is not assumed 5. Causal symmetry is not assumed	1. Many authors use the mechanics of the method to address multiple factors without referring to or engaging with the underlying assumptions of QCA methodology. 2. Some authors reference concepts and describe them in their methods or a technical appendix but the language is not used in the study report to indicate an appreciation of the applied methodology. 3. The software where used will conduct sufficiency and necessity tests but authors do not illustrate in their interpretation and reporting whether they full understand these concepts. Particularly when addressing complex scenarios of SUIN and INUS configurations. 4. A number of authors refer specifically to causal relationships, others association and for some correlations, (Schneider and Wagemann, 2012)).

6. Core mainstream statistical assumptions, such as linearity on not assumed. (Box 1.2, Rhoux and Ragin, 2009)	5. Only a small number of papers specifically refer to sets and set relations, equifinality, and asymmetric causation. Primarily study reports focus on multiple conjunctural causation. 6. Approaches range on a spectrum from those driven by theory exploration or development to those that use the method as an adjunct to regression techniques to qualify or explain those results.

Appendix 6.1

Ethical Review documentation

Introduction

Ethical approval was given to undertake a secondary synthesis of data obtained in the primary study (POISE), which had received multi-site ethical approval. Trial registration number was (ISRCTN18046709 – Peri-operative Implementation Study Evaluation (POISE). Separate ethical approval for the study undertaken for this thesis and use of this secondary data was received from the student host University (Bangor University). A memorandum of understanding set out the terms of agreement for this secondary use of primary data between Jacqueline Chandler (the student) and PhD supervisors professors Jo Rycroft-Malone and Jane Noyes. During the PhD a decision was made to only use data from the POISE trial.

Further information on use of participant data in this thesis

Original trial consent forms permitted use of the original data for secondary purposes. Jacqueline Chandler was given permission to access paper copies of the consent forms to ensure consent was given by participants. These were archived and locked in a secure room at Warwick University. No identifiable information of individuals' consent was recorded. No addresses or other contact data was obtained from patients. Patient interview transcripts were not used for secondary purposes. The thesis was conducted under the Data Protection Act (DPA) 1998.

DPA 1998 was recently updated to the DPA 2018 to reflect European Union General Data Protection Regulations (GDPR). These regulations seek to protect the processing of individual personally identifiable data used by all types of organisations (public and private) including research. The principles that underlie GDPR is that use of personal identifiable data should be fair, transparent and lawful. Use of data must be for legitimate reasons. Personal data that either directly or indirectly identifies an individual is covered by these regulations. ID identifiers (referred to as pseudo-anonymised) that seeks to protect the individuals' identity from the use of data in research can in theory be traced back through records to an individual whether living or deceased. However, it depends on the level of difficulty to identify the individual using the ID identifier. Anonymisation needs to be robust and sustainable overtime. The only source of identifiable patient information, their names, is held on consent forms and these are not available digitally and are locked away securely in archive. Similarly, this is the case for staff participants, however, names, email addresses and telephone numbers were logged originally to contact staff for telephone interviews and for other trial contact requirements. There was no reason for me to access or use this data in the original digital files.

Research that has sort informed consent from patients to use their data complies with the common law duty of confidentiality (National Health Service Act 206, section 251). This remains unchanged by the GDPR 2018.

Participant data that is no longer identifiable or where the available participant data cannot identify the individual either on its own, or in combination with other accessible information, is no longer personal data. Therefore, GDPR transparency requirements do not apply. Therefore, this work does not breach current regulations.

Ethical approval for PhD study and use of data for secondary purposes

COLEG IECHYD A GWYDDORAU YMDDYGIADOL
COLLEGE OF HEALTH AND BEHAVIOURAL SCIENCES

YSGOL GWYDDORAU GOFAL IECHYD
SCHOOL OF HEALTHCARE SCIENCES

25th June 2013

Miss Jacqueline Chandler-Oatts
63 White Road
Oxford
OX4 2JL

PRIFYSGOL BANGOR UNIVERSITY

Dear Jacqueline,

Re: Healthcare and Medical Sciences Academic Ethics Committee (HCMS AEC) review.

Proposal number: 2013-04-04 (please quote this number on all correspondence)

Project title: ***Getting evidence into practice: the implementation context***

Thank you for your submission to the AEC. As requested your application was subject to the expedited review process. The reviewers have given detailed consideration to your study and highlight only minor points that require attention. The detail of these is provided as an appendix to this letter.

I am therefore able to give approval for your study on behalf of the AEC, subject to you providing evidence of these minor amendments; please forward evidence of the requested amendments to the Ethics Committee administrators prior to commencing your study. This letter constitutes evidence of that approval should it be necessary for any applications to external/other RECs.

Should you need to make any substantial amendments to your study protocol during the lifetime of the research, you are required to submit notice of these to the AEC for further approval, prior to making any changes to the conduct of the study.

Please note that approval from this AEC does not convey automatic authority to proceed with your study. You are formally advised that it is essential to confirm with the relevant administrators whether you are required to submit your proposal to any other Ethics

Committee(s), such as Local NHS Research Ethics Committee and NHS Research Governance Departments, prior to commencing your study.

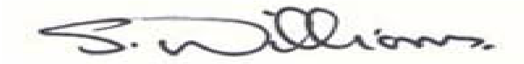
You are required to notify this AEC of any amendments to your proposal that you are required to make by any external body.

Once you have received approval from an external REC, you must provide a copy of your letter of approval for this AEC.

If you have any queries, please do not hesitate to contact myself or Dr Joyce Wilkinson Vice Chair, for clarification.

I wish you well with your research.

Yours sincerely



Dr Siôn Williams
Chair HCMS AEC.

Cc: Professor Jo Rycroft-Malone, Supervisor

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Registered charity number: 1141565

Comments

The application was well presented and contained no significant ethical issues. However, a small number of minor amendments are indicated by the reviewers:

Background:

- *The rationale for conducting the secondary analysis is stated and the original study investigators (Professors Jane Noyes and Jo Rycroft Malone) have made the original data sets accessible to Jacqueline Chandler-Oatts.*
- *The investigator indicates that there are ethical issues to consider in doing secondary analysis of data from the original POISE and EPIC studies. Original documentation (Information Sheets and Consent forms from both studies) are attached to provide evidence that participants of those Trials (POISE and EPIC) agreed that their data could be re-used.*

Requirements:

- Form RCT-YP v3DE (EPIC): Young people were required to indicate that they agreed for information to be used for 'educational purposes in the future'. The academic nature of the secondary analysis does comply with an educational need. <u>Please ensure that only the information from participants who ticked 'yes' in this particular section is used in the secondary analysis.</u>
- Staff Cons ver 2, and Patient Con Ver 2: (POISE): Patients and Staff were required to indicate that they agreed that 'anonymous data may be used again in the future'. This implies that data can be used again. <u>Please ensure that only the information from participants who ticked 'yes' in this particular section on each form is used in the secondary analysis.</u>
- Please amend Part 2 ETHICAL CONSIDERATIONS: Please tick the relevant box for Question 9 as this has not been completed *('Will you be accessing patient data, personal or confidential information (e.g. medical records), including genetic or other identifiable information, concerning identifiable individuals?')*
- It should be specified that only anonymised datasets will be considered in the secondary analyses. It is unclear who has completed the removal of any identifiable data, and how this will be quality assured before they are seen by the student. These issues could be clarified.

Recommendations:

- It would be helpful to have a copy of the original ethical approvals on file for the two studies being re-analysed.
- There is no evidence of any data sharing agreement in place for the use of the two datasets as indicated in the proposal. Such an agreement should be considered.

Response to ethical approval addressing minor amendments

Dr Siôn Williams
Chair HCMS AEC.

COLEG IECHYD A GWYDDORAU YMDDYGIADOL
COLLEGE OF HEALTH AND BEHAVIOURAL SCIENCES

YSGOL GWYDDORAU GOFAL IECHYD
SCHOOL OF HEALTHCARE SCIENCES

11th January 2012

Dear Siôn,

Proposal number: 2013-04-04

Project title: *Getting evidence into practice: the implementation context*

I am writing in response, rather belatedly, to your letter dated 23rd June 2013. I have not progressed to conducting the secondary analysis yet. I respond directly to the comments and recommendations made by the HCMS AEC below. I attach a Memorandum of Understanding drawn up with the involvement of my supervisors, Professors Jo Rycroft Malone and Jane Noyes. This document addresses the issues raised by the committee below. Please thank the committee for their deliberations and support.

Comments

Requirements:

- Form RCT-YP v3DE (EPIC): Young people were required to indicate that they agreed for information to be used for 'educational purposes in the future'. The academic nature of the secondary analysis does comply with an educational need. <u>Please ensure that only the information from participants who ticked 'yes' in this particular section is used in the secondary analysis.</u>
STUDENT RESPONSE: Acknowledged, please see attached MoU.
- Staff Cons ver 2, and Patient Con Ver 2: (POISE): Patients and Staff were required to indicate that they agreed that 'anonymous data may be used again in the future'. This implies that data can be used again. <u>Please ensure that only the information from participants who ticked 'yes' in this particular section on each form is used in the secondary analysis.</u>
STUDENT RESPONSE: Acknowledged, please see attached MoU.
- Please amend Part 2 ETHICAL CONSIDERATIONS: Please tick the relevant box for Question 9 as this has not been completed *('Will you be accessing patient data, personal or confidential information (e.g. medical records),*

including genetic or other identifiable information, concerning identifiable individuals?')
STUDENT RESPONSE: Apologies for this absence please see amended form attached and the answer is, no I will not.

- It should be specified that only anonymised datasets will be considered in the secondary analyses. It is unclear who has completed the removal of any identifiable data, and how this will be quality assured before they are seen by the student. These issues could be clarified.
  STUDENT RESPONSE: Please see attached MoU for this confirmation. It should be noted that I worked on both studies and originally accessed the individuals interviewed for example. In neither project did I access medical records. Local investigators in both studies collected demographic information and forms collecting data were anonymised by ID codes. Therefore, local sites retained personal identifiable information. Researchers would only have access to the identifiable information on the consent forms. I will need to access these forms to ensure consent was given for re-use of data. These forms are archived at the relevant research department. I will remove ID numbers for my own study. All other data, transcripts, that I will personally access will be anonymised.

Recommendations:

- It would be helpful to have a copy of the original ethical approvals on file for the two studies being re-analysed.
  STUDENT RESPONSE: Please see attached.
- There is no evidence of any data sharing agreement in place for the use of the two datasets as indicated in the proposal. Such an agreement should be considered.
  STUDENT RESPONSE: Please see attached MoU.

I hope my responses and the attached are satisfactory.

Yours sincerely,

Jackie Chandler-Oatts

Memorandum of Understanding between PhD Student and supervisors

MoU V.1 14 October 2013
PhD Memorandum of Understanding (MoU)

Between Jackie Chandler (student)

And Jo Rycroft-Malone (lead supervisor) and

Jane Noyes (second supervisor)

14th October 2013

Version 1

Purpose

This document is a memorandum of understanding (MoU) between Jackie Chandler, Jo Rycroft-Malone and Jane Noyes for the conduct of handling primary data for secondary purposes and the subsequent outputs of the intellectual material created.

Background

The consent to future use of data for educational purposes was primarily added to consent forms so that students who had not been associated with the original project could have access to an anonymised dataset for secondary analysis. In the current context both the Chief Investigators are PhD supervisors and the student was originally associated with both studies and collected the original data. The Chief Investigators can request additional analysis of their own data. In this context the dataset is not leaving the original team – but the re-analysis is being presented for an educational project. No personal data of study participants will be shared and all other data utilised in the PhD will be anonymised and falls outside the Data Protection Act 1998.

Objective 1 This MoU sets out the parameters and expectations for the use of data obtained from primary studies for secondary purposes within the PhD.

Objective 2 This MoU sets out the core principles for publications (or other outputs e.g. conference abstracts) that arise directly from the work and material created in PhD.

Responsibilities for the student (Jackie Chandler) and Supervisors (Jo Rycroft Malone and Jane Noyes) are set out below:

Objective 1

- To ensure the protection of the research participants data adhering to the agreed procedures set out below.
- To be aware of the legal and ethical duties in protecting personal data, ensuring its confidentiality.
- To work within the Data Protection Act and relevant codes of practice.
- To ensure the safe storage of data being used for secondary purposes (annoymised data).

Procedure

The primary study data to be used by the student for secondary analysis purposes is briefly described below:

- Study 1-PoISE Implementation Trial completed 2009.

  Study details: Pragmatic cluster randomised trial using time series evaluating guideline implementation strategies and a process evaluation and informed by PARiHS conceptual framework.
    - Participants: NHS Trusts and elective surgery patients
    - Primary Outcome: Duration of fast from fast start to induction of anaesthetic (food and fluids)
    - Complex interventions: Guideline implementation strategies
    - Evidence base: Guideline on peri-operative fasting
    - Process evaluation: Healthcare professionals, intervention change agents, and patient perspectives interviews and focus groups, Learning Organizational Survey, local investigator audit, evaluations of intervention fidelity and cost.
- Study 2 EPIC Trial implementing information for children and young people with diabetes completed August 2011.

  Study details: Reviewed literature, developed an age appropriate information pack for young people with diabetes type 1 and test via a pragmatic randomised controlled trial, and informed by the PARiHS conceptual framework.
    - Participants: Young people (6-18) with type 1 diabetes and their families, healthcare professionals attached to paediatric diabetes clinics.
    - Primary Outcome: Diabetes self-efficacy and quality-of-life (Diabetes PedsQL).
    - Complex intervention: Age appropriate information pack and insulin diary.
    - Evidence base: Development of age appropriate pack
    - Process evaluation: Young people and their families, healthcare professionals' perspectives via individual parent and child interviews, and professionals' survey.

1. Formal written request to be made to the Chief Investigator by the student. Student to ensure she has received clear written permission from the study lead investigators for access to and usage of the agreed data sets to be made available of the two studies of interest in the PhD.
2. On receipt of written permission, and prior to accessing anonymised data, establish that individual participant consent has been given for the data to be used for secondary purposes.
3. The process for Study 1 (POISE) consent forms will be accessed via Warwick University by the student an original researcher on the project. Identifier codes will be obtained. No personal information will be collected with the codes of consenting research participants. Access to Study 2 (EPIC) consent forms will be accessed via Bangor University under the supervision of the researcher for the study. The student was also an original researcher on this study. Similarly, identifier codes will be obtained. No

personal information will be collected with the codes of consenting research participants. Copies of consent forms will not be held separately by the student, access only is required.

4. On receiving the codes for the interview transcripts and any other permissible data where permission has been granted the student will receive access to the relevant anonymised data for storage on the student's (J Chandler) personal hard drive, secured behind password access. This will be backed up on a secure server. She will then become the data owner/custodian for the purposes of the anonymised duplicate data sets provided. The data is not shared with anyone else other than the supervisors (also the lead investigators). This data will not contain any identifying personal data for the data to be analysed. The student will create her own coding of the transcripts obtained for PhD use. The link between her coding and the original coding will be held by the original investigators and will not be held on her personal system. However, the data will need to be traced back to original source for purposes of audit.
5. It is known that all transcripts and other data are all previously coded. Once codes have been obtained, the student (J Chandler) will develop new codes for the purpose data identification for the PhD.
6. All subsequent codes will be logical and recorded on all relevant data prior to any aggregation of data.
7. The student will ensure any paper copies for the purposes of analysis created must be kept securely stored and only accessible by.
8. Data will not therefore be 'pseudo-annoymised' as required in some trials as source data verification will not be required. The student will not have access to any master lists with identifiable personal data.
9. The data is provided on the understanding by the student that is not shared for any other purpose than by the student for the PhD.
10. The student to understand that data will be required to be stored securely for at least 5 years.
11. Supervisors to ensure that a note on original data sets notes the additional use of the data for the purposes of this PhD.
12. A copy of any output from the PhD work to be lodge by the relevant principle investigator in their respective research files for the original studies.
13. The transfer of the data with requisite permissions to the student should ensure that the copy is an exact copy preserving all of the data and meta-data of the original.
14. The student will provide as part of her methods how the data will be utilised for secondary analysis purposes and software if any used.
15. The student and the supervisors are all responsible for ensuring appropriate acknowledgement of the data and its use in the PhD in any publications or other outputs (e.g. conference presentations).

Source documents used:
1. Standard Operating Procedure for Data management (NWORTH 6.01), 10th April 2013 V.5.
2. Standard Operating Procedure for Data Protection and confidentiality for Trial Data (NWORTH 4.07), 22nd February V.2.

Objective 2

- To ensure that all publications and other outputs of the PhD have publication plans and agreements in place prior to commencement of the article or abstract.
- To ensure clarity of authorship contribution warranted for any specific publication or output. Contribution to any proposed article or other output is to be agreed by all parties at the outset of a proposed article.
- Agreements to be logged in written format and signed off by all signatories.

  Procedure

  1. The supervisors are neither required nor automatically become authors on all work disseminated.
  2. The student should inform her supervisors of intended plans to develop and/or disseminate work or material derived from PhD work and associated PhD chapters.
  3. Supervisors should then be provided an opportunity to contribute to the intended PhD outputs agreeing with the student their intended and explicit contribution. The PhD may produce outputs prior to thesis submission as outputs from individual thesis chapters, as well as post submission.

This document may require updating and therefore will maintain version and date controls.

Consent templates used in original trial

Version 2 16/03/06

Centre number:______
Study number: _______
Patient identification number:______

Contact:
Jackie Chandler
Research Fellow
Royal College of Nursing Institute
Radcliffe Infirmary
Woodstock Road
Oxford OX2 6HE
Tel: +44(0)1865 224102
Fax +44(0)1865 246787
Email: jacqueline.chandler-oatts@rcn.org.uk

PATIENT PARTICIPANT CONSENT FORM 1

Peri-operative (fasting guideline) Implementation Study Evaluation

Ethics Review Committee number ______________

Please initial appropriate box

1. I confirm that I have read and understand the information sheet dated ____________(version_____) for the above study and have had an opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to take part in the study. ☐

4. I agree to data being collected and recorded from me (verbally or via questionnaire). I understand that sections of any of my medical notes may be looked at by responsible individuals from the hospital where I receive my treatment. I give permission for these individuals to have access to my to my records. ☐

5. I understand and agree that data will be anonymised and stored on a secure computer server and that anonymous data may be used again in the future. ☐

Name of patient	Date	Signature
Name of person obtaining consent (if different from Researcher)	Date	Signature
Researcher	Date	Signature

1 copy for patient; 1 for researcher; 1 to be kept with hospital notes

Version 2 16/03/06

Centre number:______
Study number: _______
Staff identification number:______

Contact:
Jackie Chandler
Research Fellow
Royal College of Nursing Institute
Radcliffe Infirmary
Woodstock Road
Oxford OX2 6HE
Tel: +44(0)1865 224102
Fax +44(0)1865 246787
Email: jacqueline.chandler-oatts@rcn.org.uk

STAFF PARTICIPANT CONSENT FORM

Peri-operative (fasting guideline) Implementation Study Evaluation

Ethics Review Committee number _____________

Please initial appropriate box

1. I confirm that I have read and understand the information sheet dated ____________(version_____) for the above study and have had an opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, <u>and with no detriment to my professional record</u>. ☐

3. I agree to take part in the study. ☐

4. I agree to data being collected and recorded from me (verbally or via questionnaire) for the purpose of research. ☐

5. I agree to the interview being audio taped, transcribed for the purpose of analysis and for the use of anonymous quotes in the final report. (delete if not relevant) ☐

6. I understand and agree that data will be anonymised and stored on a secure computer server and that anonymous data may be used again in the future. ☐

____________________ _____________ ______________________

Name of staff member Date Signature

____________________ _____________ ______________________

Name of person taking Consent (if different from Researcher) Date Signature

__________________ _____________ ______________________

Researcher Date Signature

1 copy for staff member; 1 for researcher; 1 to be kept with hospital notes

Appendix 6.2

Thomann and Maggetti (2017) Framework: External validity, internal validity and reasoning in QCA

QCA DESIGN COMPONENTS	QCA APPROACH	TOOL/METHOD	LIMITATIONS	JUSTIFICATION & EXPLANATION FOR CURRENT STUDY
External validity				
Establishing empirical scope	Case orientated – deductive/theory evaluating	*Theoretical sampling*	Representativeness of sample & generalisability	Cases are pre-selected as secondary synthesis. The data obtained is validated through previous trial and process evaluation approach. Cases (acute NHS Trusts, N=19) represent an empirical subset of examples that will have limited generalisability to the whole set (N=300+). [*add about statistical sampling in previous design*?]
Sensitivity to one or more flawed cases	Case orientated	Case knowledge, scope conditions Testing robustness to adding/dropping cases	Confirmation bias Data availability	Creating detail case studies using process tracing techniques on apriori datasets supports in-depth case knowledge and the scope of the conditions. These will then be framed within the theoretical framework. Transparency of judgements and decisions should expose confirmation bias, particular in this study and needs to manage inconsistent data appropriately. Iterative analysis will test with there are cases that skew the solution models.
Scope of counterfactual argument	Substantive interpretability	Conservative or intermediate solution	Redundancy-free models, external validity	Identifying the factors that are not in the cases observed but may be in the unobserved cases of the 'whole set'. More cases would provide a

				redundancy free model and therefore greater external validity. Forming the theoretical framework seeks to provide optimal interpretation of the solutions provided, given that there may be limitations with the parsimonious solution.
Internal validity and measurement				
Measurement error	Case orientated	In-depth knowledge of concepts cases	External validity Data availability	The study will use previously collected case details (see attached example) and building this data and any additional data retrieved from the original study files using process tracing techniques.
Systemic inaccuracy in coding	All	Adjustment factor		Iterative validation of coding that remains true to the data whilst maximising application of the theoretical framework.
Calibration errors	All, in absence of clear conceptual criteria	Calibration procedures robustness tests	Tests should involve only conceptually meaningful alternative calibrations	Following calibration procedures that will use the theoretical framework to provide conceptually informed criteria for condition and outcomes. Coding structure will be explicitly reported.
Condition errors	Substantive interpretability	Comparative presentation & inspection of parsimonious & intermediate solution Adding/dropping conditions robustness test	Redundancy-free models Limited diversity Data availability	Not applicable all though parsimonious solution will be presented and interpreted within the limits of case diversity. Pathway of data available to condition identification will be tabulated. Data limited by previous research design.

				Process will possibly reveal 'ideal' data set.
Random errors	Occurs in condition-orientated large-N	Probabilistic criteria	Case-orientation, small N Representativeness of sample	N/A
Sensitivity to changes in minimally required raw consistency levels	Case orientated	Raw consistency robustness test Case knowledge for determining threshold	Substantive interpretability Confirmation bias	N/A Some testing required with explicit transparency about decisions made – Case process panel tested.
Case based errors	Condition orientated only	Frequency thresholds	Sample size and limited diversity	N/A
Limited diversity	Especially case orientated	Thresholds for case-conditions ratio under consideration of number of configurations Increase N Most similar systems design Reduce number of conditions	Case orientation Data availability Conceptual stretching External validity	Conditions and all possible configurations of those conditions are naturally dependent on whether there are observations within the cases. Adding cases will not be an option given the context and restraints of this study and its purpose to evaluate a theoretical framework. Condition reduction using various strategies ('two step', layered-intermediate designs) will seek to manage the issues within the constraints of the original data set. The theoretical framework as a central plank of the study is expected to be well specified.

	Substantive interpretability	Two-step QCA	Under-specification of the theoretical model Coverage Redundancy-free models Complexity and scope of results Only applies when conditions can be meaningfully considered as proximate vs remote	
Validity of explanation	Substantive interpretability Case-orientated	Conservative or intermediate solution (SA, ESA, TESA)* Presentation of parsimonious & conservative/intermediate solutions Case knowledge for causal explanation Set theoretic multi-method research	Redundancy-free models External validity Does not resolve the epistemological problem External validity Data availability	For discussion will be how the methods fit with the theoretical framework and underlying epistemological assumptions as explored in chapter 3. Data set includes multi method approaches. Current study uses process tracing with QCA as an established approach (Beach & Peterson (2013).
Interpreting necessary conditions	Substantive interpretability	Empirical criteria: trivialness (coverage), relevance (RoN), theoretical and conceptual meaningfulness	Not valid according to redundancy-free models' approach	For discussion as methods are tested with the theoretical framework.

	Case-orientated	Causal process tracing with set-theoretic multi-method research	Data availability	See above
Skewed data	All, especially condition orientated large-N	Skewedness statistics/diagnosis		N/A
		Sampling, measurement, calibration and concept building techniques	External validity Data availability Conceptual stretching Theory-driven sample, model and concept specification	Process of building the argument from the theoretical framework using the data set and following discussion and interpretation the transparency of each step will ensure that limitations are clearly exposed.
	Substantive interpretability	Simultaneous subset relations diagnosis (Proportional Reduction in Inconsistency, Relevance of Necessity, XY-plots, Boolean intersections)	Meaningless under redundancy-free models approach	The data from data matrix to the truth table will precede exploration of the logic of the subset relations which will always need to remain conceptually meaningful within the original data set and the theoretical framework. Use of Schneider and Wagemann's ESA (Theory-guided approach) seeks to address implausible and incoherent solutions by removing logical remainders (unobserved configurations) as possible counterfactuals.
	Substantive interpretability	Enhanced Standard Analysis to avoid simultaneous subset relations	Redundancy-free models	
Mode of reasoning				

Clarifying the external scope of the argument		See “clarifying external validity”		This thesis sets out the external scope of the argument in chapters 2, 3, 4.
Hypothesis building/ modification	Case orientated/inductive	Deriving new theories or extension, refinement of existing theories Case orientated theory building	External validity	This approach fits with a more typical grounded theory approach. This is not undertaken in this thesis.
Hypothesis assessment	Deductive/theory-evaluating Case orientated Deductive/Theory evaluating	Case orientated theory testing Formal theory evaluation	Iterativeness of QCA approach Inductiveness of technique External validity	This thesis sets out to speculate and test the potential for operationalising SCAS using QCA synthesis to address complex causality within underlying assumptions of asymmetry, equifinality and multiple conjunction of causality.
Formulating expectations in line with the QCA approach	Deductive/theory-evaluating	Set-theoretic hypotheses on causal complexity, contingent causality, relevance of factors	Effects of causes, net effects	QCA logic is set relational rather than obtaining the average (mean) of effect across the sample (subset of the population). The selection and framing of the conditions and the outcome use set membership (presence or absence of case within the condition set). The argument for its use here is that reality is messy and observations incomplete and causality complex.
Analysis of necessity	Deductive/theory-evaluating Substantive interpretability	Deductive test of previously defined single or unions of conditions	Inductive/explorative Redundancy free models: necessary conditions must also be sufficient and non- redundant	Analysis of necessity will be conducted to explore the limits of sufficiency and necessity as causal concepts within the context of SCAS.

	Inductive/explorative	Explorative super-/subset analysis	Trivialness, relevance Substantive interpretability: unions should represent meaningful higher-order construct	N/A

Appendix 6.3

Initial process templates based on Beach and Pederson 2013

CASE ID

ID No.:	Trust Status:	Urban/rural:	Bed size:	No. Sites:	Country:	No. of Wards:	Allocated Intervention

		Causal process steps or parts of causal chain						
		Part 1	Part 2	Part 3	Part 4	Part 5	Part 6	
	ACTIVITIES	Setting up committee or dissemination structures in place	Time for process of discussion and deliberation	Decisions made	Revisions and changes to fasting policy	New Trust policy	Dissemination activities – meetings training, transfer to other information objects e.g. patient information at pre-op assessment	
CAUSE								**OUTCOME**
Guidance disseminated to Trust - Policy does not reflect current guidance								**Policy reflects current guidance**

	ENTITIES	Hospital committee structure of clinical staff set policy for trust	Hospital committee structure of clinical staff set policy for trust	Champions on committee	Admin/ secretarial/ other	Specific staff member tasked with dissemination	Technological/ intranet systems

		Causal process steps or parts						
		Part 1	Part 2	Part 3	Part 4	Part 5	Part 6	Part 7	
	ACTIVITIES	Patient receives inform-ation	*Listing* of patients in order with set start time	Patients f*asted* as if first on the list (all day lists, am/pm lists)* am 6am/pm 11am	Patient *arrives* on ward and prepped for theatre	Patient or nurse *informed* or not of position on list	Patient *remains* fasted according to original pre-op instructions Afternoon lists water removed at set time by housekeepers	*Induction* of anaesthetic	
CAUSE									**OUTCOME**
Management of the operating list									**Longer fast or no change**
	ENTITIES	Initial letter from medical secretary	*Medical secretaries Surgeons Anaesthetists*	Pre-op instructions and *pre-op assessment clinic Nurse* reinforces	*Ward nurse* checks fasting status *Anaesthetist* checks patient	Update of list (or any changes during list) from *surgeon or theatre staff* – timeliness of communication	No further communication on fasting other *anaesthetic nurse and anaesthetist* check fast status	*Anaesthetist*	
Evidence obtained								Duration of fast audit data	Duration of fast audit data –

								– primary outcome	primary outcome

			Causal process steps or parts						
		Part 1	Part 2	Part 3	Part 4	Part 5	Part 6	Part 7	
	ACTIVITIES	Patient receives infor-mation	*Listing* of patients in order with set start time	Patients *fasted* as if first on the list (all day lists, am/pm lists)*	Patient *arrives* on ward and prepped for theatre	Patient or nurse *informed* of position on list and adjusted fast time agreed	Patient *allowed* fluids up until new fast time set be 2 hours before ETA on list	*Induction* of anaesthetic	
CAUSE									**OUTCOME**
Management of the operating list									**Shorter fast or improvement but unclear**
	ENTITIES	Initial letter from medical secretary	*Medical secretaries Surgeons Anaesthetists*	Pre-op instructions and *pre-op assessment clinic Nurse* reinforces	*Ward nurse* checks fasting status *Anaesthetist* checks patient	Update of list (or any changes during list) from *surgeon or theatre staff*	Communication on fasting between *ward nurse, anaesthetic nurse and anaesthetist* check fast status at new time.	*Anaesthetist*	
Evidence obtained								Duration of fast audit data – primary outcome	Duration of fast audit data – primary outcome Coded

Appendix 6.4

Sample extraction record sheet by NHS organisation

CASE ID:

Data extraction question	Rating (present/yes (1), not present/no (0), quantity (% or number) or text response	Evidence description
Chain 1		
1h 1 • Is there documentation or a report of Trust policy, this may include sight of, or description of policy delivered through patient information given when notification of operation date is provided?		
• Is this Trust policy in place close to the 2/6 rule?		
• Is it clear that the Trust does not have policy guidance in place and either assumes traditional practice or it is clear traditional practice is policy?		
• Do Trust contacts describe structures, committees or processes that can *in principle* disseminate new policy?		
• Is this structure if present used to develop fasting policy in keeping with guidance?		
• Is a specific structure set up to develop fasting practice?		
• Is there a description of individuals given or who take		

the role to develop and negotiate fasting practice?		
Overall judgement for set membership 1h 1		
1h 2 Are meetings to develop policy described?		
Are outcomes of these meetings reported.		
Is there a record of discussion on development of the fasting policy to be implemented? (note focus is on the 2-hour fluid rule- other details of guidance/policy not relevant)		
Overall judgement for set membership 1h 2		
1h 3 • Can a clearly articulated account of Trust decision-making and agreements made at the relevant meeting or committee structure be observed in the data?		
• Did the trial change agent report their role in facilitating that change through structures or processes described above?		
Overall judgement for set membership 1h 3		
1h 4		

• Does the data report action to change documentation (to meet new policy) sent out by administrative staff e.g. patient letters?		
Overall judgement for set membership 1h 4		
1h 5 • Is there documentation of new policy stated or seen?		
• Is there a lead designated or self-designated to take on overseeing implementation?		
Overall judgement for set membership 1h 5		
1h 6 Type of activity • training on policy to key staff, • Via specific and relevant meetings of staff • Record of changes made to patient information. • Record of distribution through intranet systems. • Other awareness raising activities e.g. posters • Use of audit data feedback Number of dissemination activities		
Overall judgement for set membership 1h 6		
Chain 2		
2h 1. • Report patient survey data post intervention – for those		

that received receipt information pre-op. %		
• Report patient decision % to act differently to advice.		
• Are there any descriptions or evidence of the information provided to patients?		
• Does this information place emphasis on positive messages to drink up to 2 hours before induction of anaesthesia?		
• Is there any description of potential for contradictory information from different surgeon's/anaesthetists/nurses in the Trust?		
Overall judgement for set membership 2h 1		
2h 2. An account from individual respondents that details delivery of the operating list to ward and theatre: • Timing when delivered to wards and theatre staff (no. of days, 24 hours, morning of surgery etc.		
• How delivered via: computer system or, in printed format or both.		
Overall judgement for set membership 2h 2		
2h 3 • Is there an account of the impact of how guidance is implemented regarding the 'first on the list syndrome'?		

• Is there an account of differences between in and day patients that indicates either: No change in practice to follow fasting guidance for inpatients, or		
• Practice for inpatients follows guidance more closely.		
Overall judgement for set membership 2h 3		
2h 4. • Is there an account by a respondent of the status of patients fasting on arrival, who had a tendency to longer fasting?		
• Is there an indication that staff will take an opportunity to address this for those later on the list at admission?		
Overall judgement for set membership 2h 4		
2h 5a • Is there an account as to whether in general or not, that at the start of the list known changes are used to revise individual patient fasts?		
• Is there an account of once operating list is underway there is routine, regular, or an intermittent feedback system between ward and theatre staff on delays and changes to the list whether initiated by ward or theatre?		

• Whether there are blocks to receiving or giving this feedback.		
• Whether there is an intention to respond or responses occur for some patients (1), or whether there is no intention once the list is underway and patients are held in fast (0).		
Overall judgement for set membership 2h 5a		
2h 5b • As above and include and in addition, is there a record or intention to provide timely feedback once the list is underway, allowing fasting times to be adjusted either by anaesthetist or the ward is delegated authority to do so?		
Overall judgement for set membership 2h 5b		
2h 6a • Is overall practice in the Trust post trial intervention as suggested through respondent accounts that blanket and 'first on the list syndrome' is maintained?		
• Is there an account that attempts to implement practice change is deliberately thwarted by individuals in senior or professional roles?		
Overall judgement for set membership		

2h 6a		
2h 6b • Is there an account that regulating fast has occurred on occasions when and where possible within the Trust?	0	
Overall judgement for set membership 2h 6b		

Appendix 6.5

Raw data extraction table for Chain 2 and set membership allocation

	2h 1	2h 2	2h 3	2h 4	2h 5a	2h 5b	2h 6a	2h 6b
	Pre-op fasting information is provided to the patient in an initial letter from the surgeon's medical secretary. % of patients that receive information and % of patients that do not follow that advice.	*The surgeon (organised by the medical secretary) agrees his initial patient order that is disseminated to theatre and ward staff. This list provides an estimated start time for each listed patient. This initial list is constructed by the surgeon's medical secretary. Timing and distribution of this list.*	*Pre-op instructions given to patients will set fasting start times as if first on the list (all day lists, am/pm lists)* am 6am/pm 11am, for example. This information is reinforced (or changed) when patients attend a pre-op assessment clinic where a Nurse will emphasise required fasting instructions and encourage drinking up till arrival at hospital for day patients. Inpatients controlled by nursing staff.*	*Patient arrives on ward and is prepared for theatre by a ward nurse. They receive a visit by an anaesthetist and the surgeon. Both the nurse and anaesthetist will check when the patient last ate or drank anything to ensure they have followed information given pre-operatively – relevant for day patients. Nursing staff (instruct housekeeping staff) to control inpatient fasting times. Opportunity to update.*	*Patient or nurse are informed or not of position on list or receive an updated of list (or any changes during list) from surgeon or theatre staff – These changes are received in a timely manner to allow changes to be made to patient fasting times if warranted.*	*Regular updates of list changes (or any changes during list) from surgeon or theatre staff. Patient or nurse informed of position on list and adjusted fast time agreed.*	*Patient remains fasted according to original pre-op instructions. Afternoon lists water removed at set time by housekeepers No further communication on fasting other than anaesthetic nurse and anaesthetist check for fasting status.*	*Patient allowed fluids up until new fast time set to 2 hours before ETA on operating list. Practice of regular communication on fasting between ward nurse, anaesthetic nurse and anaesthetist who then check fast status at new time.*

A	Letters and information not updated during trial (SD allocation). 91% (2, 0.66) of patients receive information. 24.7% (3, 0.33) of patients fast differently. Policy encourages positive drinking but unclear whether patients receive this message. Although, Trust policy in place some letters from surgeons will specify 12MN.	Patient position on operating list is not confirmed until after their admission. Use computerised lists.	Trust fasts patients as if first on the list. All day lists have a greater impact on fasting times - start am list times.	Patients over fast. Some ad hoc updating by anaesthetist but no widespread common policy to update fasts on arrival to the ward.	75% (2, 0.66) of patients are happy with updating. Adhere to the first on the list syndrome. Computerised lists are updated, however, ward staff will find it difficult to find time to check. Lack of time and busyness affects capacity to regulate. No resistance. Trust described as conveyor belt nursing. Anaesthetists do check and review some fasts.	Practice to update or delegate to nurses is not done and is ad hoc.	Follows first on the list. Nurses are cautious, and some surgeons still prefer 12MN practice.	There is no account that Trust attempts to regulate fasting post first on the list as a practice.
	0.66	0.33	0.66	0	0.66	0.33	0	0
B	93.3% (2, 0.66) of patients receive information. 13.6% (2, 0.66) of patients fast differently. Fluids encouraged up to fast time. No resistance to fasting policy expressed.	Operating list availability not known but assessments are made at the beginning of the list on the day of surgery.	Patients fasted as if first on the list. Staff have more control over inpatients in ensuring that they have fluids just before fast starts.	All day list patient fast times are updated once list order known. Less control over day patients they may come in fasting longer than recommended.	Once theatre slots known patients fast will be updated. 36.4% happy with updating (4, 0). Only intention reported is the need to update those on all day lists.	No arrangements to update once the list is underway.	First on the list. No resistance to change reported.	SD trust no impetus to make any changes. No activity during trial. Allocated SD.
	0.66	0.33	1	0.66	0.33	0	0	0

C	Resistance to a 2 hour fast with a compromise at 3 hours. Encouraged to drink till 5.30 am. 85% of patients receive information (3, 0.33). 14% of patients fast differently (2, 0.33).	Anaesthetists receive list on the morning of the op and then visit patients. List produced by the surgeons.	Trust has three list start times and am pm and evening. This strengthens the view of a first on the list focus. No all-day lists mentioned. No difference between in and day patients reported	Overnight fasting results in longer fasts but patients encouraged to drink at 5.30. Respondents do not acknowledge any further updating.	Anaesthetists will negotiate on the day any list changes once they have seen patients. 50% (4,0) of patients are happy with updating.	No amendments made once list underway.	Focus on fasting for 3 hours pre-op is to target the start of the list.	No description to intervene to regulate fasts post first on the list .
	0.66	0.33	1	0	0.33	0	0	0
D	Fasting information varies from team to team at the Trust. Pre-op assessment patients receive verbal information 93.4% patients receive information (2,0.66), 40.5 decided to act differently (19.6 pre), (4,0). New policy encourages drinking up to fast start time. Surgeons not interested in getting involved in fasting care.	List not finalised until the morning of the list.	It appears patients are fasted in terms of first on the list. Nurses have more control over inpatients to ensure they have drunk before fast time starts.	Respondent does not remark on whether patients fast longer or whether there is updating on arrival to ward. However, it is clear that patients held in fasting status.	60% (3, 0.33) of patients are happy with updating. There is no evidence or reporting to indicate that updating during the list occurs. No intention to update fasting times reported.	Authority to regulate fasts is not delegated to nursing staff to manage.	Trust focus is to fast to first on the list. Respondent suggest there is a lack of support to improve practice among anaesthetists.	There is no report of attempts to regulate fasts for some or any patients post first on the list.
	0.66	0.33	0.66	0	0	0	0	0

E	Trust has a strong pre-op that sees patients 16 weeks before admission and advises patients to have food and fluids pro-actively before fast starts. 93.8% of patients receive information (2, 0.66). 12.7% of patients fast differently (2, 0.66). Surgeon's only concerned if patient has drunk and they want to push them up the list. Generally, HCPs not overly interested in fasting practice and do not entirely agree with recommendations in guidance.	Receipt of operating list is on the day of surgery. It is possible to view lists building up (computer) but final order not until day of surgery.	Trust ensures fasting practice promotes first on the list. Seems more problematic for inpatients as they want to ensure their water jugs are removed and not forgotten. This happens at 10.00 at night enforcing a 12MN practice, if no one makes the effort to give them a drink before 6.	Some patients tend to fast longer. Although whether they receive fluids did not get reported, suggesting unlikely. There was some view that the trial had raised awareness but not changes in practice.	Changes to lists still occur on the day of operation and you may not know who is first so revisions not made. 53% of patients were happy with updating (4, 0). Impacts from emergency procedures and dealing with urgent cases prevents relaxing stance on fasting. Focus is on maintaining fast once list underway. Surgeon's want to maintain fast to maintain list flexibility.	Lists are not regulated once underway. There is a strong resistance to having patients drinking fluids close to operation time.	Trust focus is on the fast of those first on the list.	Focus on theatre readiness rather than update and regulate fasts throughout list post first on the list.
	0.66	0.33	0.66	0	0	0	0	0

F	Standardisation of letters during Trial. Letters are not yet computerised. 90.5%of Patients receive information (2, 0.66), 5% fast differently (1, 1). Some surgeon's write in notes fast from midnight.	There is variability on how lists are organised and how often they get re-organised across the Trust.	There is a mix of blanket and first on the list at the Trust. There is an issue with some responding to the 2-hour rule for both in and day patients leaving medical staff concerned about patients adequately fasted. In some areas regular cancellations leave patients fasting too long staff express a frustration in trying to find the balance.	Someday patients do fast excessively. Use of theatre lounges for day patients inhibits updating. There is expectation by medical staff that patients will fast by 12MN even thought this is not Trust policy. Giving drinks to patients up till 6am can be a problem.	40% (4, 0) of patients were happy with updating. (4, 0). Lists frequently changed. Staff do question whether a patient can be allowed to have a drink	Staff are too busy to communicate when patient list order is re-organised. Also, often unable to give precise list times so wish to keep patient fasted. A lot of juggling inhibits timely communication. Not always possible to know how long an operation is going to take. So difficult to get buy in from consultants.	The Trust seems to allow first on the list as well as blanket fasting, due to persistent practice by consultants.	Attempts to regulate fasts post first on the list are made but this seems weak in this Trust.
	0.66	0	0.33	0	0.33	0	0	0.33
G	Information is standardised throughout trust as part of trial efforts. Concern about surgeon support for better practice on fasting. 98.7 of patients receive information (1, 1). 10.7% patients fast differently (2, 0.66).	Lists are organised by the secretary and consultants. List is completed the day before surgery. Access to the lists is on the computer.	Patients are fasted as if first on the list. A clear view that they cannot be fasted beyond at the initial point of arriving on the ward. Patients receive information at pre-op assessment. No differences between day and inpatients reported.	Patients do fast longer than recommended by letters. Although a majority fast as requested. No clear account that these patients will have their fasts updated on arrival.	There is no clear account. 94.1% patients are happy with updating (1,1). Trust is moving towards keeping list changes to a minimum. Changing at last minute does not allow adjustment, as oppose to planned changes from the beginning of the list.	Due to assessment at pre-op to ensure that patients are "fit for the list". Changes are likely to be last minute and therefore adjustments more difficult.	Primarily focussed on first on the list. Medical staff are not necessarily mindful of change and updating fasting rather than inhibiting such changes.	Where the fasting time is extreme a change may occur otherwise updating is not routine or commonly practiced post first on the list .
	0.66	0.66	0.66	0	0.66	0	0.33	0

H	Patient letters and information sheets amended although disappointed Trust did not adopt our information. Information refocussed message to please drink water. 96.4% of patients received information (1, 1). 25.9% fasted differently to information given. (3, 0.33) - Patients are anxious about fasting.	No problems with delivery of theatre lists. Computer systems available. Although ward staff may find access difficult.	Patients are fasted as if first on the list. A particular issue for all day lists was noted. 18-week targets were a priority at the time of the trial. Both day and inpatient treated as first on the list.	Nurses based on where patients are on the list on arrival will try to give water. Some anaesthetists did not like the removal of flexibility to move patients around. Elderly patients tend to fast longer than necessary.	Lists move around and it seems to staff feel it is too late to give drinks. 50% of patients are happy with updating (4, 0). There is a lack of awareness or sense of priority from theatre staff to consider updating ward staff to allow for adjustment to fasts. Although nursing staff feel able to challenge those that are not happy about patients having fluids two hours before an operation. There are issues with both surgeons and anaesthetists whose focus is on the planning of the list. In principle though anaesthetists accept the evidence for 2 hour fasts. During trial CA was able to promote drinking once list times were known.	There was not a wholesale approach to supporting routine updating however, awareness raising established some practice focussed at ward level and nursing staff.	The trust has guidance in place that establishes patients fasted as first on the list. All day lists a particular problem.	There is no report of attempts to regulate fasts post first on the list for some or any patients.
	66%	0.66	0.66	0.66	0.33	0.66	0.33	0

I	Policy in place close to guideline recommendation - in place for 18 months. 87.8% of patients received information (3, 0.33). 14.6 (2, 0.66) fasted differently to information given.	Operating lists and theatre organisation not a specific issue at the Trust.	It is unclear how ell current policy is implemented which should target first on the list as a starting point. No issues raised for am/pm or all-day lists response rate for all surgical admissions.	No adjustments specified to account for patients who arrive on the ward over fasted.	Due to the possibility that patients will move around the list. And some go sooner. Fasting practice is cautious. Respondent suggests a confident champion might have an effect. Need a key person to communicate between ward and theatre - not in place. No intention to regulate fasts	No delegation to manage fasting practice	At best first on the list syndrome.	Generally Trust wants flexibility in fasting practice towards longer rather than shorter fasting times. PDSA allocation did not function and so Trust did not engage with any change activities
	0.66	1	0.33	0	0	0	0	0

J	Pre-op a month before surgery. Actively encouraged to drink at the last minute before fast start time. Patients don't understand clear fluid (drink sugar drinks) and at times receive contradictory messages. 94.2% of patients receive information (2. 0.66). 11% of patients fasted differently (2. 0.66).	Operating lists distributed quite late. Surgeons and secretaries decide on the list.	Safety briefings at start of list enable changes to be made so yes first on the list (is highly likely due to anaesthetist support) and then followed up. Inpatients and day patients are equally considered. Nursing staff will provide drinks to inpatients up until fast time - which starts as if first on the list.	On arrival once list position known fast can be adjusted - nurse checks with anaesthetist. Patients arrive over fasted. If position known for all day lists then adjustments can be made.	List changes and often ward not informed and porter arrives to take patient. Changes do not happen very often. 75% (2, 0.66) patients happy with updating. Issues during list might be surgeon is slower or quicker, or patient takes longer or shorter etc. So, need to pull someone up the list is problematic and needs to be take into account. communication between ward and theatre good. There is some discussion of moving lists around without notifying ward someone is cancelled in a timely manner. KC did not feel fully supported by medical colleagues. Nurses were keen to pursue practice change.	Safer patient briefings at the start of the list encourage adjustments as list order is agreed. Better feedback regarding changes during the list are required to adjust fasts so intention is there.	Trust starting point is first on the list with some degree of follow up. Not always a priority and other aspects of care demand attention.	There is no clear account of established fasting regulation post first on the list, however, some HCPs did attempt to adjust individual fasting times.
	0.66	0.33	1	1	0.33	0.66	0.33	0.66

K	Patient letters are the major problem undertaken to change during the trial. New information encourages patients to drink to fast time. 87.5% patients received information (3, 0.33). 25.8%report fasting differently (3, 0.33).	Operating lists received at short notice. Never ready for 4pm previous day and often not before 9am as list starts. Often re-organised last minute.	Trust is moving from a 12MN blanket fasting position. Therefore, improvement is to get patients taking fluids up to first on the list. Patients seem cautious. No difference between day and inpatients.	Patients do fast longer than recommended. The new letter distributed, however staff encourage where possible to drink on arrival on ward (day). IV fluids is an option but kept to a minimum.	Trial changes were instigated at local ward level through training etc. and use of posters to regulate fasts up to 2 hours before surgery. 83.3% (1, 1) patients happy with updating. No major objections from medical staff. List re-organisation common and very little communication between ward and theatre. However, if prompted by nursing staff as to whether a patient can drink this does not seem to be objected to.	Overall Trust has shifted to a first on the list with occasional attempts to amend fasts by nursing staff once list is underway.	Fasting practice supporting first on the list initially. Busy lists re-organised frequently inhibits planning fast times.	There is no clear account that there was a deliberate policy to regulate fasting during lists post first on the list.
	0.33	0	1	1	0.66	0.66	0.33	0
L	Outcome data is poor due to response to data collection timepoints							

M	Information fasting sent in a letter nothing additional. Surgeons are not bothered how long patients are fasted.95.8% patients receive information (1, 1). 18% (3, 0.33) of patients fast differently.	Surgeons will sign off operating lists having made changes which are hopefully picked up before the day of operation at pre-op assessment. Printed lists are available, as well computerised lists.	Fasting is set to meet first on the list as an insurance policy. The nursing staff will take account of patients especially children if delays cause prolonged fasting. Day patients are cautious and arrive on wards fasting longer than required. Inpatients not a problem for first on the list.	Some patients are unconcerned about fasting and arrive with long fasts. Staff on the day unit will encourage drinking if time permits.	Day patients fast longer, and ward staff will assess as to whether given their position on the list whether they can have a drink. Re-organisation of lists on the morning of the list does not happen often. Finding beds for patients often overrides the need to focus on other care such as fasting. Communication between ward and theatre is not a feature to revise fasting times. Although acknowledged it should be. Nurses more aware on the wards and feel disempowered to initiate regulation of fasting regimes. Viewed as a Theatre responsibility. 71.2% patients happy with updating (2, 0.66)	Trial did not impact on communication and intention to adjust fasting whilst list running.	Meet first on the list syndrome. With some impact by HCPs not willing to change practice.	There is limited record of an intention to adjust fasts in response to list order post first on the list.
	0.66	1	1	0.66	0.33	0	0.33	0.33

N	Respondent describes letters to patients changing from 12MN to guideline recommended. Leaflets in pre-op are more in keeping with guideline recommendation. Some confusion will lead to elderly patients being more cautious. 93.7 (2, 0.66). (11.7 report fasting differently (2, 0.66)	Operating lists even received day before are out of date on the morning of surgery. Different lists seem to emerge. So, computer printed list is out of date to the one surgeon's and anaesthetists may have circulating. A variety of reasons can result in delays due to patient factors.	Nurses need to adhere to first on the list because of likely changes. Inpatients can be timed better and water intake before fast commences encouraged.	Someday patients arrive on ward over fasting not adhering to guidance. Patients arrival inhibits updating due to focus of first on the list.	Communication between ward and theatre improved during trial. Although only 60% (3, 0.33) of patients happy with updating. Theatre nurses informed ward nurse so that fluids could be given to some patients. However, respondents suggest that a margin of error is required for patients/surgeons that take longer or shorter time in theatre. Junior colleagues more receptive. Some indication that IV's are put up instead of amending fast.	Drivers for theatre excellence has encouraged theatre nurses to inform wards of listed patients progress to allow for adjusted fasting.	Overall there is a struggle in the Trust between those pushing for change and surgeons wishing to maintain flexibility.	First on the list strongest position held with attempts to regulate fasting post first on the list.
	0.66	0	1	0	0.66	0.66	0.66	0.66

O	Patients receive information as part of pre-op assessment. Liaise with waiting list office to ensure consistent information sometimes inconsistent. Changing information to make proactive towards fluid intake before fast. 89.5 patients received information (3, 0.33). 23.7 report fasting differently (3, 0.33)	Operating lists not received in a timely fashion. A HCP is responsiblef or co-ordinating list management.	Adherence to first on the list syndrome. No established difference between day and inpatients. Most wards in trial were inpatient.	No account of adjustment on arrival to ward. Organisation of operating a list a major issue that impacts on prolonged fasting. Surgeons may operate on other consultant lists. Comments indicate that priority to allow flexible management of lists was to maintain fasts if patient needed to move up the list.	Pressure on ward staff and pressure to maintain flexible lists makes during list updating difficult to maintain, even though staff accept guideline recommendation. Champions sought to encourage staff. 46.2 patients happy with updating (3, 0.33).	Fluid regulation not delegated to ward nurses. Onus on them to contact theatre or anaesthetists for updates. Busyness prevents opportunities.	Assume first on the list syndrome no resistance noted more theatre chaos and pressure of understaffing.	Deduce occasional regulation post first on the list attempted but not sustained.
	0.66	0	1	0	0.33	0.33	0.33	0.33
P	Removed poor information							

Q	Patient information updated during trial to focus on 2 and 6 rule - although provided by list start times initially. 81.8 (64.7) patients received information (4=0). 11.4% report fasting differently (2 0.66)	Wards receive lists in a timely manner to update patient fasts once they arrive on the ward. All day lists also managed.	Fasting controlled by Nurses and adjustments made once on the ward indicates both for day and inpatients.	Patient fasting longer are adjusted on arrival on ward.	New fasting signs for each patient inform housekeeping staff when to remove fluids indicate proactive approach. 87.5 patients happy with updating (1-1)	Respondents indicate updating and fasting of patients are closely monitored indicating knowledge of list management. Ward was either delegated or assumed authority for monitoring fasting. All staff including anaesthetists informed. So clear intention to amend fasts where possible. However, this did require constantly prompting people.	Trust adheres to first on the list with some updating throughout list. Respondent indicates the need to manage those that do not comply with proposed updating.	There is an indication that the policy disseminated widely was given authority to implement change to fasting practice (greater monitoring and regulation post first on the list). Not systematic and routine across all areas but procedures in place (Bed notices) and a wide range of activities.
	0.33	1	1	1	1	1	0.66	1

R	Report of recoding letters to patients from surgeon's and medical secretaries and standardising patient information, however, some letters to patients are intercepted and changed to meet surgeon preference. 92% patients received information (2-0.66). 12% report fasting differently (2-0.66). Patient information emphasises drinking clear fluid till fast time (first on the list).	Distribution of printed lists improved with printed lists circulated a couple of days before. Previously more chaotic were now less flexible.	Medical staff are resistant to losing flexibility over the operating list and patient flow. Adherence is focussed on first on the list syndrome. Excessive fasting occurs with day patients and less so with inpatients due to nurse control encouraging fluids overnight.	Day patients excessively fasted. They are not updated on arrival when position on list is known.	Inpatients benefitted and were fasted for the start of the list. Signs above beds were used to inform nursing staff overnight. Anaesthetists were encouraged to use their patient drug charts to specify times on their pre-op visits. However, compliance is not good. Less patients receive these pre-op visits from anaesthetists. Communication between ward and theatre good but re-scheduling not occurring very frequently. Limited attempts to update fasts during list. Some surgeons remain reluctant to update fasting times once lists underway this impacts on reluctance by other staff. 72.7% patients happy with updating (2-0.66)	There is some updating however, the overall picture was not to regulate fasts during lists. Nurses do not have delegated authority and so reliance is on anaesthetist availability - extreme case might be tackled.	Evidence was provided to illustrate that patients were not frequently cancelled or delayed so fasting practice could be better regulated. There is a mix in the Trust of blanket fasting and first on the list syndrome. Strong resistance by medical staff.	There is no clear account to regulate fast across Trust. However, limited good practice of fasting regulation post first on the list may occur occasionally for some patients in some areas.
	1	1	0.66	0	0.33	0.33	0	0.33

S	Report of standardised leaflets and booklets across Trust. 86.9 patients received information (2-0.66). 20% report fasting differently (2-0.66)	Receipt of lists overnight accessible by computer, although comment adds time needed to check computer. But amendments are made on the system and you can see how long ops will take.	Trust under pressure with 18 week targets and wants to keep patients in state of ready to go, so emphasis first on the list. In patients woken to drink till commencing fast. Some patients put milk in tea and are cancelled.	Delays regularly caused by day patients adding milk. Some influence for those receiving bowel surgery to get regulate drinks up to 2 hours before fast. This is not the case for all surgical patients.	Currently focus is on the first on the list. The onus is on nurses to prompt medical staff to consider adjustment to fast times. Anaesthetist sign off if required. It is not routine with the exception of colorectal patients on enhanced programmes. Ward-Theatre communication improved but it takes time for the phone to be answered. Also, a sense of restraint - not to phone theatre too much. Concern of moving patients up the list will not be adequately fasted. Practice change needs greater authority. 67% patients happy with updating (3-0.33)	Respondents indicate some intention to attempt to adjust fast where possible, although remain cautious.	Tendency in Trust remains focussed on first on the list syndrome. Practice is variable and different surgical areas are more receptive than others to regulating fasts. There is resistance from some individuals.	There is no clear account to regulate fast post first on the list across Trust. However, pockets of good practice occur for some patients in some areas.
	0.66	1	1	0.33	0.33	0.33	0.66	0.33

Appendix 6.6

Fuzzy set calibration for Chain 1 and Chain 2

CHAIN 1

QCA Model 1							
Conceptual Factor	**Chain 1h**	**Factor description**	**QCA model factor description -fuzzy set membership**				
		Fuzzy set membership cut off	**1**	**0.66**	**0.5**	**0.33**	**0**
		Threshold definition	**Fully in set**	**More in than out**	**Neither in nor out ambiguous - data not available (missing)**	**More out than in**	**Fully out - evidence of absence**

C1: Individual behaviour ***Impact of individuals (human agency) on systems: champions, leadership and co-operation***	1h 3 1h 5	Attitudes, beliefs, behaviour that either supports or does not support implementation. Individual characteristics of championing or leadership to push implementation of guidance and its translation into action. Individual behaviour that hinders implementation of guidance.	Trust shows evidence of a strong supportive implementation culture through championing and leadership to implement fasting policy	Trust shows evidence of supportive (not necessarily guaranteed or always in place) implementation culture through championing and leadership to implement fasting policy	There is no evidence to show whether there is a supportive implementation culture through championing and leadership to implement fasting policy or whether there is not.	Trust shows evidence of providing weak support (lack of leadership or champions) to implement guidance on fasting policy	Trust shows evidence through its leadership and key professionals (nurses surgeons or anaesthetists) poor leadership and no impetus to implement policy (not a priority or not important enough or conflicts with belief that the change is necessary)
C2: Microsystems ***Engagement between departments, wards, theatres - connectivity and communicat-ion***	1h 1 1h 2 1h 6	Communications between different structures created within the Trust to develop policy and guidance. Strategies and activities for dissemination of policy and guidance.	Trust shows good evidence of structures, processes or systems to implement fasting policy. (committees, procedures etc.)	Trust shows some evidence of structures, processes or systems to implement fasting policy. (committees, procedures etc.)	Trust does not provide any evidence of structures, processes or systems to implement fasting policy (committees, procedures etc.)	Trust indicates some evidence for the potential to implement fasting policy	Trust shows evidence that it has a poor structure or system to implement policies such as fasting.

C3: History current ***Status of system, starting point at trial start - policy development***	1h 1 1h 4	Starting point: policy in place, policy not in place, desire or consideration of need to change practice, not considered the need for change – unaware of problem/concern not raised.	Correct policy in place and awareness and attempts to ensure its implementation prior to trial	Policy needs change and attempts prior to trial attempted.	No policy identified in place	Correct or near to correct policy in place and unaware of need to change	Incorrect policy in place and no plans prior trial to change policy
C5: Intervention/ change ***Level of activity, response, adaptation***	1h 5 1h 6	Delivery of evidence through implementation strategies (trial interventions). Expected mechanism of action and so delivery of intervention to reach target change. Trial conceptual framework and the logic of strong credible evidence should support change to behaviour - guidance/intervention target.	Trust shows evidence of high level of action or activity to change policy and implement fasting policy. Irrespective of intervention allocation. Looking for evidence of Trust strategy	Trust shows evidence of moderate attempts through activity or action to implement fasting policy. Irrespective of intervention allocation. Looking for evidence of Trust strategy	No evidence of action or activity to implement fasting policy. Irrespective of intervention allocation, however, SD trusts to adhere to allocation could decide to take no action.	Trust shows evidence of attempting to undertake some action or activity but is unable to do so. Thus, prevented in some way to undertake action.	Trust shows evidence of not undertaking any activity or action on promoting fasting practice in response to Trial.

CHAIN 2

QCA Model 2							
Factor definition	**Chain 2h**	**Factor description**	**QCA model factor description - fuzzy set membership**				
		Fuzzy set membership cut off	**1**	**0.66**	**0.5**	**0.33**	**0**
		Threshold definition	**Fully in set**	**More in than out**	**Neither in nor out ambiguous - data not available (missing)**	**More out than in**	**Fully out - evidence of absence**

C1: Individual behaviour *Impact of individuals (human agency) on systems: champions, leadership and co-operation*	2h 2 2h 4 2h 5a 2h 5b 2h 6b	Attitudes, beliefs, behaviour that either supports or does not support implementation. Individual characteristics of championing or leadership to push implementation of guidance and its translation into action. Or that Individual behaviour hinders implementation of guidance.	Trust shows evidence of a positive attitude and co-operation between individual healthcare professions to implement fasting practice that indicates strong leadership or successful championing within the designated Trial area.	Trust shows evidence of co-operation, championing or leadership between individual healthcare professions to implement fasting practice that indicates capacity for change at the local level	No evidence of either co-operation or lack of co-operation, leadership of championing behaviour	Trust shows some limited (or intention to) co-operation or championing behaviour, however, this was hampered by other individuals	Trust shows evidence of mainly resistance by individuals to adopt the proposed guidance for fasting practice.

C2: Microsystems ***Engagement between departments, wards, theatres - connectivity and communication***	2h 5a 2h 5b 2h 6a 2h 6b	Communication between departments, wards, surgeon's and colleagues, to patients that either enables or hinders implementation of guidance.	Trust shows strong evidence of timely communication between ward and theatre and other related departments that indicates opportunities for individual patients to receive regulated fluid fasts before surgery.	Trust shows some evidence of timely communication between ward and theatre and other related departments with the potential to regulate individual patients' fluid fast before surgery.	No evidence to show any communication or co-operation or lack of co-operation between ward and theatre and other related departments to regulate individual patients' fluid fasts.	Trust shows evidence of communication between ward and theatre and other related departments that is constrained by factors such as time, staffing, pressures etc. to facilitate regulation of individual patients' fluid fast.	Trust shows evidence of no communication between ward or theatre that could provide an opportunity to regulate individual patients' fluid fast.
C4**: System imperative** ***Retreating to main focus of system managing the operating list***	2h 1 2h 2 2h 3 2h 5a 2h 6a	Adherence to the imperative to not threaten the smooth running of the operating list. Cautious behaviour by both staff and patients to ensure readiness for list including any delays or changes that might occur.	Trust shows evidence that it can manage the operating list flexibly (and with some stability) and allow many patients to have fluids close to 2 hours before induction of anaesthetic.	Trust shows evidence of attempting to manage the operating list in favour of the patients' need to have fluids up to 2 hours before induction of anaesthetic.	No evidence available to suggest the Trust prioritises the operating list management above the patient's need to have fluids up to 2 hours before induction of anaesthetic or otherwise.	Trust shows some evidence of cautious behaviour that prioritises the management of the operating list over regulation of the fluid fast for individual patients.	Trust shows evidence of clear a preference towards maintaining fasted patients so as not to jeopardise the management of the operating list and the patient flow through theatre.

C5: Intervention/ change ***Level of activity, response, adaptation***	2h 5b 2h 6b	Impact of intervention, whether successful in reaching target behaviour or not, whether tailoring changes or poor fidelity were issues in implementation.	Trust shows evidence that the effect of trial and the active implementation of the guidance has had a positive effect on those areas involved in the trial.	Trust shows some evidence that members have attempted to engage and implement the guidance on fasting practice.	No evidence available to determine whether the trial has had an effect on the implementation of the guidance for fasting.	Trust shows evidence of a split between those championing and those preventing a response thus preventing an action or activity to implement the guidance on fasting practice.	Trust shows evidence of not or not being able to respond to the trial's agenda to implement the guidance for fasting. This might include Trusts allocated to SD who actively decided not to respond in an active way.

Outcome set

	Outcome set description - fuzzy set membership				
	1	**0.66**	**0.5**	**0.33**	**0**
	Change detected	potential for change detected	Cannot determine	Negativ e audit results	Negative detected change (as determine d by the trial results)

Outcome concept: For the purpose of this study and worked example, changes can be intermediate but do not affect final results as determined by the Trial design. The QCA needs to reflect the Trial structure whilst simultaneously expose complex patterning (causal processes). Notably the trial was set up as cluster randomised trial and therefore the individual trial results need to be considered with caution and are treated as audit results. Individual patients were conveniently selected within Trust (allocation of intervention at Trust level). However, patient factors would have some cautionary effect on behaviour (to prolong their fast) but this could be overridden by the surgical department. Pre post audit data was analysed for each Trust with each evaluated by a hypothesis test. This is used to determine a qualitative cut off but has limited viability statistically with respect to the trial design. It acts as a marker and indicates whether there is enough data to draw conclusions. Cut points 1/0 are determined by positive trial audit results for individual Trusts. Change points were any mean difference above 1-hour set membership 0.66. less than an hour change for the better 0.5 and anything negative but not positive in the audit 0.33.	Beneficial change (as determined by the Trial (results)	Promising intermediate change to fasting practice with unclear benefit (not determined successful by trial)	No change measured (marginal difference between pre and post audit result)	Negative change in audit results between pre and post audit results	Negative change (as determined by the trial results)

Appendix 7.1

Re-calibration of condition IMP (system imperative)

Case ID	C4-IMP (2h 3, 2h 5a, 2h 5b 2h 6a (assigned process steps)	Fuzzy set assignment	CRISP set assignment
A	Trust fasts patients as if first on the list. All day lists have a greater impact on fasting times - start am list times.75% (2, 0.66) of patients are happy with updating. Adhere to the first on the list syndrome. Computerised lists are updated, however, ward staff will find it difficult to find time to check. Lack of time and busyness affects capacity to regulate. No resistance. Trust described as conveyor belt nursing. Anaesthetists do check and review some fasts. Follows first on the list. Nurses are cautious, and some surgeons still prefer 12MN practice. Practice to update or delegate to nurses is not done and is ad hoc.	0	0
B	Patients fasted as if first on the list. Staff have more control over inpatients in ensuring that they have fluids just before fast starts. First on the list. No resistance to change reported. Once theatre slots known patients fast will be updated. 36.4% happy with updating (4, 0). Only intention reported is the need to update those on all day lists. No arrangements to update once the list is underway.	0	0
C	Trust has three list start times and am pm and evening. This strengthens the view of a first on the list focus. No all-day lists mentioned. No difference between in and day patients reported. Anaesthetists will negotiate on the day any list changes once they have seen patients. 50% (4,0) of patients are happy with updating. Focus on fasting for 3 hours pre-op is to target the start of the list. No amendments made once list underway.	0	0
D	It appears patients are fasted in terms of first on the list. Nurses have more control over inpatients to ensure they have drunk before fast time starts.60% (3, 0.33) of patients are happy with updating. There is no evidence or reporting to indicate that updating during the list occurs. No intention to update fasting times reported. Trust focus is to fast to first on the list. Respondent suggest there is a lack of support to improve practice among anaesthetists. Authority to regulate fasts is not delegated to nursing staff to manage.	0	0
E	Trust ensures fasting practice promotes first on the list. Seems more problematic for inpatients as they want to ensure their water jugs are removed and not forgotten. This happens at 10.00 at night enforcing a 12MN practice, if no one makes the effort to give them a drink before 6. Changes to lists still occur on the day of operation and you may not know who is first, so revisions not made. 53% of patients were happy with updating (4, 0). Impacts from emergency procedures and dealing with urgent cases prevents relaxing stance on fasting. Focus is on maintaining fast once list underway. Surgeon's want to maintain fast to maintain list flexibility. Lists are not regulated once underway. There is a strong resistance to having patients drinking fluids close to operation time. Trust focus is on the fast of those first on the list.	0	0
F	There is a mix of blanket and first on the list at the Trust. There is an issue with some responding to the 2-hour rule for both in and day patients leaving medical staff concerned about patients adequately fasted. In some areas regular cancellations leave patients fasting too long staff express a frustration in trying to find the balance.40% (4, 0) of patients were happy with updating. (4, 0). Lists frequently changed. Staff do question whether a patient can be allowed to have a drink. Staff are too busy to communicate when patient list order is re-organised. Also, often unable to give precise list times so wish to keep patient fasted. A lot of juggling inhibits timely communication. Not always possible to know how long an operation is going to take. So difficult to get buy in from consultants. The Trust seems to allow first on the list as well as blanket fasting, due to persistent practice by consultants.	0	0

G	Patients are fasted as if first on the list. A clear view that they cannot be fasted beyond at the initial point of arriving on the ward. Patients receive information at pre-op assessment. No differences between day and inpatients reported. There, is no clear account. 94.1% patients are happy with updating (1,1). Trust is moving towards keeping list changes to a minimum. Changing at last minute does not allow adjustment, as oppose to planned changes from the beginning of the list. Due to assessment at pre-op to ensure that patients are "fit for the list". Changes are likely to be last minute and therefore adjustments more difficult. Primarily focussed on first on the list. Medical staff are not necessarily mindful of change and updating fasting rather than inhibiting such changes.	0	0
H	Patients are fasted as if first on the list. A issue for all day lists was noted. 18-week targets were a priority at the time of the trial. Both day and inpatient treated as first on the list. Lists move around and it seems to staff feel it is too late to give drinks. 50% of patients are happy with updating (4, 0). There is a lack of awareness or sense of priority from theatre staff to consider updating ward staff to allow for adjustment to fasts. Although nursing staff feel able to challenge those that are not happy about patients having fluids two hours before an operation. There are issues with both surgeons and anaesthetists whose focus is on the planning of the list. In principle though anaesthetists accept the evidence for 2-hour fasts. During trial CA was able to promote drinking once list times were known. Lists move around and it seems to staff feel it is too late to give drinks. There was not a wholesale approach to supporting routine updating however, awareness raising established some practice focussed at ward level and nursing staff. The trust has guidance in place that establishes patients fasted as first on the list. All day lists a problem.	0.33	0
I	It is unclear how well current policy is implemented which should target first on the list as a starting point. No issues raised for am/pm or all-day lists response rate for all surgical admissions. Due to the possibility that patients will move around the list. And some go sooner. Fasting practice is cautious. Respondent suggests a confident champion might have an effect. Need a key person to communicate between ward and theatre, which is not in place. No intention to regulate fasts. No delegation to manage fasting practice. At best first on the list syndrome.	0	0
J	Safety briefings at start of list enable changes to be made so yes first on the list (is highly likely due to anaesthetist support) and then followed up. Inpatients and day patients are equally considered. Nursing staff will provide drinks to inpatients up until fast time - which starts as if first on the list. List changes and often ward not informed and porter arrives to take patient. Changes do not happen very often. 75% (2, 0.66) patients happy with updating. Issues during list might be surgeon is slower or quicker, or patient takes longer or shorter etc. So, need to pull someone up the list is problematic and needs to be take into account. communication between ward and theatre good. There is some discussion of moving lists around without notifying ward someone is cancelled in a timely manner. KC did not feel fully supported by medical colleagues. Nurses were keen to pursue practice change. Safer patient briefings at the start of the list encourage adjustments as list order is agreed. Better feedback regarding changes during the list are required to adjust fasts so intention is there. Trust starting point is first on the list with some degree of follow up. Not always a priority and other aspects of care demand attention.	1	1
K	Trust is moving from a 12MN blanket fasting position. Therefore, improvement is to get patients taking fluids up to first on the list. Patients seem cautious. No difference between day and inpatients. Trial changes were instigated at local ward level through training etc. and use of posters to regulate fasts up to 2 hours before surgery. 83.3% (1, 1) patients happy with updating. No major objections from medical staff. List re-organisation common and very little communication between ward and theatre. However, if prompted by nursing staff as to whether a patient can drink this does not seem to be objected to. Overall Trust has shifted to a first on the list with occasional attempts to amend fasts by nursing staff once list is underway. Fasting practice supporting first on the list initially. Busy lists re-organised frequently inhibits planning fast times.	0.33	0
L			
M	Fasting is set to meet first on the list as an insurance policy. The nursing staff will take account of patients especially children if delays cause prolonged fasting. Day patients are cautious and arrive on wards fasting longer than required. Inpatients not a problem for first on the list. Day patients fast longer and ward staff will assess as to whether given their position on the list whether they can have a drink. Re-organisation of lists on the morning of the list does not happen often. Finding beds for patients often overrides the need to focus on other care such as fasting. Communication between ward and theatre is not a feature to revise fasting times. Although acknowledged it should be. Nurses more aware on the wards and feel disempowered to initiate regulation of fasting regimes. Viewed as a Theatre responsibility. 71.2% patients happy with updating (2, 0.66). Trial did not impact on communication and intention to adjust fasting whilst list running. Meet first on the list syndrome. With some impact by HCPs not willing to change practice.	0	0

N	Nurses need to adhere to first on the list because of likely changes. Inpatients can be timed better and water intake before fast commences encouraged. Communication between ward and theatre improved during trial. Although only 60% (3, 0.33) of patients happy with updating. Theatre nurses informed ward nurse so that fluids could be given to some patients. However, respondents suggest that a margin of error is required for patients/surgeons that take longer or shorter time in theatre. Junior colleagues more receptive. Some indication that IV's are put up instead of amending fast. Drivers for theatre excellence has encouraged theatre nurses to inform wards of listed patients progress to allow for adjusted fasting. Overall there is a struggle in the Trust between those pushing for change and surgeons wishing to maintain flexibility.	0.33	0
O	Adherence to first on the list syndrome. No established difference between day and inpatients. Most wards in trial were inpatient. Pressure on ward staff and pressure to maintain flexible lists makes during list updating difficult to maintain, even though staff accept guideline recommendation. Champions sought to encourage staff. 46.2 patients happy with updating (3, 0.33). Fluid regulation not delegated to ward nurses. Onus on them to contact theatre or anaesthetists for updates. Busyness prevents opportunities. Assume first on the list syndrome no resistance noted more theatre chaos and pressure of understaffing.	0	0
P			
Q	Fasting controlled by Nurses and adjustments made once on the ward indicates both for day and inpatients. New fasting signs for each patient inform housekeeping staff when to remove fluids indicate proactive approach. 87.5 patients happy with updating (1-1). Respondents indicate updating and fasting of patients are closely monitored indicating knowledge of list management. Ward was either delegated or assumed authority for monitoring fasting. All staff including anaesthetists informed. So clear intention to amend fasts where possible. However, this did require constantly prompting people. Trust adheres to first on the list with some updating throughout list. Respondent indicates the need to manage those that do not comply with proposed updating.	1	1
R	Medical staff are resistant to losing flexibility over the operating list and patient flow. Adherence is focussed on first on the list syndrome. Excessive fasting occurs with day patients and less so with inpatients due to nurse control encouraging fluids overnight. Inpatients benefitted and were fasted for the start of the list. Signs above beds were used to inform nursing staff overnight. Anaesthetists were encouraged to use their patient drug charts to specify times on their pre-op visits. However, compliance is not good. Less patients receive these pre-op visits from anaesthetists. Communication between ward and theatre good but re-scheduling not occurring very frequently. Limited attempts to update fasts during list. Some surgeons remain reluctant to update fasting times once lists underway this impacts on reluctance by other staff. 72.7% patients happy with updating (2-0.66). There, is some updating however, the overall picture was not to regulate fasts during lists. Nurses do not have delegated authority and so reliance is on anaesthetist availability - extreme case might be tackled. Evidence was provided to illustrate that patients were not frequently cancelled or delayed so fasting practice could be better regulated. There is a mix in the Trust of blanket fasting and first on the list syndrome. Strong resistance by medical staff.	0	0
S	Trust under pressure with 18 week targets and wants to keep patients in state of ready to go, so emphasis first on the list. In patients woken to drink till commencing fast. Some patients put milk in tea and are cancelled. Currently focus is on the first on the list. The onus is on nurses to prompt medical staff to consider adjustment to fast times. Anaesthetist sign off if required. It is not routine except for colorectal patients on enhanced programmes. Ward-Theatre communication improved but it takes time for the phone to be answered. Also, a sense of restraint - not to phone theatre too much. Concern of moving patients up the list will not be adequately fasted. Practice change needs greater authority. 67% patients happy with updating (3-0.33). Respondents indicate some intention to attempt to adjust fast where possible, although remain cautious. Tendency in Trust remains focussed on first on the list syndrome. Practice is variable and different surgical areas are more receptive than others to regulating fasts. There is resistance from some individuals.	0.33	0
Thres -holds	The imperative to ensure that first on the list or blanket fasting priority is retained = 0. Degree to which the Trust intends or attempts to regulate fasting once list has commenced 0.33-1.		

Appendix 7.2

Summary of NHS surgical department cases included QCA analysis (first and second iteration)

<table>
<tr><th>Case ID</th><th>Summary of NHS surgical department trial intervention status</th><th>Change between pre and post audit mean duration of fast times (hours)</th><th>Management in QCA analysis</th><th colspan="6">Individual NHS surgical department narrative</th></tr>
<tr><td>B</td><td>Standard dissemination only intervention assignment</td><td>Worsening in individual NHS surgical department audit mean fasting times.
Starting point: 8.91
Mean difference: -73
Post audit: 9.64</td><td>Retained in both iterations</td><td colspan="6">Patients fasted as if first on the list.
Staff have more control over inpatients in ensuring that they have fluids just before fast starts.
No resistance to change reported.
Once theatre slots known patients fast will be updated. No further regulation of fast once the list is underway.
36.4% happy with updating.
Will update those on all day lists.</td></tr>
<tr><td colspan="4">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="4">Fuzzy membership assignment for each condition set</td><td>0.33</td><td>0</td><td>0.33</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>C</td><td>Standard dissemination only intervention assignment</td><td>Worsening in individual NHS surgical department audit mean fasting times.
Starting point: 8.57
Mean difference: -0.8
Post audit: 9.37</td><td>Retained in both iterations</td><td colspan="6">Three list start times and am pm and evening. This strengthens the view of a first on the list focus.
No all-day lists mentioned.
No difference between in and day patients reported. Anaesthetists will negotiate on the day any list changes once they have seen patients.
50% of patients are happy with updating.
Focus on fasting for 3 hours pre-op is to target the start of the list. No amendments made once list underway</td></tr>
</table>

<table>
<tr><td colspan="5">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="5">Fuzzy membership assignment for each condition set</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>D</td><td>Opinion leader and web intervention assignment</td><td>Improvement in individual NHS surgical department audit mean fasting times.
Starting point: 9.35
Mean difference:1.5
Post audit: 7.58</td><td>Retained in both iterations</td><td colspan="7">Patients are fasted in terms of first on the list.
Nurses have more control over inpatients to ensure they have drunk before fast time starts.
60% of patients are happy with updating.
here is no evidence or reporting to indicate that updating during the list occurs.
No intention to update fasting times reported.
Lack of support to improve practice among anaesthetists. Authority to regulate fasts is not delegated to nursing staff to manage.</td></tr>
<tr><td colspan="5">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="5">Fuzzy membership assignment for each condition set</td><td>0</td><td>0</td><td>0</td><td>1</td><td>1</td><td>0.66</td></tr>
<tr><td>E</td><td>Opinion leader and web intervention assignment</td><td>Worsening in individual NHS surgical department audit mean fasting times.
Starting point: 8.62
Mean difference: -1.16
Post audit: 9.78</td><td>Removed due to contradiction in Crisp set re-entered into fuzzy set analysis – second iteration only</td><td colspan="7">Fasting practice targets first on the list. Fast maintained for all patients once list underway
Seems more problematic for inpatients as they want to ensure their water jugs are removed and not forgotten. This happens at 10.00 at night enforcing a 12MN practice.
Changes to lists still occur on the day of operation so fasting caution maintained.
53% of patients were happy with updating.
Impacts from emergency procedures and dealing with urgent cases prevents relaxing stance on fasting. Surgeon's want to maintain fast to maintain list flexibility. Lists are not regulated once underway. There is a strong resistance to having patients drinking fluids close to operation time.</td></tr>
</table>

<table>
<tr><td colspan="5">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="5">Fuzzy membership assignment for each condition set</td><td>0</td><td>0</td><td>0</td><td>1</td><td>1</td><td>0</td></tr>
<tr><td>F</td><td>Standard dissemination only intervention assignment</td><td>No change in individual NHS surgical department audit mean fasting times.
Starting point: 10.2
Mean difference: 0.1
Post audit: 10.14</td><td>Retained in both iterations</td><td colspan="7">There is a mix of blanket (due to persistent practice by some consultants).and first on the list at the NHS surgical department. There is an issue with some responding to the 2-hour rule for both in and day patients leaving medical staff concerned about patients adequately fasted.
In some areas regular cancellations leave patients fasting too long staff express a frustration in trying to find the balance.
40% of patients were happy with updating.
Lists frequently changed. Staff do question whether a patient can be allowed to have a drink. Staff are too busy to communicate when patient list order is re-organised.
Operating list management suffers ‘juggling’ and length of surgery unknown, timing imprecise so patient fast retained.</td></tr>
<tr><td colspan="5">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="5">Fuzzy membership assignment for each condition set</td><td>0</td><td>0.33</td><td>0</td><td>0</td><td>0</td><td>0.33</td></tr>
<tr><td>G</td><td>PDSA intervention assignment</td><td>Improvement in individual NHS surgical department audit mean fasting times.
Starting point: 9.03
Mean difference: 1.32
Post audit: 7.71</td><td>Retained in both iterations</td><td colspan="7">Fasted as if first on the list. A clear view that they cannot be fasted beyond the point of arrival on the ward. Patients receive information at pre-op assessment.
No differences between day and inpatients reported. 94.1% patients are happy with updating.
NHS surgical department is moving towards keeping list changes to a minimum. Changing at last minute does not allow adjustment, as oppose to planned changes from the beginning of the list.</td></tr>
</table>

				Assessment at pre-op to ensures that patients are "fit for the list". Changes are likely to be last minute and therefore adjustments more difficult. Medical staff are not necessarily mindful of change and updating fasting rather than inhibiting such changes.

Final conceptual condition sets				IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set				0.33	0.33	0.33	1	0.66	0.66
H	Opinion leader and web intervention assignment	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 11.06 Mean difference: 1.41 Post audit: 9.65	Retained in both iterations	Patients are fasted as if first on the list. A particular issue for all day lists was noted. Both day and inpatient treated as first on the list. 18 week waiting time targets were a priority at the time of the trial. Lists move around and it seems to staff feel it is too late to give drinks. 50% of patients are happy with updating. There is a lack of awareness or sense of priority from theatre staff to consider updating ward staff to allow for adjustment to fasts. Although nursing staff feel able to challenge those that are not happy about patients having fluids two hours before an operation. There are issues with both surgeons and anaesthetists whose focus is on the planning of the list. In principle though anaesthetists accept the evidence for 2 hour fasts.					

				During trial local change agent was able to promote drinking once list times were known. Lists move around and it seems to staff feel it is too late to give drinks. There was not a wholesale approach to supporting routine updating however, awareness raising established some practice focussed at ward level and nursing staff.

Final conceptual condition sets	IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set	0.66	0.33	0.33	1	1	0.66

I	PDSA intervention assignment	Worsening in individual NHS surgical department audit mean fasting times. Starting point: 9 Mean difference: -1.06 Post audit: 10.06	Removed due to contradiction in Crisp set re-entered into fuzzy set analysis – second iteration only	It is unclear how well current policy is implemented which should target first on the list as a starting point. No issues raised for am/pm or all-day lists response rate for all surgical admissions. Due to the possibility that patients will move around the list. And some go sooner. Fasting practice is cautious. Respondent suggests a confident champion might have an effect. Need a key person to communicate between ward and theatre - not in place. No intention to regulate fasts. No delegation to manage fasting practice. At best first on the list syndrome.

Final conceptual condition sets	IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set	0.33	0.33	0	0	0.33	0.66

<table>
<tr><td>J</td><td>Opinion leader and web intervention assignment</td><td>Improvement in individual NHS surgical department audit mean fasting times.

Starting point: 8.86

Mean difference: 2.43

Post audit: 6.43</td><td>Retained in both iterations</td><td colspan="6">Safer patient briefings at the start of the list encouraged adjustments as list order is agreed.

First on the list with some degree of follow up.

Inpatients and day patients are equally considered. Nursing staff will provide drinks to inpatients up until fast time - which starts as if first on the list.

Often ward not informed of list changes with porter arriving to take patient, although changes do not happen very often.

75% patients happy with updating.

Surgeon slower or quicker, or patient takes longer or shorter etc. affects times on list. So, patients may need to move up so fasting time should take account of possibility.

Communication between ward and theatre good, although not always timely during a list if patient cancelled.

Medical lead not fully supported by medical colleagues. Nurses were keen to pursue practice change.

Fasting regulation not always a priority as other aspects of care demand attention.</td></tr>
<tr><td colspan="4">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OU
T</td></tr>
<tr><td colspan="4">Fuzzy membership assignment for each condition set</td><td>0.66</td><td>0.66</td><td>1</td><td>1</td><td>0.66</td><td>1</td></tr>
</table>

<table>
<tr><td>K</td><td>PDSA intervention assignment</td><td>Improvement in individual NHS surgical department audit mean fasting times.
Starting point: 12.75
Mean difference: 1.37
Post audit: 11.38</td><td>Retained in both iterations</td><td colspan="6">NHS surgical department is moving from a 12MN blanket fasting position. Therefore, improvement is to get patients taking fluids up to first on the list. Patients seem cautious.
No difference between day and inpatients.
Trial changes were instigated at local ward level through training etc. and use of posters to regulate fasts up to 2 hours before surgery.
83.3% patients happy with updating.
No major objections from medical staff.
List re-organisation common and very little communication between ward and theatre. However, if prompted by nursing staff as to whether a patient can drink this does not seem to be objected to. Busy lists re-organised frequently inhibits planning fast times.
Overall NHS surgical department has shifted to a first on the list with occasional attempts to amend fasts by nursing staff once list is underway.</td></tr>
<tr><td colspan="4">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="4">Fuzzy membership assignment for each condition set</td><td>0.33</td><td>0.66</td><td>0.33</td><td>0.66</td><td>0.66</td><td>1</td></tr>
<tr><td>M</td><td>Opinion leader and web intervention assignment</td><td>Improvement in individual NHS surgical department audit mean fasting times.
Starting point: 8.63</td><td>Retained in both iterations</td><td colspan="6">Fasting is set to meet first on the list as an insurance policy against under fasting.
The nursing staff will take account of patients especially children if delays cause prolonged fasting.</td></tr>
</table>

		Mean difference: 0.74 Post audit: 7.89		Day patients are cautious and arrive on wards fasting longer than required. Ward staff will assess as to whether given their position on the list whether they can have a drink. Inpatients not a problem for first on the list. Re-organisation of lists on the morning of the list does not happen often. Finding beds for patients often overrides the need to focus on other care such as fasting. Communication between ward and theatre is not a feature to revise fasting times, though acknowledged it should be. Nurses more aware on the wards and feel disempowered to initiate regulation of fasting regimes, viewed as a Theatre responsibility. 71.2% patients happy with updating. Trial did not impact on communication and intention to adjust fasting whilst list running.						
Final conceptual condition sets				IND	MIR	IMPR	CHANR	POLAR	OUT	
Fuzzy membership assignment for each condition set				0.66	0.33	0	1	1	0.66	
N	PDSA intervention assignment	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 10.56	Retained in both iterations	Nurses need to adhere to first on the list because of likely changes. Inpatients can be timed better and water intake before fast commences encouraged.						

		Mean difference: 8.06 Post audit: 2.5		Communication between ward and theatre improved during trial. 60% of patients happy with updating. Theatre nurses informed ward nurse so that fluids could be given to some patients when list underway. However, respondents suggest that a margin of error is required for patients/surgeons that take longer or shorter time in theatre. Junior colleagues more receptive. Some indication that IV's are put up instead of amending fast. Drivers for theatre excellence has encouraged theatre nurses to inform wards of listed patients progress to allow for adjusted fasting. Overall there is a struggle in the NHS surgical department between those pushing for change and surgeons wishing to maintain flexibility.					
Final conceptual condition sets				IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set				0.66	0.66	0.33	0.33	0.66	1
O	PDSA intervention assignment	No change in individual NHS surgical department audit mean fasting times. Starting point: 7.64 Mean difference: 0.24	Removed in the final analysis due to contradiction in Crisp set re-entered into fuzzy set analysis -second iteration only	Adherence to first on the list. No established difference between day and inpatients. Most wards in trial were inpatient. Pressure on ward staff to maintain flexible lists makes list updating once underway difficult to maintain.					

		Post audit: 7.40		Staff accept guideline recommendation. Champions sought to encourage staff. 46.2 patients happy with updating. Fluid regulation not delegated to ward nurses. Onus on them to contact theatre or anaesthetists for updates. Busyness prevents opportunities. No resistance noted more theatre chaos and pressure of understaffing.					
Final conceptual condition sets				IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set				0.33	0.33	0	0.66	0.33	0.33
Q	Standard dissemination only intervention assignment	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 12.53 Mean difference: 4.84 Post audit: 7.69	Retained in both iterations	Fasting controlled by Nurses and adjustments made once on the ward for both for day and inpatients. NHS surgical department adheres to first on the list with some updating throughout list. New fasting signs for each patient inform housekeeping staff when to remove fluids indicate proactive approach. 87.5 patients happy with updating. Respondents indicate updating and fasting of patients are closely monitored indicating knowledge of list management. Ward staff was either delegated or assumed authority for monitoring fasting. Clear intention to adjust fasts where possible and all staff including anaesthetists kept informed.					

				Respondent indicates the need to manage those that do not comply with proposed updating.					
Final conceptual condition sets				IND	MIR	IMPR	CHANR	POLAR	OUT
Fuzzy membership assignment for each condition set				1	1	1	1	0.66	1
R	PDSA intervention assignment	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 10.16 Mean difference: 1.36 Post audit: 8.80	Retained in both iterations	Medical staff are resistant to losing flexibility over the operating list and patient flow. Adherence is focussed on first on the list syndrome, with some following blanket fast rules. Excessive fasting occurs with day patients and less so with inpatients due to nurse control encouraging fluids overnight. Inpatients benefitted and were fasted for the start of the list. Signs above beds were used to inform nursing staff overnight. Anaesthetists were encouraged to use their patient drug charts to specify times on their pre-op visits. However, compliance is not good. Less patients now receive these pre-op visits from anaesthetists. Communication between ward and theatre good but re-scheduling not occurring very frequently.					

<table>
<tr><td></td><td></td><td></td><td></td><td colspan="6">Limited attempts to update fasts during list.

Some surgeons remain reluctant to update fasting times once lists underway, thus other staff reluctant.

72.7% patients happy with updating. Some updating, but overall picture was not to regulate fasts during lists.

Nurses do not have delegated authority and so reliance is on anaesthetist availability - extreme case might be tackled.

Evidence was provided to show that patients were not frequently cancelled or delayed so fasting practice could be better regulated. Strong resistance by some medical staff.</td></tr>
<tr><td colspan="4">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="4">Fuzzy membership assignment for each condition set</td><td>0.66</td><td>0.33</td><td>0</td><td>1</td><td>1</td><td>0.66</td></tr>
<tr><td>S</td><td>Opinion leader and web intervention assignment</td><td>Worsening in individual NHS surgical department audit mean fasting times.

Starting point: 6.45

Mean difference: -1.45</td><td>Retained in both iterations</td><td colspan="6">Pressure of 18 week waiting list targets for surgery, so patients need to be ready and waiting to go.

Concern patients moving up list will not be fasted adequately

First on the list. Inpatients woken to drink till fast start.</td></tr>
</table>

<table>
<tr><td></td><td></td><td>Post audit: 7.9</td><td></td><td colspan="6">Cancellation due some patients adding milk to drinks.

The onus is on nurses to prompt medical staff to consider adjustment to fast times with Anaesthetist sign off.

Adjustment not routine except for colorectal patients on enhanced programmes.

Improvements to Ward-Theatre communication improved but answering phone takes time.

67% patients happy with updating.

Healthcare professionals cautious, although intend to regulate fast.

Practice is variable and different surgical areas are more receptive than others to regulating fasts. There is resistance from some individuals.</td></tr>
<tr><td colspan="4">Final conceptual condition sets</td><td>IND</td><td>MIR</td><td>IMPR</td><td>CHANR</td><td>POLAR</td><td>OUT</td></tr>
<tr><td colspan="4">Fuzzy membership assignment for each condition set</td><td>0.66</td><td>0.33</td><td>0.33</td><td>0.33</td><td>0.33</td><td>0</td></tr>
</table>

Summary of NHS surgical department cases excluded in all analyses

Case ID	Summary of NHS surgical department trial intervention status	Change between pre and post audit mean duration of fast times (hours)	Management in QCA analysis	Individual NHS surgical department narrative
A	Standard dissemination only intervention assignment This NHS surgical department did not conduct any activities and was absent across all conditions	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 12.3 Mean difference: 1.8 Post audit: 10.54	Removed due to contradiction from all analyses negative on all factors and positive on outcome could possibly indicate Hawthorne effect.	Patients fasted as if first on the list All day lists have a greater impact on fasting times 75% of patients are happy with updating. Computerised operating lists are updated, however, ward staff will find it difficult to find time to check. Lack of time and busyness affects capacity to regulate. No resistance. Described as conveyor belt nursing. Anaesthetists do check and review some fasts. Nurses are cautious, and some surgeons still prefer 12MN practice. Practice to regulate fasting not done routinely
L	Standard dissemination only intervention assignment	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 5.76 Mean difference: 1.55 Post audit: 4.21	Lack of information to extract removed from all analyses, also data contributed to audit data was low and thus would distort primary outcome data	No data extracted
P	Standard dissemination only intervention assignment. No champions. No activities limited interview data to support QCA data extraction.	Improvement in individual NHS surgical department audit mean fasting times. Starting point: 12.93 Mean difference: 1.74 Post audit: 11.19	Lack of information to extract removed from all analyses	No data extracted