Queen Mary University of London

How are process evaluations defined, valued, and shaped within pragmatic randomised controlled trials of complex healthcare interventions?

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Thesis submitted in partial fulfilment of the requirements for the Degree of Doctor of Philosophy

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Collaborations

Collaborators assisting with double data extraction and results screening in the systematic review in Chapter 6 were Gordon Forbes and Imogen Skene.

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Abstract

Background

Process evaluations are often conducted with pragmatic randomised controlled trials (RCTs) of complex healthcare interventions. Pragmatic RCTs aim to evaluate intervention effectiveness in real-world contexts, and process evaluations aim to provide understanding of how interventions achieve outcomes.

However, the scope of process evaluation is broad and there lacks a clear definition. Their value in the context of pragmatic RCTs of complex healthcare interventions has received little critical attention, and little is known about how process evaluations are shaped in this context.

The question posed by this thesis is: how are process evaluations defined, valued, and shaped when conducted within pragmatic RCTs of complex healthcare interventions?

Methods

1) Critical interpretive synthesis of process evaluation methodology literature

2) Systematic review of process evaluation conducted within a sample of pragmatic RCTs

3) Focused ethnographic case studies of 3 UK process evaluations

Findings

In this context the scope of process evaluation is very broad and there lacks a clear definition.

Value and negative consequences may stem from socio-technical processes enacting process evaluations, and formative or summative knowledge use. Different types of knowledge are perceived as more or less valuable. Value is subjective and context dependent, and there are tensions between values.

Process evaluations are shaped by the negotiation of multiple values held by researchers and other stakeholders. The real-world healthcare research contexts in which they are conducted and the abilities of researchers to navigate these also significant.

Findings contribute practical frameworks for researchers and other stakeholders planning process evaluations to plan for the value they wish to gain from process evaluations.

Conclusion

Findings provide practical and theoretical contributions to advance the methodological knowledge base of process evaluations in pragmatic RCTs, and process evaluation more broadly. The following key recommendations are drawn:

- Researchers should plan the value they wish to create from the outset of planning a process evaluation, to then inform decisions about how to design and conduct the process evaluation to create this value.
- When planning and conducting process evaluations in practice, and in theoretical discussions of process evaluation, researchers should consider:
    - How they define process evaluation
    - The role of a process evaluation within a pragmatic RCT
    - The kind of knowledge that is perceived as valuable for process evaluations to produce, including ontology, epistemology, and complexity, and how this may be reconciled with different scenarios of RCT outcome results
- Process evaluation teams should pay attention to the social processes underlying their idea sharing and decision-making and the social and physical/virtual contexts in which this takes place, with measures to promote equal and open discussions recommended.

- Barriers to conducting process evaluations efficiently and to their full potential exist in the organisations supporting healthcare research, and these should be further examined and addressed.

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Abbreviations

CCG – Clinical Commissioning Group

CRN – Clinical Research Network

CTU – Clinical Trials Unit

HRA - Health Research Authority

HTA – Health Technology Assessment

MRC – Medical Research Council

NIHR – National Institute for Health and Care Research

NHS – National Health Service

PPI – patient public involvement

RCT – randomised controlled trial

TMT – Translational Mobilisation Theory

1 Setting the scene

1.1 Process evaluations – opening up the black box

This thesis addresses the question:

How are process evaluations defined, valued, and shaped when conducted within pragmatic randomised controlled trials of complex interventions in healthcare research?

Process evaluations have been described as ***opening the black box*** of complex interventions evaluated by trials or other outcome evaluation methods (1-3). The core driver for undertaking process evaluations is an increasing recognition by many (although not all) stakeholders in healthcare research that a binary primary outcome finding that a complex intervention 'works' or 'doesn't work' is insufficient to inform policy and practice.

My primary interest in process evaluation stems from my own dissatisfaction with this binary classification of interventions as 'working' or 'not working'. This stems from many years of clinical nursing experience in which it was obvious that patients are unique and respond differently to different interventions at different times. It also stems from personal experience of receiving evidence-based healthcare interventions that did not work for me and had detrimental effects, then having my concerns dismissed and told to carry on because 'we know it works'. This has led me to consider that opening and understanding the black box, and making sense of the messy reality underlying neat and convenient 'it works' or 'it doesn't work' trial results, is a serious ethical concern.

However, from the beginning of my journey on this PhD to drawing the final conclusions it has become clear that 'opening the black box' by conducting a process evaluation is far from straightforward, particularly within 'real-world' pragmatic randomised controlled trials (RCTs). Not everybody wants to know what is inside the black box. Some people want to fully unpack it and get

into all the dark corners, while others would prefer to have a quick look, draw some conclusions to complement trial findings, and then quickly close it again. There are a multitude of possible methods and theoretical frameworks that can be used to make sense of what might be inside the black box, and reports of what the black box contains can end up in publications a very long way from the trial it relates to. Furthermore, through close examination of the social practice of opening the black box of complex interventions (in the ethnographic case studies I conducted as part of this thesis), it was also clear that there is a whole other black box between the idea to 'do a process evaluation' and eventual knowledge outputs. This is particularly the case in real-world pragmatic RCTs which are conducted in multiple real-world healthcare and healthcare research organisational contexts.

I have met many researchers who think they *ought* to do a process evaluation and want to know *how* to do one. I have met fewer who are pausing to deeply question what they are ultimately trying to achieve and why - and ask awkward questions about what happens when what we find in the black box is messy and inconvenient or we selectively examine what it contains.

Through addressing the question of how process evaluations are defined, valued, and shaped this thesis is an attempt to make sense of, in the context of pragmatic RCTs of complex healthcare interventions, what researchers fundamentally understand process evaluations to be, why they are doing them, and how they are doing them - and to critically consider the implications of these findings for all those who may be affected.

I offer frameworks for researchers to begin planning process evaluations by planning the value they aim to create, and to then plan how to realise this value in real-world healthcare contexts. Thus, rather than starting with the question '***how do we do a process evaluation?'***, researchers are encouraged to spend time critically questioning '***what are we trying to achieve by opening the black box, and what will we do with what we find?***'

1.2 Overview of chapters

In this first chapter I provide an overview of the central concepts of this question, namely healthcare research, complex healthcare interventions, pragmatic RCTs, and process evaluations. In chapter 2 I describe the scoping work undertaken to develop the research question and my personal reflections, and in chapter 3 I then outline the rationale for addressing this research question in relation to the existing knowledge base, and unpack the concept of 'value' in research.

Chapter 4 then examines the philosophical and methodological underpinnings of this thesis, giving a brief overview of approaches considered, followed by a discussion of the critical realist stance.

In chapter 5 I present a critical interpretive synthesis of the process evaluation methodology literature and a conceptual framework developed to inform the subsequent elements of this thesis. This is followed by a systematic review of process evaluations conducted within a sample of pragmatic RCTs of healthcare interventions in chapter 6.

In chapter 7 I then present focused ethnographic case studies of three process evaluations conducted within pragmatic RCTs in the UK and funded by the UK National Institute for Health and Care Research (NIHR), with a cross-case analysis.

Finally, in chapter 8 I bring together findings from the critical interpretive synthesis, systematic review, and focused ethnographic case studies to answer the research questions, discuss findings in relation to the existing knowledge base, and draw recommendations and conclusions.

1.3 Overview of chapter 1

In this chapter I set the central concept of this thesis 'process evaluation' within the wider context of healthcare research and increasingly complex human health needs. I briefly discuss complex interventions and debates about definitions of complexity, and then discuss debates and challenges relating to how to develop and evaluate complex interventions. I then introduce the concept of pragmatic RCTs and how these are used as a method of evaluating the outcomes of complex

interventions in real-world healthcare settings. Finally, I provide an overview of process evaluation and its place in the development and evaluation of complex healthcare interventions.

1.4 Healthcare research

The aim of healthcare research is to develop knowledge with the aim of improving health treatments, policies, or care (4).

1.4.1 Evidence-based practice

Healthcare research has assisted many improvements and advances to human well-being and healthcare over the past approximately 150 years (5). In 1972 Archie Cochrane argued that medical treatments should be systematically evaluated using unbiased evaluation methods, and that medical practitioners and the medical profession should continuously examine the knowledge that underpinned their practice (6). His rationale was concern about the potential harm and waste caused by the use of medical interventions of unknown or dubious safety and efficacy (6).

The uptake of evidence-based medicine grew, and other health professions including nursing and dentistry began incorporating the concept into their practice (7). In response to criticisms of evidence-based practice being a cost-cutting threat to clinical freedom, Sackett et al. (7) p. 71 published the following definition:

> *"Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research."*

While the underlying aim of evidence-based practice to provide safe and effective care is widely embraced, the underlying principles of evidence-based practice have attracted some criticism. For example, its narrow definition of evidence (8), its own adoption as the best way to practice medicine on the basis of authority voices rather than systematic research evidence (9), the treatment of

health as a commodity (5), and failure to account for complexity and individual needs (9) have been highlighted.

1.4.2 The demand for healthcare research

Despite these criticisms the evidence-based practice movement has grown and is widely accepted, bringing a continuously increasing need for healthcare research to provide the evidence to support practice.

In the UK context the Medical Research Council (MRC) was founded in 1913 and its current mission is to *'improve human health through world-class medical research'* (10). The National Institute for Health and Care Research (NIHR) was established in 2006 with the vision '*to improve the health and wealth of the nation through research'* (11). The NIHR is the research body of the UK National Health Service (NHS) and its aims also relate to providing high quality evidence-based healthcare in the NHS, and growing the research culture and patient research participation within the NHS.

The national wealth and economic growth opportunities afforded by conducting healthcare research in the NHS in the UK to the government is further reflected in the government's 2021 *Life Sciences Vision* (12), which commits to invest to tackle future health challenges, secure jobs and investment, and make the UK a leading global hub for life sciences.

1.4.3 Public health research

In this thesis the focus is healthcare research as distinct from public health research. As will be discussed later, historically much of the process evaluation guidance and methodology literature stemmed from public health research, and the aim of this thesis is to explore process evaluation in the overlapping but distinct context of healthcare research. I use the term 'healthcare' broadly but in the sense of treatments, care, and services delivered by healthcare services for the treatment of ill-health. This contrasts to public health research, which focuses on the optimisation of population health and prevention of ill-health, with services and interventions generally delivered outside healthcare settings.

1.5 Complex healthcare interventions

Concurrent with the demand for healthcare to be evidence-based and the growth of UK healthcare research, health needs and challenges have become increasingly complex. Financial pressures, an ageing population, and increasing numbers of people living with multiple long-term health issues has brought pressing needs for healthcare and health services capable of delivering complex responses to complex challenges in complex contexts (13).

The MRC published in 2000 *A Framework for development and evaluation of RCTs for complex interventions to improve health* (14). This framework addressed growing concern that non-pharmacological interventions should be as rigorously evaluated as pharmacological interventions (15). Through its focus on non-pharmacological interventions it was one of the earliest frameworks to highlight the inherent complexity of modern health interventions (16).

1.5.1 Defining complexity

This earliest version of the MRC framework defined complex interventions as consisting of numerous components, which may behave both interdependently and independently (14). It highlighted that these components may include the behavioural components themselves, the delivery of components (such as location), and parameters of components (such as timing) (14). It also underscored that complex interventions may be delivered directly to patients, to staff, or to populations, and also may be service modifications (14).

This definition of complex interventions was criticised by some, and Cohn et al. (16) argue that the framework avoids directly addressing the question of what complexity is. Hawe et al. (17) argued that by conceptualising complexity in terms of components and identifying active ingredients, the first MRC framework fails to capture the essence of a complex intervention, and that its definition in fact denotes a simple intervention.

The MRC published updated guidance in 2008 with its *Developing and evaluating complex interventions: new guidance* (18). This extended the definition of a complex intervention to include:

- ✓ *Number of and interactions between components within the experimental and control interventions*
- ✓ *Number and difficulty of behaviours required by those delivering or receiving the intervention*
- ✓ *Number of groups or organisational levels targeted by the intervention*
- ✓ *Number and variability of outcomes*
- ✓ *Degree of flexibility or tailoring of the intervention permitted* (18) p. 7

It also acknowledged a lack of clear boundary between simple and complex interventions, that there exists a broad variety of complexity, and that few interventions can be described as truly simple (18).

A similar definition of complex interventions was presented in the NIHR's 2016 essay series (19) *Challenges, solutions and future directions in the evaluation of service innovations in health care and public health* (13), with the volume described as a *'state of the art in the evaluation of complex interventions'* (13) p. xi.

This definition of complex interventions also attracted criticisms however, for being mechanistic (16), and describing complicated rather than complex interventions (20, 21). Interventions may be considered complicated if through applying appropriate formulae and expertise a particular outcome is likely to occur (20). In contrast, some argue that outcomes of complex interventions are far less predictable due to the uniqueness of individuals, formulae having limited application, and the potential involvement of many different factors (20).

Other perspectives on complexity are commonly drawn upon in different scientific fields and in the social sciences (16). For example, complexity theorists argue that complex interventions have characteristics including unpredictability, non-linear processes and causal pathways, and emergence (22). Cohn et al. outline an ecological approach to complexity as: *a dynamic and constantly emerging set of processes and objects that not only interact with each other, but come to be defined by those interactions* (16) p. 42. Reniscow and Vaughan (23) argue that the lenses of chaos theory

and complex dynamic systems are more suited to understanding health behaviour change than rational linear deterministic models.

At the time of planning this PhD in 2015, the MRC's *Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance* (22), published in 2014, echoed the definition of complex interventions set out in the MRC's 2008 guidance (18). Nonetheless, this process evaluation guidance also acknowledged limitations of the MRC's definition of complex interventions and included brief discussion of complexity science perspectives.

The MRC updated its complex intervention guidance again in 2021, after much of the data analysis of this thesis was complete. This retained the definition of a complex intervention given in the 2008 guidance, however also emphasised the need to understand how interventions interact with context, stating:

> *For complex intervention research to be most useful to decision makers, it should take into account the complexity that arises both from the intervention's components and from its interaction with the context in which it is being implemented* (24) p.2

It also recommended conceptualising complex interventions as events in systems, with systems having the properties of emergence, feedback loops, adaptation, and self-organisation (24).

1.6 Developing and evaluating complex interventions

1.6.1 MRC guidance for developing and evaluating complex interventions

As well as highlighting the inherent complexity of most health interventions, the publication of the MRC 2000 framework offered a process for the development and evaluation of complex interventions (14). The framework followed the sequential phases of drug development of:

1. Preclinical theory building
2. Phase 1 modelling

3. Phase 2 exploratory trial
4. Phase 3 definitive RCT
5. Phase 4 long term implementation

The guideline developers highlighted that their aim was not to suggest that the development of non-pharmacological complex interventions needed to strictly mirror the pharmacological process, that the process was flexible, and, depending on the state of existing research, some stages may be redundant or prioritised (14).

In the 2008 updated guidelines, these phases were refined and presented as a four-stage cyclical model of development, feasibility and piloting, evaluating, and implementation (25). The authors again highlighted that in practice the process may not neatly follow a cyclical or linear approach. Part of the rationale for its update was to draw greater attention to the need for careful and extensive early phase work and to take eventual implementation into account throughout the process (26).

1.6.2 Evaluation methods

The first MRC framework proposed that RCTs were usually the best research design to evaluate complex interventions *to 'minimise bias and provide the most accurate estimate of a complex intervention's benefits'* (14) p.2. It acknowledged that RCTs were sometimes not possible and that its framework could accommodate alternative designs.

The 2008 updated MRC framework outlined a range of alternative experimental and non-experimental evaluation approaches to classic RCTs, encouraging a pragmatic approach to methods selection and careful consideration of the benefits and trade-offs to different approaches (26). In the backdrop of a rapidly evolving methodological knowledge base it sought to provide examples of existing good practice in evaluation, rather than encouraging the adoption of radical new approaches to evaluation (26). Nonetheless it encouraged selection of experimental randomised

designs where feasible to minimise the risk of selection bias (25). The 2008 MRC framework also highlighted the importance of evaluating process alongside outcomes to understand how a complex intervention was implemented, causal mechanisms, and contextual factors which influenced outcomes (25).

The recommendation of randomised experimental research designs where possible echoed the favouring of RCT findings as sources of evidence to inform practice in the evidence-based medicine and practice movement. RCTs are on the second from top level of the hierarchy of evidence of effectiveness, with meta-analyses of findings from multiple RCTs considered the gold standard of evidence to inform practice (27). The promotion of RCTs as the gold standard of evidence to inform medicine and healthcare, as well as other fields of practice and of public policy, has also been greeted with general enthusiasm by the government, mass media, and public (5).

1.6.3 Limitations and criticisms of RCTs

However, there are also widespread criticisms of the suitability of RCTs and their underlying philosophy of logical positivism to evaluate complex healthcare interventions. Cohn et al. (16) argue that RCTs are incompatible with rich understanding of complexity, no matter how many variables are statistically tested. From a critical realist perspective, Clark et al. (28) argue that using RCTs to measure outcomes does not capture complex dynamics of interventions, contexts, and populations, and that understanding of deeper and wider causal mechanisms is necessary to improve healthcare.

In recognition of methodological developments and debates, the issue of how best to evaluate complex interventions was addressed by the NIHR in an essay series in 2016. This highlighted that '*intelligent evaluation that is sensitive to the complexity*' (13) p.xi is necessary to address the increasing complexity of health needs and contexts of health services delivery. It acknowledged growing recognition of the limitations of classic RCTs, and argued that a wider range of methods were possible, appropriate, and helpful to gain understanding of and develop solutions to complex health issues (13). It includes discussion of, among other methods, different RCT designs such as

stepped-wedge and cluster RCTs, the role of qualitative and mixed-methods research, and comparative case studies.

The most recent (2021) MRC guidance for developing and evaluating complex interventions (24) was published after much of the work within this thesis was complete. However it is important to highlight that this now recommends priority turns away from the binary question of whether interventions are effective or not in recognition that approaching research from this perspective may '*fail to deliver interventions that are implementable, cost effective, transferable, and scalable in real world conditions'* (24) p.2. In a significant step away from the prioritisation of RCTs it recommends researchers ask and answer questions that are most useful to decision makers, even if these are broad, complex, and uncertain, rather than give precise and unbiased answers to narrower and less useful questions. It also suggests research may take an efficacy, effectiveness, theory-based, or systems-based approach, thus opening a much broader range of possibilities for the evaluation of complex healthcare interventions.

1.7 Pragmatic RCTs

1.7.1 What are pragmatic RCTs?

Pragmatic RCTs are RCTs designed to test the effectiveness of interventions in real-world conditions. In the MRC's complex intervention framework, these mostly occur at the phase 3 'definitive RCT' (2000 framework) or 'evaluation' stage (2008 framework).

The results of pragmatic RCTs thus have greater applicability in the real-world than those of explanatory RCTs which are conducted in tightly controlled experimental settings (29). The concept of pragmatic RCTs was proposed by Schwarz and Lellouch in 1967 (30), who highlighted the important difference between explanatory trials providing information about the efficacy of a key component of an intervention or treatment, and pragmatic trials providing information about how to decide between two interventions or treatments under real conditions.

1.7.2 Features of pragmatic RCTs

Loudon et al. (31) developed the PRECIS-2 tool to enable RCTs to be assessed on nine domains on a five-point scale from 'very explanatory' to 'very pragmatic'. Table 1.1 lists the nine domains and provides explanations of pragmatic approaches under each domain.

Table 1.1 PRECIS-2 domains

PRECIS-2 Domain	Explanation of a highly pragmatic approach
Eligibility	Anybody with condition who is likely to be an intervention candidate if provided in usual care is eligible to participate in the RCT
Recruitment	Recruitment in usual care settings from multiple sites of patients who have already presented for care
Setting	Trial conducted in an identical setting to that in which results are intended to be applied
Organisation	Aim to integrate intervention into usual care with no additional staff or resources required
Flexibility of delivery	Allow intervention providers to determine the details of how the intervention is delivered
Flexibility of adherence	Full flexibility in how participants may engage with the intervention
Follow-up	No additional follow-up to usual care
Primary outcome	Primary outcome of clear importance to patients and measured in the same way this would be in usual care
Primary analysis	Intention-to-treat analysis using all available data

1.7.3 Advantages of pragmatic RCTs

There has been increasing interest in pragmatic RCTs as a method of evaluating complex healthcare interventions in response to some of the concerns about classic RCTs outlined in the previous section (19, 31, 32).

Sackett, a founder of evidence-based medicine, advocated pragmatic RCTs, stating that a positive pragmatic RCT primary outcome result provides powerful evidence to implement the intervention into practice (33). He highlighted that a positive primary outcome result in an explanatory RCT is ambiguous as it does not answer the question of whether typical patients will experience an improvement in outcomes in usual healthcare practice.

Other authors also highlight the limitations of explanatory RCTs in their advocation of pragmatic RCTs, including that their lack of generalisability provides little evidence to policymakers (34), and that applying evidence from explanatory RCTs to practice has been found at times to be harmful (35). Pragmatic RCTs are thereby regarded by some as moving attention towards the needs of patients, clinicians and policymakers, and away from the needs of academics, regulators and publishers (32).

Through the production of evidence with greater external validity, some authors believe pragmatic RCTs contribute to the reduction of research waste and encourage the uptake of research in practice (31), and may result in more timely and effective practice guidelines (36).

1.7.4 Drawbacks of pragmatic RCTs

There are nonetheless arguments against pragmatic RCTs. Some authors argue that their supposed high external validity is questionable, highlighting that negative or neutral results of pragmatic RCTs may also be ambiguous (33), and it is uncertain whether the intervention would have worked under optimal conditions (37). Some criticisms include that findings from trials conducted in real-world setting cannot be unproblematically transferred to different real-world settings (36), although proponents of pragmatic RCTs highlight the aim is to conduct the trial in typical settings in which the results will be applied, not simply any setting (31).

The argument that pragmatic RCTs facilitate transfer of interventions to practice more quickly and easily is also questioned, as even within real-world trials there is often supportive infrastructure that disappears when interventions are adopted in practice (38).

Kent and Kitsios (39) caution that by adopting broad inclusion criteria pragmatic RCTs are likely to include patients with little chance of benefit and higher risk of harm from interventions. Findings from pragmatic RCT therefore have the potential to drive ineffective or harmful 'evidence-based' interventions into practice to be delivered to patients who are unlikely to benefit. Similarly, the

goals of pragmatic RCTs are regarded as potentially at odds with the goals of patient centred care (40).

A further criticism of pragmatic RCTs is that internal validity may be sacrificed for external validity, and authors highlight a need to balance these priorities (41). Concerns include poor patient adherence to interventions, lack of fidelity of intervention delivery, lack of blinding, and between-group contamination, however some argue that this is precisely the real-world context that pragmatic RCTs test interventions in (42). Conversely, an advantage of pragmatic RCTs may be fewer Hawthorne effects (37).

1.7.5 Challenges to conducting pragmatic RCTs

There are also several methodological and practical challenges to conducting pragmatic RCTs in the real world of healthcare services. They may place a burden on research sites who may also be inexperienced at research (43), and when usual care is used as a control arm this may vary considerably between research sites (32). The requirements on research sites may lead to bias of inclusion of more sites experienced in research which detracts from the real-world nature of the trial (43). Some argue that pragmatic RCTs cheaper and easier to conduct than explanatory RCTs (37) but others argue they are more expensive and difficult (33). Pragmatic RCTs often collect routine clinical data as part of their real-world design, however this may be poor quality or incomplete (44, 45).

1.8 Process evaluations

This section provides a brief overview of definitions and the history of process evaluations, and discusses the main published process evaluation frameworks and guidance documents. The process evaluation methodology literature is extensively reviewed in a critical interpretive synthesis in chapter 5.

1.8.1 What are process evaluations?

In its guidance for process evaluation published in 2014 the MRC stated that there lacked a unified definition of process evaluation. The document defined them broadly as aiming '*to provide the more detailed understanding needed to inform policy and practice*' (22) p.10, highlighting that outcome evaluations alone do not provide all the answers required. Process evaluations have similarly been described as opening '*the black box of complex interventions'* (1) p.1., with their purpose '*to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes, and to provide insights to aid implementation*' (18) p.4. Essentially, process evaluations seek to explain and understand the processes by which an intervention achieves the effects or lack of effects observed in an outcome evaluation.

1.8.2 History of process evaluation

According to Linnan and Steckler (46), the concept of process evaluation was introduced in the 1960s in the realm of public health program evaluation. They cite an explanation by Suchman in 1967 (47) that analysis of the process by which programs produce their results provides valuable additional information to information about whether or not a program is successful, particularly to explain apparent failures of programs to produce results.

Linnan and Steckler (46) further elucidate that process evaluation theory and methods in public health began gaining increasing recognition in the 1980s, highlighting a 1985 case study by Basch et al. (48). Basch et al. (48) emphasised the importance of monitoring program implementation, and the potential for type III errors when inadequately implemented programs are evaluated.

Significant advances were made in conceptualising and measuring implementation of public health programs by a collaborative effort from three community-based cardiovascular disease prevention studies funded by the National Heart, Lung, and Blood Institute in the USA during the 1980s and 1990s (46). Investigators involved in these large studies took this experience and knowledge of evaluating implementation to subsequent public health program evaluations they conducted.

The Child and Adolescent Trial for Cardiovascular Health process evaluation, the results of which were published in 1997, made important contributions to the development of process evaluation methods and theory (46). Across three years of the program, the process evaluation collected data on participation, dose, fidelity, and the compatibility of the program with the schools in which it ran (49). Investigators maintained that process evaluations were critical components of program evaluation, by helping researchers understand how and why changes were achieved, and how changes differed between subgroups of the target population (50).

Aligned with the increasing complexity of interventions being evaluated, process evaluation design became increasingly complex in the 2000s (46). Baranowski and Stables proposed a minimal useful set of process evaluation components in 2000 (51), in conjunction with an overview of the process evaluations conducted within the nine 5-a-Day Projects funded by the National Cancer Institute in the USA. The eleven components proposed by Baranowski and Stables (51) mostly related to the implementation and uptake of interventions, together with consideration of contextual influences and contamination. They include suggestions for qualitative and quantitative aspects which may be studied within each component, although include little further detail of how to evaluate these aspects.

Linnan and Steckler proposed a framework for process evaluation in 2002, including seven key process evaluation components (46). This framework focused solely on implementation and uptake of programs and interventions, including context; reach; dose delivered; dose received; fidelity; implementation; and recruitment. Linnan and Stickler also recommended a systematic process for designing and implementing process evaluations, beginning with clarifying intervention theory. They recommended process evaluations be designed alongside the development of theory-informed interventions, and that key stakeholders be involved at each stage of the process. They highlighted the potential role of process evaluation in testing and developing intervention theory, although provided little detail on how this may be achieved. While Linnan and Steckler's framework has been

influential (22), the book chapter in which Linnan and Steckler present it (46) does not explain how it was developed, and its recommendations are top-level with detail lacking about how to design and undertake them. Saunders et al. (52) adapted Linnan and Steckler's framework and offered a step-by-step guide to developing a process evaluation plan for assessing the implementation of health promotion programmes in 2005.

In recognition of a lack of guidance to inform the design of process evaluations with cluster RCTs, Grant et al. (1) proposed a framework for process evaluation with cluster RCTs in 2013. This was the first process evaluation framework and guidance to not exclusively focus on public health research. It was developed from methodological and theoretical literature on process evaluation and published examples of process evaluations within cluster RCTs, and proposed additional process evaluation components to those put forwards by Baranowski and Stables' and Linnan and Steckler's frameworks. As well as implementation, Grant et al. proposed process evaluations consider how intervention theory may be used to explain effects, unintended consequences of interventions, and how context may affect the processes being examined.

1.8.3 MRC guidance for process evaluation

The MRC recommended that process evaluations be included in the development and evaluation of complex interventions in its 2008 guidance (18) however included little guidance about how to design and conduct them. The guidance outlined the purpose of process evaluations as '*to explain discrepancies between expected and observed outcomes, to understand how context influences outcomes, and to provide insights to aid implementation*' (18) p.4.

The need for detailed comprehensive guidance about how to design, conduct, and report process evaluations was however recognised by the MRC in 2010 (53), and it published *Process evaluation of complex interventions: UK Medical Research Council (MRC) guidance* in 2014 (22). At 134 pages this was considerably more substantial than any previous process evaluation guidance. It was also primarily developed from a public health perspective, however also describes itself as highly relevant

to complex intervention research in other fields, including health services research and education (53).

Following the MRC's 2008 complex intervention guidance (18) this process evaluation guidance emphasised the importance of clarifying causal assumptions about interventions will work, and using intervention theory as a basis to design process evaluations. Its proposed framework for process evaluation also included a central role of process evaluation to evaluate mechanisms of impact and identify unintended effects (22). This was a development from the earlier process evaluation frameworks of Linnan and Steckler and Baranowski and Stables, with their emphasis on implementation. It included and further developed the role of process evaluation to study implementation, drawing on more complex frameworks and debates around the evaluation of implementation in contrast to the simpler outlines offered in previous frameworks. It also included the role of process evaluation in understanding context, including how context influenced implementation and mechanisms of impact, as well as effectiveness.

Table 1.2 outlines the components of process evaluation included in the MRC's framework.

Table 1.2 MRC process evaluation components (adapted from (22))

CONTEXT		
Causal mechanisms present within the context that act to maintain the status quo, or enhance effects	**Contextual factors that shape theory of how the intervention works**	**Contextual moderators** *Shape, and may be shaped by, implementation, intervention mechanisms, and outcomes*
IMPLEMENTATION		
Dose *How much intervention is delivered*	**Fidelity** *The consistency of what is implemented with the planned intervention*	**Adaptations** *Alterations made to an intervention in order to achieve better contextual fit*
How delivery is achieved *The structures, resources and mechanisms through which delivery is achieved*	**Reach** *Extent to which target audience comes into contact with intervention*	

MECHANISMS OF IMPACT		
Mediators *Intermediate processes which explain subsequent changes in outcome*	**Participant responses** *How participants interact with a complex intervention*	**Unanticipated pathways and consequences**

The MRC process evaluation guidance included extensive discussion of the theoretical foundations of process evaluations, including frameworks, theories and current debates, as well as practical guidance on how to plan, design, conduct, and analyse process evaluations. It also included recommendations for reporting process evaluations and a checklist for process evaluation appraisal. Authors additionally presented case studies of process evaluations they had conducted, including reflections on lessons learned.

While the MRC process evaluation was comprehensive and has been widely cited, limitations have been noted by various authors. These include it not being based on systematic literature and thus potentially omitting certain perspectives (54) and not taking into account challenges to evaluating interventions in complex healthcare contexts (55).

1.9 Chapter summary

This chapter has set the scene for the research presented in this thesis and introduced central concepts:

- ✓ Healthcare research
- ✓ Complex healthcare interventions
- ✓ Developing and evaluating complex interventions
- ✓ Pragmatic RCTs
- ✓ Process evaluations

Chapter 2 now discusses the scoping work undertaken to develop the research question:

How are process evaluations defined, valued, and shaped when conducted within pragmatic randomised controlled trials of complex interventions in healthcare research?

2 Scoping and reflections to inform the research questions

Chapter 1 outlined the central concepts to this thesis. This chapter now summarises the scoping work carried out in 2015/16 to better understand the field and develop the research questions. The PhD studentship awarded to me had originally been to produce guidelines for process evaluations with pragmatic RCTs. However, the MRC process evaluation guidelines were published shortly before I began this PhD and I therefore decided to explore other avenues of research.

This chapter also provides an overview of my personal and professional experience and interests in this field, and how these informed my thinking. This also provides transparency to the reader about my personal opinions which may have influenced the findings presented in this primarily qualitative thesis. Researcher reflexivity is a vital aspect of qualitative research practice and may be explained as the awareness that the researcher and what is being studied may continuously affect each other (55a). While analysing data, writing the narratives of findings, and drawing implications I construct meaning and knowledge, rather than simply mirror reality (55b). By presenting my reflections, stances, and preconceptions in this chapter and in chapter 7, I therefore provide the reader with an understanding of how my views may have shaped the knowledge offered by this thesis.

2.1 Scoping methods

I scanned the literature and read key texts on process evaluation and pragmatic RCTs, attended research methodology conferences and trainings, held discussions with experts, and participated in many informal conversations with researchers.

2.2 Scanning the literature and reading key texts

Scanning the literature revealed a wide range of potentially useful and relevant sources of information on process evaluation. These included process evaluation reports and protocols, methodology papers, guidance and frameworks, and reflective and opinion pieces, including from fields outside of health. These also included literature relating to topics which may be part of

process evaluation, such as fidelity, or overlap with process evaluation, such as mixed-methods research.

This reading gave me the following impressions:

- ✓ The term process evaluation is very broad and being used to describe almost every type of non-experimental research design
- ✓ Several ambiguous but value-laden adjectives, such as 'high-quality', 'useful' or 'necessary', are often used to describe aspects of process evaluation and the knowledge produced by them. However, these are often used uncritically and without clarification of their meaning.
- ✓ There appear to be disagreements about the best ways to conduct process evaluation, and a variety of interpretations of 'optimal' process evaluation conduct.
- ✓ There were conflicting opinions about the benefits and drawbacks of pragmatic RCTs
- ✓ There was little explicit discussion about process evaluation with pragmatic RCTs, however I saw potential ways in which process evaluations could address criticisms of pragmatic RCTs and ways in which process evaluations and pragmatic RCTs might have conflicting aims.

2.3 Attending research methodology conferences, seminars, and trainings

There was little on the topic of process evaluation at the conferences and trainings I attended, including two attendances at the International Clinical Trials Methodology Conference. Some included many sessions on pragmatic RCTs but with almost no content or discussion on process evaluation, and I was curious why this was. I noted certain criticisms and concerns about pragmatic RCTs that I felt process evaluations could be well placed to address, and pondered this missed opportunity.

At these conferences, seminars, and trainings I also became fascinated by the human behaviour of researchers. I was interested in how some researchers were concurrently lamenting how difficult it

was to persuade clinicians to apply their trial findings in practice, while also arguing against participating in RCTs of trial recruitment processes because they felt they knew best how to recruit participants. I appreciated further how scientific evidence is created by researchers with normal human idiosyncrasies and became interested in studying the design and conduct of process evaluations as a social practice.

2.4 Discussions with experts

I met with researchers at the Pragmatic Clinical Trials Unit at my funding university to discuss my PhD and seek to understand their perspectives. Interestingly the researchers I spoke to, including triallists, trial managers, and health economists admitted they had not given much thought to process evaluations and said they rarely saw them on applications to deliver trials through the unit. They nonetheless felt exploration of methodological and operational issues relating to designing and conducting process evaluations within pragmatic RCTs would be valuable as there was likely to be increasing interest. One researcher reflected that as they became more common, process evaluations may become a 'tick-box exercise' rather than a thoughtful integral component of an evaluation.

I met with research advisors in the Research Design Service who said they rarely received requests for advice on trials including process evaluations however often advised researchers to consider them. They directed researchers to the MRC process evaluation guidance and highlighted they considered the NIHR was unlikely to fund research that did not broadly follow the principles contained within MRC guidance for complex interventions / process evaluation.

I also spoke with authors of process evaluation guidelines and pragmatic RCT methodology literature. They agreed that a clear definition of process evaluation was lacking, and that authors use many different terms for the same types of evaluations. One stated they had encountered resistance to referring to certain types of evaluation approaches as process evaluations by the

developers of those approaches. They also agreed that the MRC process evaluation guidance was far from complete and definitive, and there remained many unresolved dilemmas.

They also highlighted different perceptions of the meaning of complexity, including the opinion that the MRC complex intervention guidance was more related to complicated interventions than complexity. One author considered it would be beneficial to extend the MRC complex intervention guidance to recommend understanding context before designing interventions, as when this was inadequately conceptualised and understood interventions were likely to fail. Another author reflected on their work with triallists and that several were resistant to new definitions of complexity, and regarded increased complexity as equalling more intervention components. They observed that researchers with therapy backgrounds, regardless of whether they were qualitative or quantitative researchers, were more likely to understand complexity as complex rather than complicated.

The experts I spoke with had different views on the role of process evaluations with pragmatic RCTs Some felt these needed to be light-touch to avoid threatening the external validity of the trial findings. Others felt the more pragmatic the trial the more process evaluation was necessary to understand everything that had gone on.

Finally, several agreed that different stakeholders had different expectations of guidance and it was important to state in the introductions to guidelines the epistemological perspectives being taken.

2.5 Informal conversations

Informal conversations with researchers in various healthcare research fields highlighted the ambiguity of the term 'process evaluation'. Some believed process evaluations to be by definition qualitative, and others quantitative. There also appeared to be different interpretations of the word 'process', with some interpreting this as only investigating the processes through which the intervention works, and others the processes through which the intervention and trial were delivered. Some researchers admitted confusion about whether research they had conducted, for

example a fidelity assessment or interviews with patients, counted as process evaluation. Similarly, some considered investigation of a single process element, such as fidelity, to not be sufficient to count as a process evaluation.

It also appeared that some researchers considered research to be more publishable when labelled as process evaluation, considering retrospectively applying the label to studies not previously considered process evaluations. I speculated that with the publication of authoritative guidance by the MRC, the label process evaluation may have acquired a gravitas which meant some researchers did not consider their evaluations big enough to count as process evaluation.

However, I also encountered some hostility to the term process evaluation among qualitative researchers who were keen to clarify their studies exploring patient experiences were not process evaluations. The studies they referred to were not obviously different to other qualitative studies which others happily referred to as process evaluations, however.

Finally, despite the MRC guidance being available, many researchers expressed a lack of understanding about how to do a process evaluation and were keen to obtain advice from me.

2.6 Personal knowledge and interest in the topics

Prior to starting this PhD I had been working in the NHS as a health care assistant, student nurse, and then registered nurse for twelve years. My primary clinical interest and experience was in stroke and acquired brain injury, and I had then moved into research nursing for the five years prior to starting the PhD. I had also worked as a research assistant on the design of a RCT. The year prior to starting the PhD I had completed an NIHR-funded MRes in Clinical Research Methods. This collective experience and my personal reflections had led to my awareness of and interest in the following issues:

- ✓ Strong interest in understanding the experiences of patients to improve their care and quality of life, particularly psychological suffering

- ✓ The perspective that all patients have unique needs and contexts, and that an intervention that works for one patient may not work in the same way for another
- ✓ Concern that the often-heard phrase 'we know it works' or 'we know it doesn't work' fails to account for differences between patients and contexts, which may lead to patients being given ineffective or harmful 'evidence-based' interventions or denied the opportunity to benefit from 'non evidence-baseed' interventions
- ✓ Observing many counterproductive divisions and even hostilities between NHS clinicians and university academic researchers, who while ostensibly sharing a goal to improve care and outcomes for the same patient population appeared to have different perspectives and to be unwilling to support each other
- ✓ Having a logical mind that liked order, certainty, and attention to detail I found the idea of RCTs to establish whether interventions work or not appealing. However, at the same time I was aware that the reality was much messier and that RCTs alone were insufficient to provide effective and compassionate interventions and care
- ✓ Observing the hidden politics, power struggles, and financial paradoxes behind decisions about which research is deemed worthy of funding and which research studies NHS sites decide are worth hosting
- ✓ Observing the hidden messiness of research design and conduct in the NHS, particularly how many of my research nursing colleagues had little understanding of research processes and were unknowingly acting in ways that threatened the scientific validity of the research studies they were supporting

I began this PhD with the strong opinion that process evaluations had potential to address the limitations of RCTs by creating knowledge that would enable RCT findings to be applied in a more patient-centred and individualised manner. I felt they would have a useful role in evaluating

research processes to understand how these impacted on outcome findings, and also were a potential means of building more collaborative working between clinicians and academics. Nonetheless I still felt broadly positive about RCTs and evidence-based healthcare.

However, after starting the PhD my perspectives shifted to a much more negative and critical view of RCTs and NHS-delivered evidence-based healthcare. This arose both through networking with researchers with backgrounds in sociology and anthropology, and through becoming a patient myself and experiencing 'evidence-based' healthcare interventions that left me feeling invalidated, patronised and worse than prior to the intervention. This led to the development of the following opinions, which likely influenced me as I conducted the research presented in this thesis:

- ✓ In most contexts I would not personally consent to participate in an RCT because I would prefer an expert clinician to weigh up the best treatment option
- ✓ RCTs support a political desire for singular answers to complex 'wicked' problems so that non-clinicians can be trained cheaply to deliver 'evidence-based' interventions at a low cost, and then blame the patient when it doesn't work
- ✓ RCTs and evidence-based practice are potential barriers to innovation. Because clinicians and researchers are understandably so worried about not conforming and having innovative ideas that are not based on evidence, this stifles innovation and progress
- ✓ I fully support the holistic evaluation of interventions and believe the division into a pragmatic RCT and a process evaluation to be unhelpful and illogical

My view became that while pragmatic RCTs have the potential to provide important information, they do not 'tell the whole story'. While researchers may understand this, I was concerned that findings could be interpreted or presented as the whole story ('*it works'* or '*it doesn't work'*) and that this could have detrimental effects on patients. I saw a vital role for process evaluations to help 'tell

the story' more fully, very much adopting the realist perspective of 'what works, for whom, under what circumstances?'.

However, I was also aware that the full story may not be welcomed, and that process evaluations may give insights which are complex or inconvenient to those who value a binary trial outcome result. I believed it to be an ethical concern if process evaluation findings are ignored, or process evaluations do not adequately capture the complexities of interventions, contexts, and participant experiences and outcomes.

2.7 Chapter summary

This chapter has summarised the scoping work undertaken to develop the research questions addressed in this thesis. It has also presented a reflection on my personal and professional experiences and perspectives that informed the research questions, and which likely influenced the qualitative and interpretive findings of this thesis.

The next chapter introduces the research questions:

How are process evaluations defined, valued, and shaped when conducted within pragmatic RCTs of complex healthcare interventions?

3 Development of and rationales for the research questions

The previous chapter outlined the scoping work I undertook to gain a broader understanding of the field of process evaluations in pragmatic RCTs in healthcare research.

This chapter discusses the three research questions developed following this scoping work:

How are process evaluations defined, valued, and shaped when conducted with pragmatic RCTs of complex healthcare interventions?

This chapter discusses:

- ✓ The rationale for their selection
- ✓ Previous research addressing similar questions
- ✓ Potential applications of findings

3.1 How are process evaluations defined?

Scoping work clearly identified that there is confusion and disagreement about the meaning and scope of the term 'process evaluation' and the kind of studies that may be called process evaluations. It appears that researchers may define a process evaluation by its methods, its scale, what it studies, and/or its aims.

The MRC process evaluation guidance (22) acknowledges that there is no unified definition of process evaluation, and authors of previous reviews noted the label is used inconsistently (1, 56). One systematic review (56) reported that only 32 of 124 included 'process evaluations' used the label, although they did not describe how those not labelled process evaluations were labelled or analyse differences between those with the label and those without. Grant et al. (1) highlight that there is overlap between CONSORT reporting requirements for RCTs of certain process data and components of process evaluation, which may contribute to the lack of clear definition.

To my knowledge there are no published studies investigating how process evaluations are labelled or exploring definitions of process evaluation.

Aside from the utility of seeking to explore definitions of the central concept of this thesis, the importance of labelling and definitions may be questioned. It could be argued that if evaluations and data in trial reports achieve the same purpose, how they are labelled is unimportant. However, I believe there are potential disadvantages to a lack of clear definition. If researchers do not consider their evaluations to be process evaluation, they may not take advantage of available guidance, which could result in some evaluations being suboptimal. Evaluation efforts may be disjointed if researchers are not in agreement about the definition and scope of an evaluation. Alternatively, if researchers wish to conduct a process evaluation but have restrictive beliefs about the scope of process evaluations, then the resulting process evaluation may not reach its full potential.

While I primarily explore the context of healthcare research pragmatic RCTs in this thesis, the definition of process evaluation appears ill-defined in other contexts, and findings are likely applicable in other contexts.

3.2 How are process evaluations valued?

Scoping work highlighted that there are many potential uses of process evaluation findings, concerns about the impact of conducting process evaluations on the associated trial, and both positive and negative opinions of process evaluations. There also appear to be different opinions about what constitutes a useful or high-quality process evaluation.

I also noted during scoping potential roles for process evaluation in pragmatic RCTs, and discrepancies between the aims of process evaluations and pragmatic RCTs, both which I considered it relevant to explore.

I originally framed the research question as ***how to maximise the value of process evaluations***, however through scoping work and reflection I realised it was necessary to critically explore the entire concept of value. I considered aiming to establish how to maximise or optimise value potentially problematic, because value may mean different things to different people, may be hidden or implicit, and certain values may compete with one another or be incompatible. Maximising the value to somebody may therefore lessen the value to somebody else. Before understanding how to maximise value I believe it ethically and practically important to understand what kind of value is being aimed for, why, and implications for different stakeholders including researchers, clinicians, and patients.

3.2.1 Previous studies investigating the value of process evaluation

To my knowledge no previous studies have explicitly examined the value of process evaluations. Some authors have questioned or promoted their value (or the value of certain types of process evaluation) in critiques (57), editorials (58), reflections on process evaluations conducted (59, 60), and letters (61). Process evaluation guidance and frameworks offer reasons why it is beneficial to conduct process evaluations, however as guidance reflects the epistemological position of its developers (55), presented perceptions about value may vary.

Certain aspects of value of qualitative research with RCTs and pragmatic RCTs have been examined. The QUART study (62), published in 2014 was large mixed-methods study investigating maximising the value of combining qualitative research with RCTs in health research. It identified eight ways in which qualitative research may bring value to the trial endeavour, highlighted value sometimes was invisible, and that researchers often did not make explicit the value of the qualitative research in reporting. Its authors consider process evaluations are a subset of qualitative research that may be conducted with RCTs and highlight that process evaluations may also be solely quantitative or mixed-methods. Furthermore, its scope was to identify how to maximise the value of qualitative research *'to the trial endeavour of providing evidence of effectiveness of health interventions.'* (62)

p.xix, whereas the aim of this thesis is to explore the concept of value holistically in the context of pragmatic RCTs in healthcare research. Findings from the QUART study are therefore informative, although narrower in scope in terms of the type of process evaluation and the range of values investigated.

Jansen et al. (63) published a review in 2009 of the contribution of qualitative research to the development of tailor-made community-based interventions in primary care evaluated in RCTs or pragmatic RCTs. They report that many of their included studies were process evaluations, however this review is also narrower in scope in terms of the type of process evaluation and the range of values investigated than the questions addressed in this thesis. They found that qualitative research made little contribution to the development of interventions because pragmatic trial methodology prohibited the tailoring of interventions to local contexts. They also found that findings from qualitative process evaluations conducted alongside trials were only used post-hoc, potentially benefiting future cycles of intervention development and testing.

3.2.2 Previous studies investigating the value of other healthcare research approaches

To inform this thesis it is useful to also consider different conceptualisations of 'value' and how value has been studied in other areas of healthcare research.

3.2.2.1 Definitions of 'value'

The Cambridge dictionary (64) provides several definitions of 'value' as a noun and verb, including:

- ✓ *the importance or worth of something for someone*
- ✓ *how useful or important something is*
- ✓ *the beliefs people have, especially about what is right and wrong and what is most important in life, that control their behaviour*
- ✓ *how good or useful something is in relation to its price*
- ✓ *the amount of money that can be received for something*

In the QUART study, authors define the value of qualitative research conducted with a trial as the work or the impact of the qualitative research for the trial (62). Haywood et al. (65) in their work exploring values associated with patient engagement in health-related quality of life research add that value is 'why we do things, what is important, and to whom'.

Gradinger et al. (66) undertook a narrative literature review to identify values associated with patient public involvement (PPI) in research. In their work they define value as "*the established collective moral principles and accepted standards of persons or a social group; principles, standards or qualities considered worthwhile or desirable*" (66) p.18. They categorise the values identified in their review into three 'value systems' – normative, substantive, and process values. These are shown in table 3.1.

Table 3.1 Value systems identified by Gradinger et al. (66)

Value system	Definition	Example
Normative	Values which are an end unto themselves, often ethical or political	Empowerment
Substantive	Values which are consequences of the activity	Improving research participant recruitment
Process	Values relating to the process of doing the activity	Respect and trust

3.2.2.2 Research impact

The question of how to define and measure the impact of research studies and research programmes has received much attention. Greenhalgh et al. (67) highlight that there is an increasing expectation for researchers to demonstrate the effective use of limited public funding for research. They broadly define research impact as benefits additional to building the academic knowledge base, such as health, cultural and economic, however emphasise there are many different definitions of research impact.

Impact may be considered in terms of who or which organisations it impacts on. For example, it may have academic impact, such as journal citations, or external impact, such as mention in mass media

or trade press (68). The impact of trials may be demonstrated by their contributions to systematic reviews, or to stopping the use of certain health technologies (69).

The *Payback Framework* (70) classifies impacts into five categories: knowledge, benefits to future research, benefits to policy, benefits to health and the health system, and wider economic benefits.

Rycroft-Malone et al. (71) discuss four different types of knowledge impact, which are outlined in table 3.2

Table 3.2 Types of knowledge impact proposed by Rycroft-Malone et al. (71)

Knowledge use	**Definition**
Instrumental	Direct impact on policy or practice
Conceptual	Impact on thinking, attitudes, understanding
Symbolic	Use of knowledge as a political tool to legitimise particular practices
Process	Impacts resulting from the learning gained from research involvement

Research value and impact is often discussed in terms of value for money, and reduction in research waste. For example, an editorial in *The Lancet* titled 'Maximising the value of research for brain health' (72) discusses value in terms of increasing efficiency and reducing waste. The NIHR has an *Adding value in research framework* with ten principles to increase the probability of studies they fund having impact that justifies the costs involved (73). Some research impact assessment models focus on monetary value of health gains achieved from health research (69).

3.2.3 Challenges and considerations when researching value

The papers investigating value highlight the subjective nature of values. O'Cathain et al. (62) reflect that their personal perceptions of the value of qualitative research are beyond its value to a trial, and it was difficult to put these perceptions of value to one side. Gradinger et al. (66) note that their own interpretations may have influenced the values associated with PPI which they identified in their study, and highlight that some of these values may not be perceived as such by others. They also caution that values such as 'quality' and 'validity' may mean different things in different

contexts, and people may have differing understandings and expectations of them. Furthermore, value may not be articulated in research reports (62), or may be expressed in terms of aims or outcomes (66).

When identifying the value of qualitative research, O'Cathain et al. (62) highlight a challenge as being that there is often not evidence that value has occurred. For the same reason, assessing research impact is generally agreed to be challenging, no matter which approach is used. A feature of many definitions of research impact is that it is in some way demonstrable (67, 69). However, Greenhalgh et al. highlight that usually short-term intermediate outcomes are easier to capture, but that longer term accumulative influences on things such as infrastructure and partnership-building are difficult to determine (67). The London School of Economics' handbook for maximising research impact (68) defines impact as 'a recorded or otherwise auditable occasion of influence from academic research on another actor or organization'. It stresses that it is not a change in activity or output stemming from this influence, as such things always have multiple influences (68).

3.2.4 Conceptualising and investigating 'value' in this PhD

This brief overview of definitions of value in research highlights there are many different possible interpretations of 'value'. This shows it pertinent to conceptualise and explore as broadly as possible the potential value and negative consequences of process evaluations in the context of pragmatic RCTs of healthcare interventions. It is also important to critically analyse potential interactions and conflicts between values, and for whom value is created and why.

These findings will both broaden the methodological knowledge base and be of practical use to researchers and other stakeholders involved in commissioning, designing, conducting, disseminating, and using the findings of process evaluations.

3.3 How are process evaluations shaped?

Given that process evaluations may vary widely, there are multiple interpretations of the term, and there appears to be little agreement on the value they can or should create, it is also important to explore how process evaluations are shaped into the designs and knowledge outputs they become. This then enhances understanding of how and why they are valued, and how they create value.

3.3.1 Previous studies investigating how process evaluations are shaped

To my knowledge no previous research has explicitly addressed how process evaluations are shaped, however some studies contain elements which are informative.

Masterson-Algar et al. (55) developed consensus guidelines for process evaluation in neurological rehabilitation using a systematic review and nominal group technique. They found that process evaluations are often shaped by what is realistic to achieve in context and the ontological and epistemological standpoints of investigators. Legrand et al. (74) conducted a survey of the needs and experiences of health promotion professionals in France regarding evaluation of interventions, including process evaluation. They identified barriers to conducting process evaluations relating to data collection, finding or developing appropriate data collection tools, lack of time, and lack of expertise.

In a paper reflecting on their experiences, Clarke et al. (75) discuss challenges encountered conducting a process evaluation with an interdisciplinary team. They report how strategic, practical, and individual level challenges brought by differences in standpoints and skills affected the design and conduct of the process evaluation, and how these were addressed.

Process evaluation guidance is available, which clearly has an important role in shaping process evaluations. It is important to highlight however that none of the four most widely known process evaluation frameworks/guidance (1, 22, 46, 51) were developed using systematic literature searches or primary research. The lack of formal consensus processes and systematic searches to develop these guidance documents renders them liable to an element of subjectivity and lack of robustness

(55). Furthermore, with the exception of Grant et al.'s framework (1), all were developed mostly from a public health perspective so do not necessarily address issues pertaining to conducting process evaluations in healthcare research contexts.

The MRC process evaluation guidance (22) contains useful information about methodological and operational challenges and considerations when designing, conducting, and disseminating process evaluations, much of which is based on the experiences of authors who discuss exemplar case studies of process evaluations they have conducted.

Some systematic reviews of process evaluations have examined methodological and design characteristics of process evaluations in specific fields (56, 76-79). While these provide useful descriptive information about characteristics of process evaluations, they do not inform understanding of why process evaluations have these characteristics.

3.3.2 Previous studies investigating how other types of research is shaped

In the distinct but overlapping field of qualitative research with trials and mixed-methods research, qualitative studies have investigated the functioning of research teams. These have identified the value placed on different components by research leads (62, 80), power dynamics (81), and methodological disrespect (82) may shape qualitative research design, conduct, and outputs. As discussed in chapter 2, through scoping and experiences I felt it important and useful to investigate how process evaluations were shaped through the social practices of researchers, and these studies suggest this investigation is warranted.

Some studies have used qualitative interviews to explore the views of stakeholders about pragmatic RCTs (83), qualitative research with RCTs (80), and mixed-methods research (82, 84). Participants in these studies had a range of experiences and backgrounds. All explored participants' general experiences, with some also exploring experiences of a specific trial or research project.

There are also examples of studies using case study approaches to investigate research practices. Wells et al. (85) used an in-depth multiple case study approach to investigate '*the untold role of context in seven RCTs of complex interventions*'. They report how this method enabled them to explore the subtle, complex, and idiosyncratic impact of context on trial findings, which was generally not reported and available via first-hand insider accounts of the trial. They acknowledge a limitation of their findings that most data in the cases came only from principle investigators.

Lunde et al. (81) present a single case study of the experiences of a researchers working on a mixed-methods health research study, collecting data using interviews and documentary analysis. They report how they had initially attempted to analyse data to identify barriers to data integration, however abandoned this attempt because it was clear complex power and relationship dynamics were at play, which were not adequately captured by delineation of barriers.

3.3.3 Investigating how process evaluations are shaped in this PhD

The literature gap presented in this section suggests that critical analysis of how process evaluations are shaped has both theoretical and practical utility. Findings from studies investigating the practice of mixed-methods studies suggest exploring how research teams shape process evaluations is important.

In combination with findings about how process evaluations are valued, understanding how they are shaped has practical utility to aid researchers to plan process evaluations with greater clarity about what value they are aiming to achieve and why, and how best to achieve that value.

3.3.4 Chapter summary

This chapter has introduced the three research questions addressed in this thesis and the rationales for their selection. It has discussed the literature gaps that this thesis aims to fill, and potential applications of the findings.

The next chapter presents the philosophical and methodological underpinnings of the research conducted to answer these research questions.

4 Philosophical and methodological underpinnings

This chapter begins with an overview of the three elements of this thesis and their underlying philosophy. I then briefly discuss philosophical and methodological traditions in the field of methodological healthcare research, and a summary of various approaches considered for this thesis. I then discuss the philosophical stance of critical realism which underpins this thesis.

4.1 Philosophical and methodological overview of this thesis

To address the research questions of how process evaluations are defined, valued, and shaped when conducted within pragmatic RCTs of complex healthcare interventions, this thesis consists of three strands of work:

- ✓ A critical interpretive synthesis of process evaluation methodology literature, with the aim of developing a conceptual framework to inform the rest of the thesis.
- ✓ A systematic review of a sample of published pragmatic RCTs and the process evaluation contained within them
- ✓ Focused ethnographic case studies of three process evaluations being conducted with NIHR-funded pragmatic RCTs. These were also informed by Translational Mobilisation Theory (86), a practice-based organisational theory which examines the mechanisms by which projects are mobilised and enacted in organisational contexts.

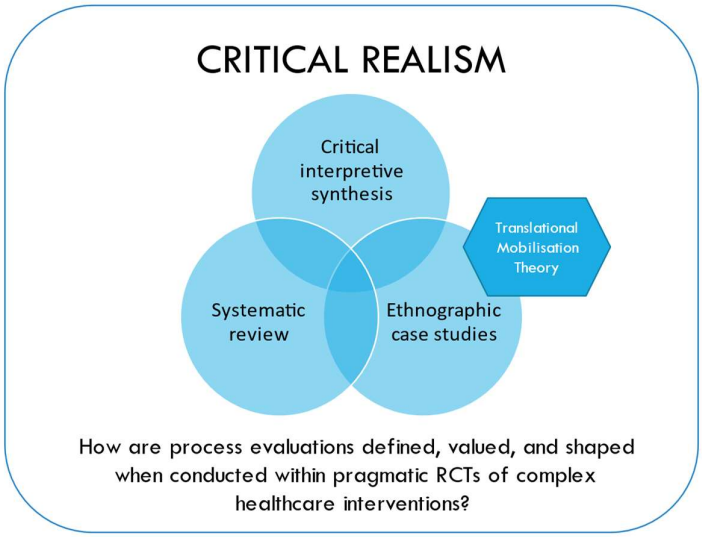
These aspects are mostly qualitative however the systematic review also includes descriptive quantitative elements.

While each strand has its own methods, the overarching philosophical framework is critical realism. With its interpretive epistemology, realist ontology, and inclusion of causal mechanisms I considered this an excellent fit. It allows exploration of the range of different interpretations of the

meaning of process evaluation and perceptions of the value it has and creates. It also allows investigation of causal mechanisms of how process evaluations are shaped and how they may create value.

Figure 4.1 shows the research questions, the three elements of this thesis which seek to answer these questions, and how all are contained in the overarching philosophy of critical realism.

Figure 4.1 Thesis overview



The three strands of work inform each other and were not conducted in a strictly linear manner. The critical interpretive synthesis and conceptual framework developed from this provided concepts to explore in the systematic review and case studies, and findings from the systematic review and case studies provided further possible interpretations of the findings of the critical interpretive synthesis.

In the final discussion section of the thesis when drawing findings from the three strands together I use critical realist principles to offer possible explanations for findings.

I discuss critical realism and organisational theory in more detail in sections 4.4 and 4.5 of this chapter, and the methodology and methods of each strand of work in their respective chapters. The next sections briefly discuss other philosophical and methodological approaches considered and the reasons for not adopting them.

4.2 Philosophical and methodological underpinnings of research on the methodology and practice of healthcare research

It is interesting to note that the theory and practice of healthcare research is itself based on little evidence. Treweek et al. (87), for example, lament the thin and weak evidence available to support decision about how to select and implement trial processes, and promote the undertaking of RCTs to develop evidence for how to design and conduct RCTs.

As discussed in chapter 3, there is little published primary research on process evaluation methodology or practice. Most of the literature items included in the review presented in chapter 5 are researchers' reflective accounts of and commentaries on experiences of designing and conducting process evaluations, or general reflective or opinion pieces on the topic of process evaluation. Much of 'what we know' about process evaluation is therefore based on anecdote, reflection, and expert opinion. While this lack of systematic empirical research is a limitation, this type of experiential knowledge is argued to be valuable and important (88, 89).

None of the few research reports discussed in chapter 3 included discussion of the philosophical and methodological underpinnings of the reported research. There is therefore little ontological or epistemological tradition in this field, which provides a rich opportunity to explore this subject from new angles.

4.2.1 Philosophical approaches to evaluating research impact

There are however a range of philosophical approaches to assessing research impact, and Greenhalgh et al. (67) outline five philosophical assumptions upon which the evaluation of research impact may be based. These are summarised in table 4.1.

Table 4.1 Philosophical approaches to evaluating research impact (adapted from (67))

Philosophical assumption of evaluation of research impact	**Purpose of evaluation**	**Assumptions about how knowledge has impact**
Positivist	Predictive generalisations	Knowledge directly impacts policy and practice (possibly with the adoption of principles of implementation science)
Constructivist	Interpret meaning	Knowledge has indirect impact, such as through influencing the mindlines of practitioners
Realist	Theoretical generalisations	Knowledge has impact through interactions between the reasoning of practitioners and policymakers and the contexts in which they are applying the knowledge
Critical	Learning, challenge, emancipation	Knowledge has impact through building critical consciousness, advocacy, lobbying
Performative	Map changing dynamics of actor networks	Knowledge has impact via actors who mobilise other actors

4.3 Considerations for the ontological, epistemological, and methodological stance of this thesis

Given that there was little previous research addressing these questions, the overall research approach was exploratory. I wanted to identify as broadly as possible the range of definitions of process evaluation and the range of values of process evaluation. However, I also wanted to go beyond description to seek to explain why there are a broad range of definitions, and why there are different interpretations of value. I also wanted to understand how process evaluations create

value, and, given there is such wide variety in what a process evaluation may be like, to explore how they become the form they take.

The unit of investigation, or phenomenon, under study is 'the process evaluation'. One of my research questions is to explore multiple meanings of 'process evaluation' as scoping revealed 'process evaluation' as a term laden with ambiguity and positive and negative associations. I also began to understand process evaluations themselves as being events in complex systems, particularly when conducted in pragmatic RCTs in messy complex real-world settings rather than controlled laboratories. I also believed there is likely to be different perceptions among stakeholders in the same process evaluation, and therefore the question of how the differing views are shared and negotiated to shape the 'final version' of process evaluations is also important.

I therefore considered it vital to select philosophical and methodological standpoints that could adequately capture this complexity. In agreement with Stake (90) p. 3, my stance is that '*problems will be treated superficially if complexities are not fully understood*.'

I now briefly outline philosophical and methodological perspectives I considered when planning this thesis and the reasons for not selecting them.

4.3.1 Positivism

Positivism takes the basic stance that there exists a single objective reality independent of the human mind, and the role of research is to deliver measurable account of this reality (91). A core positivist assumption is therefore that an intervention (in this case a research project) has an impact which is measurable and reproducible in different settings (92).

Taking a positivist stance would mean defining value in terms of objective measurable constructs (for example 'number of publications') and assuming that these constructs had an inherent value on which everybody agreed. This clearly did not fit my position that value is subjective, and the same objects or events may be perceived as more or less valuable by different people in different

contexts. It would also mean assuming there to be universal truths of how each value construct could be maximised, for example analysing associations between a dependent variable of value such as 'having a publication' and independent variables such as 'number of process evaluations previously conducted by lead researcher of process evaluation team'. I considered this approach superficial and not in keeping with my own understanding of the inherent complexity of multiple human actors jointly undertaking research studies in real-world healthcare contexts (92).

4.3.2 Interpretivism

Interpretivism takes the basic epistemological stance that knowledge is entirely socially constructed, and the ontological stance that an independent reality does not exist outside of the human mind. Many interpretivists hold more moderate versions of this ontological stance and do not deny that a physical reality exists independently, however generally pay attention only to socially constructed beliefs about that reality, rather than the reality itself (5). Interpretivists also believe different meanings held by different people are valid and true, although many acknowledge it is problematic to uncritically accept all interpretations as equal (93).

I originally considered an interpretivist approach as its epistemology allows for multiple meanings of 'process evaluation' and 'value'. I also wanted to treat each interpretation as valid in the context of the person experiencing them and to expose the range of perceptions that exist.

However, I realised that interpretivism was less useful for understanding why different people hold different beliefs and did not offer a satisfactory means of examining how process evaluations are shaped. While I agreed with the position that phenomena have multiple possible causes, I did not agree with the interpretivist view that it is futile to seek to understand causality in some way (94).

4.3.3 Grounded theory

I considered using constructivist grounded theory as a method of analysis and to draw elements of the PhD together in a more logical and structured way. It appealed to me as a systematic yet flexible methodology with the ability to go beyond description to explanations and understanding of why

things are the way they are (95). It also appeared a good methodology to examine complexity, issues of power, and understanding of the implicit meanings of participants (96).

However, after speaking with an expert in grounded theory (97), I decided against this approach. It seemed difficult to envisage developing a core category or theory to answer the research questions, which is the aim of grounded theory. This exploration and reflection however led me to conceptualise my questions as being evaluative, which led me to consider realist evaluation.

4.3.4 Realist evaluation

I also considered using a realist review and realist evaluation methodology. The central question posed by realist approaches to evaluation is 'what works, for who, in what circumstances?' (98). Its usefulness for evaluating research impact has been discussed (67) and there are published examples of realist reviews and evaluations of research programmes (71) and research approaches (99).

Its central assumption, '*that different research inputs and processes in different contexts may generate different outcomes*' (67) p.11 fitted well with my beliefs about process evaluation and value. It's configuration of CMO formulas (context + mechanism = outcome) (100) also seemed to offer possibilities for exploring how process evaluations are shaped.

Nonetheless I also decided against using this approach. This was partly because when I discussed it with researchers, including an expert in realist evaluation (101), they could see the potential of the method but felt it could become confusing and unwieldy in practice. As realist evaluation was designed to evaluate interventions which aim to create certain outcomes, it would mean conceptualising a process evaluation as an intervention, and its values as outcomes. Although this was possible, because I wanted to explore all possible values and not specific outcomes, it seemed it had the potential to generate an overwhelming number of CMO formulas.

However, exploring realist evaluation helped me understand that its underpinning philosophy seemed a good fit for my research questions and my beliefs about reality, and helped me turn to critical realism as the eventual underpinning of this thesis.

4.4 Critical realism

Critical realism is a philosophical approach to both natural and social sciences. It does not prescribe methods and may utilise both qualitative and quantitative approaches (5). Based originally on the work of Roy Bhaskar, it aims to capitalise on the strengths and address the limitations of positivism and interpretivism by taking a middle ground, with a realist ontology and interpretivist epistemology (5, 28). It assumes the universe to be neither a singular orderly reality nor chaotic and unknowable; and acknowledges the importance and influence of human interpretations while not equating human interpretations with truth (28).

Critical realism appealed to me as a paradigm for this thesis because it fits my views about the limitations of RCTs in healthcare research, in particular that dichotomous findings of 'it works' or 'it doesn't work' are unhelpful (102). Similarly, I do not consider process evaluations to have value or not have value, but rather value is continuously created on a dynamic spectrum.

Critical realism offers a toolkit of practical theoretical and analytical ideas and, as recommended by Alderson (5), I did not aim to apply all its concepts but rather apply its underpinning philosophy and selected concepts that appeared useful to aid my analyses and interpretations.

4.4.1 The three levels of reality

Critical realism offers a three-level analysis of reality, of the empirical, the actual, and the real (5). The empirical level is what we sense and experience and is the level of epistemology. The actual level is the world that exists independently of human thoughts and is the level of ontology. The real level is the level of causal mechanisms of objects and events, and is also the level of ontology (5).

Table 4.2 shows how I applied these three levels of reality to this thesis.

Table 1.2 Levels of reality in critical realism

Level of reality	Meaning	Examples
Empirical	Subjective appraisals of the meanings of objects and events, measurements of objects and events	Interviews with case study participants, my fieldnotes, my interpretations of the literature, authors' reflections in articles
Actual	Actual objects and events.	Written documents, audio-recordings of case study meetings.
Real	Causal mechanisms that led to objects and events (how process evaluations are shaped and how 'valuable' or 'harmful' objects and events are created or occur)	Using theories and abductive reasoning to explore possible explanations for findings

4.4.2 Realist ontology and interpretivist epistemology

The realist ontology sets the position that events and objects exist at the actual and real levels independently of human minds, and are intransitive (5). Therefore, when I identify values, for example, these refer to events and objects that exist independent of human thought, and these events and objects do not themselves change according to what humans think about them.

However, critical realism maintains that humans can only know about objects and events through their interpretations, and therefore has an interpretivist epistemology (5). Accordingly, in this study I take the standpoint that concepts such as 'value' and 'process evaluation' are socially constructed. Thus, different people may hold different meanings of 'value' and 'process evaluation', and different people may interpret the same object or event differently. Furthermore, the same person may interpret the same object or event differently in different contexts. Objects and events are therefore not inherently valuable, for example, because the concept of value is constructed by humans.

Critical realism also maintains that while the causal mechanisms underlying objects and events are independent and intransitive (realist ontology), they are also unobservable and therefore only possible to be understood via transitive interpretations (interpretivist epistemology) (5). They also exist and have effects regardless of whether humans know or believe that they do.

In this study I take the stance that these unobservable mechanisms exist and are underlying how the process evaluations are shaped and the value or harm they may create. To attempt to understand these causal mechanisms I will use existing theoretical frameworks to offer interpretations of what is happening at the real level.

4.4.3 Open systems and demi-regularities

An aim of this thesis is to find *relatively enduring tendencies* or *demi-regularities* (5). Critical realism maintains that universal regularities and simple cause and effect connections do not exist in the open systems of social reality, however neither is social reality random and chaotic (5). Social systems have some degree of order but are also enduringly complex, meaning theory is necessary to obtain understanding (103).

4.4.4 Structure and agency

Within critical realism there is a complex interplay between structure and agency, with structures considered determining rather than determinist (5). Both individual factors and contextual factors are understood to affect events and outcomes, with neither emphasised over the other (28).

4.4.5 Generative causation

In contrast to positivism, in critical realism causation is generative rather than linear or successionist. Events are viewed as the result of '*many factors coming together in certain combinations and given the right circumstances or context to causally generate new events*' (28) p.E70. This differs from successionist perspectives on causation, which infers causation from multiple observations of the same sequence of events (28).

4.4.6 My critical stance as a researcher

I did not set out to design this study from a critical perspective. However, as I analysed data and reflected on my own personal concerns about healthcare and health services research grew over the

course of this PhD (see chapter 2), I have reflected on my own stance while completing data analysis and writing this thesis.

My aim at the outset of this study and throughout most of data analysis was to present different perspectives on value and harm of different actors, and explain how these different perspectives came about. It was not to offer my own judgement on what was valuable or harmful, or what value process evaluations should aim to produce. Similarly, while aiming to explore possible causal mechanisms to explain how process evaluations are shaped through the negotiation of different values, my aim was not to offer my value judgements. I saw my own values and opinions as something to be reflexive of, make explicit, and seek to ensure as far as possible through triangulation did not influence my findings.

At the stage of writing up the study I find myself questioning whether assuming this more neutral stance may have prevented me fully exploring and questioning potential harms, thus presenting findings that do not pick up on injustices and negative consequences to certain stakeholders. Indeed, as Alderson (5) p. 123 highlights, the term 'stakeholders' which I used freely throughout this PhD suggests "*an equality that denies how unequal the power and the 'stakes' may be.*" Therefore, while accepting this limitation and not seeking to change the design at the end of the study, in my final discussion I bring a more critical perspective.

4.4.7 Abduction and generalisability

Critical realism employs abductive or retroductive reasoning to arrive at findings and explanations (5). The terms abduction and retroduction appear to be used interchangeably in much of the literature, therefore for the purposes of this thesis I use the terms 'abduction' or 'abductive reasoning'.

Abduction may include insights, expertise, common sense, and informed imagination. It is often referred to as inference to the best explanation and is the development of a theoretical or

explanatory idea (104). The product of abductive reasoning is a suggestion that something *may be* a certain way (105).

This contrasts with deduction, which uses hypothesis testing to prove that something *must be* a certain way (105). It also differs from induction, which produces possible generalisations, or hypotheses to be tested, from data about particular cases.

From a critical realist stance, the aim of this thesis is to illuminate different interpretations held by different stakeholders in different contexts, and to suggest underlying causal mechanisms that shape process evaluations and create value. From this standpoint, generalisable universal truths do not exist, however it is possible to obtain demi-regularities with theoretical generalisability (5).

I anticipate the knowledge generated within this thesis may therefore most usefully be applied as a tool to facilitate researchers and other stakeholders to collaboratively plan the value they would like to obtain from a process evaluation and consider how that may be most likely achieved. It will offer a range of considerations rather than a set of universal rules about how to maximise the value of process evaluations.

4.4.8 Theoretical framework

The use of theory aids research conducted using a critical realist paradigm, as it aids understanding of complexity and causal mechanisms (103). For the case studies element of this thesis, I therefore sought a theoretical framework to help me examine in more depth and detail how the process evaluation case studies were being shaped, how they were valued, and how they created value. I anticipated this would enable me to examine the real practice of doing evaluations in the real world in depth and from multiple perspectives.

Translational Mobilisation Theory (TMT) (86) is a practice-based theory which takes a project as its unit of analysis, and enables systematic investigation and understanding of how the project is

mobilised and enacted in organisational contexts. It was developed in a healthcare context, and its developers provide an example of how it may be applied to a healthcare research study (86).

In this section I briefly discuss philosophical and methodological considerations of using TMT, while I introduce TMT in detail in chapter 7 and explain how I applied it to the case studies element of this thesis.

Although TMT was not developed from a critical realist perspective, I considered it to fit a critical realist philosophy and one of its developers agreed its concepts, being grounded in extensive empirical data, could be used to understand the level of real causal mechanisms (106). TMT is based upon four core assumptions about the nature of organisational work, which I considered useful to inform this study. These are outlined in table 4.3.

Table 4.3 Core assumptions of Translational Mobilisation Theory (107)

Core assumption	**Explanation**
An ecological approach	Systems of work and organisations are dynamic and emergent, with complex inter-relationships between humans, materials, and technologies
A process view of organisations underscoring the agency of those who work in them	Social structures are conceptualised as continuous accomplishments that exist through their enaction
All activity is mediated through artifacts	Artifacts may be material or cognitive. They are the means through which people in organisational systems create and understand the objects of their practice, and condition the possibilities for action
Collaborative work is distributed between people and across materials and technologies	Humans make sense of and utilise available resources and social structures in conducting their work within organisational contexts. The objects of this work are distributed in time and space between people and between resources and structures.

4.4.9 Applying critical realism to this thesis

The three strands of this work all share the philosophical underpinnings of critical realism outlined in this chapter. I will apply additional elements of critical realism as appropriate to findings from these three strands to assist with analysis and interpretation.

4.4.10 Chapter summary

This chapter has provided an overview of the three elements comprising this thesis, and how these fit together under the philosophy of critical realism.

Chapter 5 now presents the first of these three elements, a critical interpretive synthesis of the process evaluation methodology literature, including a conceptual framework for the overall thesis.

5 Critical interpretive synthesis

5.1 Critical interpretive synthesis introduction, aims and objectives

This chapter presents the methods and findings of a critical interpretive synthesis of process evaluation methodology literature. As discussed in chapter 3 there has been little primary methodological research on process evaluations and the factors that influence their design and conduct, and the concept of value of process evaluations has received little critical attention.

The aim was therefore to develop a conceptual framework from the literature to inform the rest of this thesis. Within this conceptual framework I aimed to identify how process evaluations may create value, how process evaluations are valued, and potential contextual influences on process evaluations. I also aimed to explore the scope of the term by identifying variables of studies which may be considered process evaluations.

The specific objectives of this synthesis were:

1. To outline the potential scope of process evaluations
2. To identify potential sources of value from process evaluations
3. To identify and describe contextual factors which may shape process evaluations
4. To identify and critically analyse themes of values associated with process evaluations

Part of the work presented in this chapter has been submitted for publication:

French, C., Dowrick A., Fudge, N., Pinnock, H. and Taylor SJC. What do we want to get out of this? A critical interpretive synthesis of the value of process evaluations with a practical planning framework, 17 May 2022, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-1616970/v1]

5.2 Critical interpretive synthesis methods

5.2.1 Design overview

This review draws on principles and approaches of critical interpretive synthesis outlined by Dixon-Woods et al. (108). Critical interpretive synthesis is argued to be better suited to reviews where the potentially informative body of literature is heterogenous and large, and where there are no agreed and consistent definitions of concepts of interest (108). It also critically examines aspects of the literature not apparent in text form, such as the types of assumptions upon which arguments are presented (108).

This review was based on diverse literature including process evaluation guidance, systematic reviews, primary research, opinions about process evaluations, and discussion of methodological and practical issues. I did not restrict literature to pragmatic RCTs or health services research as I considered it useful to gain a broad perspective on how process evaluations may be valued and shaped in any context.

Rather than aggregating findings, I used whole literature texts as qualitative data including editorials, reflective accounts, introductions, and discussion sections. The aim was to synthesise what authors were stating in relation to process evaluations anywhere in the texts and use induction and interpretation to inform the conceptual framework.

5.2.2 Search strategy

Following recommendations by Dixon-Woods et al. (108) and in consultation with a medical librarian I utilised the following search strategy to maximise inclusion of potentially relevant literature:

1. Reference list and citation searches from four major process evaluation frameworks using Web of Science and Google Scholar. Table 5.1 details the references from which references and citations were obtained.
2. Searches for author keywords ‘process evaluation’ in the following databases:

a. Embase / Medline

b. Scopus

3. Search Ethos database of doctoral theses for 'process evaluation'
4. Literature items not located by the searches but which I knew contained relevant important information about process evaluation from scoping work

Table 5.1 Reference list and citation searches sources

Process evaluation framework	References searched
MRC *Process evaluation of complex interventions*	Web of Science (53) Google Scholar (22) Reference list (22) Full guidance document (22) had few references in Web of Science
Grant et al. *Process evaluations for cluster-randomised trials of complex interventions: a proposed framework for designing and reporting*	Web of Science, Google Scholar, Reference list (1)
Linnan and Steckler: *Process evaluation for public health interventions and research*	Web of Science, Google Scholar, Reference list (46)
Baranowski and Stables: *Process evaluations of the 5-a-day projects*	Web of Science, Google Scholar, Reference list (51)

5.2.3 Inclusion

Dixon-Woods et al. (108) highlight that critical interpretive synthesis may usefully include literature from overlapping fields, and that papers may contain highly relevant information about the concepts of interest but not ostensibly be about that concept. They also argue that as the purpose is to build theory rather than aggregate findings it is appropriate to include all types of evidence, with the focus more on theoretical relevance than methodological quality (108). However, they also highlight that it is mostly not feasible to include every possible item of relevant literature. Given these recommendations, and the findings of scoping outlined above, I placed the following limits on the type of literature to include:

- ✓ Specifically discussing 'process evaluation', operationalised by use of the term 'process evaluation' in the title, abstract, or keywords.

- ✓ Mainly focussing on issues relating to the theory or practice of process evaluation rather than reporting or synthesising the results of process evaluations. These could include issues, debates or opinions relating to methodology, theory, conduct, epistemology, or ontology. Therefore, reports of process evaluations were included when an aim of the paper was to discuss relevant issues using that process evaluation as an example, but papers simply reporting the findings of a process evaluation were excluded.
- ✓ No limits on the type of literature identified through the search methods
- ✓ No limits on fields of practice or outcome evaluation method

5.2.4 Inclusion criteria

I included published literature (including editorials, letters, commentaries, book chapters, research articles) and PhD theses that met all the following criteria:

1. Used the term 'process evaluation' in the title, abstract, or keywords
2. Discussed process evaluation in any field
3. Discussed process evaluation accompanying any kind of outcome/effectiveness evaluation, intervention development work, or standalone process evaluation

5.2.5 Exclusion criteria

1. Items which only reported process evaluation protocols or findings – these were only included if they also discussed wider process evaluation issues (e.g., methodological, operational)
2. No full-text available online
3. Not in English language

5.2.6 Results screening

I screened the titles and abstracts of all results, obtaining full texts where necessary to aid decisions about inclusion.

5.2.7 Data analysis and synthesis

I did not conduct appraisal of quality of the included literature items as it included diverse items such as editorials and opinion pieces, and the aim was not to aggregate research findings.

Methods for this review developed iteratively as I became familiar with the literature and tried various ways of making sense of the content to address the review aims.

I considered what authors stated, implied, and discussed about implications and impacts of process evaluation (both positive and negative), the purposes of process evaluation, and what makes a 'good' or 'useful' process evaluation. I also examined debates about methodological issues and statements by authors about definitions and scope of process evaluation. In line with the critical interpretive synthesis approach (108), I aimed to be critical through questioning assumptions and proposed solutions relating to process evaluation issues discussed in the literature.

To sensitise me further I kept in mind the conceptualisations of value discussed in section 3.2, particularly the value system of 'process', 'substantive' and 'normative' values outlined by Gradinger et al. (66). This enabled me to consider values possibly stemming from 1) the process of doing of process evaluation; 2) the impact of process evaluation or 3) the perceived intrinsic worth of process evaluation, respectively.

I began by reading several papers at random to gain familiarity and identify potential categories and concepts for each review aim. I used NVivo to code sections of texts and develop an initial coding framework, then read further papers to add to and refine this. Having reviewed approximately half of the papers, I then drafted a literature review narrative, which prompted further reflection on and

refinements of categories. I then reviewed the remaining papers and coded sections of texts to add any new ideas to categories in the final narrative.

5.2.8 Reflexivity

As stipulated by the developers of critical interpretive synthesis (108) I engaged in ongoing reflexivity to question whether my own preconceptions and opinions led me to favour or place greater emphasis on perspectives aligned with my own beliefs and values. I kept a reflexive journal and critically discussed emerging ideas and concepts with my supervisors.

5.3 Critical interpretive synthesis findings

5.3.1 Search results

Figure 5.1 shows the results of the different search strategies and table 5.2 shows characteristics of the included publications. Searches were conducted in September 2017. A table describing all included studies is in appendix 2.

Figure 5.1 Search results

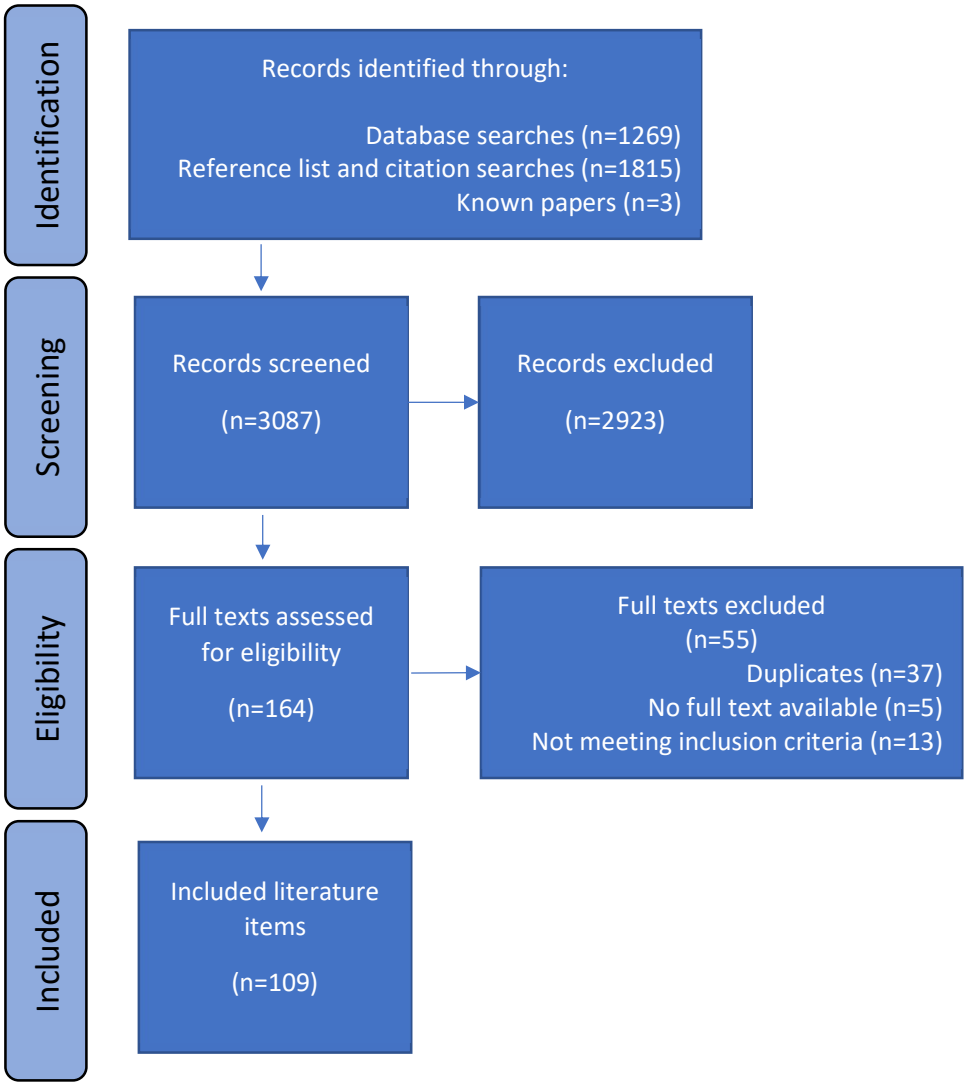


Table 5.2 Characteristics of included publications

	Number of items (n=109)
Year of publication	
2015-2017	31
2010-2014	36
2005-2009	21
2000-2004	15
Pre-2000	6
Type of literature	
Journal article	93
Book chapter	4
Editorial	4
Online document	3
Letter	2
PhD thesis	2
Journal article collection	1
Field of practice	
Health	107
Education	2
Country of lead author	
UK	48
USA	30
Netherlands	9
Australia	7
Denmark	3
South Africa	2
Brazil	1
Canada	1
Ireland	1
Zimbabwe	1
Focus of literature item	
Process evaluation approach / framework / guidance	42
Methodological / operational / ethical issues	28
Use of a method / theory in process evaluation	13
Value of process evaluation	12
Review of process evaluations	10
Multiple foci	4
Type of accompanying evaluation	
Trial	59
Not specified	35
Standalone process evaluation	7
Intervention development	2
Quasi-experimental	2
Pilot study	2
Feasibility study	1
Pragmatic formative process evaluation	1

5.3.2 Summary of findings and conceptual framework

This section provides a brief overview of the findings and presents the conceptual framework. This orients the reader to the subsequent findings sections and how they fit into the conceptual framework.

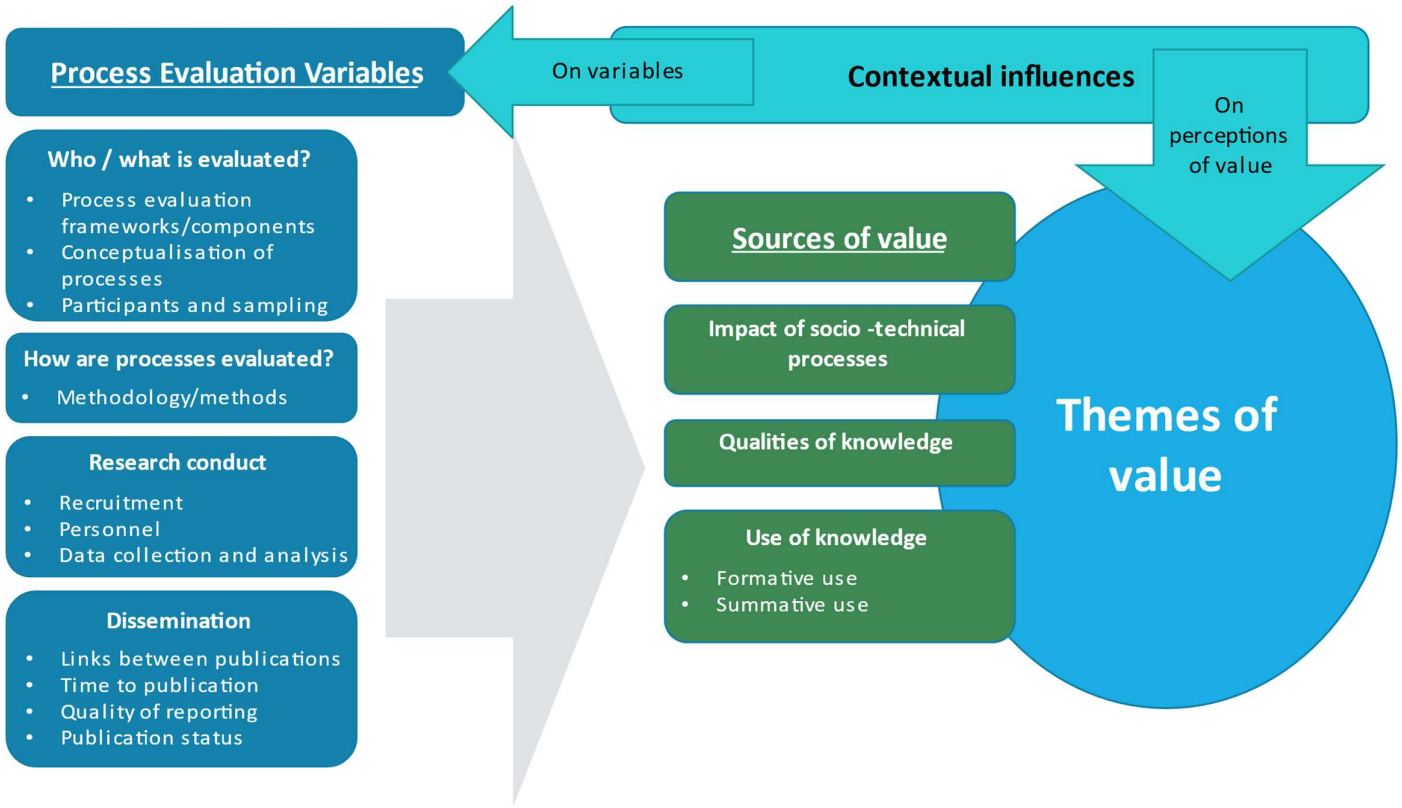
I identified 13 themes of value of process evaluations, some of which also included negative consequences. Value may stem from the knowledge generated by process evaluations and the socio-technical processes employed to produce the knowledge. Process evaluation knowledge may create value through its formative and/or summative use, and through the characteristics of the knowledge. Certain characteristics of knowledge may result in it being perceived as more or less valuable by different stakeholders in different contexts.

However, the potential scope of a study labelled as a process evaluation is very broad. Process evaluations vary widely in the processes they evaluate (for example fidelity and participant responses), how they conceptualise these processes, the methods they use to evaluate them, and the scale of the evaluation. Therefore, the value and negative consequences that may arise from process evaluations are in part contingent on variables in process evaluation design, conduct, and dissemination which shape the process evaluations and the knowledge they create. These variables may also be influenced by contextual factors.

Perceptions of value and negative consequences are subjective and context dependant, and there are potential tensions and trade-offs between values.

Figure 5.2 shows the conceptual framework developed to summarise these findings.

Figure 5.2 Conceptual framework of process evaluation value



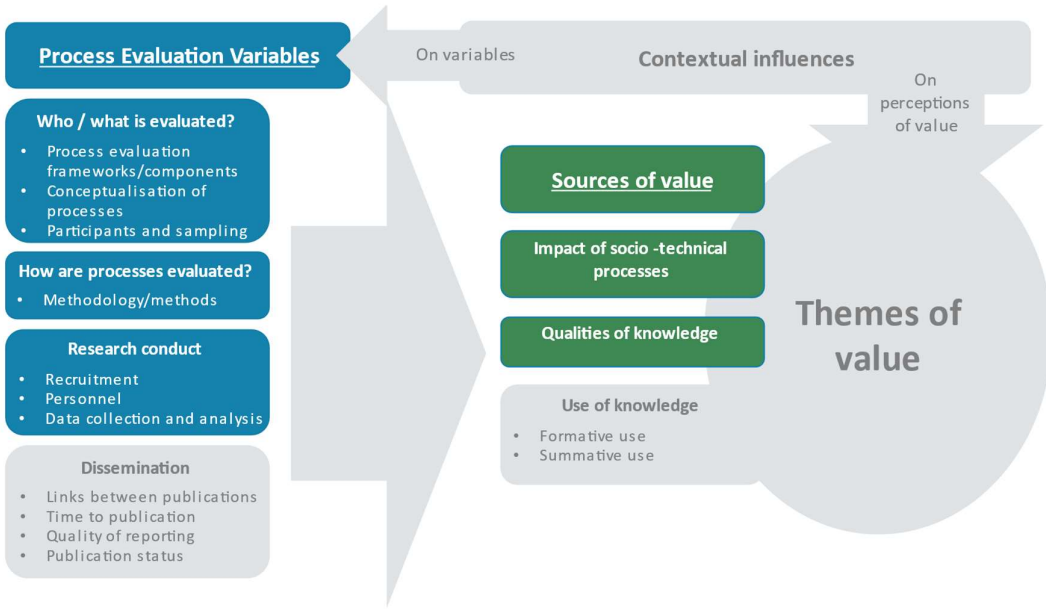
The following sections expand on this conceptual framework to discuss in detail the different forms process evaluations may take; the different types of knowledge process evaluation may produce; different ways in which process evaluation knowledge may be used; and contextual factors which may shape process evaluations and influence how they are valued. The final findings section draws out and critically analyses themes of values and harms.

5.3.3 The design and conduct of process evaluations and the type of knowledge they produce

This section discusses key issues and areas of debate about how process evaluations may be designed and conducted, and the different kinds of knowledge which may be produced as an output of these variables in design and conduct. In doing so it shows the potential scope of the label 'process evaluation', and also considers the value and negative consequences that may arise from these design and conduct variables.

Figure 5.3 shows how these findings fit into the conceptual framework.

Figure 5.3 Conceptual framework elements discussed in findings section 5.3.3



5.3.3.1 Issues and debates relating to process evaluation design

This section discusses issues and debates relating to process evaluation design, which are listed in box 5.1.

Box 5.1 Issues relating to process evaluation design:

- ✓ Standardisation or tailoring to each study?
- ✓ Pre-planned, or flexible and responsive?
- ✓ Use of theory in process evaluation
- ✓ Studying context
- ✓ Studying implementation
- ✓ Linking process and outcomes
- ✓ Using mixed quantitative and qualitative methods
- ✓ Sampling and obtaining multiple viewpoints
- ✓ Stakeholder involvement in design
- ✓ Evaluating outcome evaluation processes
- ✓ Timing of process evaluations

Standardisation, or tailoring to each study?

There are efforts to develop process evaluation frameworks for specific fields of practice, which set out key constructs and measures to be included in process evaluations in that field, such as mHealth interventions (109) and organisational health and wellbeing (110). Standardisation of methods and measures, including details such as data timepoints, is also considered useful (111, 112). Some authors use terms such as 'essential' and 'crucial' to describe some or all components of process evaluation (46, 51, 111), while other guidance for process evaluation advocates a middle ground, with certain aspects standardised and others flexible to the needs of the evaluation (22, 113).

The main perceived benefit of standardisation is that it can better inform wider knowledge, policy and practice by facilitating comparison of interventions between different studies (22, 46, 111, 112). Further benefits of standardisation are that it is perceived to result in better quality process evaluations (111, 114), help researchers to focus on the most relevant and important areas (109), or make them more comprehensive and thereby more informative (115).

There are however perceived drawbacks to standardisation, and benefits of tailoring process evaluations to the unique needs, challenges and opportunities of each intervention and its context.

From this standpoint, process evaluation design should be a considered process rather than a 'tick-box exercise' (116). Intervention theory (22, 116) and stakeholder input may usefully guide prioritisation of questions (22, 117, 118). Methods and data collection techniques and tools may need to be tailored to interventions (114, 119, 120) and participants (121, 122) It is also possible that emerging issues will require a change of methods or focus during the process evaluation (22). Tailoring process evaluations in this manner is considered more likely to gain the most useful knowledge (1, 22), and to engage participants and stakeholders (121).

Pre-planned, or flexible and responsive?

The MRC guidance (22) advocates that process evaluations should be designed with sufficient flexibility to allow response to issues that arise during the research. Flexibility may allow better examination of complex and unpredictable realities (58, 109, 123), with protocols strictly prespecifying aims and methods being unhelpfully restrictive and unresponsive to unanticipated events (121, 124). For example, Odendaal et al. (125) found in the course of their process evaluation that different participants preferred different data collection methods and adapted accordingly.

In contrast, most of the benefits of specifying a strict protocol for process evaluations relate to the knowledge that it generates being considered more trustworthy. Wight and Obasi (2) recommend that subgroup analyses are pre-specified, so that the process evaluation can be designed with sufficient power to avoid false-positive results. Adhering to a protocol is also considered to minimise the risk of misleading findings resulting from post-hoc analyses and data dredging (2, 113, 126).

Use of theory in process evaluation

Most authors agree that specifying underlying intervention theory enhances process evaluation design, and therefore the relevance of the produced knowledge. There are however differences in opinion about the most appropriate kinds of theoretical models and how these are best used.

The MRC process evaluation guidance (22) strongly recommends logic models as a means of illustrating intervention theory and describing the complex intervention under evaluation. However,

logic models have been criticised as overly simplistic representations of reality, rigidly linear, and possibly not containing the actual theorised mechanisms of the intervention but only intervention components and intended outcomes (116, 127). More sophisticated and complex theoretical models including interactions between intervention elements, contextual factors, non-linear relationships, emergence, and feedback loops are suggested by some to better reflect the complex nature of reality investigated in a process evaluation (116, 127-129). Examples include complex systems theory (129, 130), realist evaluation (128), and theory-based evaluation (131).

The MRC guidance (22) recommends using intervention theory to select priority process evaluation questions, suggesting that process evaluations may usefully focus only on certain elements of the theory. However, others maintain that achieving understanding of the system holistically will result in more useful knowledge. It is considered more likely to lead to innovation and improvement in interventions (56, 116), more successful implementation into new settings (56, 127, 132, 133), and better understanding of outcomes (127, 134, 135). As different elements of process evaluation complement each other and contribute potentially unique information, if certain elements are not included this may result in a different interpretation of outcome results than would have been obtained by including them (136).

Several authors also highlight that the means through which interventions achieve their effects may be unanticipated or unrecognised, and therefore process evaluations should use methods to enable mechanisms which were not theorised at the outset to be understood (137, 138).

Studying context

While outlining a range of approaches for in-depth examination of context, the MRC guidance (22), emphasises quantitative testing of pre-hypothesised contextual moderators with outcomes. Both Steckler and Linnan's (46) and Baranowski and Stables' (51) process evaluation frameworks discuss context in similar terms. However, this approach is criticised for isolating elements of process, which may lead to erroneous or incomplete understanding, for example if researchers fill gaps in

knowledge with speculative links between process and outcomes (123) or important contextual variables are not included (114). A wide range of potentially influential contextual factors are outlined in the literature, including organisational factors such as institutional frameworks and relational dynamics (139), past activities and current events (140), the wider social, cultural, political context (116), and the skills and experience of intervention staff (56). Wells et al. (85) highlight additionally that trials themselves are important contextual factors, and factors such as staff attitudes to randomisation may be influential.

Many authors furthermore emphasise that context changes over time (1, 56, 85). Its effects are multi-directional, being potentially altered by as well as itself altering complex interventions (138) and may act variably in subtle or powerful ways (114). Thus, another argument is that by not conceptualising context as a multi-level and dynamic system, quantitative moderation analyses do not properly reflect the complexity of the contexts they examine. (56, 116, 141, 142). Wells et al. (85) also argue that adequate portrayal of context requires multiple methods, sources, and perspectives. A variety of methods of studying context in ways which capture this complexity are described in the literature, most of which do not appear in the MRC guidance (22). These include linguistic ethnography (141) ethnography (123), techniques such as visualisation and story-telling (139), realist evaluation (128) and research team reflection (143).

Studying implementation

The MRC process evaluation guidance (22) extensively discusses different definitions of and frameworks for studying implementation. It highlights how studying implementation of complex interventions is not a simple case of determining whether interventions were delivered as intended. It rather should consider how implementation is achieved or not; how interventions are implemented within systems; and debates around fidelity vs adaptations.

Other authors similarly argue that implementation, especially fidelity, should be conceptualised as multi-dimensional in order to accurately make links between intervention implementation and

evaluation outcomes. (120, 144). Humphrey et al. (120) caution that if implementation is studied unidimensionally then lack of intervention effect may be incorrectly attributed to an aspect of poor implementation, when in fact an aspect which was not studied was the true source of the issue. Similarly, Masterson-Algar et al. (56) argue that process evaluations should take into account learning curve effects, where staff delivering complex interventions within evaluations will typically improve their implementation of interventions throughout the course of the evaluation. This highlights that measures of implementation are likely to vary through the course of the evaluation, which has implications for the links that can be made between implementation and outcome.

Another issue widely discussed is whether implementation should be considered in terms of fidelity to the underlying theoretical principles of the intervention, rather than to a specified form and content of intervention components (22, 113, 145). It is recognised that adaptations of interventions to local contexts is often necessary and desirable, and may imply more skilled and nuanced delivery, resulting in better outcomes (22, 137). Lack of fidelity may alternatively indicate drift from the underlying principles of the intervention, suggesting poor implementation (22). Humphrey et al. (113) highlight that it may be important to establish reasons for adaptations by intervention deliverers, who may or may not have consciously adapted the intervention.

Linking process and outcomes

There is considerable criticism of process evaluations which are solely descriptive and make no or poor links to outcome results (22, 124, 146-148). Nonetheless, there are various interpretations of linking or integrating process and outcome evaluation results and the best way to do this.

Statistical methods of integrating process and outcome data are considered optimal by many (22, 46, 51, 146). These include on-treatment analyses (3, 22, 146, 148), subgroup analyses (146, 148), and more complex methods such as structured equation modelling (3). However it is cautioned that

the trial may not be powered for post-hoc subgroup analyses, and methods such as on-treatment analyses lose randomisation, both of which may introduce bias (146).

It is also cautioned that potential reasons for outcome results are multifaceted. Abraham et al. (149) stress that negative results may be due to failure to implement intervention properly, failure of intervention design, or failure of theory of intervention design. They therefore suggest that simply measuring fidelity to avoid type III errors does not properly establish reasons for results. Humphrey et al. agree, (120) highlighting that assessing single dimensions of implementation may lead to further type III errors as it is tempting to attribute causality to that single cause.

The best use of qualitative process data to explain outcome results is also debated. Qualitative findings are sometimes described fairly uncritically as giving complementary insights to outcome results (1), however Munro and Bloor (57) emphasise that qualitative research cannot explain outcomes deterministically. Oakley et al. (150) caution that factors identified in standalone qualitative process evaluations may appear intuitively to be important influences on outcomes, but in quantitative analysis may prove not be so. Some qualitative approaches are felt to have stronger explanatory capability, such as ethnography (134), or the use of theoretical explanatory frameworks (56), such as complexity theory (130).

Using mixed quantitative and qualitative methods

Mixed qualitative and quantitative methods are strongly recommended by the main process evaluation guidance (1, 22, 46, 51). However, there are several different applications of 'mixed methods' and different perceived benefits of employing them in process evaluation.

One application is analysing qualitative data inductively to identify potential mediators and moderators to examine quantitatively (53, 146). Strange et al. (146) argue that this use of mixed methods reduces the likelihood of bias in process evaluation findings, and provides greater theoretical understanding of reasons for outcome results. A common criticism of this approach is that it is reductionist and neglects complexity (3, 114, 123).

Another application is triangulation to validate quantitative and/or qualitative findings, or for qualitative data to gain deeper insights into trial findings. Several authors highlight challenges and problems with doing this however. Munro and Bloor (57) caution that qualitative findings are by nature indeterminate, nuanced, and qualified, and each method produces unique findings in regard to their precise focus and level of abstraction. They also maintain that qualitative findings from a small number of sites cannot unproblematically make overall changes to interventions.

The knowledge generated by trial outcomes and qualitative process evaluations may thus be difficult to reconcile (137), and if there is conflicting data problems may arise judging which data are more reliable (151). Boeije et al. (152) caution that qualitative findings may challenge the mindsets of triallists, and that negative qualitative findings are potentially demoralising. The credibility of qualitative findings may be doubted (60), or they may not be properly integrated (80).

Several authors also highlight how knowledge of these potential challenges may lead to qualitative process evaluations being designed to be subservient to the needs of the trial (153), avoid looking for problems (60), or frame questions around researchers' rather than participants' concerns (137). It may also lead to qualitative process evaluations being undertaken as separate studies (153), and thus not achieve true holistic understanding of complex interventions (137).

Sampling and obtaining multiple viewpoints

Process evaluations may collect data directly or indirectly from any stakeholder in the intervention or outcome evaluation, most commonly participants and staff delivering the intervention. Other stakeholders include families or carers of participants (154), researchers (151), and managers in the organisations delivering the intervention (134). It is widely seen as desirable to obtain a wide range of views in process evaluations, although some caution that certain stakeholders may be better placed to contribute insights into certain issues than others (118, 128). Furthermore, sites or participants are likely to change over time (1).

One rationale for obtaining a range of perspectives is to gain a more complete picture of events directly from all of those whose views may be influential (122). Another rationale is to triangulate and validate data from different sources, thereby aiming to increase the accuracy and credibility of the findings (117, 155). However, others argue that different stakeholders will have differing perceptions and priorities, which may change over time, and understanding these differences enables better understanding of complexity (134, 139, 154).

It is also suggested that there is moral value in promoting the voices of everybody involved and respecting the dignity and validity of multiple viewpoints (121). Including multiple perspectives in process evaluations may heighten engagement of stakeholders (156), particularly from people who are not usually asked to provide their views (139).

Sampling decisions impact the knowledge produced and perceptions of its utility. Several authors caution that qualitative findings from individual sites cannot be unproblematically applied across all contexts (57, 136, 153). However others argue that including all stakeholders in qualitative process evaluations leads to unmanageable volumes of data, with theoretical saturation having been achievable with a much smaller sample (22).

Several authors emphasise that process evaluation data should also be collected in control groups, to enable between-group contamination to be assessed (3, 111, 135), and understand the nature of usual care in control groups (1). Oakley et al. (150) highlight a further benefit of exposing control participants to the process evaluation research processes, as this allows assessment of how research processes affect participants and bring potential Hawthorne effects.

Stakeholder involvement in design

Involving stakeholders in design helps process evaluations to ask research questions relating to their areas of need and concern. This may increase the likelihood of process evaluations generating useful knowledge (46, 157, 158), with some considering it naïve or reckless for researchers to base process evaluations solely on their own views on what is important (109, 118). Cornwall and

Aghajanian report (139) obtaining a more realistic picture through engaging with stakeholders who are not usually consulted than simply being directed to 'showcase' sites. Stakeholder involvement is considered valuable for deciding how best to conduct process evaluations. For example, Haynes et al. (159) reflect that early stakeholder involvement allowed them to choose the most acceptable and hence successful data collection method.

Evaluating outcome evaluation processes

Masterson-Algar (160) reports that in the development of process evaluation guidelines there was disagreement between stakeholders about whether trial processes counted as part of process evaluation. Within the MRC process evaluation guidance, process evaluation relates solely to intervention processes. However, other process evaluation frameworks suggest that they may also usefully investigate outcome evaluation processes.

Process evaluations may usefully examine recruitment processes to the outcome evaluation, including reasons for participants and sites agreeing or declining to participate (1). This may identify selection bias, aid assessment of generalisability, and inform post-trial implementation of the intervention (1). Masterson-Algar et al.'s (56) proposed guidance for process evaluation in neurological rehabilitation also stresses the importance of examining recruitment processes to understand how these may influence intervention outcomes.

Bakker et al.'s process evaluation framework (161) includes consideration of whether the intervention was evaluated properly, including handling of missing data and the 'reach' of obtaining follow-up data. Baranowski and Stables' process evaluation model (51) also includes this form of reach under their component 'maintenance', as they stipulate examination of how participants are kept involved in data collection as well as in the intervention.

Some authors highlight that trials themselves are part of the context of the interventions they investigate. Morgan-Trimmer and Wood (123) highlight that trial results inform about the effects of an 'intervention plus trial' as opposed to purely an intervention, and suggest using ethnographic

methods in process evaluation to consider how the role of the researcher may shape effects. Similarly, Oakley et al. (150) suggest that an important role of process evaluation is to consider how intervention outcomes are influenced by the way in which the experience of being researched influences the data collected from participants. Wells et al. (85) identified evidence of trial contexts influencing, and possibly being essential to, the effectiveness of interventions, and that this may change over time. In common with the previous authors, they highlight the importance of making this influence explicit, and that process evaluation may be a useful means of studying context in this way.

Timing of process evaluations

There are arguments for collecting process evaluation data both before and after the intervention period. For intervention staff, there is concern that participating in data collection such as interviews and focus groups will influence the way they carry out their role, thus reducing internal validity (162). For trial participants, there is concern about Hawthorne effects (22), and process evaluation data collection becoming part of the intervention (128). There are also concerns that burdening trial participants may cause attrition from and thereby harm the trial (160). Collecting data after the intervention has finished allows exploration of reasons for unexpected trial outcomes (57), and allows participants to retrospectively make sense of experiences (3). However, there are concerns that retrospective sense-making may produce biased socially-desirable narratives (123, 163), and late data collection brings potential recall bias (147, 162).

It is also recommended by many that process evaluation data are collected at multiple timepoints to reflect changes over time (1, 22, 154). This is important to take account of factors such as evolving context (116), intervention teething problems (53, 153) and learning curve effects (56). However, collecting data at multiple timepoints may be burdensome, potentially harming rapport achieved during interviews (153), or causing attrition.

There are also debates about the timing of process evaluation data analysis. Some argue this should occur without prior knowledge of outcomes, which may bias the interpretation of qualitative data (62, 164), and result in data dredging (146). However, others argue this prevents useful exploration of unexpected outcomes (57, 62), and may waste potentially valuable qualitative data (22). O'Cathain et al. (62) highlight examples of qualitative data being analysed in light of trial results to generate useful findings to inform practice, such as making decisions between intervention found to have equivalent effects (165).

5.3.3.2 Issues and debates relating to process evaluation conduct

The previous section discussed 11 themes of debates relating to process evaluation design. This section discusses four themes of debates relating to process evaluation conduct, which are outlined in box 5.2.

Box 5.2 Issues relating to process evaluation conduct

- ✓ Separation or integration of process and outcome evaluation teams?
- ✓ Collecting process evaluation data
- ✓ Stakeholder involvement in process evaluation conduct
- ✓ Recruiting process evaluation participants

Separation or integration of process and outcome evaluation teams?

The perceived advantages of full separation of process and outcome evaluation teams are reducing bias in both the process evaluation and outcome evaluation findings. If outcome evaluators gain insight into how the intervention is functioning through involvement with the process evaluation teams, this may bias their interpretation of outcomes (22, 124). Outcome evaluators may also have vested interest in the intervention and outcome results (53). Process evaluators are often unblinded, and therefore separation reduces the likelihood of accidentally revealing participant allocations (22). Similarly, process evaluation participants may be more willing to honestly express concerns if the process evaluators are separate from the trial (53, 60, 128).

There are however advantages of integration. Integration may facilitate linkage of process and outcome data and collaborative planning and management of data collection to reduce participant burden (22). Reynolds et al. (143) give an example of how ongoing sharing and jointly reflecting on emerging interview data allowed a problem of dissatisfaction of data collectors to be addressed immediately, which could have damaged the evaluation if left unaddressed until the end of the trial. However, several authors discuss how the advantages of integrated teams may be achieved through open communication and good relationships and engagement between separated teams (22, 80, 143).

Collecting process evaluation data

Due to resource limitations, it may be necessary for staff delivering the intervention to collect or provide process evaluation data (22, 162). This may introduce bias (2, 120, 153, 162), burden intervention staff (147), and lead to concerns about participant confidentiality (150) or missing consent forms (153). These problems may be detrimental to the accuracy and quality of the process evaluation data (22, 46, 162). Such challenges may be addressed however through sufficiently training intervention staff, explaining the purpose of the data and careful design and piloting of data collection tools (46, 111, 136, 147, 153, 162).

Nonetheless there are also significant challenges when researchers collect process evaluation data. Researcher presence may change behaviour or be damagingly obtrusive to the intervention (120, 153). As well as potentially biasing the outcome results, this may bring issues around ethics and privacy (136). It is also important that researchers receive sufficient training, and interrater reliability is addressed when several researchers conduct observations (50, 166).

The rapport and relationship between researchers and participants is also significant. Morgan-Trimmer and Wood (123) state that ethnographic interviews are likely yield more detailed, relevant, and potentially less biased data if researchers are familiar with the social setting and trusted by participants. Moore (153) reflects on the power dynamics between an interviewer linked to a trial

and intervention implementers whose employment could be contingent on that trial demonstrating positive outcomes. He reflects that it may discourage open responses from interviewees, and that the interviewer has a responsibility to provide fair and balanced data to understand reasons for poor implementation from multiple perspectives. Roe and Roe (121) discuss collecting data using group discussion, and highlight that this requires skilled researcher facilitation to deal sensitively with issues such as emotional responses to criticism.

Process evaluations may also use data that are routinely collected outside of the evaluation. This reduces participant burden, however may not be the required quality and may bring ethical issues around consent for its use (120).

Involving stakeholders in process evaluation conduct

Stakeholder involvement may facilitate data collection during the process evaluation by enhancing access and buy-in (122, 125, 157), provide richer information (125, 134), increase the chance of uptake of results into practice (157, 158), give stakeholders a voice (157), and enhance trust in and communication with researchers (122, 157). Platt et al. (122) report a further benefit of providing stakeholders from different research sites opportunities to network with each other, which would otherwise have not occurred.

Howarth et al. (138) highlight however that tension may occur when stakeholders expect feedback during a pragmatic trial, but providing feedback would damage the trial's ability to establish causality. They therefore advise completing a mandate for involvement jointly with stakeholders to avoid misunderstanding.

Recruiting process evaluation participants

Recruiting the planned sample of process evaluation participants and collecting complete data may be problematic. Difficulties are reported with process evaluation recruitment (151, 159), self-selection bias tending to result in overrepresentation of engaged participants (153, 159, 167), and

selective gatekeeping of potential participants (122). Masterson-Algar et al. (56) emphasise the need for process evaluation reports to provide details of recruitment strategies.

5.3.3.3 Section summary

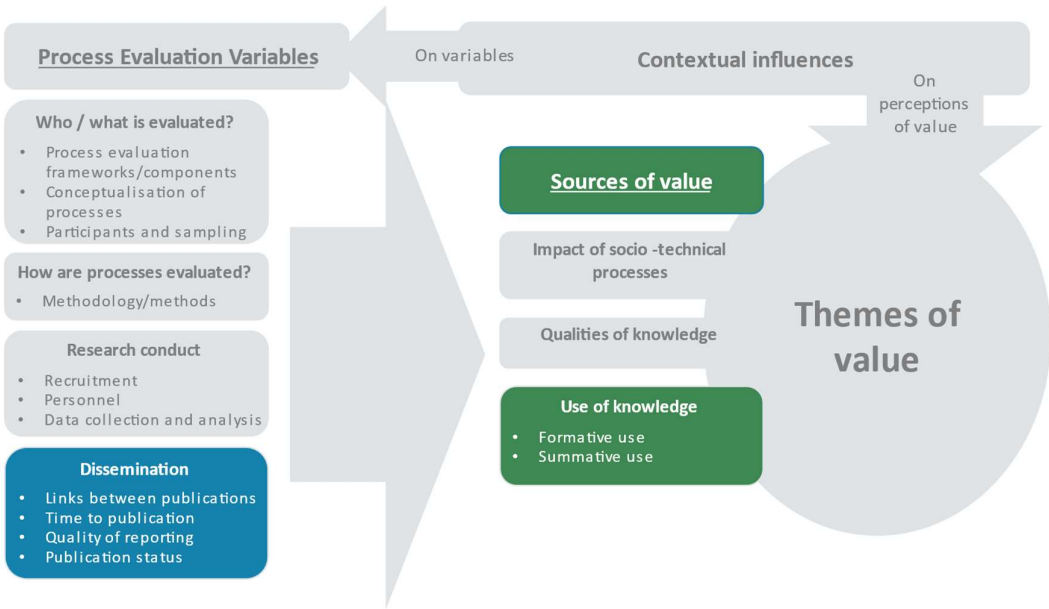
This findings and discussion section has discussed issues and debates in the literature about the multitude of ways process evaluations may be designed and conducted, the type of knowledge they create, and potential values and negative consequences of different variables.

The next findings and discussion section examines how process evaluation knowledge may be used formatively and summatively, and issues relating to process evaluation dissemination.

5.3.4 Use and dissemination of process evaluation knowledge

This section firstly discusses how process evaluation knowledge may be used formatively. It then considers the different types of information that summative process evaluation knowledge may provide, and how this knowledge may be used. Finally, challenges to and recommendations for dissemination of process evaluation knowledge are outlined. Figure 5.4 shows these how these findings fit into the overall conceptual framework.

Figure 5.4 Conceptual framework elements discussed in findings section 5.3.4



5.3.4.1 *Formative use of process evaluation knowledge*

Formative, or developmental, approaches to process evaluation use emerging findings to make adjustments to implementation, the intervention, or outcome evaluation processes during the evaluation (52, 147). These uses are summarised in table 5.3.

Table 5.3 Formative uses of process evaluation knowledge

Type of formative use	Examples
Implementation monitoring and quality control	Continuously check and make adjustments to keep interventions 'on track' (52) by monitoring and correcting fidelity, adaptations, reach, and/or dose (46, 50, 117, 162, 168, 169).
Formative intervention improvements	During intervention development, feasibility, and piloting, make adjustments and improvements to interventions to optimise for definitive evaluation stage (22). Outside of RCTs some process evaluations may include an explicit aim to develop the intervention within the outcome evaluation
Altering outcome evaluation processes	In pilot and feasibility stages refine outcome evaluation processes ready for definitive evaluation (113). Enhance understanding of the learning-curve effects of staff, which may be used to establish the necessary length of the trialled intervention period (56)

The formative uses outlined in table 5.3 are planned formative uses of knowledge. However, the literature included some discussions of unplanned formative application of knowledge. Murtagh et al. (170) describe how qualitative process evaluation data led to discontinuation of a trial arm as it showed the intervention was confusing participants, and thus potentially producing data which lacked validity. Reynolds et al. (143) explain that process evaluation data enabled investigators to take timely action to improve recruitment processes, and address dissatisfaction from intervention staff with trial data collection procedures.

5.3.4.2 Summative use of process evaluation knowledge

In contrast to formative process evaluation, summative approaches to process evaluation use findings after outcome evaluation is complete (52, 147). This review identified five broad uses of summative knowledge:

- ✓ Enhance understanding of outcome results
- ✓ Add information to outcome results
- ✓ Inform intervention development
- ✓ Support implementation of interventions into practice
- ✓ Inform wider knowledge

Process evaluation knowledge enhancing understanding of outcome results

Table 5.4 summarises the different ways information provided by process evaluation knowledge may enhance understanding of outcome results.

Table 5.4 Process evaluation knowledge enhancing understanding of outcome results

Information provided by process evaluation	Examples
Internal validity	Implementation - help determine whether lack of intervention effect due to implementation failure or intervention failure, (3, 22, 46, 51), thereby helping avoid 'type III errors', or 'false-negative' trial results (147, 155) Help identify over-implementation which may lead to false-positive results (153)
External validity	Reach of intervention and participant characteristics (1, 22, 46, 51, 161) Trial recruitment processes (1, 56, 111, 171), including recruitment of clusters or sites (1). Context - understanding of the required conditions for interventions to have desired effects, and assessment of intervention transferability to different settings (2, 120). Mechanisms of impact - enable judgement about whether mechanisms would have the same effect in different settings (3, 22), which may be enhanced by knowing which intervention components were or were not implemented (172). Acceptability of interventions (171).

Information provided by process evaluation	Examples
Reasons for outcome results	Implementation – help determine whether lack of intervention effect due to implementation failure or intervention failure (3, 22, 46, 51) Mechanisms of impact – help determine whether lack of effect due to problems with intervention theory, or problems with implementation or intervention design (149) Context – helps assess potential masking of intervention effect through studying contamination between intervention and control groups (51, 111, 155), usual care in control groups (120), and external contextual factors (50, 144) Participant or staff views about the intervention (164)
Variation in outcome results	Fidelity and adaptations within and between clusters (1). Context – impact of broad factors such as social deprivation (138) and patient characteristics on intervention responses (146), or uptake (3, 51). Differences in patient experiences and perspectives about the intervention (137, 147). Distinguish which factors contribute most to variation (1, 18), and the reasons behind variations (22, 159).

Process evaluation knowledge adding information to outcome results

Table 5.5 summarises the different ways process evaluation knowledge may add information to outcome results.

Table 5.5 Process evaluation knowledge adding information to outcome results

Information provided by process evaluation	Examples
Unexpected consequences	May be positive or negative (22), including broader impacts than prespecified outcomes (60), and be valued by participants more than the primary outcome (137).
How the intervention works	Mechanisms of impact - intervention theory (1, 22), change processes (149), mediators and moderators (22), intermediate or proximal outcomes (149, 155), role of different intervention components (18, 22, 111, 116, 120, 157) Context – impact on intervention functioning (22, 46)
Experiences and perceptions	Acceptability, satisfaction, and feasibility of interventions (1, 22) – participants often intervention participants and staff; however may usefully include a wide range of stakeholders (118, 154).

Process evaluation knowledge informing intervention development

Process evaluation knowledge may be used after the outcome evaluation to optimise or modify interventions. Understanding reasons for positive outcomes may aid optimisation of interventions (25, 159), and understanding variation in results may inform modification and optimisation of interventions to particular groups and settings (126, 159). Increased awareness of unintended effects and outcomes is valuable modify interventions to avoid potentially harmful effects (173). Leeming et al. (137) suggest that understanding unanticipated proximal positive or negative impacts, and their meanings to participants, may lead to reconsideration of intervention theory. Understanding how an intervention works helps make improvements (18, 139), and informs development of future generations of similar theory-informed interventions (46). Knowledge gained through understanding participant experience may provide valuable insights to inform improvements (51, 147, 174). These may be practical suggestions, such as optimising the amount of time allocated to certain programme components (136), or challenging researcher assumptions about participants' worldviews (116).

Process evaluation knowledge supporting implementation of interventions into practice

Process evaluation knowledge may provide guidance for policymakers, practitioners, and researchers about how best to introduce interventions to settings to achieve successful uptake. This may be achieved through increasing understanding of external validity (2, 53, 133, 135, 139, 160), explaining how positive effects have been achieved and sustained (112), and informing about the level of permissible fidelity to maintain effects (144).

Understanding the varying effects of interventions for different people in different contexts can inform how to apply, tailor, and target interventions appropriately to different groups and in different settings (25, 120, 126, 137, 146). Similarly, identifying the active ingredients of interventions and understanding how their implementation affects outcomes is valuable for informing how interventions may be adapted or optimised when transferred to practice (113, 120, 127, 138, 166). Alia et al. (166) also suggest that this provides understanding of which intervention components need to be implemented with high fidelity, and which may be tailored to local contexts.

Process evaluation knowledge about experience and perceptions may provide evidence of its feasibility in practice, and therefore help convince clinicians and policymakers to adopt controversial but effective interventions (62). Alternatively, it may suggest that interventions shown as effective in a trial are likely nonetheless to face difficulties when attempting to implement into practice (62). These data may also incorporate suggestions about how implementation processes and structures may be improved (174), or enhance understanding of how implementation deliverers' understanding and perceptions of interventions impacted on delivery, which may then inform post-evaluation implementation (153). Data on patient experience may also be useful to help clinicians and patients decide which intervention to choose in practice if both are found to have similar effects in the RCT (62).

The formative monitoring role of process evaluation during a trial may have value for supporting later implementation of the intervention into practice, by providing a tested method of maintaining quality (166). Similarly, Moore (153) suggests that process evaluations may highlight aspects of

interventions for which insufficient monitoring procedures have been built in, which can then be improved for implementation outside the research setting.

Process evaluation knowledge informing wider knowledge

Examining intervention theories and causal pathways may usefully inform more general theories about similar interventions, such as those of behaviour change (52, 111, 135, 149, 172), and may generate questions and hypotheses for future research (1). Process evaluation knowledge about successful implementation strategies and behaviour change techniques, has potential value to researchers and practitioners involved with similar interventions or contexts (139, 153, 175-177). Understanding variation in outcome results according to factors associated with staff delivering interventions may be useful to inform wider research, policy, and practice (56, 146). Process evaluation may contribute to the evidence base about which types of interventions are fruitful to pursue, modify, or should be avoided within certain fields of practice (122, 178). Understanding of contextual barriers and facilitators to implementation could provide general knowledge about implementation to assist other intervention developers to develop more feasible interventions and successfully implement these (52). Exploring patient experiences through process evaluation may give valuable incidental insights to improve general health service delivery (80).

5.3.4.3 Process evaluation dissemination

The previous section discussed how process evaluation knowledge may be used to create value. However, for summative process evaluation knowledge to be accessed and used by a wider audience, effective dissemination is vital. There are however many reported weaknesses to process evaluation dissemination, and due to the wide variety of possible methods there are no agreed quality standards for reporting process evaluations (22, 56).

Many authors criticise that detail on methods is lacking and choices are not justified (1, 3, 56, 116, 120, 134, 153, 155). Humphrey et al. (120) found in their thematic literature review that there was often little or no discussion of quality, validity, and credibility in qualitative process evaluation reports. There is reproach that some process evaluations are reported as divorced from outcome

publications, sometimes with little or no mention of the other (1, 80, 116, 148, 152). Process evaluations also sometimes are not published (22, 80), and with no justification of why elements were published over others (153). These weaknesses means it may be difficult to assess the validity and credibility of findings (1, 116), assist the design of future process evaluations (3, 134), and make cross-study comparisons (155).

It is however acknowledged as challenging to report process evaluations comprehensively and well when they are large studies with vast amounts of data, and multiple methods (22). Barriers include journal word limits (22, 80), lack of dissemination resources (22), perceptions that trial outcomes must be published before process evaluations (85); lower status of process evaluations than outcome evaluations (22); and journals being unwilling to publish all trial and process evaluation publications due to differing methodological or theoretical conventions (22). O'Cathain et al. (80) found in an interview study that qualitative research within trials may be less likely to be published when it is seen as of lesser importance than trial publications, and less likely to be published in high-impact journals necessary for academic career progression.

There are however several solutions presented to improve dissemination. Reporting guidelines recommend process evaluation and trial outcome publications cross-reference one another (1, 22), and that a protocol or full report describing all elements of the trial, process evaluation, and any other associated work, is referenced in all papers (22). As an example of a journal facilitating process evaluation dissemination, in their editorial, Hatcher and Bonell (177) praise the *AIDS* journal for publishing both outcome and process evaluation articles in the same issue, maintaining that in doing so the journal facilitates valuable contributions to research, and ultimately to patient health.

Bakker et al. (161) propose a graph for concisely summarising process evaluation results, which they suggest can be presented alongside outcome results. The MRC process evaluation guidance (22) highlights the importance of dissemination outside of academic publications and in lay formats. It may be helpful to involve stakeholders in designing the format of reports and facilitating

dissemination (46, 157). Diaz et al. (158) suggest stakeholder involvement from the outset of the process evaluation helps them use results for real change, rather than being passive recipients. It is possible however that stakeholders may be reluctant to hear negative findings (22).

5.3.4.4 Section summary

This findings section has discussed the ways process evaluation knowledge may be used formatively or summatively to create value. It has also discussed challenges and enablers to effective dissemination of knowledge to optimise the value that is realised.

The next findings section examines the contextual factors that may shape process evaluations.

5.3.5 Contextual factors that may shape process evaluations

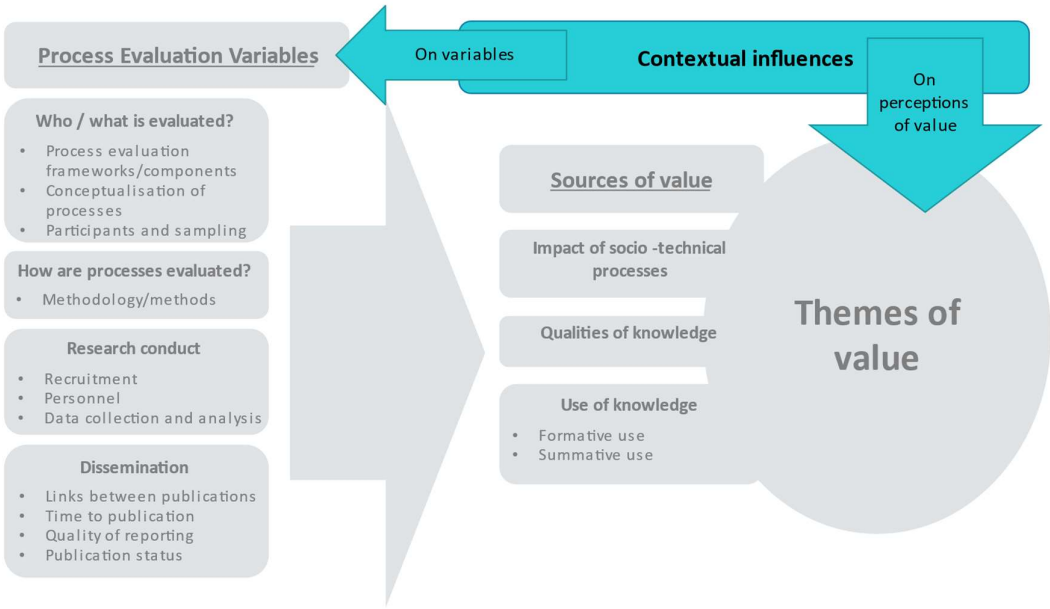
Within the discussions of the issues relating to process evaluation design, conduct, and dissemination above, several key contextual influences emerge. As well as being a potential topic of process evaluation, it appears that context influences what it is perceived as possible and desirable to do in process evaluation. However, it also appears that perceptions of the influence of these contextual factors vary, and differing interpretations exist of whether some contextual influences are barriers or facilitators. The literature reports instances of incorrect assumptions that certain contextual factors are barriers, and examples of how it is possible to overcome some contextual barriers with the appropriate knowledge.

This section outlines key contextual influences on process evaluations and their potential impact. These are:

- ✓ Resource availability
- ✓ Process evaluation guidance
- ✓ The process evaluation research settings
- ✓ The nature of the intervention and outcome evaluation
- ✓ Status of process evaluations and methods

Figure 5.5 shows how these findings fit into the conceptual framework.

Figure 5.5 Conceptual framework elements discussed in findings section 5.3.5



5.3.5.1 Resource availability

It is often highlighted that process evaluations are by nature time-consuming and expensive, due to the complexity of issues investigated and the time-consuming nature of collecting and analysing qualitative data (22, 78, 134, 138, 148). Lack of finance, time, and expertise are therefore commonly cited barriers to conducting process evaluations, and may shape process evaluations in several ways.

Insufficient resources may limit what is investigated in a process evaluation, by necessitating investigation of only certain process evaluation components (1, 22) or elements of interventions (147). It may limit the number of sites or participants (1, 22), require process evaluation data to be collected by intervention deliverers (22, 120, 162), exclude resource-intensive qualitative methods (78, 134), or restrict timing of data collection to coincide with RCT data collection (155). Furthermore, insufficient researcher expertise may result in poorly constructed process evaluations (118), process evaluations lacking explanatory power (134), or restriction of the complexity of

research questions (52). It may also be a barrier to dissemination, especially in academic publications (133).

The most commonly identified reason for lack of resources is that process evaluations are afforded a lower status than outcome evaluations by funders (57, 78, 134, 160). However, it is also suggested that it may not always be true that funders are unwilling to fund process evaluations, but that researchers may bid for low funding due to a perception this makes their bid more competitive (22), or researchers submit poor quality funding applications with insufficient consideration of costs (80). The MRC process evaluation guidance (22) stresses that researchers have a responsibility to apply for sufficient funds and secure appropriate expertise, carefully budgeting for the amount of time required to collect and analyse large amounts of data.

There are also suggestions for how to undertake process evaluations well in the face of limited resources. Careful planning of process evaluations can take account of the available time, funds, and expertise so that time is not wasted on unnecessary data (56, 57). Technology can enable some process data to be collected from all participants at a low cost and with minimal inconvenience (163). Several authors recommend prioritisation of key issues, although there are varying recommendations about how these are prioritised. The MRC guidance (22) recommends addressing key issues well, while Yeary et al. (111) maintain that specialty-specific guidance on what should be included in a process evaluation will minimise cost while maximising information. Leontjevas et al. (171) suggest prioritisation of 'first order' data which establishes trial validity over 'second order' data which provides implementation knowledge. However, as discussed above, others have concerns that only examining processes in isolation results in findings which may give an incomplete or erroneous picture of reality. There are also concerns that if guidelines rank elements of process evaluation in order of priority, this may lead to funders only ever paying for these areas (160).

5.3.5.2 Process evaluation guidance

Process evaluation guidance may shape process evaluations through its availability or lack thereof, its worldview, and the range of possibilities it presents.

A common lament in the literature is a perceived lack of methodological guidance for process evaluation and there are a wide range of persectives on the kind of guidance that is lacking. There are calls for more research and guidance on integrating process and outcome data (3, 56, 78, 148), mixing qualitative and quantitative methods (140), defining process evaluation components (56, 78), studying context (138), identifying and measuring elements of interventions (145), and understanding changes over time (120). There are also perceived needs for process evaluation frameworks and guidance which take account of specific research contexts and fields of practice (109, 179).

It is highlighted that without guidance, planning and conducting process evaluation is challenging (112), and some researchers may even be put off attempting one (56). Interestingly however this review identified a wide range of literature which does present guidance for process evaluation. These include an exemplar of the use of complexity theory to analyse process evaluation data (130) and a worked example of a fidelity assessment and identifying essential elements of a semi-flexible complex intervention (145). Some papers, for example (115) state explicit aims of both presenting process evaluation results and showcasing process evaluation methods. In the perceived or actual absence of process evaluation guidance Griffin et al. (151) suggest it is useful to consult experienced researchers in the field for guidance about suitable process evaluation methods. There are also calls for better reporting of process evaluations, with comprehensive reports considered to provide a useful resource for other process evaluation researchers (1, 22).

Process evaluation guidance presents a particular worldview about the kinds of methods and approaches which should be utilised, which may not always be explicit (120, 160). For example, Leeming et al. (137) highlight that the MRC process evaluation guidance advocates studying mechanisms of change through researcher hypotheses, and does not mention other qualitative methods such as phenomenology and discourse analysis which would bring valuable alternative insight. There are also criticisms of the MRC guidance, such as perceptions that it poorly addresses

how to examine context (180). Masterson-Algar (160) found during consensus work to develop process evaluation guidance for neurological rehabilitation different views were expressed about what a process evaluation should be, dependent on researchers' backgrounds and perspectives.

The wide potential range of process evaluation approaches and methods also appears to be a possible barrier to conducting process evaluations, with confusion over the 'best' approaches. O'Cathain et al. (62) suggest that their review of all of the possible ways in which qualitative research can be used within RCTs may actually contribute to problems of excessive data. Some authors perceive that more directive guidance for process evaluation decreases the complexity of undertaking process evaluations (109) and aids researchers to conduct them (112).

5.3.5.3 The process evaluation research settings

Several authors discuss challenges to collecting accurate and complete process evaluation data in healthcare settings. Data quality may be compromised if concurrent events prevent participants from having time to fully participate in data collection, or even prevent their participation (151). Similarly high staff turnover may negatively impact on access to participants and engagement with the process evaluation (122). Different sites may have different organisational, ethical, and political issues and concerns, bringing site-specific challenges to process evaluation conduct (122). Even when attempting to fit around clinical routines, problems are possible such as clinical priorities overriding planned data collection, such as during staff meetings (134).

To address contextual constraints, guidance for process evaluation specific to fields of practice is useful, as it can take into account opportunities and constraints particular to these settings (3, 160). Planning process evaluations in collaboration with stakeholders, gatekeepers, and potential participants is also recommended (111, 134, 147). Others highlight the importance of data collection tools balancing ease of use and acceptability in the setting with obtaining satisfactory data (134, 147). Maar et al. (109) argue that in multicultural contexts constructivist participatory approaches are better suited to investigating different understandings of interventions.

5.3.5.4 The nature of the intervention and the outcome evaluation

The nature of the trial may constrain the process evaluation, particularly if it is large, complex, and multi-site, as collecting data from multiple sites presents logistical challenges (57). Process evaluations also need to be designed in a way which does not compromise the goals of the outcome evaluation. This includes minimisation of Hawthorne effects and care to avoid participant burden which may lead to attrition or lack of engagement (22).

Interventions with multiple interdependent components and involving multiple stakeholders are more challenging to study (119). Moore (153) highlights that interventions involving private one-to-one consultations, are less suited to intrusive observational methods, as this may potentially harm the intervention, such as by decreasing rapport.

The regulatory context surrounding RCTs in health services may also be challenging, as the requirements and policies of ethics boards, funders, and clinical trials units may not be conducive to flexible and iterative qualitative process evaluations (22, 123). Howarth et al. (138) call for ethics boards to take a sympathetic stance towards the iterative nature of qualitative research, and allow researchers to follow emerging themes without requiring substantial ethical amendments.

5.3.5.5 Status of process evaluations and their methods

The status of process evaluations and the methods they employ within research teams and in the wider research context may shape process evaluations.

The MRC guidance (22) stresses the importance of both process and outcome evaluation being properly overseen by a lead investigator who gives both equal value. However, within the literature there are several examples of qualitative process evaluations being afforded lesser status.

An example of difference in status of qualitative process evaluations is provided by two contrasting reports about the credence given to qualitative data suggesting problems with interventions. In one case (60), trial investigators disputed qualitative data and felt they should not act on them during the trial, however appeared willing to act on informal data gained through their own interactions

with the same people who provided the qualitative data. In contrast, Murtagh et al. (170) report that qualitative data suggesting that a trial intervention arm was confusing and distressing to participants was considered sufficient evidence to discontinue the trial arm. They report that this problem had been raised informally, but that investigators required the qualitative process evaluation data to act.

Leeming et al. (137) highlight potential problems caused by epistemological differences between experimental methods investigating outcomes and some qualitative approaches investigating experiences. They suggest that this may either result in separation of research efforts, thereby sacrificing holistic understanding, or the 'shoehorning' of qualitative research into RCTs to fit their epistemological assumptions, thereby reducing its potential to provide rich alternative insights. They suggest that an alternative approach would be to embrace differences between approaches and consider them lenses to view the same phenomenon from different perspectives.

To increase their status and value, several authors emphasise that process evaluations should be considered integral to outcome evaluations from the outset (2, 50, 125). Some go further to suggest it is useful to conceptualise a single study including process and outcome evaluation, rather than two discrete enterprises (62, 127). Process data monitoring committees may provide an important forum for more objectively considering how to act on process data during trials (60, 181). Effective and open channels of communication and engagement between process evaluation and outcome evaluation teams are also recommended (22, 80).

In the wider research context, barriers between social science and medicine and between qualitative and quantitative research may impact on the status afforded to process evaluations (153). Academic career and institutional pressure to focus publications in high-impact journals and secure high-profile grants may detract from the value of qualitative research (80). Howarth et al. (138) suggest that the norms, expectations, and practices of researchers and research consumers, as well as of

institutional structures such as funding and publishing models, require critical examination of the degree to which they support contextually sensitive research such as process evaluations.

Some authors report however that there is a sense of improvement in the status of qualitative research in trials. These include more mixed-methods and qualitative researchers on funding panels (138), and increased publication of process evaluation protocols and the inclusion of qualitative research in policies and procedures of clinical trials units (62).

5.3.5.6 Section summary

This findings section has discussed contextual factors which may shape the design, conduct, and dissemination of process evaluations and thus may influence the value process evaluation create.

The final findings section draws together 13 themes of values identified throughout these findings sections and critically analyses tensions between values.

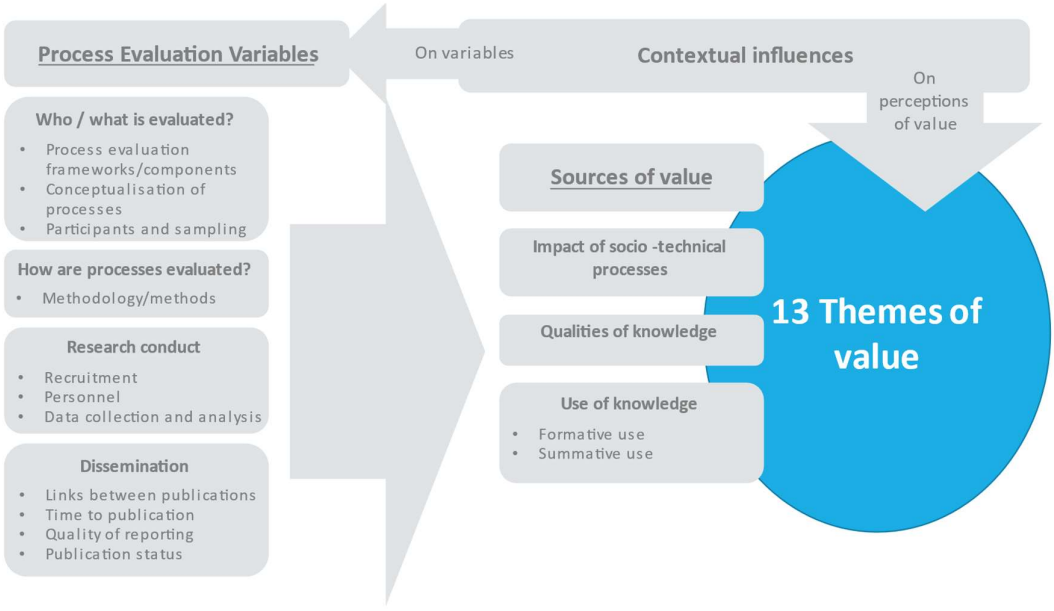
5.3.6 Themes of value of process evaluations

The previous findings sections have explored:

- ✓ The wide variety of socio-technical processes that may be used to design and conduct process evaluations.
- ✓ Different characteristics of process evaluation knowledge
- ✓ How process evaluation knowledge may be used and disseminated
- ✓ How context may shape process evaluations

This final section draws out and critically analyses the themes of value from these previous sections. Figure 5.6 shows how these findings fit in the conceptual framework and box 5.3 lists the themes of value.

Figure 5.6 Conceptual framework elements discussed in findings section 5.3.6



Box 5.3 Themes of value from process evaluations

- ✓ Improving interventions
- ✓ Supporting implementation of interventions into practice
- ✓ Contributions to wider knowledge
- ✓ Financial
- ✓ Relationships
- ✓ Ethics
- ✓ Giving people a voice
- ✓ Meeting a requirement
- ✓ Education and development
- ✓ Knowledge completeness
- ✓ Knowledge credibility
- ✓ Knowledge accuracy
- ✓ Impact on the outcome evaluation

5.3.6.1 Improving interventions

Section 5.3.4.2 outlined how summative process evaluation knowledge may be used to develop interventions post-evaluation, and in some types of evaluation formative improvements to interventions may be a goal of process evaluation. Making formative improvements to interventions during process evaluation has the potential value of making them more effective and sustainable (58, 63, 117, 166, 182). These benefits may be gained through both the improvements to the interventions, and through the engagement process with intervention staff (134).

A key tension however is whether interventions can be ultimately most usefully improved during the evaluation, or by using summative process evaluation evidence to improve them afterwards. The loss of internal validity caused through formative improvements to interventions means in RCT contexts formative improvement is not desirable. In this regard the suitability of RCTs to evaluate complex interventions is questioned by some authors, with Jansen et al. (63) suggesting that pragmatic RCT methodology constrains the improvement, effectiveness, and sustainability of interventions. Riley et al. (60) similarly question the wisdom of waiting until the end of an evaluation to confirm interventions are 'sticking a square peg in a round hole'. Moreover, if the outcome evaluation shows negative results, and is not part of an ongoing research programme, there may not be funds available to make post-hoc improvements and then conduct a further trial.

Similarly, tensions exist between monitoring and correcting fidelity to ensure internal validity of trial results, and allowing the adaptation and tailoring of interventions to local contexts (22). This adaptation and tailoring may be regarded as a form of formative improvement by practitioners, and perceived benefits include interventions becoming more patient-centred (160) and better fit and consequently greater feasibility in local settings (56). Therefore, the value of avoiding an erroneous trial result due to low internal validity may be obtained at the expense of these improvements to interventions. The MRC process evaluation guidance (22) highlights different conceptualisations of fidelity however, suggesting that permitting tailoring sometimes may be possible and appropriate within RCTs, while maintaining fidelity to the core functions of the intervention (22).

The perceived usefulness of process evaluation findings to improve interventions post-evaluation may be impacted by the form of knowledge generated by the process evaluation. If findings are nuanced or participants have diverse opinions, it may be difficult to apply these to improving an intervention that has been developed as uniform and tested in an RCT (57). Although process evaluations are considered to improve the external validity of trials, process evaluation findings themselves may lack generalisability as they were generated in unique contexts (57, 166).

5.3.6.2 Supporting implementation of interventions into practice

The knowledge gained through process evaluations may be used to support implementation of interventions into practice following a positive outcome evaluation, as outlined in section 5.3.4.2. Their value is thus often presented as closing the research-practice gap, and improving the usefulness of trial evidence by making it less likely it will be wasted and ignored (180). However, as with the theme of improving interventions above, the type of knowledge generated by the process evaluation may influence perceptions of its ability to inform implementation.

Engagement of stakeholders through conducting the process evaluation may also contribute to successful implementation by those stakeholders after the evaluation (157, 158). However, this stakeholder engagement must be balanced with any outcome evaluation requirements for minimal contamination of interventions and settings.

5.3.6.3 Contributions to wider knowledge

There are many ways in which process evaluation evidence can contribute to the knowledge base beyond the intervention under investigation, as outlined in section 5.3.4.2. Process evaluations may also make valuable methodological and theoretical contributions to the field of process evaluation itself, such as through publishing their protocols and exemplars of overcoming methodological challenges (22, 159).

The MRC process evaluation guidance (22) suggests it is useful for process evaluation researchers to consider how findings may be applicable to wider settings and wider audiences to increase appeal to journal editors and hence increase chance of publication. While this certainly brings benefits, it does

however suggest an undervaluing of the core function of process evaluation to provide knowledge about the specific intervention and outcome evaluation with which it is associated.

5.3.6.4 Financial

The various ways in which process evaluation knowledge may be used are sometimes described in terms of bringing financial value. By explaining outcome results process evaluations may help justify money spent on trials with outcomes that are not positive (157, 160), and help avoid future expensive mistakes in interventions, theory, and research (123, 152). Identifying the active ingredients of interventions may inform removing minimally effective components, thereby reducing cost (111, 113, 120). Understanding the mechanisms of interventions, and how they may affect other areas of health systems, may also be valuable for informing strategic overall investment in health (179). Grant et al. (180) argue that a better provision of information on the influence of context on trial outcomes will help stop trial findings being ignored by policymakers and practitioners and thereby help prevent financial losses through unused research findings. The role of process evaluation knowledge in increasing the likelihood of interventions being successfully transferred to practice, and helping others avoid mistakes, may be used to justify the expense of process evaluations (123).

It is also argued that formative use of process evaluation knowledge to monitor and correct implementation during an evaluation has potential financial value, through avoiding spending money researching interventions which are not implemented correctly (52, 118). This highlights a tension between formative use of process evaluation knowledge to correct implementation, or summative use to provide retrospective understanding that lack of effect was likely due to poor implementation. Although it could be argued that the former is financially advantageous, it would not be congruent with the aims of outcome evaluations seeking to establish effectiveness in real-world settings, such as pragmatic RCTs. Furthermore, Baranowski and Stables (51) suggest that knowledge of variation in implementation of different intervention components can be used to

make inferences about the effectiveness of different components. They maintain that this is more cost-effective than conducting multiple trials to evaluate the effect of each component.

In terms of negative financial consequences, the MRC process evaluation guidance (22) cautions that process evaluations may waste money through inefficiency and collecting too much data.

5.3.6.5 Relationships

Process evaluations may help enhance relationships between people they involve. Roe and Roe (121) describe how their use of dialogue boxes as a data collection tool built trust and identity within a group of participants. Platt et al. (122) report how a process evaluation provided stakeholders from different research sites opportunities to network with each other, which would otherwise have not occurred.

Participant and stakeholder engagement achieved during process evaluation, such as through employment of qualitative methods and involvement in data collection, may be perceived as beneficial through enhancing trust, communication, and a sense of mutual understanding between researchers and participants (121, 122, 157). However, within RCTs there is concern that participant engagement may cause Hawthorne effects, and that engagement of intervention staff may reduce external validity.

Process evaluations also have the potential to be detrimental to relationships. Platt et al. (122) reflect that feeding back negative findings during process evaluations to intervention implementers and stakeholders may place strain on relationships where there is existing discord. They also caution that if not done sensitively it may negatively affect morale and engagement with the research team. Howarth et al. (138) highlight that tension may occur when stakeholders expect feedback during a pragmatic trial, but providing feedback would damage the trial's ability to establish causality. They therefore advise completing a mandate for involvement jointly with stakeholders to avoid misunderstanding. Roe and Roe caution that collecting process evaluation data in groups may raise status issues and concerns about repercussions between participants (121).

5.3.6.6 Ethics

Some authors consider that well-designed process evaluations help trials fulfil ethical obligations to offer sufficient information to inform practice and research (141, 149), thereby framing inclusion of a process evaluation with an outcome evaluation as an ethical act in itself.

Process evaluation conduct may however raise ethical concerns relating to consent, confidentiality and participant wellbeing. Ellard et al. (174) discuss that their process evaluation involved conducting observations in care homes, which raised ethical issues as not all of the residents has consented to take part in the RCT and / or the process evaluation. There are also issues around confidentiality of individual participant responses, and sensitive handling of information that could be detrimental to others (121, 122). Process evaluations may also use routinely collected clinical data, which may bring ethical issues around consent for its use (120). Some authors caution of potential emotional ill-effects on process evaluation participants, such as embarrassment discussing sensitive issues (22).

Complex ethical issues may arise when non-formative process evaluations reveal problems during an outcome evaluation. Riley et al. (60) reflect on ethical dilemmas caused when qualitative data suggested problems with an intervention's contextual fit. They argue that there is an ethical imperative to act on information to improve participants' outcomes and prevent damage to relations with stakeholders and morale during the trial, rather than not acting on this knowledge. However, they also consider the potential ethical harm, as perceived by trial investigators, of damaging the trial and the evidence it would produce by unjustifiably acting on potentially unreliable qualitative data. Riley et al. (60) propose a solution as establishing process data monitoring committees formed of various stakeholders as a forum for debating such potentially ethically contentious scenarios.

Murtagh et al. (170) similarly reflect on an ethical obligation to act on emerging process evaluation findings to prevent distressing participants and collecting potentially invalid trial outcome data. In their case, agreement was reached with trial investigators to discontinue a trial arm, however they

highlight the complexities of this decision. They also propose that process evaluation may help monitor the ethical conduct of trials, in a similar way to a data monitoring committee.

5.3.6.7 Giving people a voice

Some authors argue that through giving people a voice, process evaluations have moral value and play a role in empowerment. Franzen et al. (167) describe how asking youth participants how to improve their intervention signified they were listened and empowered, however with the important caveat that their views were acted upon. In their collaborative process evaluation Roe and Roe (121) set out commitments to evaluation, including promoting the voices of everybody involved, and that their methods and findings reflect the dignity and validity of multiple viewpoints. Process evaluation may enable intervention staff to provide opinions that they may otherwise not feel comfortable to articulate (60), although this is more likely if process evaluation researchers are separate from the outcome evaluation and/or intervention teams (53, 60, 128).

However, while many advocate obtaining multiple perspectives, dealing with multiple voices can be challenging. Manchaiah et al. (154) highlight that it may be impossible to know whose views are more important. They do suggest however that understanding a diversity of views may usefully inform later patient-clinician shared decision-making. Riley et al. (60) agree with the impossibility of reaching a common understanding of reality through diverse perspectives, however caution of potential problems if powerful actors control or dominate discourses. They discuss how anecdotal and informal data obtained by trial investigators appeared to be given more weight than to qualitative process evaluation data from intervention deliverers. They emphasise that it is vital that conflicting views are made transparent in terms of their origins and limitations, and conflicting interpretations are openly discussed. Nonetheless, Riley et al. (60) also argue that qualitative researchers will obtain more meaningful and useful knowledge by explaining differing interpretations and making judgements about which may better reflect reality, rather than simply describing a range of views.

5.3.6.8 Meeting a requirement

There may be a value in process evaluation that it fulfils a requirement by funding bodies and research commissioners (161, 183), prominent guidance (25, 184), or calls within fields (56, 148). For example, the Education Endowment Foundation, an education charity, commissions an implementation process evaluation alongside every outcome evaluation that it funds (113).

Nonetheless, a quote from an interview study investigating the value of qualitative research within RCTs (80) observes that on many grant applications process evaluations appear tokenistic, without sufficient funds or expertise to conduct an integral high-quality process evaluation. This suggests that if the main motivation to undertake a process evaluation is to meet a requirement it may not bring as much value as it could.

5.3.6.9 Education and development

The MRC process evaluation guidance (22) highlights that process evaluations are sometimes undertaken by PhD students, primarily to reduce costs. Process evaluations thus may provide opportunities for education and development, which has value to the individual and the wider research community. However, it emphasises that such junior researchers are very unlikely to possess a sufficient range of methodological and theoretical skills and experience to lead a high-quality process evaluation, and they must be overseen by sufficiently skilled and experienced researchers (22).

5.3.6.10 Knowledge completeness

Process evaluations appear to be considered by some authors to create value by adding knowledge that outcome evaluations do not or are unable to provide, thereby providing more holistic understanding of interventions and their effects.

Wight and Obasi (2) discuss that RCTs often necessarily investigate a heterogenous sample in order to have sufficient power to demonstrate an effect, but certain participants are highly likely to benefit from the intervention more than others. They argue that by obtaining an aggregate effect size, RCTs obscure variation in participant response, and therefore process evaluations are valuable to unpack

this 'black box'. The MRC guidance (22) also raises this issue, highlighting that an overall positive effect in a trial may mask inequalities, and process evaluations may therefore provide insights into these. Similarly, an apparent lack of effect on a primary outcome may mask variable contextual influences, such as levels of deprivation, on effects, with some subgroups in fact appearing to benefit from the intervention (138). Wight and Obasi (2) also highlight that outcome evaluations do not investigate the influence of contextual factors, which means predicting the success of transferring interventions to practice in other settings is challenging. Moore et al. (53) emphasise that effect sizes in isolation do not inform policymakers whether trial outcomes will be replicated in different contexts. It is emphasised that qualitative process evaluations may discover unexpected outcomes that are impossible to predict or access using experimental methods (116, 139), and that such outcomes may be of value to participants (137).

Process evaluations may also add knowledge to outcome evaluations by enabling voices to be heard that may otherwise be neglected (60, 133, 156). Riley et al. (60) argue that only those presenting trial outcomes usually account publicly for what occurred in trials, while Liu et al. (133) suggest that process evaluations can shine light on patient perspectives which are often overlooked.

Another consideration within this theme is the completeness of the knowledge generated by the process evaluation itself. As discussed throughout this section, there is an array of possibilities regarding what process evaluations may study and how they may study it. Furthermore, operational challenges, such as to participant recruitment and data collection, may limit how process evaluation designs are enacted. Therefore, the knowledge generated by process evaluations is likely to provide only a partial picture of reality. However, as acknowledged by the MRC (22), it is extremely unlikely in practice that process evaluations would be able to study every possible aspect of interventions and their effects. That process evaluations may only provide a partial picture of reality does not therefore detract from their value; however if knowledge incompleteness is not recognised and acknowledged this may be problematic.

Firstly, reporting guidance for process evaluations (1, 22) emphasises the importance in transparency about design decisions, including rationales for the selection of certain methods and objects of study. This enables clear interpretation of findings in light of understanding of what was and was not investigated and why (1). Nonetheless, as discussed in section 5.3.4.3, many authors highlight that process evaluations are often poorly reported in terms of design decisions. Secondly, there is disagreement about the ability of different approaches, theories and methodologies used in process evaluation to provide a complete picture of reality. As discussed in section 5.3.3, certain theoretical frameworks, methods, and conceptualisations of implementation, context, and complexity are criticised as being, for example, unidimensional, reductionist and rigidly linear. The perceived value of process evaluation knowledge may therefore be influenced by perceptions about the ability of various methodologies, epistemologies, and ontologies to represent reality. Thirdly, there is concern that process evaluation knowledge may draw incorrect conclusions from incomplete knowledge. A commonly discussed example is when implementation is not conceptualised as multi-dimensional, and therefore potentially incorrect links between intervention implementation and evaluation outcomes are made (120, 144).

5.3.6.11 Knowledge credibility

A value of process evaluation is sometimes to increase the credibility of RCTs by addressing criticisms of their limitations (146), potentially therefore improving the science of RCTs, and helping prevent abandonment in favour of less rigorous non-experimental or non-randomised research methods (164). The language used to describe these advantages over RCTs conveys two perspectives. Some authors emphasise the strength of experimental approaches in assessing outcomes, but highlight their natural limitations of not explaining why interventions work or not (112, 149). Therefore, process evaluations are regarded as complementary, with researchers capitalising on different strengths of both evaluation types. However, some language has a more critical tone, suggesting limitations of experimental outcome evaluations stem from deliberate

ignoring or naivety on the part of experimental evaluators (22, 53, 56, 148). The value of process evaluation is thus perhaps framed more as rescuing or protecting the evidence base.

The credibility of process evaluation knowledge itself may also be questioned, with different types of knowledge being variously perceived as more or less legitimate for certain uses. In section 5.3.5.5, status issues relating to qualitative research were discussed, with examples of how it may be afforded less credibility and hence less able to achieve its potential value. Further features of process evaluation which may affect its credibility include, as discussed in section 5.3.3, include how differing views are reconciled, the nature of theories, how complexity is understood and studied, and which methodologies are employed.

5.3.6.12 Knowledge accuracy

A key summative use of process evaluation knowledge is to highlight potential errors in outcome results. This may be achieved by providing information about external validity (155, 160), internal validity (62), or reasons for outcome results (22, 56, 149, 155, 172). Process evaluations are often considered to help identify 'type III errors', or 'false-negative' trial results, where lack of effect is caused by poor implementation (147, 155).

As highlighted earlier in section 5.3.3, there are however arguments about the process evaluation design and type of knowledge necessary to correctly interpret outcome results and avoid errors. For example, several authors highlight that correct understanding of outcome results requires a holistic approach, taking into account multiple complex and multi-faceted possible causes, hence requiring investigation of multiple process evaluation components (22, 116, 138, 144). Similarly, if implementation is not measured in multiple dimensions, this risks further type III errors (120). Therefore, process evaluations which only examine one potential cause of outcome results are likely to themselves provide limited or incorrect understanding (22, 138).

Used formatively, keeping interventions, implementation, and trial processes on track, process evaluations may help avoid erroneous trial results through maximising fidelity and therefore internal validity (162, 171, 172). This raises the question however of whether it is more valuable to

distinguish between ineffective interventions and poor implementation at the end of trials, or avoid poor implementation in the first place. The rationale for not using knowledge formatively to correct implementation may be to avoid artificially influencing outcome results in pragmatic RCTs (22). It may also not be logistically possible in large multisite trials (169).

A further issue is process evaluation methods potentially harming the internal or external validity of outcome results through becoming part of interventions, having therapeutic effects, or interfering with real-world delivery. Humphrey et al. (120) cite a study by Smith et al. (185), which found larger effect sizes in studies in which implementation was assessed. This may be addressed through careful planning of process evaluation methods and timing (62, 143, 153). Process evaluation activities may also be conducted in both intervention and control groups, in order to equalise potential Hawthorne effects between groups (143, 150). Reynolds et al. (143) highlight that there appears to be very little guidance on how to recognise such intervention effects of evaluation activities. However, they stress the need for consideration of how evaluation activities are perceived by participants and what their effects may be, and suggest a reflective approach by researchers to identify effects and interpret outcomes.

5.3.6.13 Impact on the outcome evaluation

Formative process evaluations may contribute to the success of outcome evaluations through making interventions more effective and/or through enhancing evaluation processes such as data collection. Correcting implementation formatively may make increase the likelihood of positive outcome results (58, 63, 117, 174). Linnan and Steckler (46) highlight that providing feedback to stakeholders through monitoring and quality control may generate enthusiasm, which may be beneficial to the success of the intervention and evaluation. Staff involved in delivering interventions are likely to expect and wish to improve their practice (134, 162), and therefore collaboration to improve interventions may have the value of engaging and motivating staff involvement with the evaluation (134). Formative process evaluation may also engage staff by sustaining interest and reassuring that their energies are being put to good use, particularly in trials

lasting several years (182). Formative improvement of trial processes is likely to contribute to outcome evaluations being successfully completed, through enhanced cooperation of those collecting data and timely corrective action on problems which threaten the evaluation (143). In more explanatory RCTs, formative monitoring and quality control of implementation and trial processes is likely to be desirable, to ensure internal validity. However, in pragmatic RCTs, which aim to minimise researcher interference and assess real-world effectiveness (63), this may be problematic.

It is however possible for process evaluations to cause tension with stakeholders, and therefore potentially damage the outcome evaluation. Process evaluation involvement may be perceived as burdensome by participants, and thus potentially cause participant drop-out or loss of enthusiasm by intervention deliverers (22).

Some authors reflect on weighing up factors to balance potential benefits and harms of methods. Byng et al. (178) reflect that their retrospective interviews were problematic in that memories focused on especially good or bad experiences, with a loss of nuance. However, they feel that conducting interviews during the intervention would have altered it, and been unacceptable in an RCT context despite likely obtaining more useful data. Griffin et al. (115) reflect that process evaluation of complex interventions with multiple components is always requires weighing-up the ability to obtain detailed and inclusive data against the consequential burden on participants.

5.3.6.14 Section summary

This section has outlined and critically discussed 13 themes of value from process evaluations, considered potential tensions between values, underscored that value is context-dependent, and highlighted how different stakeholders may perceive value differently.

In the final section of this chapter I briefly discuss the overall findings of this review, its strengths and limitations, and implications for the rest of this thesis.

5.4 Critical interpretive synthesis discussion

In this chapter discussion I summarise findings in relation to the objectives of the critical interpretive synthesis, and briefly discuss how findings address the thesis research questions of how process evaluations are defined, valued, and shaped. I discuss findings more extensively in relation to findings from the other thesis elements and the existing knowledge base in the main discussion in chapter 8. This chapter ends with consideration of the strengths and limitations of this critical interpretive synthesis.

5.4.1 Summary of findings

Table 5.6 summarises the findings of the critical interpretive synthesis in relation to the initial objectives.

Table 5.2 Summary of findings of critical interpretive synthesis

Objective	Findings
Objective 1: To outline the potential scope of process evaluations	The scope of the term 'process evaluation' is very broad. Process evaluations may vary in terms of: ✓ The processes they evaluate ✓ How they conceptualise these processes ✓ The ontology, epistemology, methodology, and methods they employ to evaluate these processes ✓ Their operationalisation ✓ Their size and scale ✓ Their aims and research questions
Objective 2: To identify potential sources of value from process evaluations	This review has identified three sources of value and potential negative consequences of process evaluations: ✓ The socio-technical processes used to conduct the process evaluation ✓ The characteristics of the knowledge generated by the process evaluation ✓ How process evaluation knowledge is utilised formatively and/or summatively Because the potential scope of process evaluations is broad, the socio-technical processes and characteristics of knowledge may vary widely between process evaluations.
Objective 3: To identify and describe contextual factors which may shape process evaluations	This review identified five contextual factors which may affect how process evaluations are designed, conducted, and disseminated: ✓ Resource availability

Objective	Findings
	✓ Process evaluation guidance ✓ Research setting ✓ Nature of the intervention and outcome evaluation ✓ Status of process evaluations and their methods Context may also affect perceptions of value and negative consequences.
Objective 4. To identify and critically analyse themes of values associated with process evaluations	This review identified 13 themes of value, some of which included potential negative consequences: ✓ Improving interventions ✓ Supporting implementation of interventions ✓ Contributions to wider knowledge ✓ Financial ✓ Knowledge completeness ✓ Knowledge credibility ✓ Knowledge accuracy ✓ Ethics ✓ Giving people a voice ✓ Meeting a requirement ✓ Education and development ✓ Relationships ✓ Impact on the outcome evaluation The ways in which some values and harms are best achieved or avoided are sometimes subjective. Some values and harms appear to be interdependent, with some values potentially also causing harms, or negating another value.

5.4.2 How are process evaluations defined?

Findings show clearly that a unified definition of process evaluation is lacking. Although all literature items included in this review used the term 'process evaluation', the studies they described under this term varied considerably. Having completed this synthesis it is important to note that none of the included items presented the full scope of process evaluation methods discussed in the whole body of included literature, and the scope and definition of process evaluation presented by a single source is therefore limited. These findings strongly support the importance of further examining the meaning of the term 'process evaluation' in the context of pragmatic RCTs of healthcare interventions in the rest of this thesis, and exploring potential consequences of a lack of clear definition.

5.4.3 How are process evaluations valued?

Findings show that there are many ways in which process evaluations may create value and negative consequences, and that process evaluations may be valued in different ways by different people in different contexts.

Considering the findings overall, there are two broad perspectives on value. In the first, value centres on supporting the scientific endeavour of obtaining a valid outcome result and the needs of researchers. Process evaluations should minimally contaminate or compromise the successful completion of interventions and outcome evaluations, and if knowledge is used formatively this is to correct implementation to ensure internal validity. Process evaluation knowledge provides retrospective understanding and is based on the same philosophical assumptions as the outcome evaluation, favouring standardisation and pre-specified protocols. The utility of process evaluation knowledge is to complement outcome evaluation findings, and its value may depend on what the outcome findings show.

In the second perspective, value centres on sustainable intervention development, improving practice, and developing relationships with stakeholders. Process evaluations may be regarded as opportunities to employ methodologies with different philosophical assumptions to RCTs, with flexible designs tailored to interventions and settings. They are likely to favour methods that result in nuanced, contextually sensitive, and in-depth findings reflecting assumptions that reality is unpredictable and complex. Adaptation and tailoring of interventions to local contexts is viewed positively, with process evaluations examining how this occurs rather than monitoring and correcting.

Where there are tensions between values these generally reflect differences between these two perspectives. For example, process evaluation methods that enhance engagement with participants may increase the effect of the intervention during the evaluation, which may be seen as desirable by some and as a problematic Hawthorne effect by others.

While both perspectives on value likely reflect a shared goal to advance knowledge and improve practice and outcomes for intervention recipients, the philosophical stance of process evaluation researchers and other stakeholders determines views on how this may best be achieved. Process evaluation researchers with a more positivist stance are likely to believe a positive primary outcome result with high internal validity provides the best evidence to improve practice. In contrast, process evaluation researchers with a more interpretivist stance are likely to consider in-depth understanding of how participants experience interventions more likely to result in improved practice and outcomes.

These two perspectives mirror an observation by Mannell and Davis (186) in a commentary on the use of qualitative methods in RCTs. They highlight the two different standpoints of maximising value to a trial protocol and maximising intervention effectiveness. It is clearly difficult to accommodate both perspectives and all the needs and expectations of different stakeholders within a single process evaluation, however it appears important to take into consideration different perspectives on value and critically reflect on potential tensions and trade-offs. Findings on value presented in this chapter therefore highlight the importance of in-depth exploration in case studies of how value and tensions between values and perspectives are negotiated within process evaluation teams and with stakeholders in the contexts in which process evaluations are enacted. Case studies also provide an opportunity to examine more closely how socio-technical processes used to enact process evaluations may create value or negative consequences.

5.4.4 How are process evaluations shaped?

Findings show five broad contextual factors that may shape how process evaluations are designed, conducted, and disseminated. Importantly, findings highlight that these contextual factors may be interpreted differently, for example with researchers making incorrect assumptions about resource availability. The literature also includes solutions to challenges and reflections on resolving dilemmas, suggesting it is valuable for researchers planning process evaluations to seek out

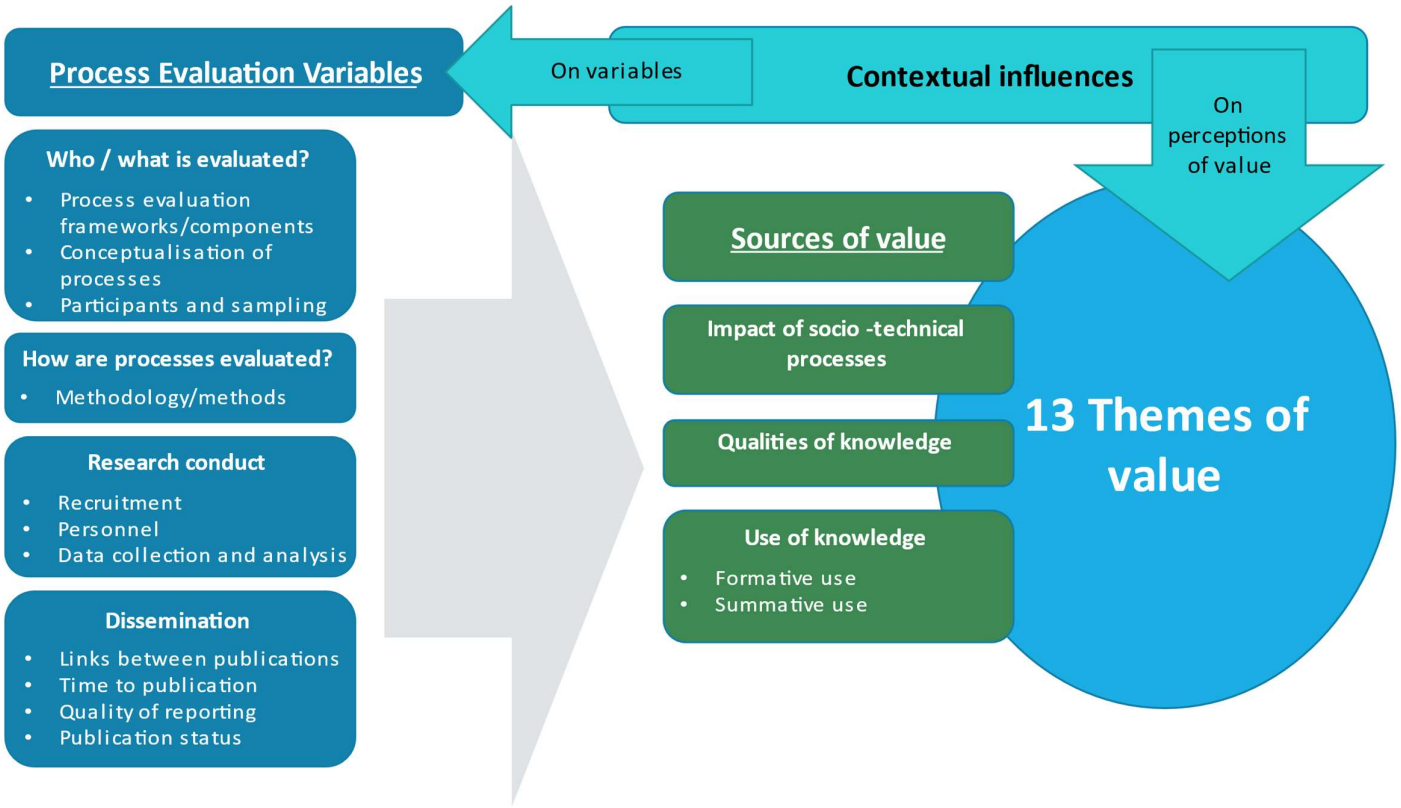
literature to help plan for and address challenges. This demonstrates that detailed examination using ethnographic case studies of how context sets the possibilities for process evaluation design, conduct, and dissemination, and how researchers interact with these contextual factors is warranted. This is particularly pertinent in the context of pragmatic RCTs conducted in real-world healthcare settings, which are by nature complex settings.

The range of debates and opinions about how process evaluations can and should be designed and conducted shows that process evaluations are shaped by researchers' opinions and decisions about philosophical, methodological, and operational issues. Process evaluation guidance and literature usually presents a certain worldview, and this may also therefore shape process evaluations. This suggests it is important for process evaluation researchers to be aware of the range of possibilities and make considered and contextually informed choices about philosophical, methodological, and operational issues from the outset of process evaluation design, in collaboration with stakeholders. It also highlights the value of examining in detail in ethnographic case studies the social processes by which researchers make decisions.

5.4.5 Conceptual framework

The conceptual framework developed from this critical interpretive synthesis (shown again in figure 5.7) provides a structure to inform the design of and situate the findings of the systematic review and ethnographic case studies elements of this thesis. As it was developed from the broad and non-specific literature on process evaluation it provides an overview of the possibilities for process evaluation from which to consider the specific context of complex healthcare interventions evaluated by pragmatic RCTs.

Figure 5.7 Conceptual framework of process evaluation value



5.4.6 Strengths and limitations

The broad inclusion criteria for this review, including relating to process evaluation in various fields and with various outcome evaluation methods, has given a wide range of insight. However, a wide range of potentially informative literature were excluded from this review, including those relating to overlapping fields. This means literature may have been omitted which may have provided different insights, and the findings presented cannot be considered exhaustive.

The author texts used as data for this synthesis may have been influenced by expectations and limitations of publishing journals. Exploring the concepts in this way captures perspectives which authors have decided to publish, and other aspects of value are likely to be uncovered through other methods.

Although I have outlined review methods as explicitly as possible, in line with critical interpretive synthesis (108) the review was by nature interpretive and creative, therefore it is not possible to provide full transparency about step-by-step methods.

This review presents my interpretation of this body of literature, and I acknowledge that this will have been influenced by my pre-existing opinions and knowledge. Nonetheless I used reflexivity and discussed findings and reflections with my supervisors to ensure I did not unduly prioritise certain perspectives.

5.5 Chapter summary

This chapter has presented a critical interpretive synthesis of process evaluation methodology literature, addressing the thesis questions of how process evaluations are defined, valued, and shaped from a broad and non-specific perspective. From this it has presented a conceptual framework to inform the design and situate the findings of the remaining elements of this thesis. The systematic review and ethnographic case studies elements of this thesis now focus on the specific context of process evaluations in pragmatic RCTs of complex healthcare interventions, and

therefore develop and populate this conceptual framework in relation to how process evaluations are defined, valued, and shaped within this context.

Chapter 6 presents the methods, findings, and discussion of the systematic review of the process evaluations associated with a sample of pragmatic RCT primary outcome results papers published in 2015.

6 Systematic Review

6.1 Systematic review introduction, aims and objectives

This chapter presents a systematic review of the process evaluation conducted within a systematically obtained sample of pragmatic RCTs of health services interventions published in 2015.

Its overall aim is to provide a baseline description of the state of process evaluation in the context of pragmatic RCTs in health services research, and to address aspects of each of the three PhD research questions.

Specific objectives are, within a systematically obtained sample of published pragmatic RCTs of health services research interventions to:

1. Describe the process data reported in trial results papers
2. Describe the frequency of separate process evaluation publications
3. Describe use of the label 'process evaluation'
4. Describe the characteristics of process evaluations
5. Synthesise reported practical barriers and facilitators to process evaluation conduct
6. Synthesise the reported values of the process evaluations
7. Describe the accessibility of process evaluation results

Findings from this systematic review have been published (187).

6.2 Addressing the research questions

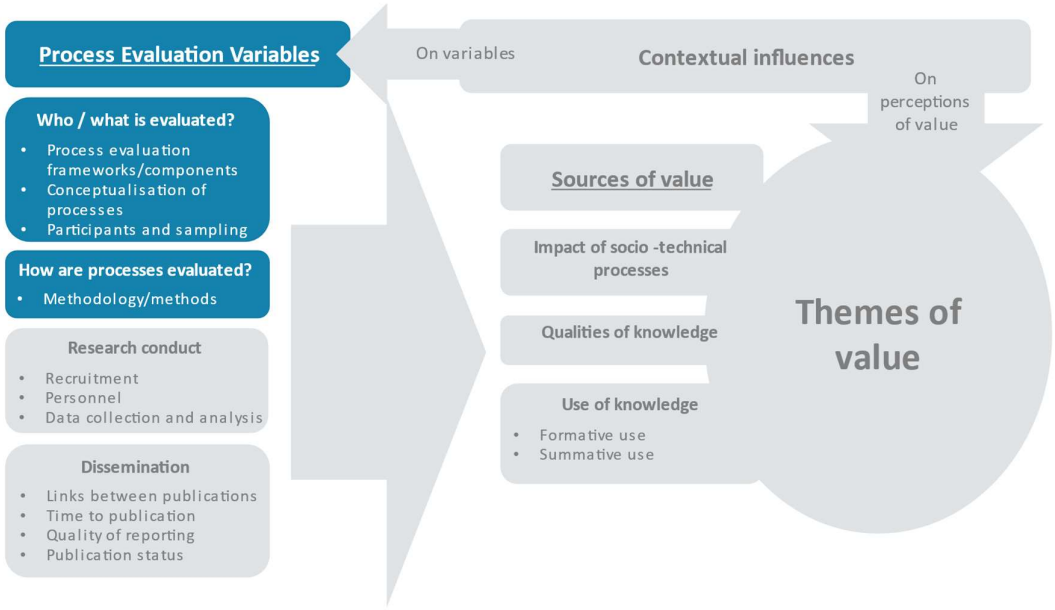
Findings from this systematic review build upon the conceptual framework developed in chapter 5. In this section I show how this review addressed each research question and how findings fit in the conceptual framework.

6.2.1 How are process evaluations defined?

I developed an operational definition of process evaluation to allow me identify process evaluation studies within the index sample of pragmatic RCTs, regardless of how they are labelled. I then described how the studies were labelled and sought to identify any differences between those labelled as process evaluation and those not labelled as process evaluation. I also described data in the index pragmatic RCT results papers which mapped to process evaluation components included in the MRC process evaluation guidance (22).

Findings fit into the coloured sections of the conceptual framework shown in figure 6.1.

Figure 6.1 Conceptual framework elements discussed in systematic review relating to how process evaluations are defined



6.2.2 How are process evaluations valued?

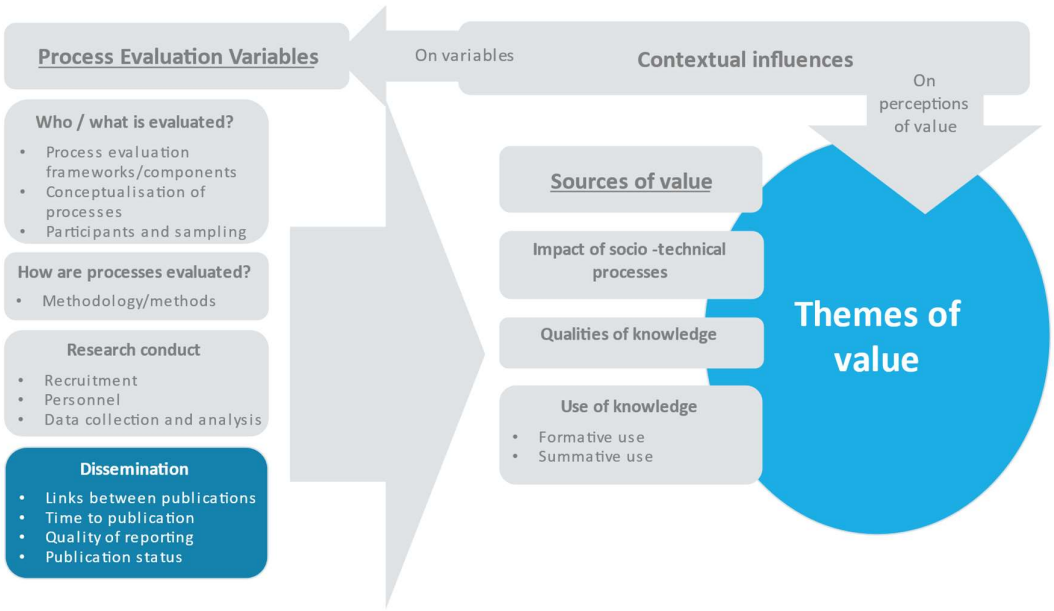
I synthesised any value reported by authors in publications, operationalised as stated rationales for undertaking the process evaluations or implications of the process evaluations.

I also described the frequency of process evaluations in the sample, publication status, the length of time between publication of the pragmatic RCT results and process evaluation, and whether the process evaluation was mentioned in the trial results paper and the trial registry entry. Although

these do not directly inform about value, I may be able to make inferences from these findings to build the overall findings in this thesis.

Findings fit into the coloured sections of the conceptual framework shown in figure 6.2.

Figure 6.2 Conceptual framework elements discussed in systematic review relating to how process evaluations are valued

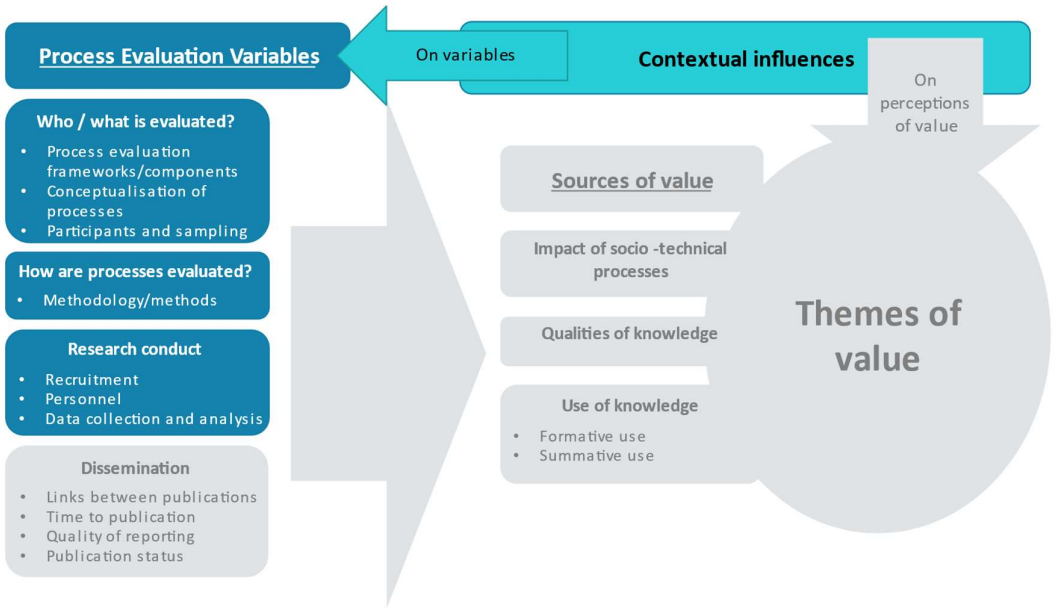


6.2.3 How are process evaluations shaped?

I described any barriers and facilitators to conducting the process evaluations reported by authors. I also described the methods used by each process evaluation and the process evaluation components investigated.

Findings fit into the coloured sections of the conceptual framework shown in figure 6.3.

Figure 6.3 Conceptual framework elements discussed in systematic review relating to how process evaluations are shaped



6.3 Systematic review methods

This is not a traditional systematic review as the aim is to examine methodology and reporting of process evaluations rather than synthesise the findings from those process evaluations.

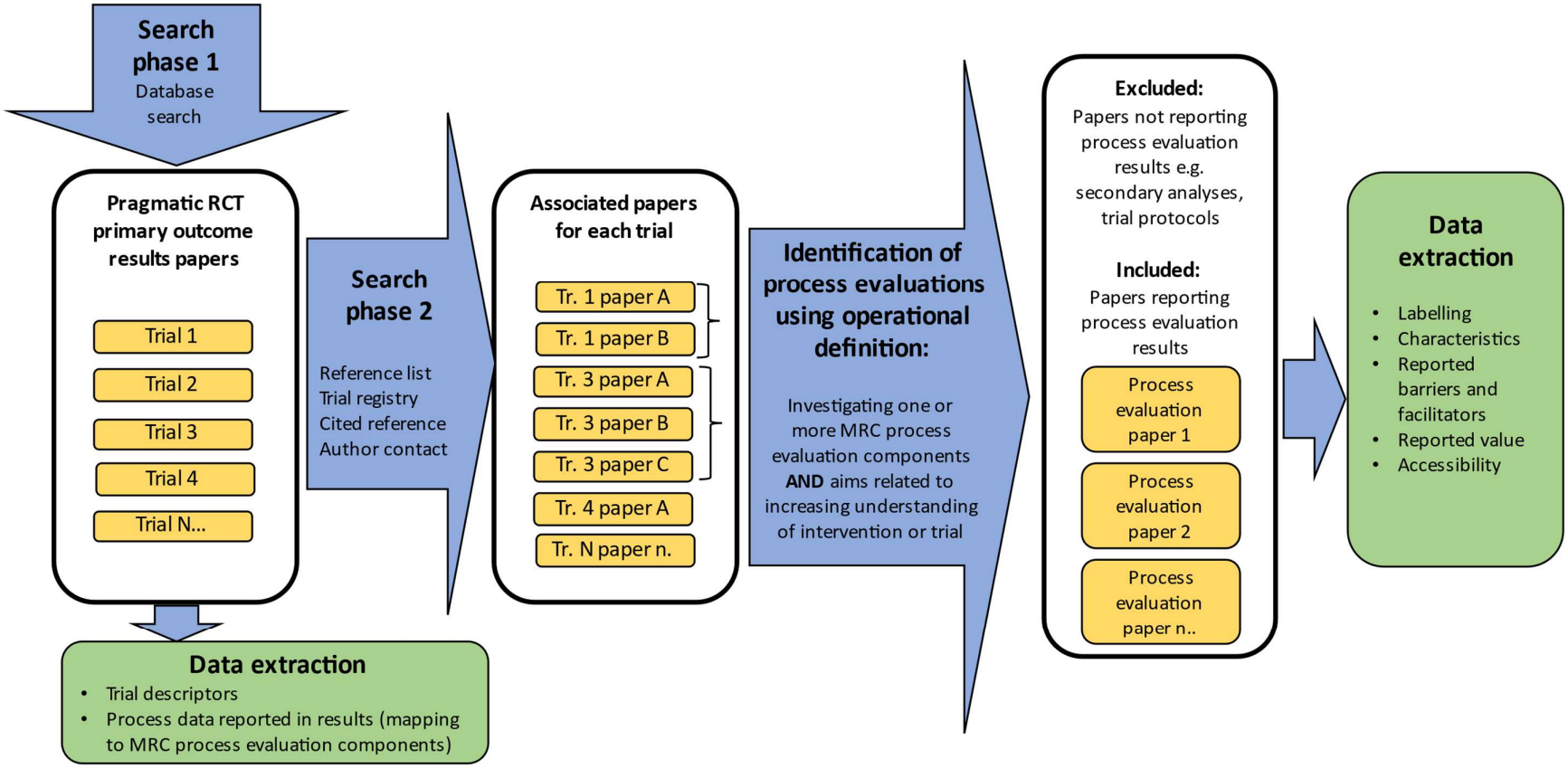
6.3.1 Design overview

Given that I was already aware that the label 'process evaluation' is used inconsistently, a key design challenge was how to identify process evaluations to include. Previous systematic reviews of process evaluations have used two different approaches. Some (56, 133, 188) used primary searches for process evaluations, with search strategies including a variety of alternative terms. Others (77, 78, 111, 189, 190) searched for intervention studies, then examined the process evaluation reported in these studies. Most of the latter only examined process evaluation reported in the article identified in the primary search, however two (78, 111) also undertook secondary searches for process evaluations published as separate papers from the main intervention study.

I decided to follow the two-stage search strategy (78, 111), conducting a primary search for an index sample of pragmatic RCT primary outcome results papers (hereafter referred to as trial papers), then searching for process evaluation publications associated with each index trial paper. This design enabled me to better meet the objectives of this review because it provided information about how frequently process evaluations were conducted and allowed investigation of the 'process evaluation' reported in trial papers.

Figure 6.4 provides an overview of the design

Figure 6.4 Systematic review design overview (reproduced from (187))



6.3.2 Search phase 1

The aim of this phase was to systematically identify a feasibly sized index sample of primary outcome results papers of healthcare research pragmatic RCTs (trial papers). I limited the trial paper publication year to 2015, chosen to allow for a time-lag between publication of the trial papers and additional publications. I also limited the search to publication in Medline Core Clinical journals, due to limited resources and to make the work feasible with a doctorate, while ensuring inclusion of high-profile healthcare research trials.

The only restriction placed on interventions was that they were healthcare interventions delivered by a health service, to distinguish from public health interventions. I did not place any restrictions on intervention complexity as I considered this too difficult to operationalise consistently.

6.3.2.1 Search phase 1 strategy

I conducted the searches using Ovid Medline using the keywords 'pragmatic' and 'trial'. The search strategy is given below.

1. (pragmatic and trial).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

2. limit 1 to (english language and humans and "core clinical journals (aim)" and yr="2015" and (clinical trial, all or clinical trial or controlled clinical trial or pragmatic clinical trial or randomized controlled trial))

6.3.2.2 Search phase 1 inclusion criteria (PICOS)

- ✓ Population: any
- ✓ Intervention: any delivered by a health service

- ✓ Comparator: any
- ✓ Outcome: any
- ✓ Study: pragmatic randomised controlled trial (defined as use of the word 'pragmatic' to describe the RCT in the title or abstract)

6.3.2.3 Search phase 1 exclusion criteria

1. Papers not reporting the primary trial outcome
2. RCTs labelled as pilot, feasibility, or implementation studies.
3. Trials of health interventions not delivered within health services, for example by charities

6.3.2.4 Search phase 1 results screening

I screened titles and abstracts against the inclusion and exclusion criteria, obtaining full-texts when necessary, and keeping records of decisions and reasons for exclusion on an Excel database. A second researcher independently screened results, and any disagreements or uncertainties were then discussed with my supervisors to reach a final decision on inclusion.

6.3.3 Search phase 2

The aim of search phase 2 was to identify all publications associated with each index trial paper identified in search phase 1.

6.3.3.1 Search phase 2 strategy

I used several strategies to maximise the chance of identifying all associated publications. These were carried out in the following order:

1. Reference list screening of trial paper.
2. Searching the appropriate trial registry using the trial registration number in the trial paper.
3. Citation search of trial paper using Web of Science.
4. Citation search of trial paper using Google Scholar.
5. Contacting the corresponding authors of trial papers.

For stages 3 and 4, as well as manually screening the citation search results, I conducted electronic text searches of these for the trial paper's first author surname. This was because it was not always clear from titles, and sometimes from abstracts, that papers were related to the same trial.

For stage 5 I emailed the corresponding authors of the included trial papers and listed the identified associated publications. I asked whether:

- ✓ I had missed any publications
- ✓ Whether any further publications were pending
- ✓ Whether any process evaluation was conducted but not planned to be published (I did not define process evaluation in the email)

During data analysis I realised that some *Health Technology Assessment* (HTA) reports included a publication list in the 'acknowledgements' section. I had not used the method of checking the acknowledgements section in HTA reports to identify associated publications, however following this discovery I did so. I identified one additional publication through this method.

6.3.3.2 Search phase 2 inclusion criteria

I included publications relating to each included trial which either further reported the trial or its methods, or which reported evaluations undertaken in association with that trial. I excluded editorials, letters, systematic reviews and meta-analyses including the trial, and where the trial was part of a series, the reports of the sibling trials.

6.3.3.3 Identifying publications containing process evaluation results

I screened titles and abstracts and when necessary full texts of the publications identified in search phase 2, and categorised each as follows:

- ✓ Process evaluation
- ✓ Trial protocol
- ✓ Extended reporting of trial
- ✓ HTA monograph*

- ✓ Extended follow-up of trial
- ✓ Health economics evaluation
- ✓ Description of intervention / intervention development
- ✓ Pilot / feasibility studies
- ✓ Post-trial development
- ✓ Secondary analysis or sub-study
- ✓ Other

*HTA monographs are published reports of trials funded by the UK *National Institute for Health Research Health Technology Assessment* programme, published in their journal *Health Technology Assessment*. These trials are required to report findings of the trial and all associated evaluations funded by the HTA in this format, additional to any publications in journal articles.

To identify process evaluation studies without the label 'process evaluation' I developed an operational definition, given that I was unable to find a singular definition in the literature:

1. Investigation one or more process evaluation components included in the *Process evaluation of complex intervention: UK Medical Research Council (MRC) Guidance* (22), outlined in table 6.1 below, AND
2. Aim related to increasing understanding of the intervention or trial

Table 6.1 MRC process evaluation components (adapted from (22))

CONTEXT		
Causal mechanisms present within the context that act to maintain the status quo, or enhance effects	**Contextual factors that shape theory of how the intervention works**	**Contextual moderators** *Shape, and may be shaped by, implementation, intervention mechanisms, and outcomes*
IMPLEMENTATION		
Dose *How much intervention is delivered*	**Fidelity** *The consistency of what is implemented with the planned intervention*	**Adaptations** *Alterations made to an intervention in order to achieve better contextual fit*

How delivery is achieved *The structures, resources and mechanisms through which delivery is achieved*	**Reach** *Extent to which target audience comes into contact with intervention*	
MECHANISMS OF IMPACT		
Mediators *Intermediate processes which explain subsequent changes in outcome*	**Participant responses** *How participants interact with a complex intervention*	**Unanticipated pathways and consequences**

The second criterion was used to distinguish process evaluations from secondary analyses and sub-studies which aimed solely to broaden wider knowledge (for example, relating to the wider patient population or validating outcome measures).

Given that this process was subjective I held a consensus meeting with my supervisors. In this we discussed every paper I considered possibly could be categorised as a process evaluation and reached a joint final decision on inclusion.

6.3.4 Data extraction and analysis

As this was a review of methodology and reporting it was not necessary to conduct quality appraisal of the included studies.

I extracted data from all trial results papers identified in search phase 1, and all papers categorised as process evaluations identified in search phase 2. I undertook most data extraction independently, however for parts of the review that were more subjective I undertook double data extraction with the help of colleagues.

6.3.4.1 Trial characteristics

I extracted the data shown in table 6.2 from each trial paper to describe the characteristics of each index trial.

Table 6.2 Data extracted from each trial paper

Data category	Data field
Intervention characteristics	• Intervention type • Setting of intervention delivery • Country of intervention delivery • Intervention recipients • Intervention deliverers • Clinical specialty
Trial characteristics	• Design • Individual or cluster randomisation • Comparator • Funder • Primary outcome result – positive/not positive
Publication characteristics	• Journal name • Month and year of print publication

Appendix 3 details the operationalisation and extraction methods for each data field. The field 'primary outcome result' was in some trials difficult to determine. I therefore discussed uncertainties with one of my collaborators who was a statistician, and any remaining uncertainties with my supervisors, to jointly agree the final categorisation.

I extracted data to an Excel spreadsheet and collapsed free text data into categories. I conducted quantitative descriptive analysis using SPSS.

6.3.4.2 Process evaluation components reported in trial papers

I used the MRC process evaluation components (see table 6.1) to identify all 'process evaluation' reported in trial papers.

I mapped data items reported in the results sections to these components, recording whether each process evaluation component was reported in the trial paper at least once. For example, I mapped a trial flow diagram to the process evaluation component 'reach'. This was complex as the MRC guidance (22) does not clearly define every component and I worked with two colleagues to independently map the first seven trial papers and compare results. I then mapped the remaining trial papers independently and discussed any uncertainties with these colleagues and my supervisors.

I only extracted data from the results sections of the trial results papers. Some trials reported trial results in HTA monographs as well as the trial results paper identified in search phase 1. In these cases, I extracted data on process evaluation components from the index trial paper first, and the extracted from any further data from the HTA monograph which was not included in the index trial paper.

Each time I identified a process evaluation component I also noted the use of any 'process' label. I extracted all data to an Excel database and analysed using SPSS.

6.3.4.3 Process evaluation papers

Some process evaluations were reported across more than one paper. In these cases, I extracted data from all the papers into one dataset for each process evaluation.

Table 6.3 summarises the quantitative data fields collected from each process evaluation identified in search phase 2.

Table 6.3 Quantitative data fields collected from each process evaluation

Category	Data fields
Characteristics	• Process evaluation components investigated • Whether the processes investigated related to the intervention or trial • Methodology • Data collection method
Accessibility (some data also collected for other paper types for comparison)	• Journal publishing process evaluation results • Time to publication of process evaluation results from trial paper • How I found the paper in the search
Links with main trial	• If the process evaluation is mentioned in the trial paper • If the process evaluation results paper refers to the trial • Where in the process evaluation results paper the trial is first named or referenced • If the process evaluation results paper is included in the trial registry
Labelling	• Whether the evaluation was labelled as a process evaluation anywhere in the set of papers for the trial • Evaluation label given in the title of the process evaluation results paper • Any other evaluation label given in process evaluation results paper

I extracted these data to an Excel spreadsheet and analysed using SPSS.

I extracted qualitative data on reported value and reported practical barriers and facilitators to process evaluation conduct. I operationalised 'reported value' as rationales for undertaking the process evaluation or implications of the process evaluation and/or its findings, and operationalised 'barriers and facilitators' as practical issues relating to designing or operationalising the process evaluation. I used NVivo to read each process evaluation results paper, extract relevant sections of text and code these thematically.

6.4 Systematic review results

Search phase 1 resulted in an index sample of 31 pragmatic RCT trial papers and search phase 2 resulted in 21 publications categorised as reporting process evaluation results.

Search phase 1 was performed on 22 March 2018, resulting in a final sample of 31 trial results papers of pragmatic RCTs in health services research.

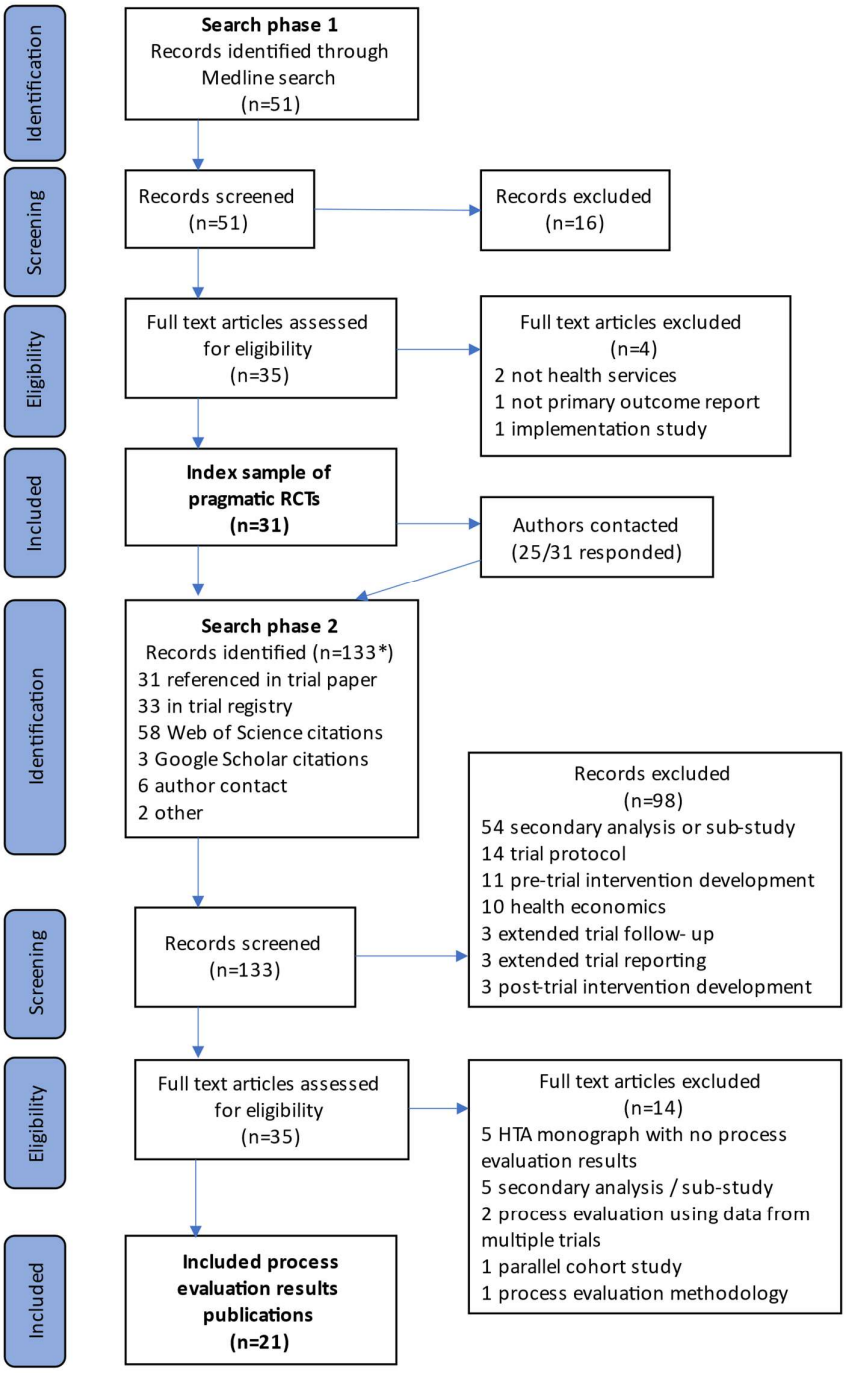
Search phase 2 was originally conducted in March and April 2018. I updated this search phase in December 2019, except contacting authors, to submit this review for publication as I was delayed in completing the review through an interruption of my PhD. I found an additional 30 papers in the search conducted in December 2019, and two were journal articles reporting process evaluations contained in HTA monographs.

25/31 corresponding authors from the trial papers replied to the original requests for information in March and April 2018, and none stated any further process evaluation had been conducted.

The results of the consensus meeting to decide which papers met the operational definition of process evaluation is in appendix 4.

Figure 6.5 provides an flow diagram of the results from search phases 1 and 2, and the categorisation of associated publications.

Figure 6.5 Adapted PRISMA flow diagram (reproduced from (187))



*each paper is included only once reflecting the method by which it was first found.

6.4.1 Description of the sample of pragmatic RCTs identified in search phase 1

Table 6.4 shows the characteristics of health services interventions included in the sample, and table 6.5 shows the characteristics of the pragmatic RCTs.

Table 6.4 Characteristics of health services interventions

Intervention characteristics	Number of trials (n=31)	Intervention characteristics	Number of trials (n=31)
Intervention category		**Clinical specialty**	
Pharmacological treatment strategy	9	Emergency medicine	4
Clinical procedure	4	Asthma	3
Therapy intervention	4	Mental health	3
Clinical treatment strategy	3	Critical care	2
Model of care provision	3	Orthopaedics	2
Reminder system	3	Rheumatology	2
Health promotion	3	Stroke	2
Medical device	2	Ambulance service	1
		Cardiology	1
Setting of intervention delivery		Diabetes	1
Hospitals	13	Endoscopy	1
Mixed	6	ENT	1
Outpatient clinics	4	Faecal incontinence	1
Primary care	4	Falls prevention	1
Community	2	Gynaecology	1
Ambulances	1	Obstetrics	1
Care homes	1	Paediatric immunisation	1
		Palliative care	1
		Rehabilitation	1
Country of intervention delivery		Trauma	1
UK	12		
USA	8		
Australia	3		
Netherlands	2		
Brazil	1		
Canada	1		
France	1		
France, Belgium and Switzerland	1		
Hong Kong	1		
	1		
Intervention recipients			
Patients	28		
Patients and staff	2		
Patients and practices	1		

Table 6.5 Characteristics of pragmatic RCTs

Pragmatic RCT characteristics	Number of trials (n=31)	Pragmatic RCT characteristics	Number of trials (n=31)
Randomisation level		**Comparator**	
Individual	25	Usual care	15
Cluster	6	Other intervention(s)	10
		Stepped-wedge control period	2
Design		Comparing two settings	1
2-arm	22	Comparing two deliverers	1
Non-inferiority (2-arm)	4	No intervention	1
3-arm	3	Sham procedure	1
Crossover	1		
Stepped-wedge	1	**Publishing journal**	
		British Medical Journal	7
Primary outcome result		Lancet	7
Not positive	15	JAMA	5
Positive	11	Canadian Medical Association	2
Non-inferiority trial	4	Journal	2
Unclear	1	JAMA Pediatrics	1
		Critical Care Medicine	1
Funder		Gut	1
Public	25	JAMA Internal Medicine	1
Multiple funders	3	JAMA Psychiatry	1
Charity	1	Journal of Allergy and Clinical	1
Independent Organisation	1	Immunology	1
Unknown	1	New England Journal of Medicine	1
		Nursing Research	1
		The American Journal of Psychiatry	1

6.4.2 Description of the process evaluations identified in search phase 2

The total number of process evaluation studies across the 21 process evaluation results publications was 17, as some were published in both a journal article and HTA monograph. Table 6.6 provides details of the 17 process evaluation studies identified in search phase 2.

Table 6.6 Description of included process evaluations

Reference(s)	Description of process evaluation	Methodology and data collection methods	Intervention or trial processes	Process evaluation components	Labelled as process evaluation
Ball 2018 (191)	Investigated effect of mild cognitive impairment in participants on intervention outcome	Quantitative, Trial dataset	Intervention	Contextual moderators	No
Clark 2015 (192)	Explored patient perceptions of acceptability of intervention in both groups, and motivations for agreeing or refusing to participate in the trial	Qualitative, Interviews	Intervention and trial	Participant responses Reach Contextual moderators Unintended consequences Causal mechanisms in context	No
Grubbs 2015 (193)	Investigated which factors predicted patient uptake of an element of the intervention found to mediate the primary outcome	Quantitative, Medical record review	Intervention	Contextual moderators	No
Handoll 2016 (194) Handoll 2015 (195)	Described how the intended fracture population was practically achieved in pragmatic RCT, including results of formal independent assessment and classification of trial fractures	Quantitative, Detailed author description, Trial dataset	Intervention and trial	Reach	No
Handoll 2014 (196) Handoll 2015 (195)	Described processes undertaken to ensure usual care received by both groups in trial was good quality and comparable, including results of methods described	Quantitative, Detailed author description, Deliverer self-report	Intervention and trial	How delivery is achieved Fidelity	No
Hall 2017 (197)	Investigated mediators of intervention outcome	Quantitative, Trial dataset	Intervention	Mediators	No
Hill 2016 (198)	Explored perceptions of ward staff about how intervention contributed to	Qualitative, Focus groups	Intervention	How delivery is achieved Participant responses	No

Reference(s)	Description of process evaluation	Methodology and data collection methods	Intervention or trial processes	Process evaluation components	Labelled as process evaluation
	outcome, and experience of intervention being delivered on their ward			Contextual moderators Causal mechanisms in context Contextual factors shaping intervention theory	
Hill 2016 (199)	Explored patient experiences of intervention and perceived barriers to engagement	Qualitative, Semi-structured questionnaires	Intervention	Participant responses Causal mechanisms in context Contextual factors shaping intervention theory	Yes
Hill 2015 (200)	Explored perceptions of intervention deliverers of delivering intervention and how the intervention worked	Qualitative, Focus groups, interview, field notes, intervention notes	Intervention	How delivery is achieved Contextual factors shaping intervention theory Participant responses Causal mechanisms in context	Yes
Keding 2019 (201) Handoll 2015 (195)	Explored how patient and surgeon treatment preferences impacted recruitment, trial conduct, and patient outcomes	Quantitative, Trial dataset	Intervention and trial	Reach Participant responses Contextual moderators	No
Knowles 2015 (202) Littlewood 2015 (203)	Explored patient experiences of the intervention, including acceptability, ease of use, barriers to engagement, content, accessibility, and support. Also explored healthcare professional perceptions of feasibility and which patients intervention most suited to.	Qualitative, Interviews	Intervention	Participant responses How delivery is achieved Reach Causal mechanisms in context Contextual moderators Unintended consequences Contextual factors shaping intervention theory	Yes
Nichols 2017 (204) Williams 2015 (205)	Explored experiences of patients about intervention, with focus on patient adherence, and how changed over time	Qualitative, Interviews (longitudinal)	Intervention	Participant responses Causal mechanisms in context Contextual moderators How delivery is achieved	No

Reference(s)	Description of process evaluation	Methodology and data collection methods	Intervention or trial processes	Process evaluation components	Labelled as process evaluation
Novak 2015 (206)	Investigated whether and how trial sites supplied thawed plasma in a timely manner	Quantitative, Detailed author description, Observation, reports from sites	Intervention and trial	Fidelity How delivery is achieved	No
Sands 2016 (207)	Explored how the flexible complex intervention was delivered in real-world complex settings	Qualitative, Trial dataset	Intervention	How delivery is achieved Adaptations Contextual moderators Participant responses Unintended consequences Contextual factors shaping intervention theory Fidelity	No
Saville 2016 (208)	Explored preferences and experiences of intervention deliverers about various aspects of intervention	Quantitative, Questionnaire	Intervention	How delivery is achieved	No
Tjia 2017 (209)	Investigated patients' perceptions of benefits and drawbacks of intervention	Quantitative, Questionnaire	Intervention	Participant responses	No
Vennik 2019 (210) Williamson 2016 (211)	Explored views and experiences of parents and practice nurses of intervention and usual care	Qualitative, Interviews	Intervention	Participant responses How delivery is achieved Contextual factors shaping intervention theory Causal mechanisms in context Unintended consequences	No

6.4.3 Results objective 1: Describe the process data reported in trial papers

The 31 trials reported a median of 5 (IQR=3; range 1-9) process evaluation components in their trial papers. None of these were labelled as process evaluation in any trial paper.

Table 6.7 shows how many trial papers included each process evaluation component.

Table 6.7 Process evaluation components in the trial papers

Process evaluation component	Number of trial papers reporting the component n=31
Reach	31
Contextual moderators	20
Participant responses	20
Unintended pathways and consequences	19
Causal mechanisms that act to maintain the status quo, or enhance effects	12
Fidelity	12
Adaptations	11
Contextual factors that shape theory of how the intervention works	10
Dose	8
Mediators	2
How delivery is achieved	0

Appendix 5 lists the included 31 pragmatic RCT results papers, and the process evaluation components reported in each. Appendix 6 shows the data items mapped to each process evaluation component in the trial papers and process evaluation papers.

6.4.3.1 Other 'process' labels

There was very infrequent and inconsistent usage of any 'process' labels in the trial papers, with four trials using a 'process' label for one or more items. These alternative labels are detailed in table 6.8 below and were not used consistently within trial papers.

Table 6.8 Use of 'process' labels

Label	Item	Process evaluation components	Number of trial papers using label
Process measures	Treatments implemented by intervention deliverer	Fidelity	1
	Median times taken to deliver aspect of intervention	How delivery is achieved / fidelity	1
	Participant satisfaction with treatment; Participant performance of home exercises; Number of sessions attended by participants	Participant responses	1
Process outcomes	Median number of intervention sessions delivered to patients	Dose	1
	Number of patients completing action plan; Participant asthma control	Participant responses	2
	Frequency and reasons for nonadherence to treatment algorithm by patient and deliverer	Participant responses / fidelity	1

6.4.4 Results objective 2: Describe the frequency of separate process evaluation publications

Twelve of the 31 pragmatic RCTs had at least one associated publication classified as reporting process evaluation results. There were 17 distinct process evaluation studies published across 21 publications, with some published in both a journal article and HTA monograph. Two trials (212, 213) had three process evaluations studies and one trial (214) had two process evaluation studies. Although it is likely that these multiple process evaluations in the same trials formed part of one overall process evaluation, as each was presented as a distinct study, I extracted data from each individually.

6.4.4.1 Comparison of process evaluation frequency with other evaluations conducted alongside trials

Table 6.9 shows process evaluations were conducted with a slightly lower frequency to health economics evaluations and secondary analyses/sub-studies, although several trials conducted more than one secondary analysis/sub-study.

Table 6.9 Frequency of process evaluations and other evaluation types

Type of evaluation	Number of trials including at least one of each evaluation (n=31)	Total number of each evaluation
Health economics	14	14
Process evaluation	12	17
Secondary analysis/sub-study	15	58

6.4.5 Results objective 3: Describe use of the label 'process evaluation'

Only three of the 17 identified process evaluation studies were labelled as process evaluations (199, 200, 202, 203) and all were qualitative studies. Only one of these was clearly labelled as 'process evaluation' in the article title (200). One was described as 'informing a process evaluation' in the main article text (199). The other was referred to as a process evaluation by the trial paper (215), but not labelled as a process evaluation in the reporting journal article (202) or HTA monograph (203).

One further study was not labelled as a process evaluation but cited the MRC process evaluation guidance was as a rationale for undertaking it (197).

One trial (212) had three qualitative studies published in the same journal: a qualitative interview study labelled as 'a process evaluation' (200), a qualitative questionnaire study reported as 'informing the process evaluation' (199), and a qualitative interview study labelled as a 'qualitative evaluation' (198). The articles indicated that the studies were interlinked, and formed a 'sequential mixed-methods study' (200).

None of the journal articles reporting process evaluation results (n=16) used the keyword "process evaluation"**.**

6.4.5.1 Labels used in process evaluation publications

Table 6.10 shows the labels given to the process evaluations in the titles of their reporting papers (16 journal articles and 5 HTA monographs).

Table 6.10 Type of study named in titles of process evaluation publications

Title label	Number of reports (n=21)
None	14
Qualitative study	3
Qualitative evaluation	2
Content analysis	1
Qualitative interview study	1
Qualitative process evaluation	1

Of the 14 reports with no title label, one used a label - 'qualitative study' - within the paper.

6.4.6 Results objective 4: Describe the characteristics of process evaluations

6.4.6.1 Methodology

Nine process evaluations were quantitative (191, 193-197, 201, 206, 208, 209) and eight qualitative (192, 198-200, 203-205, 207, 210, 211). The reporting articles of three quantitative process evaluations (194, 196, 206) also presented detailed narrative descriptions of trial or process evaluation methods.

6.4.6.2 Data collection methods

Of the 8 qualitative process evaluations, 4 collected data using interviews, 1 used focus groups, 1 used questionnaires, 1 used trial data (therapy notes), and 1 used a combination of methods (focus groups, interview, researcher reflective notes, and deliverer notes).

0f the 9 quantitative process evaluations, 4 used trial data, 2 collected data using questionnaires, 1 collected data from participant medical records, 1 used deliverer self-report, and 1 used observation and provider-report.

6.4.6.3 Trial or intervention processes

Five process evaluations evaluated both trial and intervention processes (192, 194-196, 201, 206). Of the latter, one explored patients' experiences of trial participation qualitatively (192) and two described in detail the trial processes undertaken to ensure fidelity (196, 206). One investigated the trial processes for defining the pragmatic RCT trial population, by undertaking independent assessment of the radiographs used by recruiting surgeons to determine trial inclusion (194). Another investigated the impact of surgeon and patient treatment preferences on trial recruitment and adherence to trial follow up (201).

6.4.6.4 Process evaluation components

Table 6.11 shows the number of process evaluations reporting each MRC process evaluation component

Table 6.11 Number of process evaluations reporting each MRC process evaluation component

MRC Process evaluation component	Number of process evaluations reporting this component (n=17)
Participant responses	10
How delivery is achieved	9
Contextual moderators	8
Causal mechanisms present within the context	7
Contextual factors that shape theory of how the intervention works	6
Reach	4
Unexpected pathways and consequences	4
Fidelity	3
Adaptations	1
Mediators	1
Dose	0

6.4.7 Results objective 5: Synthesise reported practical barriers and facilitators to process evaluation conduct

I identified three main themes of reported practical barriers and facilitators. These were:

- Collecting complete and accurate data in health services settings
- Recruiting the process evaluation participants
- Complex regulatory systems.

6.4.7.1 Collecting process evaluation data in real-world health services settings

There were reports of challenges to obtaining routine clinical data for use in process evaluation and of both barriers and facilitators to collecting primary data for the process evaluation. Table 6.12 summarises these.

Table 6.12 Barriers and facilitators to collecting process evaluation data in healthcare settings

	Barriers	**Facilitators**
Routine clinical data	Needing to make repeated requests for data (194) Standard formats of data not being optimal for use in the process evaluation (194)	
Primary process evaluation data	Patients being tired (199) Interruptions (199) Unexpected patient transfer or discharge (196, 199)	Involving clinical staff responsible for collecting data in form design (196) Ensuring forms fit with routine clinical data collection (196) Using tick boxes (196) Piloting forms (196) Paying hospitals for data return (196) Learning from previous trials (196)

6.4.7.2 Recruiting the process evaluation sample

Several papers reported difficulties recruiting process evaluation participants in health services settings, however several also reported solutions to challenges. Table 6.13 summarises these barriers and facilitators.

Table 6.13 Barriers and facilitators to process evaluation recruitment

Barriers	Facilitators
Trial recruitment slowing (202, 203) Clinical staff leaving post or not having enough time to participate (198) Sites selected to participate in process evaluation not having enough participants with certain characteristics to meet planned sampling frame (204) NHS restructuring meant unable to get timely governance approval to recruit from a site (202, 203)	Conducting an additional interview with a staff member unable to participate in a focus group (200) Changing the protocol from focus groups to interviews to offer flexible times and locations (202, 203) Use of telephone interviews to enable recruitment from all sites (192) Using convenience sampling to pragmatically ensure adequate recruitment (202, 203)

6.4.7.3 Complex regulatory systems

One process evaluation (201) which quantitatively investigated the effect of patient treatment preference on trial processes and outcomes reported that the funder requested they did not undertake a qualitative study. The authors also report that they did not receive ethical approval to ask patients declining trial participation reasons for declining, which they consider would have enhanced the process evaluation.

In another process evaluation report it was noted that patient care journeys being spread over multiple settings meant multiple research governance approvals were required to collect process evaluation data (196).

6.4.8 Results objective 6: Synthesise the reported values of the process evaluations

Process evaluations were reported as adding value to the intervention, adding value to the trial, or adding value to something external to the trial and intervention. Within these three categories were 13 sub-categories of value.

Figure 6.6 summarises these values. Table 6.14 provides further details of each value with examples, and the number of process evaluations reporting each value.

Figure 6.6 Summary of reported values of process evaluations (reproduced from (187))

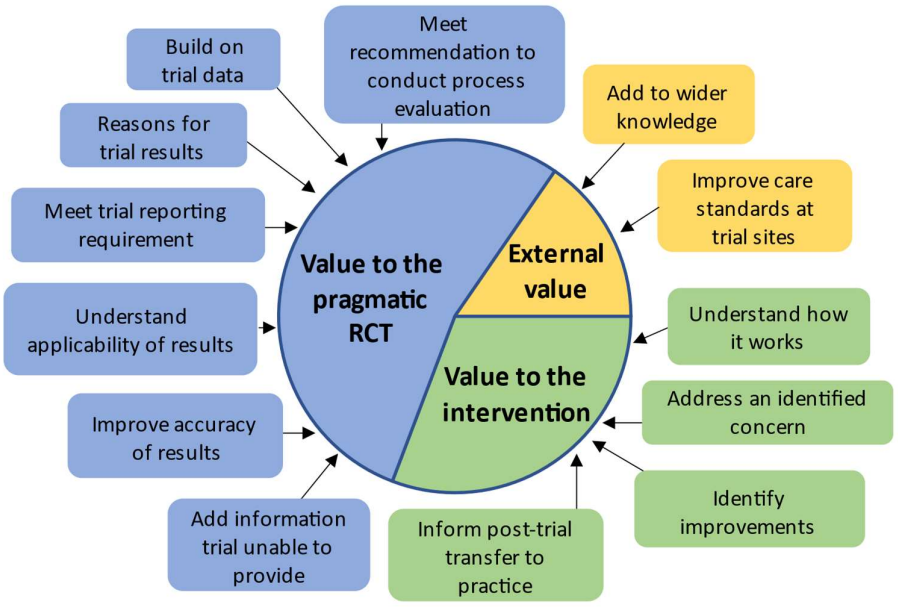


Table 6.14 Details of reported values of process evaluations

Value category with details	Process evaluations reporting this value (n=17)
Adding value to the intervention	
Supporting implementation of the intervention into practice • Targeting or tailoring the intervention to specific patients • Aiding replication of a complex intervention • Understanding how patients engage with the intervention • Understanding providers' viewpoints and willingness to collaborate • Developing tools / strategies for implementation • Targeting the intervention to specific groups • Highlighting important components of the intervention to implementers • Highlighting benefits of the intervention to promote uptake • Highlighting effective delivery strategies • Providing evidence of feasibility / acceptability • Tailoring delivery to different groups • Highlighting importance of roles of different people / agencies in ensuring successful delivery • Addressing barriers to implementation or uptake of the intervention • Recommendations for training or support to participants or deliverers • Suggesting how intervention could fit into existing care pathways • Highlighting potential disadvantages of the intervention • Recommendations for information to give to patients considering intervention • Recommendations for clinicians to help decide between interventions • Recommendations for further intervention implementation research • Highlighting lack of equipoise in deliverers	15
Improving the intervention Recommendations for further development of the intervention based on process evaluation findings: • Recommendations to keep all components of the intervention • Adding stronger monitoring protocols to promote adherence • Adaptations to design for patients with reduced cognition Recommendations for further research relating to the intervention: • Effectiveness over time • Effectiveness in different contexts • Different modes of delivery e.g. group settings • Intervention refinement, e.g. to improve patient experience	10
Addressing an advance concern about the intervention • Acceptability of the intervention to patients / deliverers • Participant adherence • Complexity of intervention delivery • Influence of participant cognition on intervention effectiveness	7
Understanding how the intervention works	4

Value category with details	Process evaluations reporting this value (n=17)
• Intervention mechanisms • Content delivered in a flexible intervention	
Adding value to the pragmatic RCT	
Providing reasons for trial results • Possible reasons for non-positive trial results • Explanations for positive trial results • Explanations for other trial data	8
Adding information not provided by the trial • Participant or deliverer concerns • Key components of intervention • Added clarification, nuance, context • Perspectives of participants after time for reflection • Concurrent treatments received by trial participants • Experiences and perceptions – things important to participants, minority views	6
Informing about the accuracy of trial results • Assessing comparability of standard care between both randomised groups • Qualitative findings helping confirm quantitative data on satisfaction • Avoid survivor bias • Accurately define the trial population and facilitate purpose and interpretation of trial • Investigating threats to internal validity	6
Building on trial data • Explore findings from a subgroup analysis conducted in the trial • Expand on the quantitative questionnaire data collected in the trial about participant acceptability and satisfaction	2
Meeting trial reporting requirements • Meeting CONSORT requirements for pragmatic and nonpharmacologic trials	1
Meeting recommendation to conduct process evaluation • Citing recommendation by MRC process evaluation framework to conduct mediation analysis	1
Understanding the applicability of trial results • Evaluating whether the intended pragmatic trial population was achieved in the trial • Investigating threats to external validity from patient or provider treatment preference	2
Explaining issues with trial conduct • **Reasons for requiring recruitment extension**	1
Address a concern identified in advance about the trial	1

Value category with details	Process evaluations reporting this value (n=17)
• **Threats to recruitment, internal validity and external validity from patient and provider treatment preferences**	
Adding value external to the intervention or RCT	
Contributing to wider knowledge • Future trial design • Understanding patient populations and patient experiences • Understanding the problem addressed by the intervention • Improving clinical practice in the field • Informing design of similar interventions • Highlighting that findings supported or refuted the existing knowledge base • Methodological recommendations	16
Improving usual care at trial sites ✓ Highlighting gaps in current care provision	1

Values relating to the pragmatic RCT design

Very few articles specifically discussed value in relation to the pragmatic nature of the RCT. One process evaluation article (207) highlighted that the presented qualitative content analysis describing 'the pragmatic reality' of intervention delivery would facilitate post-trial replication of a highly flexible intervention in complex settings. Another process evaluation article reporting a qualitative interview study with intervention recipients and providers (211), maintained that findings offer real-life insights to facilitate post-trial implementation.

The reports of three process evaluations belonging to the same trial (194-196, 201) discussed in detail how the process evaluations supported the validity of pragmatic RCT results. In one (194, 195) the process evaluation confirmed that the pragmatic RCT sample was pragmatic as intended, and supported the pragmatic methods used to assess RCT eligibility. In another (195, 196) the process evaluation provided evidence of comparable real-world clinical practice in both the intervention and usual care delivered across trial sites. The final process evaluation (195, 201) assessed the impact of real-world patient and surgeon preference on internal and external validity of the pragmatic RCT.

6.4.9 Results objective 7: Describe the accessibility of process evaluation results

6.4.9.1 Publication status

All process evaluations included in the final sample (n=17) had published their results. None of the trial paper authors who responded (25; n=31) stated that they had undertaken a process evaluation which was unpublished. The results of an excluded process evaluation with a published methodology paper (216) were not published at the time of this review. The first author of the methodology paper informed me that she had presented results in her PhD thesis but had not had time to publish them in a journal yet (217).

6.4.9.2 Publishing journal

16 process evaluations published results in journal articles, and none were published in the same journal that published the trial paper. The journals publishing the process evaluation results are shown in table 6.15.

Table 6.15 Journals publishing process evaluation results

Journal	Number of process evaluation results journal articles (n=16)
BMJ Open	4 (3 from same trial)
Bone and Joint Research	2 (2 from same trial)
Academic Pediatrics	1
Arthritis Care and Research	1
British Journal of General Practice	1
British Journal of Occupational Therapy	1
Disability and Rehabilitation	1
Journal of Palliative Medicine	1
Journal of Traumatic Stress	1
Open Heart	1
Transfusion	1
Trials	1

Six of the 12 trials with process evaluation(s) were funded by the UK NIHR HTA programme and published an HTA monograph (192, 195, 203, 205, 211, 218). One HTA monograph contained findings from 3 process evaluations studies (195). One process evaluation was only reported in the HTA monograph (192). Six process evaluation studies were published at least in part in both a journal article (194, 196, 201, 202, 204, 210) and HTA monograph (195, 203, 205, 211). Two process evaluations were part of HTA funded trials; however results were only reported in journal articles (197, 207), not HTA monographs.

6.4.9.3 Time to publication

Table 6.16 shows the median number of months from print publication of the trial paper to online publication of the process evaluation results in the different formats identified in the search.

Table 6.16 Time between publication of trial paper and process evaluation results

Publication type	Median number of months to publication from trial paper
Journal article (n=16)	15.5 (range -3 – 42; IQR 18.25)
HTA monograph (n=5)	1 (range 0-4; IQR 3).
Soonest of journal article or HTA monograph (n=16)	5 (range 0-36; IQR 15.5)

6.4.9.4 Mention of the process evaluation in trial paper

Thirteen of the 17 process evaluation studies (191, 193, 197-201, 204-207, 209-211) had no mention in their corresponding trial papers.

6.4.9.5 Process evaluation publication inclusion in trial registry

Twelve of the 16 process evaluation journal articles (191, 197-201, 204, 206-208, 210) were not included in the trial registry entries. The five HTA monographs reporting process evaluation findings (192, 195, 203, 205, 211) all appeared in the trial registry. Therefore, 9/17 process evaluations were published in a publication (journal article or HTA monograph) that was included in the trial registry entry.

6.4.9.6 Search method required to locate process evaluation publications

A forward citation search of the index trial paper was required to locate 9/16 of the process evaluation journal articles. Two process evaluation journal articles (206, 207) did not appear in the trial results paper, trial registry, or forwards citation searches. These were located by chance before contacting authors as they were mentioned in other papers associated with the trials.

6.4.9.7 Mention of the trial in the process evaluation paper

All process evaluation journal articles (n=16) named or referred to the associated trial somewhere in the paper, however 9/16 did not name or explicitly link it to the trial in the title or abstract (191, 193, 194, 198-200, 208-210).

When the trial was not named in the title or abstract it was difficult to identify the process evaluation in the citation search results.

6.5 Systematic review discussion

6.5.1 Summary of findings

Table 6.17 summarises the findings from each objective of this systematic review.

Table 6.17 Summary of systematic review findings

Objective	Findings
1: Describe the process data reported in trial papers	All trial papers reported data which mapped to process evaluation components, with a median of 5 components per trial
2. Describe the frequency of separate process evaluation publications	Approximately one third (12/31) of the pragmatic RCTs included in this review had published process evaluations, published across a total of 17 papers
3. Describe use of the label 'process evaluation'	Only 3/17 process evaluation studies were labelled as process evaluation, and of these only one contained the term 'process evaluation' in the title of the paper. These numbers were too low to conduct any meaningful comparison between studies labelled as process evaluation and those not labelled as process evaluation. Apart from the three labelled as process evaluation being qualitative, I noted no distinguishing features.
4. Describe the characteristics of process evaluations	The 17 process evaluations employed a variety of qualitative (8/17) and quantitative (9/17) methods and evaluated a broad range of process evaluation components, including trial processes.
5. Synthesise reported practical barriers and facilitators to process evaluation conduct	The review identified several barriers to conducting process evaluations in real-world health services contexts, relating to data collection, participant recruitment, and regulatory systems. Nevertheless, some authors also shared solutions and facilitators to successful data collection and recruitment.
6. Synthesise the reported values of the process evaluations	Authors reported a wide range of values process evaluations brought to interventions, pragmatic RCTs, and the wider research and practice arena.
7. Describe the accessibility of process evaluation results	Accessibility and visibility of process evaluation results was often suboptimal as many process evaluations were not mentioned in trial papers and few process evaluation journal articles were included in trial registries. The median time to publication of process evaluation articles following trial results articles was over one year. Not naming trials in titles or abstracts of process evaluation publications, and not labelling or indexing them as process evaluations made locating process evaluations in citation searches of trial papers difficult. Nevertheless, when published in HTA monographs process evaluations were generally timely and easily accessible.

6.5.2 How are process evaluation defined?

Findings from this systematic review concord with findings from the critical interpretive synthesis in chapter 5, that there appears to be no clear definition of process evaluation. The term is used inconsistently in publications, even in reports of studies relating to the same trial. Extensive process data were published in the trial papers in this sample of pragmatic RCTs, and the distinction between this suite of process data and 'a process evaluation' is unclear. It is also unclear whether the authors of study reports included in this review because they met the operational definition of process evaluation, of which only 3/17 were in some way labelled as a process evaluation, considered their studies to be process evaluations or not, or if labelling decisions related to publication factors.

6.5.3 How are process evaluations valued?

Findings show a wide range of ways in which process evaluations may add value to interventions, pragmatic RCTs, and wider knowledge. The values identified in the synthesis of values reported by authors of process evaluation reports (section 6.4.8) mostly fit within the value themes relating to how the use of process evaluation knowledge identified in the critical interpretive synthesis in chapter 5, namely:

- ✓ Supporting implementation of interventions into practice
- ✓ Improving the intervention
- ✓ Knowledge accuracy (providing information to aid accurate interpretation of pragmatic RCT results)
- ✓ Knowledge completeness (providing information not provided by pragmatic RCT results)
- ✓ Contributions to wider knowledge
- ✓ Meeting a requirement

The value of improving usual care at trial sites was also identified, which is a new value theme from those identified in the critical interpretive synthesis.

Findings from this systematic review also show that despite this wide range of reported values, in 2015 process evaluations were far from routine in pragmatic RCTs of healthcare interventions, with only approximately one-third of pragmatic RCTs in the sample including one. Findings from this review are unable to provide insight into the reason for this finding, however it could be inferred that, at the time these pragmatic RCTs applied for funding, process evaluations were not valued highly enough by researchers and/or funders in this context to make them more routine.

Findings on visibility and accessibility of process evaluation reports in relation to trial primary outcome reports are significant to the question of value. From the starting point of a pragmatic RCT primary outcome report, there were significant barriers to even identifying that process evaluations had been conducted and to locating reports. This reflects the issues relating to dissemination of process evaluations identified in critical interpretive synthesis (section 5.3.4.3), and highlights that the potential value provided by process evaluation knowledge is likely difficult to maximise when there are not direct links between outcome and process evaluation publications. At the time of publishing most process evaluation reports included in this review the MRCs process evaluation guidance was published, which includes reporting guidance emphasising the importance of linking publications (22).

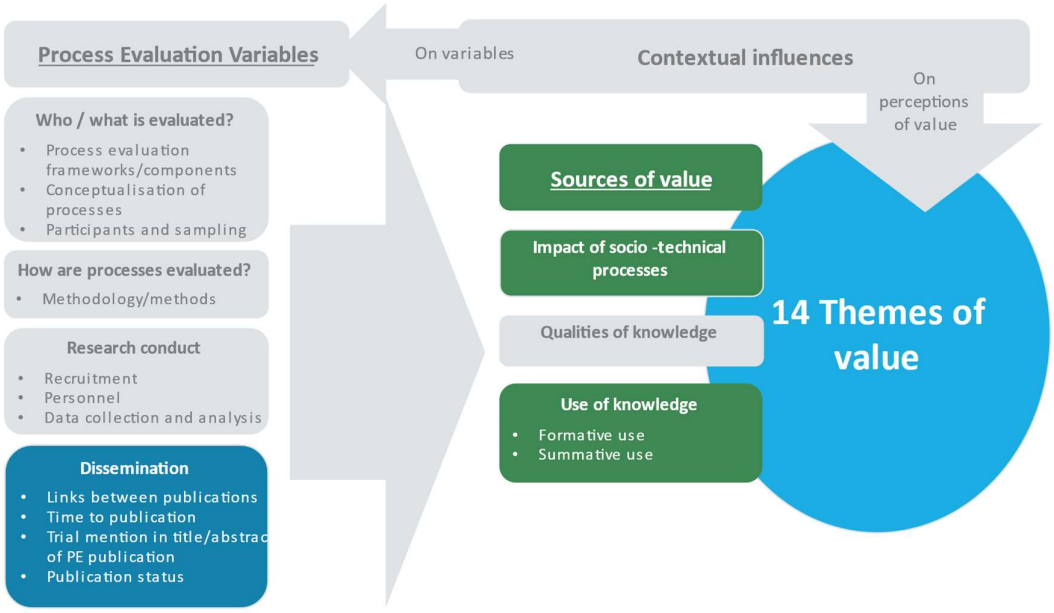
Of course, as most included studies were not labelled as process evaluations this may explain why this guidance was not followed, however reasons for this lack of accessibility and linkage are likely to be more complex. It is reasonable to infer that this divorcing of process evaluation reports from pragmatic RCT primary outcome reports likely reflects a lesser status afforded to process evaluations. Many process evaluation journal articles did not mention their connections to the trial in their titles and abstracts, and contributions to wider knowledge was the most widely reported value. This reflects the MRC process evaluation guidance advice that authors may need to emphasise the ways in which process evaluation findings are more widely applicable to secure publication (22). However, given that the process evaluations in this context are conceived to be

part of pragmatic RCTs, and the knowledge they produce may add considerable value to interventions and pragmatic RCTs, it is reasonable to question why their publications are often divorced and portray process evaluations to a degree as a sub study rather than an integral part of the overall evaluation of a complex healthcare intervention.

It is important to highlight however that some HTA monographs reported process evaluations alongside pragmatic RCT outcomes and integrated discussion of findings, which demonstrates a useful reporting format.

Figure 6.7 shows how the findings relating to how process evaluations are valued from this systematic review fit in the conceptual framework developed in chapter 5.

Figure 6.7 Systematic review findings relating to value



6.5.4 How are process evaluations shaped?

Findings from this review echo findings from the critical interpretive synthesis that process evaluations may have a wide range of characteristics. Nonetheless findings do not shed light on how

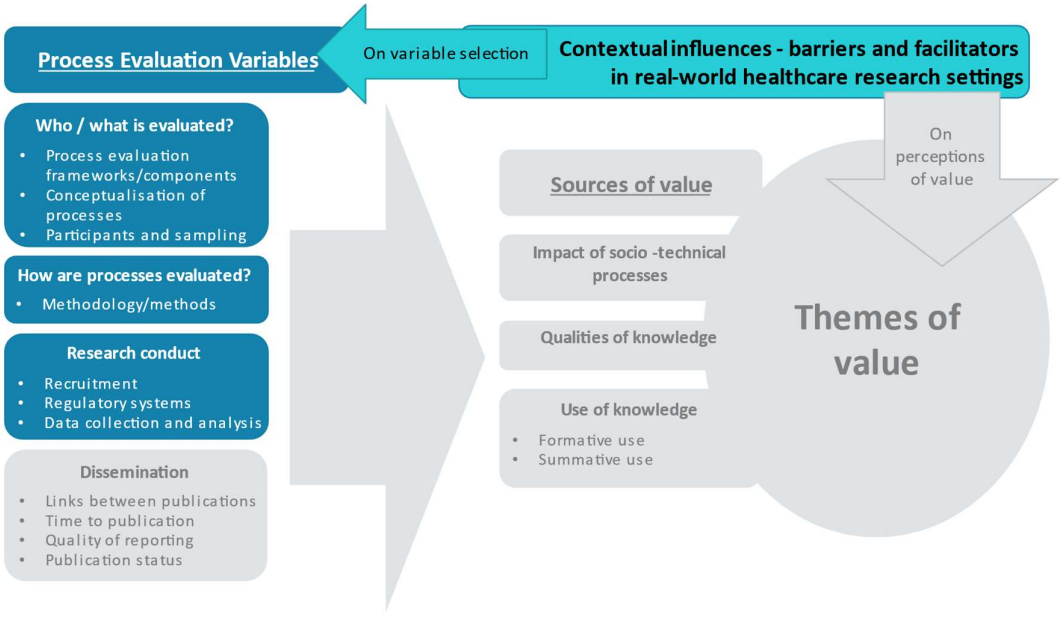
process evaluations came to have these characteristics, and therefore in-depth examination of the social processes leading to design decisions in ethnographic case studies is important.

Findings on barriers and facilitators to conducting process evaluations echo and add new insights to the contextual factors shaping process evaluations identified in the critical interpretive synthesis in section 5.3.5. The barriers identified in this systematic review all related to the challenges of conducting process evaluations in real-world healthcare contexts, relating to collecting timely and quality data, recruiting participants, and navigating healthcare research regulatory systems. This again demonstrates that in-depth exploration of the realities of conducting process evaluations in pragmatic RCTs in healthcare contexts is warranted.

Findings also show however, similar to the critical interpretive synthesis, that it is possible to find solutions to challenges and conduct process evaluations successfully in potentially challenging healthcare contexts. It is therefore important to examine in the case studies whether and how researchers are able to anticipate and address challenges, and not simply regard barriers and facilitators as deterministic shaping factors.

Figure 6.8 shows how these findings relating to how process evaluations are shaped fit into the conceptual framework developed in chapter 5.

Figure 6.8 Systematic review findings relating to how process evaluations are shaped



6.5.5 Strengths and limitations

A significant strength of this review is that it was based on an index sample of pragmatic RCTs, rather than an index sample of process evaluations. This enabled me to gain information about the frequency of process evaluations conducted, including in comparison to other types of evaluation conducted within these RCTs. It enabled scrutiny of all identified associated publications to each trial which could be considered process evaluations, thereby highlighting inconsistencies in labelling and the nuances of what may or may not be considered a process evaluation. It also enabled me to identify the large number of process evaluation components which were reported in the trial papers.

This review was necessarily based on a sample of pragmatic RCTs, meaning the degree to which findings are representative of process evaluation practice in pragmatic RCTs not included is uncertain. Nevertheless, the sample was selected systematically and with robust double-checking of trial inclusion. Trials reported in journals not included in Medline Core Clinical Journals were not included, however given the journals included the sample is likely to include the most high-profile and best funded trials published in 2015. Trial reports identifying the trial as pragmatic elsewhere in the trial paper to the title and abstract were not included, which may have affected the findings.

Using the MRC process evaluation framework to identify these process evaluation components was a further strength, given that it is the most recent and high-profile framework. However the challenges encountered applying this bring limitations to the review findings. I involved 2 independent reviewers in the process and spent considerable time attempting to define each component, however it is possible that others would have defined these differently and obtained different findings. Nonetheless I have listed the items included for each component, allowing readers to judge their agreement. I did not have time or resources to create final operational definitions for each process evaluation component, and then reapply these to the whole sample. This means the quantitative findings about the frequency of each component in the trial papers may be slightly inaccurate, however, I consider the whole process was sufficiently robust to provide useful indicative information. This section of the review proved much more challenging than anticipated, and the final method was a pragmatic solution to a complex task.

The search for associated publications was comprehensive and robust, using a variety of approaches and with most authors responding to the request for information. There is therefore only a small chance that a process evaluation was missed.

The process for categorising associated publications was robust, including detailed consideration of papers which could be classed as process evaluations with my supervisors, who have extensive experience of conducting process evaluations. Nevertheless, some of our final decisions were borderline, and others may have categorised these differently and included different evaluations in the final sample of process evaluations. However, the complexity of the task of categorising evaluations as process evaluations or not is itself an interesting finding.

I conducted most data extraction for this review alone, given that I did not have the resources to undertake full double data extraction, increasing the possibility of errors and omissions. Nonetheless I did enlist help to double data extract the most subjective data fields.

In synthesising the value and barriers and facilitators reported by authors, finding are limited to those that authors chose to report. Papers reporting results are unlikely to articulate problems or negative impacts of process evaluations, or lack of perceived value in relation to the trial. Findings do not therefore provide an exhaustive list of values or barriers and facilitators.

At the time of completing the write up of this thesis in 2022 it is important to reflect that if this systematic review were to be conducted again with more recent pragmatic RCT results publications, the results are likely to be different in some respects. With eight years having passed since the publication of the MRC process evaluation guidance (22), pragmatic RCTs being published now were likely designed with this guidance available and more awareness of process evaluations. It is therefore likely that more trials would include a process evaluation, and that more would use the label. As the guidance included reporting guidelines which emphasised the importance of linking process and outcome publications (22), it can be hoped that this has led to improved accessibility of process evaluation findings. Furthermore, while updating the critical interpretive synthesis presented in chapter 5 for publication, I noted an increase in papers reporting the use of more complex and varied methods for process evaluation, suggesting that the characteristics of process evaluations would likely also have become more diverse.

6.6 Chapter summary

This chapter has presented a systematic review of process evaluations associated with a sample of primary outcome results papers from pragmatic RCTs of healthcare interventions published in 2015. Findings have built on the conceptual framework developed in the previous chapter and have addressed the research questions of how process evaluations are defined, valued, and shaped specifically in the context of pragmatic RCTs of complex healthcare interventions.

Chapter 7 now presents the methods, findings and discussion of three focused ethnographic case studies of process evaluations within pragmatic RCTs of healthcare interventions conducted in the UK and funded by the NIHR.

7 Focused ethnographic case studies

7.1 Case studies introduction

This chapter presents the methods and findings of focused ethnographic case studies of three process evaluations conducted within NIHR-funded pragmatic RCTs in the UK. Although I conducted single case analyses as part of the analysis process, the primary analytic output is a cross-case analysis.

The aims were:

- ✓ To explore how the process evaluations were defined
- ✓ To identify ways in which the process evaluations had created value, were creating value and had the potential to create value
- ✓ To understand differences in how the process evaluations were valued among stakeholders and how these differences were negotiated
- ✓ To understand how the process evaluations were shaped by stakeholders and contexts

In section 7.2 I outline the focused ethnographic case study methodology and rationales for this choice. I then provide details of the methods and research processes used, and ethical considerations in section 7.3.

In section 7.4 then introduce and explain how I operationalised and applied the theoretical framework of Translational Mobilisation Theory (TMT) (86) to the study. I also explain how I applied the conceptual framework developed in chapter 5.

I describe the three case studies and their associated pragmatic RCTs in section 7.5, before presenting the four themes of findings from the cross-case analysis in section 7.6. Within these findings I include some discussion in relation to the wider literature when this aids interpretation of

findings which are not directly related to the research questions, for example organisational literature on teamwork. The chapter concludes in section 7.7 with consideration of strengths and limitations.

The main discussion of case study findings to answer the research questions, in relation to findings from chapters 5 and 6 and the wider literature is presented in chapter 8.

7.2 Case studies methodology overview

This study was a focused ethnographic multiple case study design, drawing on Stake's instrumental multiple case study approach (93) and focused ethnography (219, 220).

In this section I outline the multiple case study approach and focused ethnography and discuss why these fit the aims of this study. I also discuss the participant/observer role and the insider/outsider status of the researcher, the positions I adopted and how I fulfilled them, and the reasons for my choices.

7.2.1 Multiple case study design

As Stake (93) highlights, the multiple case study design is well suited to studying how the same phenomenon (in this instance process evaluation) operates at different sites. Each case is formed of a network of people, activities, relationships, problems, and contexts, and a feature of case study research is to examine these holistically (93). The aim is to study real cases operating in real contexts, and collect and portray multiple views and experiences relating to the same case (93). This approach therefore yields greater understanding of situational complexity and how the unique contexts of each process evaluation may result in the same phenomenon taking on '*different lives or forms, depending on the particular hosts or local conditions'* (93) p. ix.

The multiple case study design therefore appealed to me as an opportunity study what going on in process evaluations in depth and in real time. I viewed it as well suited to the research questions and underlying critical realist position of this PhD, because it would facilitate understanding of how

people may have different perceptions of value, and how different perspectives are negotiated to shape the process evaluations.

Stake (93) highlights tension between paying attention to understanding the issues in each single case and paying attention to the overall aims of the multi-case analysis. He underlines the importance of understanding the unique contexts of each single case so these do not become lost in the final multi-case analysis. In this study the theoretical framework, TMT, enabled me to separately explore the influence of individual contexts of each single case and then in the cross-case analysis examine differences between contexts to address the research questions.

7.2.2 Ethnography

Stake (93, 221) does not refer to ethnography in his discussions of case study methods, and the case study approach is flexible and amenable to a variety of qualitative and quantitative methods and ontological and epistemological standpoints (222). Differences and similarities between ethnography and case study approaches have been discussed, with Willis (223) noting more parallels than distinctions. Nonetheless I considered it helpful to explicitly employ ethnographic principles to inform the design of these case studies.

Both the case study approach and ethnography place value upon studying the whole, in contrast to reductionist research approaches which value studying interactions between isolated variables (104, 224). Both aim to collect data in real-world settings where the phenomenon is occurring, rather than abstractly in artificial settings (223). Stake's case study approaches are interpretive (93, 221) and thus have more in common with the ethnographic aim of untangling multiple complex and potentially opposing perspectives (134), than do more positivist case study approaches such as those of Yin (222).

The ethnographic focus on human behaviour and its cultural influences is not necessarily a feature of case study approaches. As human behaviour was at the heart of the research questions (humans create and shape process evaluations, and value is created and experienced by and for humans) I

considered using ethnographic principles to inform the case studies highly relevant and valuable. This became more heightened from my scoping work and personal experiences and reflections (see chapter 2) in which I became fascinated in the ways researchers behaved as humans, and the underlying human social processes that create scientific knowledge.

The ethnographic approach also allowed me to seek out and embrace ambiguity, nuance, and unpredictability to understand process evaluations as complex projects operating in complex social and cultural contexts (134). This reflects my stance and the findings of the critical interpretive synthesis (chapter 5) on the value of process evaluations being subjective and context dependent. Through ethnography I also reinforced my aim to gain an emic perspective of process evaluations and exploring the perspectives on value of the researchers undertaking them, rather than imposing an etic perspective (116).

7.2.3 The focused ethnographic multiple case study design

The words 'instrumental' and 'focused' in the context of ethnographic case studies emphasise that the aim was to gain insight into a specific pre-defined issue of interest, in this case how the process evaluations were valued and shaped. This is in contrast to intrinsic case study (221) and conventional ethnography (219), which would have been a more open-ended in-depth exploration of (most likely) a single process evaluation.

Focused ethnography differs from conventional ethnography through:

- ✓ Focus on a specific issue (220)
- ✓ Episodic short-term field visits (220)
- ✓ Intensive data collection methods such as digital recording of short, focused episodes of data collection, rather than writing fieldnotes over an extended period (219)
- ✓ The researcher having background knowledge of the phenomenon and the cultural group (220)

I decided to conduct three focused ethnographic case studies with findings presented as a cross-case analysis rather than a more in-depth single case study for four reasons.

Firstly, a single in-depth ethnographic case study would have involved either becoming a participant in a process evaluation through obtaining a formal role, or spending extended periods observing the day-to-day activities of team members such as through spending time in a research office environment. This was impractical due to personal circumstances, and I also considered day-to-day research work to be less amenable to direct observation compared to more active work such as clinical work. It may also have presented more ethical challenges, particularly relating to confidentiality of intellectual property and sensitive participant data. The characteristic episodic field visits of focused ethnography (219) were more practical, presented fewer ethical challenges, and lent themselves well to the work of conducting process evaluations which often centres around formal episodic events.

Secondly, given the broad aims of my research questions and that the lack of previous research in this area made this study exploratory, I considered examining multiple cases rather than a single case more likely to result in a broader overview of how process evaluations are valued and shaped.

Thirdly, I considered the between-case comparisons enabled by a cross-case analysis would yield rich insights into the influence of context on the process evaluations and enable greater understanding of potential shaping factors. Finally, given my extensive and experience of working in healthcare research, I had the recommended background knowledge of the phenomenon and the cultural group I was studying (220).

While I considered focused ethnography an excellent fit for researching the conduct of process evaluations and for my prior knowledge and experience and practical constraints, focused ethnography has been criticised for being superficial compared to conventional ethnography. Nonetheless Knoblauch (219) counters that the short period of data collection is compensated by

the intensity of data collection through recording, with intensive and more detailed data analysis of shorter episodes rather than less intensive analysis of longer episodes.

7.2.4 The participant or observer role

It is generally agreed that there is a continuum between solely being a participant and solely being an observer (225). I took primarily an observer role in each case study, however I was aware that it was very likely that I could become a participant to some degree, even if this was unintended. In my capacity as a PhD student studying process evaluation, I knew I may be asked for advice or opinions which may in some way alter the phenomena I was studying.

I discussed this issue with the chief investigators and lead process evaluation researchers at the start of the case studies, who understood the implications and expressed interest in supporting my research aims. In all three cases we agreed I would not take an active participation role and they would not seek my opinions about their process evaluation, however if people asked me general questions about process evaluation, I would answer them. I noted and reflected in my fieldnotes when this occurred, these instances thus becoming part of the data.

Appropriate sharing of the researcher's knowledge with participants may lead to greater acceptance and trust, as well as acknowledge participants' contributions to the research (225). I considered this important in this study, as many participants expressed interest in my work, and sharing my knowledge and reflections when requested felt to me important to facilitate rapport and cooperation, and convey respect and gratitude to participants. I also considered that this could help mitigate the potential consequence participants feeling their performances were being judged through being observed, which may cause them to alter their behaviour (226). To further mitigate against giving the impression participants' performances were under scrutiny I emphasised throughout the consent process and fieldwork that the research purpose was to explore and understand, rather than judge against external standards.

7.2.5 Insider or outsider status

I considered myself a relative outsider within the case studies as I was not a team member or employed within the organisations hosting the process evaluations. This carried potential advantages and disadvantages. Participants may have been cautious about expressing concerns or controversial opinions, or felt they should portray themselves, their team, and/or their organisation in a good light in the presence of an outsider (225). This may have been especially pertinent in the highly regulated arena of healthcare research. Conversely however, outsider status may have allowed me to ask questions about everyday occurrences to which answers are seemingly obvious, but may provide significant insight (225).

Nonetheless I considered I also had a degree of insider status given my role as a PhD researcher and career background as a research nurse and research assistant with extensive experience of working on health services research RCTs in the NHS and academia. I highlighted these roles on the participant information sheet, and mentioned them in informal conversations with participants. I considered this would facilitate data collection by building rapport with participants. Nonetheless I was mindful of not sharing my experiences in a way that could potentially influence participants' views and behaviour, that is not 'contaminating' these case studies by bringing in my own experiences. I continuously reflected on my insider-outsider status and the potential impact of this on the data throughout the study (225). I also paid attention how I dressed, presented myself, and communicated with participants throughout the fieldwork. I aimed to fit in and be unobtrusive to prevent outsider status being a barrier to data collection (225).

7.2.6 Section summary

This section has discussed the rationale for and methodological considerations of the focused ethnographic multiple case study design, and my role as a participant/observer and insider/outsider status. The next section details the research design, methods, research processes and ethics of the study.

7.3 Case study methods

This section details the research design and methods used. I first provide an overview of the study design, then discuss sampling and recruitment of cases. I then discuss the potential ethical issues raised by the study and how I addressed these, including obtaining consent from participants. Finally, I outline the data collection and analysis methods, and how I undertook triangulation.

7.3.1 Research design overview

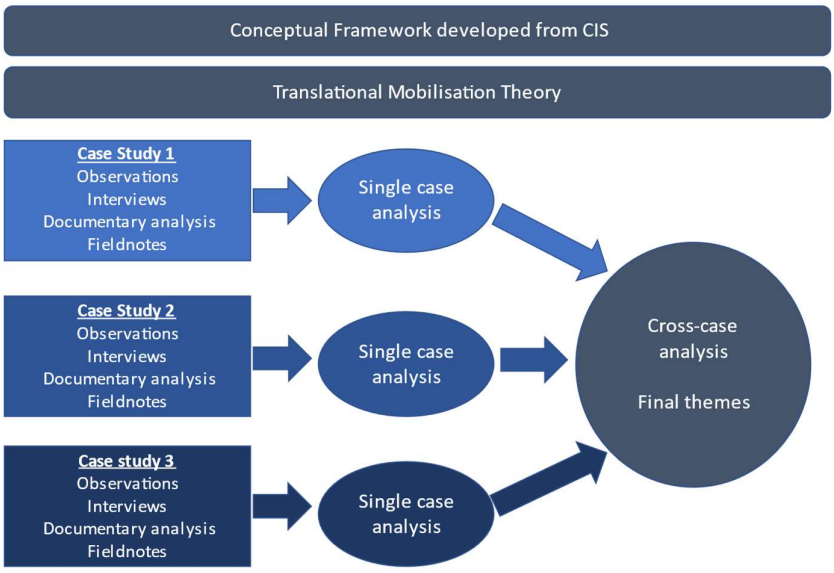
I included three process evaluations (cases) being conducted within pragmatic RCTs in the UK and funded by the NIHR.

The focus of these case studies was the emic perspectives of the research teams designing, conducting, and disseminating the process evaluations. I collected data only from actors with direct responsibility for or involvement in aspects of the design, conduct, and dissemination of the process evaluations and pragmatic RCTs, including researchers and clinicians. I did not collect data from participants in the process evaluations or pragmatic RCTs, or any other stakeholders. Although their perspectives would have added important insights, focusing only on the research teams but across three different single case studies enabled me to closely examine research team perspectives.

I collected data from the cases and their contexts using fieldnotes, interviews, observations of meetings, and documentary analysis.

I used the conceptual framework developed in the critical interpretive synthesis and TMT to inform data collection and analysis of the single cases. I then conducted a cross-case analysis to identify final themes answering the research questions of this PhD. Figure 7.1 shows an overview of the case studies design.

Figure 7.1 Case studies design overview



7.3.2 Sampling of cases

With my supervisors I judged that three case studies would be feasible and provide rich opportunity for cross-case analysis comparison of how contexts shape process evaluations and influence how they are valued.

I aimed to purposively sample cases which shared certain elements of context to enable some degree of like for like comparison. These shared characteristics were being conducted in pragmatic RCTs funded by the NIHR in the UK. However as identified in section 5.3.5, the nature of the intervention, outcome evaluation, and research settings of process evaluations may influence how they are valued and shaped. I therefore aimed to include process evaluations which varied on contextual factors, namely:

- ✓ Healthcare setting
- ✓ Host organisation

- ✓ Type of intervention
- ✓ Healthcare specialty

I also aimed to select cases at different stages in the research process to gain insight into the planning, conduct, and data analysis stages.

7.3.2.1 Case inclusion criteria

- ✓ Process evaluation being currently conducted within a pragmatic RCT of a nonpharmacological healthcare intervention
- ✓ Process evaluation and pragmatic RCT being conducted solely in the UK
- ✓ Pragmatic RCT funded by the NIHR

7.3.2.2 Case exclusion criteria

- ✓ Process evaluations not within pragmatic RCTs (for example within feasibility and pilot studies)
- ✓ Process evaluation researchers, pragmatic RCT chief investigator, or trial manager do not consent to participation

7.3.2.3 Approaching and inviting cases to participate

I obtained ethical approval to approach and recruit cases via the following methods:

- ✓ Direct invitation via email via professional contact details (available in the public domain), such as contact authors in publications, or contact details on funder websites.
- ✓ University research departments, Clinical Trials Units and the Research Design Service – identification of current researchers meeting the inclusion criteria, and sending invitations to participate, by a nominated person in that organisation.

I received expressions of interest from several researchers who were planning to conduct a process evaluation however none met the inclusion criteria.

Through discussion with my supervisors, due to potential concerns about confidentiality, we judged that I would be more likely to gain access to collect data from in-progress NIHR funded RCTs if they provided introductions via colleagues they anticipated would be interested in and willing to host my study. Therefore, there was an element of convenience sampling as the three cases that were included were all recruited via introductions from my supervisors. My supervisors were also co-investigators on two of the included process evaluations.

7.3.3 Ethics

The study was approved by the Queen Mary University of London ethics committee (reference QMREC2050a).

7.3.3.1 Consent of cases

Once the process evaluation researchers and RCT chief investigator expressed interest in participation I sent them the participant information sheet. I discussed the study with the chief investigators and process evaluation lead researchers, and anyone else they considered necessary, via email or face-to-face meetings as convenient to them.

Once they had agreed to participate, they agreed to take responsibility for undertaking any checks with host organisations (such as clinical trials units) that there was no objection to participation. I provided documents about this study for the RCT site files as requested.

I agreed the time period of involvement in the cases and which data I would collect with the chief investigators and process evaluation lead researchers.

7.3.3.2 Individual participant consent

I obtained written informed consent from all interview participants and all people present when observed meetings were audio-recorded, using the participant information sheets and consent forms in Appendix 7.

I obtained signed consent from participants once for the whole case study, verbally checking for continuing consent when there was ongoing participation.

It was important to inform participants that informal conversations and events outside of the formal meeting spaces could also form part of my observations (221), and I set this out in the participant information sheet.

Due to the introduction of GDPR regulations and on instruction from the Queen Mary University of London ethics committee, the participant information sheet and consent forms were updated in July 2018. In agreement with the ethics committee participants signed the new version of the consent if they provided data after the change, but it was not necessary to reconsent participants who had already provided data and who did not provide further data.

I observed meetings relating to the RCT and wider research programmes as part of context data collection. In agreement with the chief investigators and ethics committee I took field notes but did not audio-record these, and people present at these meetings did not sign a consent form. Rather the chief investigator checked prior to the start of the meeting that there was no objection to my presence and taking notes for the study. This was because some meetings involved large numbers of people and we considered it would be difficult and potentially disruptive to obtain signed consent forms from everyone prior to the meeting.

7.3.3.3 Potential ethical issues

Table 7.1 outlines the ethical issues I considered when designing the study and the actions taken to address them.

Table 7.1 Case studies potential ethical issues

Potential ethical issues	Actions
Confidentiality The researcher will have access to data which may contain confidential intellectual property, or may have negative implications for professional reputation. The researcher will not have access to any identifiable data from participants in the research study being investigated.	All identifiable data about individuals, organisations and research studies will be anonymised in raw data, write-ups and all dissemination activities. The chief investigators and lead process evaluation researchers will be offered the opportunity to approve manuscripts for confidentiality concerns prior to publication. Any identifiable participant data (i.e. consent forms and participant contact details) will be stored securely and separately from research data. Participants will provide written informed consent prior to any audio-recording. Audio-recordings will be deleted following transcription and checking. All transcripts and fieldnotes will be anonymised and stored electronically in accordance with Queen Mary University of London data security guidelines. During case studies, if participants reveal any issues which may be sensitive (such as disagreements between team members), permission will be sought to sensitively discuss these in data collection with other team members, if this would be appropriate to the aims of this research. During case studies, the researcher will check that any documents provided for analysis contain no identifiable data from participants in the research study being investigated, and request these to be anonymised if necessary.
Participant burden The topic of the research is related to professional activities and not considered sensitive or contentious. Nonetheless it is recognised that any topic has potential to cause distress. Participants will give their time to participate in the study. This may be inside or outside of work time, depending on their preference. Interviews are likely to take up to an hour.	Participants may withdraw consent at any time Participants may pause or stop episodes of data collection at any time Should a participant become distressed the researcher will offer to pause or stop the data collection episode, and discuss issues in confidence. If necessary the researcher will direct participants to appropriate occupational support. All data collection will occur at a time and location convenient to participants (in a public location or place of work)

Potential ethical issues	Actions
	Participants will not receive any reward or incentives, however may benefit from reflection on practice. If requested, the researcher will share relevant resources, knowledge and insights with participants.
Observing malpractice Although considered unlikely, it is possible that the researcher may observe instances of serious research malpractice	The researcher will discuss any concerns with her supervisors in order to decide an appropriate course of action.

7.3.4 Data collection

7.3.4.1 Cases and contexts

I defined process evaluations as the cases and the associated pragmatic RCT as part of their contexts. It is recognised that often boundaries between cases and context are blurred (222) and certainly there are often significant areas of overlap between process evaluations and pragmatic RCTs. For example, the same researchers may conduct the pragmatic RCT and the process evaluation, and data may be collected for both the pragmatic RCT and process evaluations on the same questionnaire.

However, given that I have already identified the potential difference in relative status between process evaluation and pragmatic RCTs, and that process evaluations are often presented as separate studies (as discussed in chapter 6) it was important to separate the process evaluation from the pragmatic RCT and view it as the case, and consider how was valued by and in relation to the RCT, as well as the value it created for the pragmatic RCT.

It was also a central issue to investigate how the process evaluation and pragmatic RCT may on one hand formed a complete project and on the other hand may be regarded as separate and with potentially competing and contradictory values (as discussed in chapter 5).

I did not plan prospectively to collect data about any other specific element of context, apart from the pragmatic RCTs, rather to be guided by the issues arising within each case to collect data from elements of the wider context which appeared pertinent to the research questions.

7.3.4.2 Being in the field

I conducted an initial data collection for each case study from summer 2018 to early 2019. I then interrupted my PhD for 9 months and conducted a further period of data collection from March to October 2020.

As each process evaluation and RCT were conducted across multiple organisations there was not a single geographical location that defined the field. The field was spread across multiple locations including universities, healthcare settings, and governance organisations.

In keeping with focused ethnography, I conducted intermittent field visits within each case study for a specific purpose, which in all cases was pre-arranged and to observe formal meetings held in university buildings. During these visits I was able to opportunistically have informal conversations with participants and observe informal interactions between them.

The Covid pandemic began during the data collection period, and all activity within the case studies began to take place online. I therefore also observed online meetings and conducted all interviews online via video calls.

I also was copied into emails between researchers on occasion and these also became part of the field.

As I was only able to collect data for a relatively short period of the lifespan of the process evaluations and RCTs and did not have capacity to analyse unlimited qualitative data I created a core dataset to aim to collect for each case study. This core dataset, shown in table 7.2, ensured comparability across cases, and was created with guidance from my supervisors based on their extensive experience in the field. I then collected additional data on a case-by-case basis depending

on what was happening in the process evaluations and following suggestions from the researchers about potential informants who could provide data relevant to my research questions.

The only context data I included in the core dataset related to the pragmatic RCT. I decided which other context data to collect according to issues that arose during data collection.

Table 7.2 Case studies core dataset

Data collection method	Core dataset
Documents	**Case – process evaluation**
	• Protocol and amendments • Participant information sheets and consent forms • Participant invitation documents • Funding applications • Publications • Web pages relating to the process evaluation
	Context - RCT
	• Protocol and amendments • Participant information sheets and consent forms • Funding applications • Publications • Web pages relating to the RCT
Observations	**Case – process evaluation**
	• At least one process evaluation meeting
	Context - RCT
	• At least one trial management group meeting or similar
Interviews	It is likely that these interviewees will be involved in both the process evaluation and the RCT, and so both case and context data will be collected in the same interview. Interviewees may also be able to provide data on other elements of context. • Process evaluation lead researcher • Chief investigator of RCT

7.3.4.3 Reflexive fieldnotes

I kept ongoing fieldnotes for each case study noting down general impressions, questions, and observations as they occurred to me and following any interactions with participants. I included my own administrative interactions with participants as data, for example emails arranging meeting observations, as these often provided useful insights into participants' concerns and contexts.

Continuous reflection on preconceptions, emotions and possible reasons for interpretations of events is important, and can be achieved through a reflexive diary and inclusion of personal reflexivity in field notes and the final report (225).

Fieldnotes included my reflections on my potential influence on the process evaluations and their contexts, as I became part of the context of the process evaluations. I also reflected on my own assumptions and biases and how these may be influencing my interpretations. I paid attention to how my own assumptions affected which data I chose to collect and the interpretations I made of the data I did collect.

Stake (93) states it is difficult to balance under-anticipating (being too open-minded) and over-anticipating (using existing concepts too rigidly), highlighting the need to anticipate what might be important but be prepared for subtle unexpected issues. I regarded the concepts I brought into data collection and analysis as tools to guide me, sensitise me to possibilities, and prompt participants to deeper and more extensive responses. However, I used these loosely and aimed to seek the emic perspective on what was important to participants.

7.3.4.4 Observations

I observed formal meetings in person or online. During the periods of data collection I discussed with the lead process evaluation researchers which meetings were most appropriate to observe, taking into account my research aims and any potential for my presence to be detrimental to certain meetings.

With consent of all attendees I audio-recorded process evaluation meetings. Digital recording allowed me to then focus attention during meetings on ethnographical reflections, observations, and points of interest (219). As discussed in the ethics section, I took field notes only of pragmatic RCT meetings as to gain individual consent from all attendees for audio-recording was potentially too disruptive to the research teams.

I took minimal notes during in-person meetings to avoid giving participants the impression they were under scrutiny and potentially causing discomfort or disrupting the normal flow of meetings. I wrote up extensive field notes as soon as possible after each meeting.

In all meetings I checked with the chair where they would prefer me to sit, and reflected in fieldnotes the attention I paid to my own presentation and potential impact on the meeting as an observer.

7.3.4.5 Piloting observational data collection

With permission of attendees, I observed a meeting of a process evaluation held in my department, not included as a case study, to pilot observational data collection procedures. From this I understood the utility of audio-recording meetings where possible so I could focus writing field notes on descriptions and impressions of social processes and context, rather than documenting the content of the discussions. It also helped me reflect on how I could position myself in the room and collect data unobtrusively and sensitised me to observe social processes such as power dynamics in the live case studies.

7.3.4.6 Interviews

Due to Covid I conducted all interviews online via a video meeting platform convenient to participants. Because all participants were professionals and had experience of meeting via video this did not cause any obvious problems. Furthermore, with the exception of two researchers, I had already met participants at least once face-to-face, which facilitated rapport and information sharing.

I created a core interview guide and adapted it for the different roles participants had in the process evaluation or context, and incorporated questions following up issues I had observed. The core index guide is in Appendix 8.

Interviews were semi-structured with open questions and opportunities for participants to talk about any issues they considered important and relevant additional to the questions asked. I began interviews by asking participants for information about their background and role. This served the dual purpose of gaining descriptive contextual information and helping participants feel at ease.

As highlighted by Blaikie (227) I was aware that interview participants may be have been going about their work in an unreflective, taken-for-granted manner, and therefore my job as the researcher was to encourage reflection to discover their meanings and interpretations. I therefore used prompts from the concepts in the literature review, TMT, and emerging themes to try to encourage deeper reflection in interviews.

I was also conscious that I was often interviewing senior researchers and qualitative researchers with extensive experience, which heightened my awareness of my own 'performance'. I was also conscious to strike a balance between probing for deeper reflection and underlying meaning and avoiding alienating participants by appearing to be trying to catch them out. I referred to guidance on elite interviews (228) in preparation, and reflected after interviews on whether my concerns had led me to hesitate in asking what I perceived as more difficult questions.

7.3.4.7 Documents

I collected documents as agreed with process evaluation lead researchers in electronic format. As well as analysing these documents in isolation in the same way as interview and observation transcripts, I examined the whole set official documents for each case study (such as protocols and participant information sheets). This was to note differences between the value that was emphasised in different documents, for example to patient participants and to staff participants.

7.3.4.8 Data management and security

I created a case index and case file for each case study. I stored electronic documents and audio files in a password-protected file on a password-protected laptop, backed up on two encrypted USB

drives stored in separate secure locations. I stored paper documents in a secure location at my home address.

I imported all documents into NVivo for analysis and stored the NVivo files securely in the same locations described above.

7.3.5 Data analysis

As highlighted by Stake (221) p71 '*There is no particular moment when data analysis begins'*.

I began data analysis throughout the data collection phase, including in the process of gaining access to and organising the case studies. I formed and noted initial impressions, interpretations, and points of interest. My fieldnotes from observations and interviews include points of analysis and interpretation, as well as documenting events.

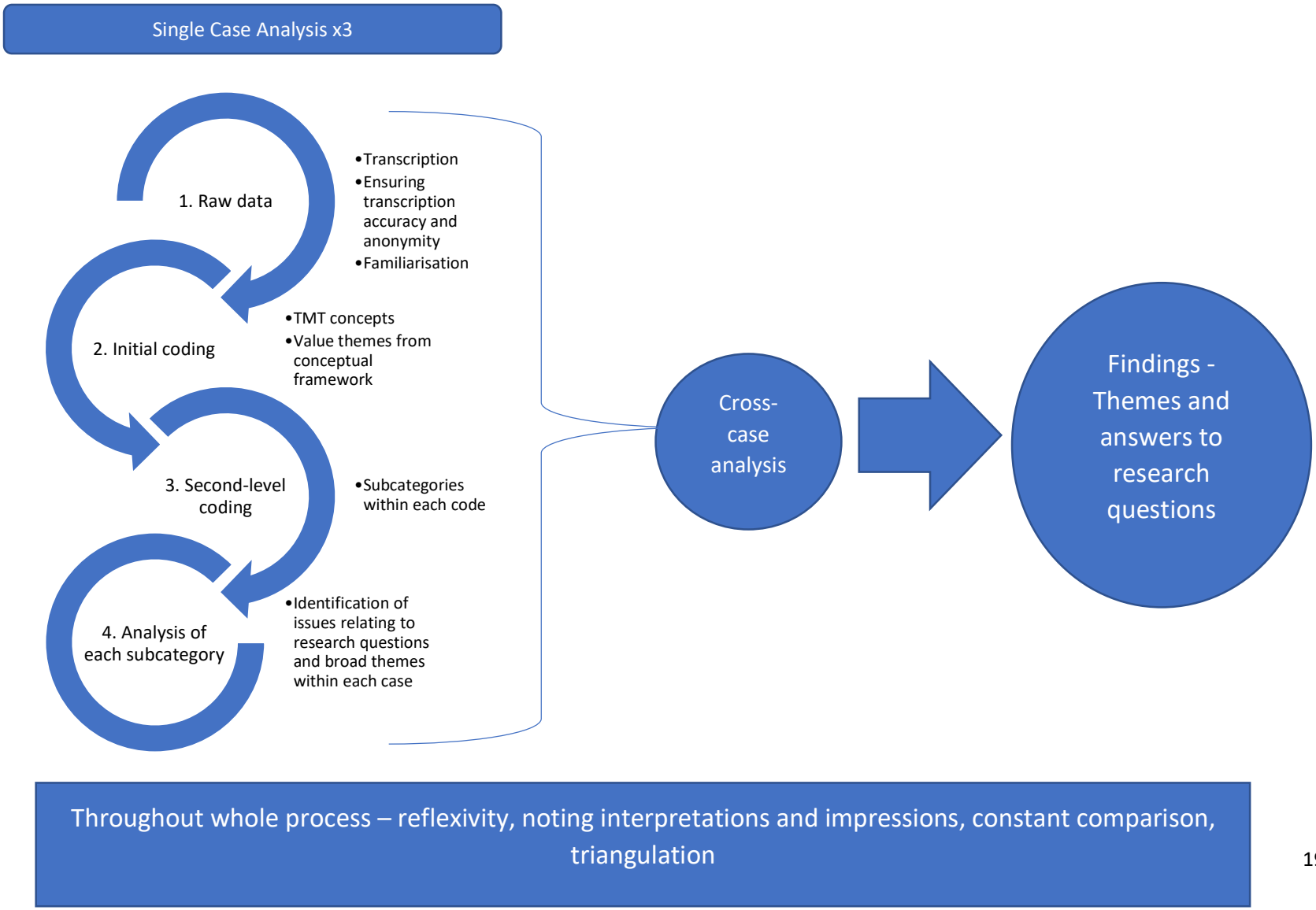
Within cases I undertook a preliminary analysis of initial observation data using TMT to inform interview topics. I also at times drew on an analysis point from one case to inform data collection in another case, by enquiring whether an issue that was prominent in one case had also been an issue in this case, and if not, why not.

As stated earlier, part of the work analysis was developing my own understanding of TMT and how I could best apply this to the large volume of data. The end analysis method therefore in part developed during the process of analysis, and while I attempted to be systematic the process was by nature iterative and non-linear. In this section I outline the procedures I developed and followed while also acknowledging the iterative and interpretive process also strongly resonated with Stake's description:

'The page does not write itself, but by finding, for analysis, the right ambience, the right moment, by reading and rereading the accounts, by deep thinking, then understanding creeps forwards and your page is printed' (221) p73.

Figure 7.2 provides an overview of the data analysis process.

Figure 7.2 Data analysis overview



7.3.5.1 Single case analysis

I undertook the single case analyses case by case, starting with the case with the most data. I noted similarities and differences between cases and questioned why there were differences, noting down contextual differences which I hypothesised could explain these differences. Often this was when an issue appeared a barrier in one case but not another, so I examined contextual differences that could explain why this was so. Table 7.3 details the single case analysis process.

Table 7.3 Single case analysis process

Step 1 **Raw data**	**Transcription**	• Majority of audio transcribed verbatim by a professional transcriber • I transcribed some audio files of meetings verbatim, adding further fieldnotes and interpretations – also start of data familiarisation
	Transcript checking	• I listened to all audios against transcripts checking for accuracy • Anonymisation of transcripts • Added further fieldnotes, interpretations, impressions • Data familiarisation through this process
Step 2 **First level coding**	**Data management**	• All raw data files checked against case index • All raw data files imported into NVivo
	Raw data first level coding	• Coded each piece of raw data using TMT concepts and value themes from conceptual framework • Coding was mostly of sections of text, not line by line • Further noting of interpretations and impressions • Initial categories developed inductively within each code
	Researcher triangulation	• Selected transcripts and raw data extracts coded by supervisors and at researcher forums within my department – discussion with critical outsiders (93).
Step 3 **Second level coding**	**Subcategories within each code**	• Selected relevant questions provided by Allen's operationalising TMT document (ref) to aid further interrogation of data • Categories within each code of initial coding framework refined and new categories developed • Noting broader themes and interpretations • Constant comparison between cases
Step 4 **Higher level themes**	**Summaries of each code created**	• Word documents created to write bullet points for each code within a category to summarise the data, including paraphrasing or direct quotes from participants

	Summaries of each code analysed	• Noting patterns and higher-level interpretive themes – drawing on Allen's questions (ref) and my research questions

7.3.5.2 Cross-case analysis

By the end of the three single case analyses I had identified broad themes within each case, and contextual factors within each case that appeared to be significant in shaping the process evaluations and creating value. I brought these together with the summaries created in step 4 of the single case analyses, read them all and began to compare cases.

I made notes and created mind-maps on paper, and using software (Scapple) that enabled me to move sections of text around the screen and create links between them. I frequently returned to the single case raw data and codes and categories developed in NVivo to sense-check, add examples, develop findings. Appendix 9 contains some examples of the analysis in progress.

I discussed emerging themes and findings of interests with my supervisors and other researchers, which helped triangulation and gave me suggestions for wider theoretical literature and contextual information that could inform understanding. I read this additional literature and contextual information, which further informed my understanding and analysis.

Stake (93) cautions that many readers of multiple case study reports wish to understand the aggregate and what is common across cases, meaning the unique vitality of each case could disappear. However, what was striking in the cross-case analysis was the differences between cases and what these revealed about how process evaluations were being shaped. Thus, the unique contexts of each case were integral to the cross-case findings and there seemed no question they would become lost.

The end output of the cross-case analysis was 4 broad themes, and within each a narrative addressing the original research questions.

7.3.6 Triangulation

I followed Stake's recommendations for triangulation in multi-case research (93). While my epistemological stance was interpretivist I agreed with Stake's assertion (93) that it was necessary to check my interpretations of the cases and the data to check for misunderstanding, omissions, and that my interpretations made sense to participants.

I undertook the following triangulation:

- ✓ Triangulation with critical insiders (93). During interviews I directly asked participants about some of my interpretations from observations, and at the end of the interview engaged in reflexive discussion with participants who were interested in discussing my PhD research questions in relation to their process evaluation and more widely. All participants were aware of my research questions and aims. During these discussions participants often reflected on experiences of other process evaluations and how findings fitted with these.
- ✓ Triangulation of data sources. I recognised that participants may be unwilling to share views of the process evaluation which differed from the 'common version'. I therefore used multiple data collection methods to triangulate responses.
- ✓ Triangulation of data with critical outsiders (93). I shared selected raw data with my supervisors and at departmental research forums and invited impressions and interpretations. I also presented elements of my in-progress analysis at departmental research forums, inviting discussion of emerging themes and areas of uncertainty. These opportunities led to several new insights which influenced the final themes and provided proxy member checking as most researchers at these forums had similar roles and experience to those of case study participants. In particular these forums enabled me to better understand the social atmosphere and power dynamics of meetings I observed.

7.3.7 Section summary

This section has detailed the research design, sampling and recruitment of cases, ethics, data collection, data analysis, and triangulation procedures.

The next section introduces and discusses the theoretical framework of Translational Mobilisation Theory, and how this was used with the conceptual framework developed in chapter 5 to inform data collection and analysis and address the research questions.

7.4 Case studies application of conceptual framework and Translational Mobilisation Theory

This section introduces Translational Mobilisation Theory (TMT) and the rationale for selecting it to inform these case studies. It then explains how I operationalised and applied the conceptual framework of process evaluation developed in chapter 5 and TMT to data collection and analysis to answer the research questions.

7.4.1 Introduction to Translational Mobilisation Theory

TMT is a middle range theory developed by Allen and May (86) to analyse social projects. It is a sociological and practice theory, grounded in data from ethnographic research into the organising work of hospital nurses (229). It also draws together insights from several previous sociological and organisational theories, including Normalisation Process Theory and Actor-Network Theory (86).

TMT offers a means of systematically describing, analysing, and comparing how goal-directed institutionally sanctioned projects of collective action progress in time and space via complex organisational processes in complex institutional contexts (86, 107). It proposes mechanisms through which projects are mobilised and the relationships between these mechanisms and the institutional contexts in which they are enacted (86).

Thus, I considered TMT an excellent fit for undertaking case studies of how process evaluations (institutionally sanctioned projects of collective action) are shaped (via complex organisational

processes) in healthcare research (complex institutional contexts). Furthermore, in their introductory paper to TMT Allen and May (86) provide an example of TMT applied to the analysis of a health research project.

7.4.1.1 Overview of TMT concepts

Table 7.4 provides a summary of the TMT concepts

Table 7.4 The concepts within Translational Mobilisation Theory

Core concept	Sub-concepts
The Project *"A sociotechnical ensemble of institutionally sanctioned strategic activity mobilized across a distributed action field" (86) p.7*	Primary project Sub-projects Project actors Intersecting projects Lines of work
The Strategic Action Field *"The institutional context in which projects emerge and are progressed and which provide the normative and relational frame for collective action" (86) p.8*	Organising logics Structures Technologies and materials Interpretative repertoires
Mechanisms *"Processes through which agents operating within a strategic action field mobilise projects, drive action and enact institutions" (86) p.8*	Object formation Reflexive monitoring Articulation Translation Sense-making

7.4.1.2 Development of my understanding of TMT

My understanding of TMT developed during the design, data collection, and data analysis phases of this study. It was only through applying it and reading and rereading Allen's further papers (107, 230), the TMT website (231) and direct contact with Davina Allen (106) that I feel I developed my understanding of how it to my study. My background in nursing helped me understand the concepts as Allen's nursing examples of its application resonated with my clinical experience (230).

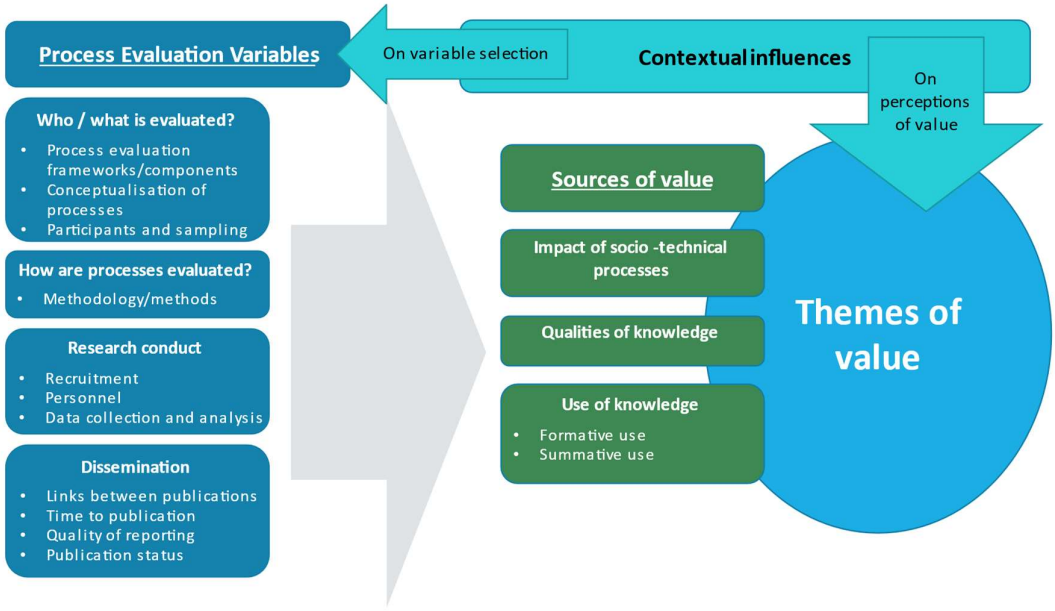
Because of this it was not a neat process of applying the theory to data collection and analysis, rather an iterative process of gaining new insight and going back to reapply to parts of the data. The

way I interpreted and applied it may differ in places from the intention of the developers, however in the next section I explain how I interpreted it and applied it in this study. With the knowledge I now have of the theory I am aware I could have used it differently from the outset to inform data collection and analysis and likely gain richer and deeper insights.

7.4.2 Fitting together the conceptual framework and TMT

Figure 7.3 shows the conceptual framework developed in chapter 5, which shows how process evaluations may create value, and be influenced by context.

Figure 7.3 Conceptual framework of process evaluation



From this conceptual framework I developed the following initial research questions to inform data collection and analysis.

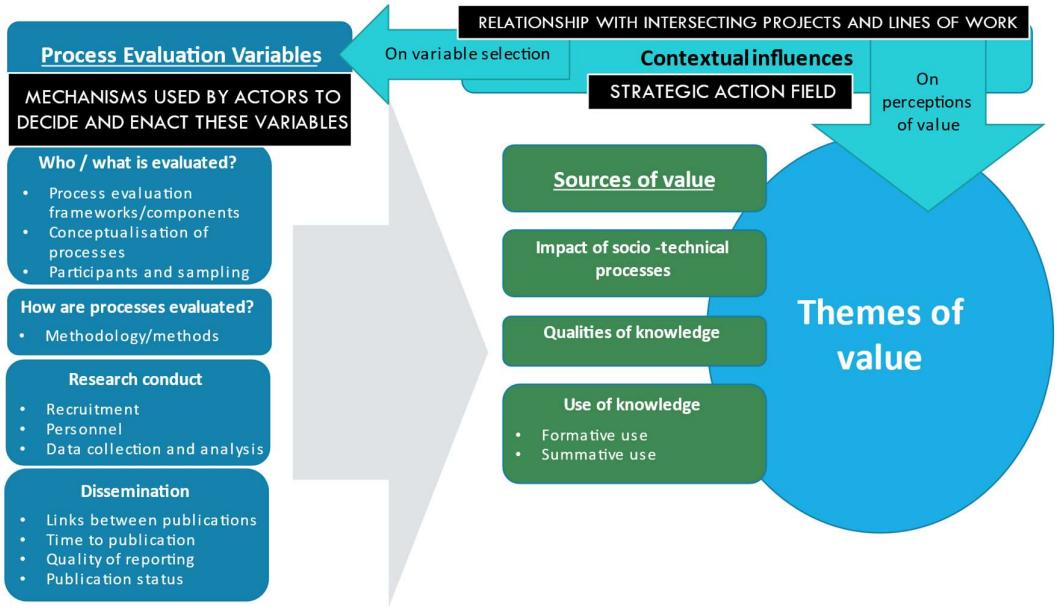
- ✓ Which socio-technical processes are being used and why?
- ✓ What values and negative consequences arise due to these socio-technical processes?
- ✓ What kind of knowledge is the process evaluation generating, and why?
- ✓ What values and negative consequences arise from this kind of knowledge?

- ✓ How is the knowledge from the process evaluation being used/planned to be used and why?
- ✓ What values and negative consequences arise or potentially arise from these uses of the knowledge?
- ✓ How is context shaping the process evaluation?
- ✓ How does context influence perceptions of the value of the process evaluation?

7.4.2.1 Applying TMT to the conceptual framework

Figure 7.4 shows a top-level overview of how I then used TMT to deepen and broaden elements of the conceptual framework (black rectangles are TMT).

Figure 7.4 Conceptual framework with TMT



I used TMT to explore and describe the influence of context in more depth. Its core concept of the **strategic action field** and associated sub-concepts provided a lens to identify contextual factors and language to describe them. I explored how the **intersecting projects** of the pragmatic RCT and associated evaluations such as health economics were themselves contexts that shaped the process

evaluation. I also examined how **lines of work** of research team members and the bodies they interacted with, such as Clinical Research Networks, impacted on the process evaluation.

The core concept of **mechanisms** enabled me to describe and explore the socio-technical processes of project work, beyond standard research processes (such as conducting a qualitative interview) and operational processes (such as gaining access to a research site).

The following sections explain how I applied each core concept and associated sub-concepts in more detail.

7.4.3 TMT core concept - The Project

The core concept of the project is defined as:

> *An institutionally sanctioned socio-material network of time-bounded collective action which follows a trajectory in time and space* (86) p.7

Table 7.5 outlines the sub-concepts of the core concept of **the project** and how I applied them in the case studies.

Table 7.5 Sub-concepts of the project (adapted from (231))

TMT Sub-concept	**Case study elements classified within sub-concept with examples**
Primary project *The focus of collective action*	The process evaluation
Sub-projects *A discrete component of collective action within a primary project*	Separate components of the process evaluation, for example patient interviews, focus groups
Project actors *Discrete social or material element within a project of action*	People with direct or peripheral involvement in the process evaluation The process evaluation documents, such as the protocol, the funding application Key technologies, such as the intervention, the database
Intersecting projects *Project of action that may affect or be affected by the primary project*	The pragmatic RCT Any other elements of the research programme, such as health economics evaluations

TMT Sub-concept	Case study elements classified within sub-concept with examples
Lines of work *Recurrent activity that feeds into multiple projects*	The other job roles of the project actors, for example clinical, lecturing, other research projects The work of the ethics committees The work of the clinical research sites

For the purposes of this analysis, I defined the process evaluation as the **primary project**. I defined **sub-projects** of the process evaluation as the separate elements of each process evaluation, for example the patient interviews sub-project, the staff focus groups sub-project, the Covid questionnaire sub-project, and the mixed-methods analysis sub-project. It is important to note that there was often overlap between sub-projects of the process evaluation and sub-projects of the RCT and other evaluations, for example when a single questionnaire collected both trial and process evaluation data.

In actuality, in all three case studies the process evaluations and their sub-projects were contained within the overall funding applications, protocols, and ethics applications of the pragmatic RCTs. However, in this analysis I defined the process evaluation as the primary project as it was the phenomenon under investigation. I defined the pragmatic RCT as an **intersecting project**, along with any other studies contained in the funding envelopes such as health economics evaluations and intervention development.

Although complex, it was highly informative to conceptualise the process evaluations, pragmatic RCTs, and other elements such as health economics as separate projects despite their ostensibly being part of the same project within a funding envelope. As I highlight in subsequent sections there were instances of apparent discord and competing agendas between the process evaluation and pragmatic RCT, and often actors spoke of them as separate projects.

Human **project actors** often had official roles on both the pragmatic RCT and the process evaluation. Non-human **project actors** included official documents such as protocols and contracts, and technologies such as databases and intervention components. Some served both the pragmatic RCT and process evaluation.

For the purposes of this analysis, I divided human **project actors** into three groups:

- ✓ **The research team** – anybody who had direct responsibility within their role for any aspect of designing, conducting, and/or disseminating the process evaluation. This included process evaluation researchers, trial managers, the chief investigator, statisticians, trial co-applicants, patient public involvement (PPI) members, and administrators. Because in all three case studies the process evaluations were embedded in the pragmatic RCTs, even though some actors such as trial co-applicants had very little involvement in the process evaluations, I included them in this group as they were part of the team responsible for it.
- ✓ **Process evaluation participants** – anybody from whom data were collected for the process evaluation. Some members of the research team also became process evaluation participants, for example in case study 1 a sub-project of the process evaluation was interviews with the intervention development team.
- ✓ **Process evaluation facilitators** – anybody whose assistance or approval was needed to progress the process evaluation, but without direct responsibility for designing, conducting, and/or disseminating it. This included ethics committee members, university finance managers, clinical trial unit staff, and clinical research network staff.

I only collected data directly from research team actors, however process evaluation participants and process evaluation facilitators clearly also had central roles in shaping the process evaluation and were potential recipients of its potential value and negative consequences. As I discuss in later

sections, an important shaping factor appeared to be how the research team predicted and made sense of the values and interests of the process evaluation participants and process evaluation facilitators.

Many actors had multiple **lines of work**, and these were often significant contextual factors impacting on process evaluation progress.

7.4.4 TMT core concept – Mechanisms

The core concept of mechanisms is defined as:

> *Processes through which agents operating within a strategic action field mobilise projects, drive action and enact institutions* (86) p.8

Table 7.6 outlines the sub-concepts of mechanisms and how I applied them in the case studies.

Table 7.6 Sub-concepts of mechanisms (adapted from (231))

Sub-concept	Case study elements classified within sub-concept
Object formation *Elements of a strategic action field that provide a set of normative conventions that define the purpose and scope of possible action*	Formal shared practice objects, for example an ethics amendment form, an email trail, a participant information sheet. Informal practice objects, including the identity/understanding of the process evaluation held in the minds of individual actors
Reflexive monitoring *Practices through which actors evaluate a field of action to generate awareness of project trajectories*	Keeping the process evaluation aligned with the protocol, ethics approvals, new regulation (e.g. GDPR), funding report deadlines
Articulation *Practices that assemble and align the diverse elements (people, knowledge, materials, technologies, bodies) through which object trajectories and projects of collective action are mobilised.*	Aligning process evaluation data collection with RCT timelines Organising focus groups Organising extensions to researcher contracts of employment
Translation	Forums for sharing and discussing ideas and making decisions, for example formal meetings, sending

Sub-concept	Case study elements classified within sub-concept
Practices that enable practice objects to be shared and differing viewpoints, local contingencies, and multiple interests to be accommodated in order to enable concerted action.	documents by email for comments, corridor conversations
Sensemaking *Practices though which actors order, construct, and mobilise projects and enact structures and institutions*	Weighing up and negotiating competing values and organising logics to make decisions about how to proceed with the process evaluation

The mechanisms sub-concepts enabled me to examine two research team activities that were central to shaping the process evaluations and gave significant insights into how they were valued. These were:

1. Academic and operational decision-making

2. Implementing academic and operational decisions in the contexts of health services research

When examining decision-making and decision implementation, the TMT sub-concept of **object formation** enabled me to see that within all case studies:

- ✓ The process evaluation did not have a single stable identity, rather within each case study there were always multiple socially constructed versions of the same process evaluation (**practice objects**) in circulation across time and space (86).

- ✓ Each human actor appeared to hold the process evaluation as a practice object in their own mind, reflecting their own values, interests, and agendas.

- ✓ Practice objects also existed in the form of documents. These could be formalised, for example ethics- and regulatory-approved protocols and participant invitation letters, or more transient, for example emails approaching research sites

- ✓ Whichever form the practice object took, each was permeated with identity and meaning given to it by the actor(s) that created it (86). Each was a "*selective representation"* of the process evaluations, constructed with the aim of achieving a certain outcome (230).

Conceptualising the process evaluation as multiple practice objects with multiple meanings was central to this analysis of how process evaluations were valued and shaped. It enabled me to examine how actors formed their own versions of the process evaluation according to what they valued, and how these different versions were negotiated to make academic and operational decisions which impacted on the value the process evaluation would create. It also enabled me to examine how formalised documentary practice objects used to conduct the process evaluation, such as a protocol, remained open to multiple interpretations. It also shed light on how formal knowledge outputs presented only a singular version of the process evaluation knowledge.

The sub-concepts of **reflexive monitoring**, **sensemaking**, and **translation** enabled me to examine how research team actors undertook this negotiation and creation of multiple practice objects, both individually and collectively. I identified what was being reflexively monitored to provide insight into what each actor was valuing. I investigated how actors individually and collectively made sense of the different practice objects to determine what they wanted the process evaluation to do and become, and what they perceived it was possible for the process evaluation to do and become. I examined how the process evaluation was shaped by translation mechanisms, shining light on the technical/material and social contexts in which the sharing of ideas and making decisions occurred.

The sub-concept of **articulation** enabled me to study the mechanisms that supported the formal academic and operational work of the process evaluation, described as *'the work that makes the work work'* (230) p.40. An example of this was the time spent finding the right person to speak to in CRN (Clinical Research Network) offices to facilitate the process evaluation in case study 3. This provided important insights into how process evaluations were valued, and how they were shaped by the demands of articulation work.

7.4.5 TMT Core concept – the Strategic Action Field

The core concept of the strategic action field is defined as:

> *The institutional context in which projects emerge and are progressed and which provide the normative and relational frame for collective action* (86) p.8

Table 7.7 outlines the sub-concepts of the strategic action field and how I applied them in the case studies.

Table 7.7 Sub-concepts of the strategic action field (adapted from (231))

Sub-concept	**Example case study elements classified within sub-concept**
Organising logics *Elements of a strategic action field that provide a set of normative conventions that define the purpose and scope of possible action.*	Ethics Safety Confidentiality Efficiency Medical Model
Structures *Elements of a strategic action field that differentiate social actors (divisions of labour, social worlds, hierarchies, departments, units, teams, interfaces).*	Research ethics committees Universities and departments Trial steering committee Clinical trials units NHS sites Academic roles Job titles Gender Professions
Materials and technologies *Elements of a strategic action field that provide agents with the materials and technologies to support their practice.*	Video-conferencing facilities for meetings NHS data capture systems Meeting rooms Databases
Interpretative repertoires *Elements of a strategic action field that provide agents with a set of cognitive artefacts and relational resources for interpreting and making sense of the objects of practice (classifications, scripts, categories, discourses).*	Clinical experience Research experience Personal knowledge

In all three case studies the process evaluations took place in multiple **strategic action fields** concurrently**,** including university departments, clinical trials units, clinical practice settings, and,

post onset of the Covid pandemic, home environments. The sub-concepts of the strategic action field enabled me to examine how the process evaluations were shaped by their contexts, how research team actors negotiated the contexts, and how process evaluations appeared to be valued by their contexts.

Organising logics was a central concept I used to operationalise 'value', on the assumption that actors' organising logics would reflect what they valued. Differences between organising logics of different actors and organisations, and how these were negotiated provided key insights to address the research questions. Research team actors appeared to draw on a range of **interpretative repertoires** to define organising logics and to understand how to negotiate organising logics. These thus helped me explore why different research team members valued different things, and how they were able to negotiate different organising logics to progress the process evaluation.

Each research team actor operated within multiple **structures**, and how they enacted and negotiated these structures was significant to addressing the question of how process evaluations are shaped. **Materials and technologies** often appeared to influence the course of process evaluations, and the ability of individual actors to utilise materials and technologies was also important.

7.4.6 Summary of TMT applied to case studies

Using organising logics as a proxy for 'value' enabled me to examine how the process evaluations were shaped by the values different actors brought to their involvement with them, and how these values were negotiated. It thus enabled me to question:

- ✓ Which organising logics do individual actors bring from their strategic action fields into the design, conduct, and dissemination of the process evaluations?

- ✓ How do actors collectively negotiate these different organising logics within their different strategic action fields through the mechanisms of object formation, reflexive monitoring, and sensemaking?
- ✓ Which organising logics eventually take priority and why? How do these organising logics create value and negative consequences?
- ✓ Do any values or negative consequences arise from this negotiation and prioritisation of organising logics?
- ✓ How does articulation work shape the process evaluation, and does the articulation work itself bring any values or negative consequences?

7.4.7 Section summary

This section has introduced Translational Mobilisation Theory and outlined how I applied its core and sub-concepts to the conceptual framework of process evaluation developed in chapter 5. It has also explained how I used the sub-concepts to address the research questions.

The next section introduces and describes the three case studies.

7.5 Case study descriptions

This section describes the three case study process evaluations and the pragmatic RCTs in which they were conducted and summarises the data collected within each case study.

To ensure anonymity I have not included clinical specialties or detailed descriptions of interventions, aims, and research designs.

As discussed in section 7.3.2.3 my supervisors were involved in two of the case studies. One of my supervisors was a co-investigator on one of the pragmatic RCTs, and another of my supervisors was a co-investigator on another and had a role in the process evaluation.

7.5.1 The pragmatic RCTs

All case study process evaluations were part of pragmatic RCTs funded by the National Institute for Health Research (NIHR) and were conducted solely in the UK.

Table 7.8 describes the pragmatic RCTs in which the process evaluations took place.

Table 7.8 Description of the three case study pragmatic RCTs

	Case Study 1	**Case Study 2**	**Case Study 3**
NIHR funding programme	Programme Grant for Applied Research	Health Technology Assessment	Health Technology Assessment
Type of pragmatic RCT	Individually randomised	Individually randomised	Cluster randomised
Type of intervention	Electronic intervention with clinician facilitator support	Comparison of two existing medical/surgical treatment options	Multi-component intervention including staff training and patient management systems
Intervention development	Intervention developed within same programme grant	Interventions already in routine clinical practice	Intervention previously developed and tested in pilot trial by same team
Intervention recipients	Patients	Patients	Staff
Healthcare setting	Patient access at home, facilitated by secondary care clinical service	Secondary care	Primary care

In case study 1 the intervention was being developed and tested within a programme grant, with plans for the team to roll-out the intervention if it proved effective in collaboration with a charity partner. The process evaluation aimed to establish fidelity of delivery of aspects of the intervention, patient and staff experiences and views of the intervention, and contextual influences on intervention use and effectiveness. This process evaluation was the middle of the three cases in terms of size, with seven sub-projects. The core team was two researchers however a further four researchers had significant input, along with the trial and programme managers and statistician. It also collected data over the course of the pragmatic RCT, including longitudinal qualitative data.

In case study 2 the pragmatic RCT was comparing two existing medical/surgical treatment options to inform clinical practice in a high-risk condition. The aim of the process evaluation was to examine pragmatic RCT recruitment and follow-up processes during an internal pilot, because the team anticipated recruitment could be challenging. The process evaluation thus was formative as findings were intended to inform changes to processes if necessary. This was the smallest process evaluation, involving two researchers and three sub-projects over a relatively short timescale.

In case study 3 the intervention being trialled had been developed and tested in a pilot trial by many of the same team as conducting the current pragmatic RCT. Unlike the other two case studies, the process evaluation had an iterative design, with findings from one subproject designed to inform the next. With 16 subprojects this was the largest and most complex process evaluation, and the cluster design of the pragmatic RCT added significant operational complexity. This was the only process evaluation to employ researchers specifically for the process evaluation, and there were two teams. Different team members spent different amounts of time involved with the process evaluation, with six researchers contributing. There was also significant input from trial managers and some input from the wider pragmatic RCT team including statisticians and database managers.

7.5.2 The process evaluations

Table 7.9 describes the three process evaluations.

Table 7.9 Description of the three process evaluations

	Case Study 1	**Case Study 2**	**Case Study 3**
Number of subprojects	7	3	16
Process evaluation investigates	Fidelity of intervention delivery Participant responses to intervention Stakeholder views of intervention Contextual influences on intervention	Trial recruitment and follow-up processes as part of internal pilot	Acceptability and usability of intervention Mechanisms of impact of intervention Influences on uptake, effectiveness, and sustainability of intervention

	Case Study 1	Case Study 2	Case Study 3
Process evaluation methods	Mixed methods	Mixed methods	Iterative mixed methods
Process evaluation participants	Patients Intervention staff Intervention development team	Patients Patients' partners/carers Trial recruitment staff	Staff receiving intervention Patients Trial team members

7.5.3 Process evaluation team structure

In case studies 1 and 2 all researchers had substantive posts at their employing university and worked on the process evaluation with time bought out of their substantive post. The researchers on the teams undertook the academic research work of the process evaluations, while operational work was mostly conducted by trial and programme managers and coordinators.

In case study 3 the lead researchers similarly had substantive posts with time bought out, however the process evaluation employed researchers specifically to undertake most academic and operational research work of the process evaluation.

Case study 1 had a core team of the lead process evaluation researcher (senior lecturer) and a process evaluation researcher in an advisory role (professor). Three other researchers (professor, reader and research fellow) contributed to different subprojects of the process evaluation. The chief investigator (professor) took an active role in the process evaluation, including chairing its meetings. The operational work of the process evaluation was largely carried out by the programme manager and trial manager and trial team. The lead process evaluation researcher was based at the same university as the chief investigator and programme team.

Case study 2 had a core team of the lead process evaluation researcher (research fellow) and a second researcher (professor). They were based at the same university as the trial team, and the operational work of the process evaluation was largely carried out by the trial manager and trial team.

Case study 3 had two core teams, initially a process evaluation team and a qualitative team although they decided to work together as a process evaluation team as they realised early in the study the divide into process evaluation and qualitative was unhelpful. They were based at different universities and neither process evaluation team were based at the same university as the trial team. One team consisted of the lead process evaluation researcher (senior lecturer) and 2 job-sharing research assistants (one whole-time equivalent) who were employed to undertake most of the academic and operational work of the process evaluation. The second team consisted of the qualitative lead (professor) and for a few months a research assistant was employed to undertake some of the academic and operational work. A process evaluation adviser (research fellow) also contributed to the academic work at various time points. The operational work of the process evaluation was largely carried out by the research assistants, however the trial managers also advised on or undertook some of this work.

7.5.4 Summary of data collected in each case study

I began observing case study 1 when the process evaluation was being designed, during the intervention development stage of the programme grant. I ended data collection when the process evaluation was partway through data collection.

I began observing case study 2 as the pragmatic RCT and process evaluation opened and began recruiting patients. I ended data collection after the planned process evaluation work was complete, although the team had plans to possibly undertake more process evaluation.

I began observing case study 3 midway through the process evaluation and ended data collection while data from the process evaluation were being analysed.

Each case study presented different opportunities for observations of meetings. I collected much more observational data in case study 3 as the researchers held a two-day and a half-day meeting to

discuss the process evaluation with the RCT team, whereas in the other two case studies only hour-long meetings were held. In case study 2 I had planned to attend more meetings however one was cancelled, and I was asked not to attend another as the researchers felt the topics under discussion were too sensitive.

In case study 2 I was unable to interview the chief investigator as planned for the core dataset. I invited them on three separate occasions however they stated they were unable to due to a heavy workload. The case study 2 process evaluation was much smaller than those in the other case studies, and I therefore only interviewed two process evaluation researchers, who advised me there was nobody else relevant to interview.

Table 7.10 summarises the data I collected in each case study.

Table 7.10 Data collected in each case study

	Case Study 1	**Case Study 2**	**Case Study 3**
Observations	2 in person process evaluation meetings 2 in person programme management group meetings 2 online programme management group meetings	2 in person process evaluation meetings 2 in person trial management group meetings	1 in person 2-day meeting between process evaluation teams and RCT team 1 online meeting between process evaluation team and RCT teams 2 online process evaluation meetings
Total time of observations	6 hours	4 hours	18 hours
Interviews	Chief investigator Process evaluation lead Process evaluation qualitative researcher Process evaluation advisor	Process evaluation lead Process evaluation researcher	Chief investigator Process evaluation lead Process evaluation qualitative lead Process evaluation 2 job-sharing research fellows (joint interview)

	Case Study 1	Case Study 2	Case Study 3
	Intervention development lead/RCT principle investigator Programme manager Trial manager/new programme manager Research fellow with multiple roles in programme including aspects of process evaluation		Process evaluation qualitative research fellow Process evaluation advisor Trial manager Clinician trial co-applicant, involved in intervention development and delivery
Total number of interviews	8	2	8
Total number of interview minutes	369	91	401
Mean interview length	46 minutes	46 minutes	50 minutes
Documents	RCT protocol and amendments (process evaluation protocol included within) Funding application form RCT participant information sheet and consent form Process evaluation participant information sheets and consent form 53 emails Study website	RCT protocol and amendments (process evaluation protocol included within) RCT participant information sheet and consent form Process evaluation participant information sheets and consent form 5 emails Study website	RCT protocol and amendments (process evaluation protocol included within) Funding application form RCT participant information sheet and consent form Process evaluation participant information sheets and consent form 14 emails Study website 2 publications Interview topic guides

7.5.5 Section summary

This section has introduced and described the three case study process evaluation and their associated pragmatic RCTs. It has also summarised the data collected in each case.

The next section presents the findings of the cross-case analysis across four themes.

7.6 Case study findings

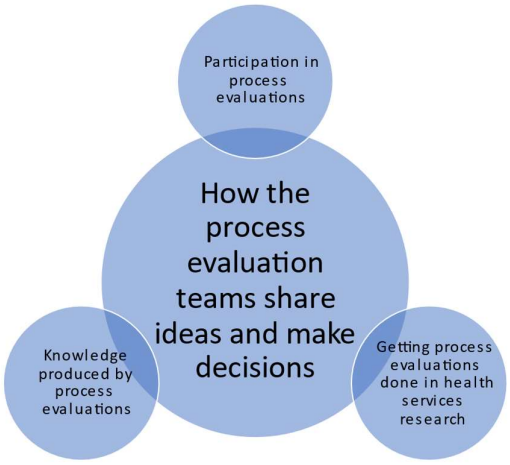
7.6.1 Overview of findings

I present the findings of the cross-case analysis of the three case studies in four themes:

1. How research teams share ideas and make decisions
2. Participation in process evaluation – value to participants, negative consequences to participants, and how participants are valued
3. The knowledge produced by process evaluations – what kind of knowledge is valued and how can the knowledge create value or negative consequences?
4. The work of making process evaluations happen in the contexts of pragmatic RCTs, the NIHR and the NHS

Theme 1 mostly addresses the question of how process evaluations are shaped, while themes 2, 3, and 4 address how they are valued and shaped, and the value that process evaluations create. As shown in figure 7.5, theme 1 is key to the other three themes, as idea sharing and decision-making by process evaluation teams is central to producing knowledge, enabling participation, and getting process evaluations done.

Figure 7.5 Relationships between themes



7.6.2 Participant anonymity

To further protect the identities of participants I use the pronoun 'they' throughout with no reference to gender.

7.6.3 Theme 1 – How research teams share ideas and make decisions

Throughout the design, conduct, and dissemination of the process evaluations were multiple decision points. These included proactive decisions, for example how to invite participants, and reactive decisions in response to contextual events, for example how to ensure participant consent was compliant with new GDPR regulations.

In this theme I examine the mechanisms of how research team actors made operational and academic decisions about the process evaluations and identify factors which appeared to be significant in shaping these decisions. In this theme I focus on processes, and elaborate on the content of ideas and decisions in subsequent themes.

Figure 7.6 shows an overview of the idea sharing and decision-making process. Individual human actors brought their own ideas, organising logics, and agendas, identified through their own personal reflexive monitoring and sensemaking. They also brought their own abilities and willingness to articulate and advocate for their own ideas, organising logics, and agendas.

Individual research team actors came together to discuss ideas and make decisions through a process of collective reflexive monitoring and sensemaking to translate the process evaluation into a new practice object that would enact that decision. The mechanisms occurred in their own strategic action fields, such as Zoom meetings, which influenced how they were enacted.

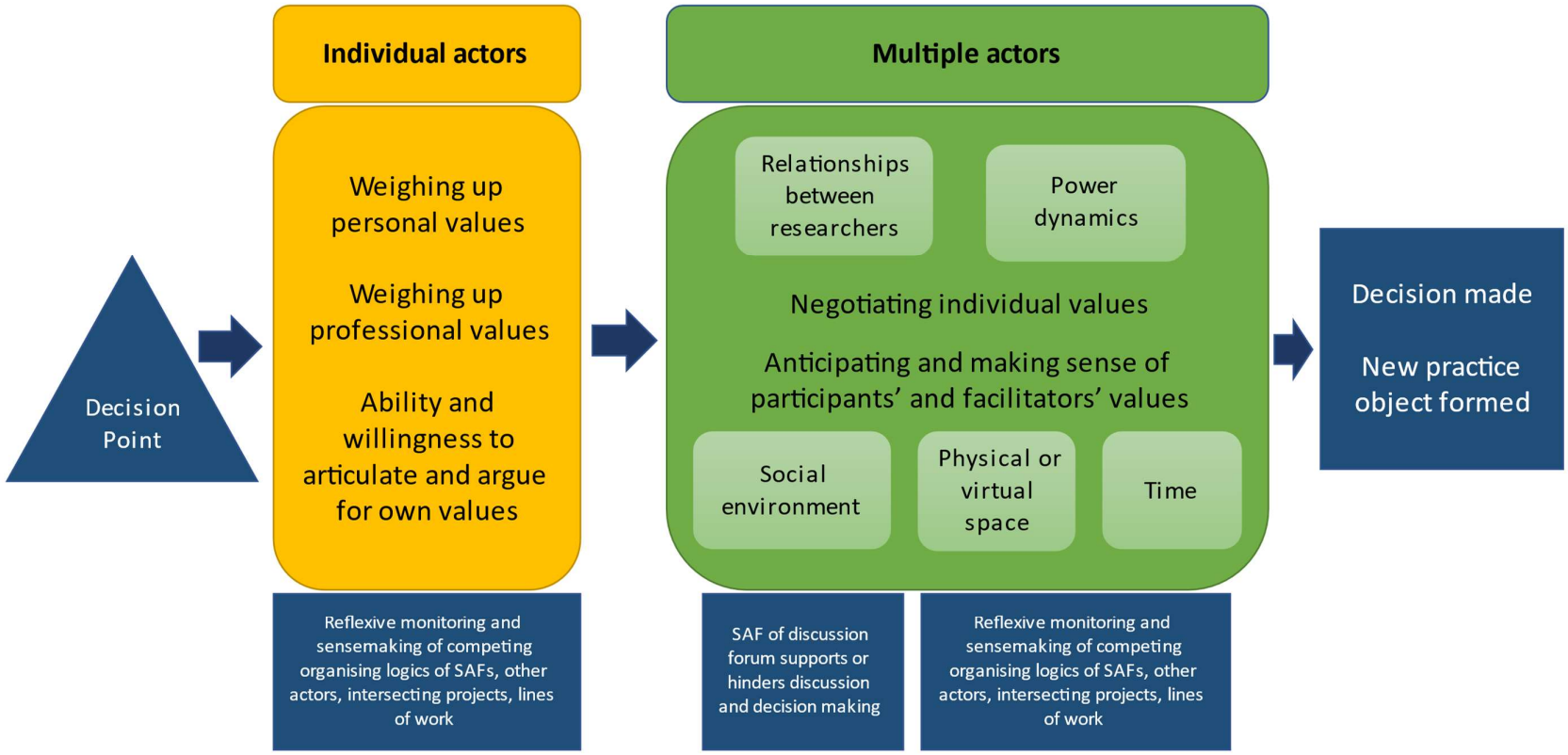
In this process they negotiated the ideas, organising logics, and agendas they brought to the discussion, in effect addressing the questions:

- ✓ What do *we* want to achieve and how?
- ✓ What do we want *the process evaluation* to achieve and how?

In this theme I discuss how research team actors shared and negotiated their own ideas and values to make decisions that shaped the process evaluations.

In subsequent themes I address how research team actors anticipated and made sense of participants' and facilitators' values and how these contributed to decisions.

Figure 7.6 Idea-sharing and decision-making process



7.6.3.1 Personal reflections on this theme

I brought my own extensive experience of working in research teams into analysis of this theme, as well as my strong personal interest in human behaviour, psychology, neuroscience, and interpersonal dynamics.

During reflections I noted on occasion that I had in my mind taken sides with or felt more affinity towards certain individuals within the case studies. Similarly, I noticed I felt less natural rapport with other individuals. While I made every effort to approach each interview and interaction in the same way, I acknowledge there were participants I felt more comfortable speaking with, which could have affected the amount and depth of data I obtained from these participants. I also was continuously reflective and mindful to ensure I treated the views of all participants as equally valid and did not undertake data collection and analysis in a way that favoured the views of participants with whom I felt more affinity.

I recognise that this theme brought up feelings of discomfort for me. I had concerns about causing distress to participants through asking probing questions about team dynamics and tensions, which I know led to me at times not asking the questions which, on reflection, may have yielded richer insights. I was also conscious of not causing embarrassment or harm to participants through including observations of individual levels of confidence or discussing things participants said in interviews about team tensions in this analysis. I therefore acknowledge my analysis was shaped by the knowledge this thesis would potentially be read by participants, although I took every measure to ensure anonymity.

I also acknowledge that my presence as a researcher may have itself affected how the research teams shared ideas and made decisions. Most obviously this could have occurred during observations where I was physically or virtually present and audio-recording, however this could also have occurred through awareness I was copied into certain emails. Through my informed consent processes, I aimed to mitigate this by emphasising my role was to understand things as they were, not to audit or evaluate performance. Furthermore, I paid careful attention to presenting myself as

relaxed and professional, clearly present and attentive but without obviously reacting to points of interest or taking notes that I considered could create feelings of defensiveness or caution in attendees.

7.6.3.2 Individual reflexive monitoring and sensemaking

As shown on the left of in figure 7.6 in yellow, individual research team actors bring their own personal and professional values and organising logics to team discussions. I observed on many occasions research team actors undertaking their own individual reflexive monitoring and sensemaking about which perspective to share or argue for.

Weighing up competing professional values

Many research team actors described in interviews how they as individuals made sense of competing professional organising logics to decide their perspectives. A common example was weighing up operational and academic priorities, such as balancing the academic value of lengthy questionnaires against potential participant burden. I also observed individual sensemaking during meetings when actors thought aloud to arrive at their perspectives, and research team actors often appeared to carefully consider express the reasons for the perspectives they arrived at, acknowledging trade-offs.

Research team actors often acknowledged that the structure of their named role in the process evaluation and/or pragmatic RCT required them to adopt particular organising logics. For example, trial and programme managers prioritised feasibility and not adding burden to the trials, chief investigators prioritised sticking within timeframes, and some qualitative researchers appeared to prioritise understanding nuance and complexity. This interview quote from a programme manager illustrates this:

> *"..because of my perspective, I'm coming far more from this from an operational point of view than an academic point of view, so I guess the [professor name] will argue, will argue the academic point of view and I will argue the actual how doable is this if we do it in this format, with these current incentives that we're offering, will people actually complete this?*

What evidence do we have that people will complete this? And that's the point of view that I'm coming in from."

This fits with a proposition outlined by Allen and May (86) that organisational structures such as named roles in research projects require the actors fulfilling the roles to account for their actions in a way that aligns with the expectations of that role.

However, I rarely observed research team actors presenting singular, fixed, and predictable organising logics that may be expected of their role in the process evaluation and pragmatic RCT. Rather, most research team actors anticipated and incorporated competing organising logics potentially held by actors in different project roles into their individual reflexive monitoring and sensemaking. As a result, they often presented considered views anticipating possible objections and demonstrating respect and empathy for others' perspectives.

A likely contributory factor is that in all three case studies many research team actors had experience and understanding beyond their named role in the process evaluation or pragmatic RCT. In all three process evaluations the senior researchers were also co-applicants on the programme or trial funding application. Moreover, most process evaluation researchers in all three case studies had experience of conducting RCTs and associated operational issues, such as dealing with ethics amendments and recruitment challenges. Most process evaluation researchers expressed deep understanding of and empathy for the demands of the pragmatic RCTs. Similarly, I observed many instances of individual pragmatic RCT team members showing understanding of and interest in issues relating to process evaluation, such as understanding complexity. For example, in one meeting I noted the statistician appeared to have deep understanding of process evaluation concepts through their insightful questions.

The individual sensemaking processes I observed showed that almost always research team actors drew on their own experience to arrive at their conclusions about which perspectives to bring to discussions. They frequently drew on knowledge of concurrent or recent research studies in which

they were involved, for example when discussing which aspects of the intervention to examine and which methods to use. Notably, research team actors rarely appeared to draw on the literature or process evaluation guidance as an interpretative repertoire, although the lead process evaluation researchers all discussed how they had used guidance and literature when initially applying for funding and designing the process evaluation. During observations, their primary interpretative repertoires appeared to be their own expert and tacit knowledge of clinical practice, academia, and health services research design and conduct.

Indeed, the lead process evaluation researchers in all case studies appeared to value the perspectives and ideas that actors with extensive relevant experience could bring to decision-making and sought to include them in discussions. Similarly, the process evaluation teams included researchers with expertise in process evaluation, and both chief investigators I interviewed stated how important it had been to them to ensure researchers with the right expertise were in the teams.

> "*I suppose that was where I relied on my colleagues who had more experience, such as [names], who were more experienced than I was in designing process evaluations, and I think that's where I drew on their theoretical understanding. So I wouldn't say that I'm necessarily familiar myself, very familiar, with the process evaluation literature and what needs including. So I think that's where good teamwork comes in, that I've got people on the team who did understand this world and were up with the literature or at least talking a good talk! <Laughs> And took their advice rather than feeling that I had to go off and read the process evaluation literature before we decided what we'd include."*

This interpretative repertoire resonates with the concept of "*mindlines"* proposed by Gabbay and le May (232) to describe primary care clinicians' use of *"collectively reinforced, internalised, tacit guidelines"* rather than directly consulting written evidence and guidelines. In their ethnographic study they found that clinicians almost always took shortcuts to attaining what they believed would be the best knowledge to inform practice by discussing and seeking advice from trusted actors in

their networks (232). This was a behaviour I observed frequently in the case studies, and it seemed mindlines and the professional networks used to inform them were an extremely important interpretative repertoire in the case studies. I discuss this further in subsequent themes and in the discussion of case study findings.

Weighing up personal values

As well as sensemaking of competing professional organising logics, I observed numerous examples of research team actors making sense of their own personal agendas when deciding which ideas and perspectives to bring to discussions.

At times, research team actors' own sensemaking processes resulted in deciding not to bring ideas, information, and perspectives to team discussion. There were examples of research team actors weighing up their personal concerns of undesirable repercussions if they expressed their genuine views in relation to the process evaluations. For example, a researcher told me that they had noticed things in the data but did not dare discuss these with the rest of the team as they felt this would not be well received. A researcher with a role advising on process evaluations reflected during their interview with me that at their academic grade it could be difficult to balance arguing for sufficient resources to fund a high-quality process evaluation because:

> "*you don't wanna make such a pain of yourself that they don't ask you to bid on the next study*".

These examples suggest a lack of psychological safety to take the interpersonal risks of openly voicing opinions and concerns, which is a known barrier to creativity and knowledge integration (233).

I also observed instances of more explicit sensemaking of personal values. This often occurred in discussions about what the process evaluation should investigate. I noted that some research team actors often used phrases in meetings such as "*for me the most interesting thing is"* and *"what I*

want to know is". There were several examples where certain researchers articulated their individual views about what the process evaluation should examine, which were tangents to the planned focus of the process evaluations and appeared to stem from their own research and career interests. Sometimes researchers jokingly acknowledged their own agendas:

> "*But I mean it's obviously up to [chief investigator name] and everybody to decide. We don't have to have this in. Certainly I would like it in – [profession members] always want it. Partly because we get very good publications from it!"*

Research team actors sometimes explained how their personal values and assumptions about others' values shaped their interpretations of artifacts such as data, protocols, and rules. For example, when presenting process evaluation findings to the trial team, one presenting researcher said they had decided to present only the simple themes as they assumed these were most interesting to the trial. In another example, process evaluation researchers explained how they did not agree that an aspect of the already ethically approved protocol was ethical, and wished to change it.

Ability and willingness to articulate and argue for values

I observed some researchers check themselves when they expressed their own interests, acknowledging they were beyond the scope of the process evaluation. I also observed instances of researchers arguing for their own interests to be included, resulting in discussions about whether these were appropriate or possible to include. Across the case studies I observed research team actors demonstrate a spectrum of apparent willingness to bring individual ideas, agendas and values to team discussions, from deciding to not disclose them to presenting them as a ready-made decision.

When I first noticed this during data collection and analysis I regarded these differences as solely factors within individuals, for example that researchers had different levels of confidence. However, I brought this point to one of the departmental meetings in which I discussed case study

data with colleagues, and it was highlighted to me that the data also showed the social atmosphere of meetings did not appear conducive to actors feeling comfortable to share ideas freely. This was a turning point in my interpretation of the data and led me away from framing all issues as within individuals, which I realised was what I had thus far been doing without awareness. It led me to appreciate the influence of multiple factors on individual behaviour, and therefore sensitised me the potential impact of factors such as relationships and social environments as shaping factors in the process evaluations. I discuss these factors later in this theme.

Nonetheless research team actors certainly appeared to have different levels of confidence and comfort in sharing their ideas, expressing their opinions, and arguing for their perspectives – as demonstrated by large variation in individual behaviour within the same meetings. It was difficult to identify any clear social structures which accounted for these individual differences, apart from the researchers holding more senior academic positions generally appeared more confident and forthcoming and less hesitant when expressing opinions. This was not universal however, as some junior researchers appeared extremely poised and confident, and some more senior researchers more apologetic in their expression of opinions. It seemed that the individual personalities of researchers were the most influential factors in their behaviour. This observation fits with the critical realist stance highlighted by Porter (103), who states that while agents are influenced by social structures, the mechanisms of making choices lie in the individual psyches of agents. It also is reflected in findings from a study showing that personal characteristics and past experiences of healthcare professionals were factors in their perceived psychological safety in healthcare teams, along with team-level factors (233).

7.6.3.3 Collective reflexive monitoring, sensemaking, translation, and object formation

As shown in the green boxes of figure 7.6, the next stage of the decision-making process was research team actors coming together to share and negotiate ideas, and form new practice objects which would enact the decision. These were often formal meetings, however I also observed other

discussion forums, such as the circulation of documents via email for comments. These discussion forums were themselves strategic action fields which influenced how the mechanisms played out.

Time available to share ideas and make decisions

Various factors affected the time available to research team actors to share ideas and make decisions, and time appeared to sometimes limit the contributions of some researchers.

Most process evaluation researchers in all case studies had substantive posts with time bought out for their role in the process evaluation. They therefore had many other lines of work such as teaching and involvement in other studies, and admitted these process evaluations were often not at the forefront of their minds or forgotten for months at a time. All were used to juggling their time across studies in this way, but there were many examples of them rushing to catch up on the process evaluation with other work having taken priority. It was also problematic when pragmatic RCT timelines changed, and process evaluation researchers were unable to easily rearrange time they had allocated to the project.

Aside from this, in case studies 1 and 2 time did not appear to be a significant issue affecting idea sharing and decision-making. In contrast, time appeared to be the primary organising logic in case study 3. The case study 3 process evaluation had sixteen subprojects and an iterative design. This meant many more proactive decision points were naturally reached while conducting the process evaluation. Moreover, the nature of the intervention and the cluster pragmatic RCT design meant many detailed and nuanced discussions and decisions were required as researchers navigated operational and academic challenges and complexity. This resulted in the case study 3 process evaluation having a less stable identity and much more potential to grow and morph. As one process evaluation researcher put it:

> *"..the process evaluation has turned into such a monster of complexity".*

However, while there were many more complex decisions to be made in case study 3, it appeared there was not always sufficient opportunity to discuss and make decisions with enough time and consideration.

In the meeting between the process evaluation and pragmatic RCT teams I noted at the start of the meetings there seemed like a great deal of ground to cover in the timeslots allocated in the agendas. Agenda items frequently ran over time, and often complex discussions had to be stopped partway through. The chief investigator and clinical co-applicant were only able to attend parts of meetings with the process evaluation team, and sometimes arrived late due to clinical work overrunning. The chief investigator was asked to make major decisions about the future of the process evaluation when they had had little time to consider them, although they acknowledged this and said they would take more time to reach decisions. I reflected that this short allocation of time to discuss complex issues was likely detrimental to idea sharing and discussion.

The chief investigator and other pragmatic RCT team members in case study 3 had many competing demands on their time, which impacted their availability to be involved in idea sharing and decision-making in the process evaluation. The process evaluation researchers reflected that they sympathised with their busyness but noted it could be difficult to get the feedback and suggestions from them on circulated documents that they considered crucial to designing and conducting a quality process evaluation.

Researchers were employed in case study 3 to undertake the process evaluation and they did not have other lines of work in their roles so could dedicate their full attention to the project. However, because they were employed on fixed-term contracts, there was doubt that they would still be employed at crucial decision points because the pragmatic RCT had encountered severe delays. During the period I observed they were attempting to summarise all the complex process evaluation findings from many different subprojects into a format that would mean other people could pick their work up later to complete it. As well as the potential impact this had on the knowledge

produced by the process evaluation, this situation had some negative emotional impact on the researchers who had invested time and effort in a project they would prefer to see to completion.

The physical and virtual environments of idea sharing and decision-making

The physical and virtual spaces in which ideas were shared and decisions made could facilitate or hinder communication between research team actors.

Prior to the Covid pandemic I observed face-to-face meetings at the host universities in all three case studies. In case study 1 all process evaluation and programme group meetings I observed took place in a large bright room with plenty of space for all participants to sit around a table. These meetings were approximately one hour long. In case study 2 the process evaluation meetings were a similar length and took place between only two researchers but in a large meeting room.

In case study 3 I observed a two-day meeting at the university hosting the pragmatic RCT between the process evaluation teams and the pragmatic RCT teams. I noted that the room for the duration felt cramped, and this was particularly felt when the wider trial team including statisticians and health economists attended and had to squeeze chairs into the corner of the rooms. Several research team actors commented to me how tiring the day had been.

Post onset of the Covid pandemic, video-conferencing technology appeared to influence how ideas were shared and decisions made in meetings. In some online meetings I observed technological interferences to communication, including distracting audio feedback and researchers with poor home internet connection. This meant some research team actors missed parts of meetings and reported finding it difficult to follow discussions. Some researchers also appeared unconfident using the technology, or their devices would not work in clinical environments. The availability of video-conferencing platforms at the start of the pandemic was also variable, with some universities not allowing access or not subscribing to some platforms. However, I also observed that shared frustrations and difficulties adapting to the new technology provided opportunities for humour and good-natured small talk which appeared to facilitate relationships between research team actors.

Social environment of sharing ideas and decision-making

I sensed differences in the social atmosphere and contexts of meetings across the case studies which may have influenced idea sharing and decision-making.

In case study 1 the chief investigator chaired all meetings and I observed in my fieldnotes the meetings had an air of calm efficiency and the meetings ran according to their agendas and on time. As far as I observed they were relaxed and professional, sought contributions from everybody, and had clear oversight. All attendees appeared engaged and undistracted, and confident with their contributions.

In case study 2 the process evaluation meetings I observed were between two researchers. One took a lead role, but the discussions appeared fully inclusive and collaborative. In the trial management group meetings, there appeared to be more tension at times however, and while the chief investigator chaired the meetings efficiently and professionally, I noted instances of some attendees paying less attention or showing some discord. The tension seemed to be related to the pragmatic RCT being high-risk, and differences of opinion between organisational stakeholders.

In case study 3 meetings were chaired by the process evaluation leads. While both were friendly, professional, and efficient, sometimes I noted they could be slightly apologetic and hesitant about the process evaluation at times during meetings with the trial team. During online meetings between the process evaluation and pragmatic RCT teams, members of the pragmatic RCT team often appeared distracted. For example, one kept dropping out of the meeting without warning to attend to other matters relating to the pragmatic RCT, and another came back late from the coffee break and missed the main part of the meeting relevant to them.

I reflected that I could not imagine this happening in the case study 1 process evaluation meetings when the chief investigator was chairing, and wondered if the chief investigator had chaired this meeting whether the pragmatic RCT team would have given the meeting their full attention. It also led me again to question the value placed on the process evaluation by the pragmatic RCT team,

despite frequently expressing appreciation for the importance for the process evaluation. Research on virtual work meetings has shown that multi-tasking during online meetings may be perceived as disrespectful and a signal that multi-taskers perceive the meeting as of lesser importance (234). It is possible that this also may have contributed to the less confident contributions of some process evaluation researchers in the meeting.

In all case studies, particularly case study 3, sharing frustrations and jokes about videoconferencing, university bureaucracy, and research infrastructure seemed to play an important social role in creating a sense of unity and collaboration between research team actors despite their sometimes-differing agendas and unfamiliarity with one another. The importance of such opportunities for human connection over shared experiences at the start of meetings is highlighted by Rock (235) at the level of human neurobiology. He maintains that such interactions facilitate rapport and a sense of safe connection which then facilitates effective team working (235).

Relationships between process evaluation team members

Relationships between process evaluation team members appeared important influences on idea sharing and decision-making. Case studies 1 and 2 each had one distinct core process evaluation team, while case study 3 had two process evaluation teams based at different universities.

In case study 3 all process evaluation researchers acknowledged tensions between the teams due to a lack of clearly defined roles and responsibilities, and major delays to one team's contributions due to the lead researcher taking up a new role at a different university. These tensions affected how ideas were shared and decisions made between the teams. I observed instances of each team having had their own discussions of ideas and presenting decisions as a done deal to the other. One team appeared keen to contribute to one subproject of the process evaluation but the other team was reluctant to agree, and it appeared there had been a history of attempts at joint working that had not been successful.

The researchers I spoke to did not consider the geographical distance between them and cross-institutional working to be a problem, rather difficulties stemmed from researchers not knowing each other previously and it being difficult to manage expectations. The lead process evaluation researcher reflected in interview part of their oversight role had been managing relationships and trying to keep everyone happy.

Furthermore, in case study 3 process evaluation researchers appeared to hold differences in opinion about the value of different sub-projects, and the overall purpose of the process evaluation. In case studies 1 and 2 all process evaluation researchers often expressed strong interest and desire to improve the outcomes and experiences of the patient population served by the intervention. In contrast, in case study 3, possibly because the intervention was delivered to staff not patients, process evaluation team members seemed to have diverging views about the relevance of including patient perspectives and less explicitly unified in a desire to improve patient outcomes and experiences.

In case study 1 and 2 I observed no tension in relationships between process evaluation team members. A researcher in case study 1 however reflected that the geographical distance between them and other team members caused by working at different universities created a feeling of isolation from the rest of the team and lack of involvement in everyday decisions. They expressed some concern that this meant had not fulfilled their responsibilities to the best of their ability.

Another researcher who undertook qualitative interviews for the case study 1 process evaluation reflected:

> *"I feel a bit like an add-on. And I don't mean that negatively, it's necessary, it's the way it is…"*

This researcher was also employed at a different institution but did not consider this to be the cause of the disconnect. They felt they worked well with the team as they had previously worked together

for many years, and this familiarity facilitated working across institutions. Not being part of the core process evaluation team and joining only to conduct interviews was the factor that led to them feeling their involvement was somewhat disjointed:

> *"When they first sent me the stuff saying, 'We need to do some interviews.' I went, 'I haven't got an interview schedule' <chuckles> 'cause it hadn't been sent through and when I looked at it there were some… I did query some questions on it because it didn't make sense and so that went back and got adjusted a little bit and then we went from there. But I will do that because I'm experienced enough to be able to anticipate how difficult it could be to use questions that aren't quite good."*

This reflection also highlights the significance of individual researchers' experience and confidence in working effectively in cross-institutional teams.

Relationships between process evaluation team members and pragmatic RCT team members

In case study 1 all process evaluation meetings I observed were attended by members of the programme grant team who had a role in an aspect of the process evaluation and chaired by the chief investigator. Similarly, the core process evaluation team were grant co-applicants and participated in programme group meetings. Throughout my observations in case study 1 I gained the impression of an overall sense of unity and common purpose between all team members across the whole programme as well as in the process evaluation. Upon leaving a meeting I observed one of the researchers commented how well the team worked together, unlike other teams they were involved with

> "…*where everyone just goes off and does their own thing without consulting anyone else".*

The chief investigator appeared to play a significant leadership role in creating this team unity. The chief investigator chaired all the process evaluation meetings I observed and took a proactive role in process evaluation decision-making. While in the other two case studies the process evaluation

leads called on the chief investigator as they felt necessary for contributions to discussions and decision-making, in this case the chief investigator explained to me:

> *"I would want to be part of those decision-making. It wasn't always what I say goes. It was a negotiation and a discussion, but I suppose some of my colleagues, … tend to want to gather everything just in case we need it. At some point I just had to say, 'That's too much.'...I would feel responsible for understanding but also having an overview of what we were actually asking people."*

This chief investigator appeared to consider full involvement in the decision-making process essential to fulfilling their role. They also appeared to have fewer lines of work than the chief investigators in case studies 2 and 3 and in my observations appeared less distracted by other responsibilities.

Another factor that struck me as important was that all team members across the programme appeared united in their commitment to improving care and outcomes for the patient group and saw the process evaluation as an essential part of this endeavour. All members of the wider programme team I interviewed expressed strong interest in and support of the process evaluation as an important element of the overall programme. While there were examples of research team actors disagreeing on certain decisions, the data I collected all suggested ideas were shared and decisions made about the process evaluation jointly and openly as a programme team.

However, in interviews some participants spoke of some discord with the wider pragmatic RCT team at the Clinical Trials Unit (CTU), who were not present during observations. The chief investigator had decided to work with the CTU at a different university because they had worked with them successfully previously, rather than deciding to work with the CTU at their employing university which hosted the programme grant. The trial manager, who was employed by the CTU and later became the programme manager, also proactively facilitated the communication and relationship between the CTU and the academic team through basing themselves part-time in the CTU office and

part-time with the academic team. They reflected that they had seen a need to facilitate smooth relationships because there had been significant delays and communication issues with aspects of the trial being undertaken by the CTU.

In case study 2 the core process evaluation team were also grant co-applicants and were both employed by the CTU. In this case the process evaluation researchers knew first-hand what was happening in the pragmatic RCT and it seemed to arrive at many decisions themselves about the process evaluation. However, in a trial management group meeting I once observed the chief investigator appearing to favour their own clinical experience over data reported by a process evaluation researcher, appearing quite dismissive of the process evaluation qualitative data. This led me to question how openly ideas were discussed and decisions made.

Nonetheless in case study 2 the pragmatic RCT and process evaluation teams including the chief investigator appeared unified in seeking to improve care and outcomes for the patient group, and seemed united in a concern to achieve an ethical informed consent process for trial. All data I collected suggested the pragmatic RCT team were fully supportive of the process evaluation aims.

A significant difference in case study 3 was that the two process evaluation teams were based at different universities to the chief investigator and pragmatic RCT team at the CTU and separated by a large geographical distance. Although both process evaluation teams' lead researchers were grant co-applicants, the process evaluation seemed more separated from the pragmatic RCT than in case studies 1 and 2.

While expressing a lot of interest in and appreciation of the importance of the process evaluation, the chief investigator took a less proactive role than in case study 1. They did not chair any meetings I observed between the process evaluation and trial teams, and only attended parts relevant to them. The trial team appeared less involved, and in meetings I frequently heard the phrase '*what do you want from us*', suggesting they regarded it as a separate project. I noted while observing a face-to-face meeting between the trial and process evaluation team:

Seems a friendly rivalry at times – especially trial manager – making jokes about e.g. please don't make it complicated – protecting the trial from needing amendments etc

Nonetheless, the chief investigator and trial manager made a major decision about the process evaluation without apparent involvement of the process evaluation team. In a meeting between the process evaluation and trial teams when discussing a recently submitted application to the funder for and extension to the pragmatic RCT, after a pause a process evaluation researcher enquired whether they had also asked for an extension to the process evaluation. The chief investigator said no, and it struck me that this was a surprising way to communicate a major decision with potentially significant ramifications for the process evaluation.

The trial managers also had little operational involvement in the process evaluation as the process evaluation researchers took on most of this responsibility, unlike in the other two case studies. However, the trial managers appeared to play a critical role in facilitating and advising the process evaluation researchers on operational matters. Furthermore, prior to the process evaluation researchers being employed, the trial managers had started some of the process evaluation work such as adding process data collection fields to the trial data collection systems. This necessitated a lot of communication between the process evaluation researchers and trial managers querying data that had been collected at the start of the trial.

The process evaluation researchers and trial manager expressed appreciation for each other's support despite being previously unknown to one another.

"*…they're very responsive, and actually I had worked with another CTU in a brief way, and I found them a disaster to work with, because they just wanted us to do it their way, rather than seeing themselves as facilitating our work. Whereas the [CTU name] have really bent over backwards in many ways to try and be helpful."*

> *"one of the things that really helps is that while I've developed, over the last couple of years, especially through [charity research group], a fairly good relationship with [qual lead name], we've met and talked and worked on things and the development of the protocol amendment that was associated with the interviews went really well, she took that and a sort of a trial manager's dream for, as a trial manager, you don't have to do it, the academic who's in charge of that really took it."*

I noted on several occasions that the trial managers appeared highly emotionally invested in the intervention and trial, which they also reported due to their long history of involvement including with the previous pilot trial. They also appeared to fully appreciate the complexity of the intervention and its variability of implementation and effectiveness at different cluster sites and expressed a lot of interest in process evaluation findings. These seemed important factors in their willingness to share ideas and contribute to decision-making, and indeed although one trial manager had been moved to a different study in the CTU, they remained willing to take the time to share important knowledge for the process evaluation.

Similarly, as noted in the previous section, the process evaluation researchers all frequently spoke of their experience working on and understanding of running RCTs, which appeared to facilitate the relationship. This is an excerpt from my fieldnotes of the first meeting I observed between the pragmatic RCT team and process evaluation teams:

> *PE team all seem very au fait with trial and NHS research infrastructure – seem to have experience of it and know how they need to fit in – does not seem to be a surprise that barriers, discuss as joint problems. Ask for advice from TMs – seem very respectful of expertise and experience in navigating ethics etc.*

Nonetheless, I noted at times an element of division between the trial management team and process evaluation team. For example, in the same meeting I noted:

Sense of the PE team wants to do this but that's not going to work – noticed trial manager looked a bit incredulous or bored at times, silently shaking head. Towards end trial managers seemed to physically lean back (both sitting on corners at far end) – as if taking a back seat on discussion, thinking not going to work but being a critical fly on the wall over the discussion?

The lead process evaluation researcher had previously worked at the same university and on the same team as the chief investigator and pragmatic RCT team in the pilot study of the intervention. All parties felt this greatly facilitated working across institutions and greatly aided communication. The teams also attended a social event together when the process evaluation team travelled to the trial team for a two-day meeting. I overheard many positive comments about how this had enabled them to get to know one another better, and the process evaluation researchers expressed appreciation that the wider team including statisticians and health economists seemed genuinely interested in the process evaluation.

Power dynamics

During data collection and analysis I reflected on power and who or what appeared to be in a position of power in the idea sharing and decision-making I observed, and how this power was enacted.

Most of the time it appeared ultimate power lay outside all research team actors, and decisions were often made based on what would be required by process evaluation facilitators, particularly the funder, and to a lesser extent process evaluation participants. Put simply, without gaining the necessary approval from facilitators and without participants agreeing to participate, the process evaluations could not be enacted. Decisions were often made based on what was likely to be approved by these external actors, and also limited by the inflexibility and constraints of these external actors. As I will illustrate in subsequent themes, this meant research team actors needed to

sometimes undertake significant creative effort to translate the process evaluation into practice objects that would gain approval of those with this power.

Power also often lay with non-human actors such as databases and electronic interventions, which once built were fixed and determined some of the possibilities for the process evaluations. The current approved version of the pragmatic RCT protocol (which in all cases contained the process evaluation protocol) also held significant power. To change the process evaluation design or conduct outside of the parameters set out in the protocol would require administrative time and effort, which often trial managers were keen to avoid.

In all three case studies all research team actors appeared unified in treating the funder as having the final say in decisions even though the funder was never present at the discussions. Actors often made reference to the final approved funding application that stipulated the agreed research design, what the funder report needed to include, and boxes that needed to be ticked for the funder. The power of the funder was especially visible in case study 3, as the pragmatic RCT had encountered delays that necessitated applications for costed extensions that affected how the process evaluation would be able to proceed.

The aim of pragmatic RCTs to arrive at a primary outcome result also held a position of power over the aims of the process evaluations. In all case studies all process evaluation researchers acknowledged this and complied with measures to prioritise the success of the trial, for example ensuring process evaluation data collection did not jeopardise trial retention or data collection. As discussed earlier, this may have been related to the positions held by process evaluation researchers on the trial, and their own experience of working on RCTs.

Nonetheless, I observed differences between case studies. In case study 3 the process evaluation team often deferred to the pragmatic RCT team, frequently thanked them for their time, and appeared keen to work around the trial team's needs as much as possible. This suggested to me the process evaluation team themselves saw the pragmatic RCT as more powerful, perhaps regarding

the process evaluation as a potential inconvenience rather than an integral part of the overall study. I wondered whether the insufficient time allocated to discuss ideas and make decisions was indicative of the process evaluation being perceived of lesser value than the trial. In the data I collected there were frequent examples of the trial manager having the final say in decisions about the process evaluation which could have interfered with the smooth running of the RCT, and it seemed the process evaluation team mostly deferred to their decisions despite recognising these would cause limitations to the process evaluation.

In case study 1 there seemed less deference by process evaluation researchers to the pragmatic RCT. This was perhaps related to the oversight and chairing of the process evaluation meetings being undertaken by the chief investigator, and both the RCT and process evaluation being part of a wider programme grant with clearly defined roles within it. The programme manager appeared to hold less power over the process evaluation than the trial manager held over the process evaluation in case study 3, as illustrated by this quote from their interview:

> *"It was a huge questionnaire, it takes so long to complete, and there were lots of questions and there was lots of pushback from myself for that and from [CI name] as well but certainly from myself, and I would like to say that the battle was mostly lost on my side <laughs> and those questions went in."*

In all case studies the chief investigator held power over the final decisions due to their having overall responsibility for delivery of the grant. Nonetheless, as explored in this chapter, there were differences in the way chief investigators fulfilled these positions of power. In case study 1 the chief investigator took proactive oversight while allowing the process evaluation team to lead it. In case study 2 the role of the chief investigator was less clear and I did not have opportunity to interview them, however I did not observe the same oversight as in case study 1. In case study 3 the chief investigator explained in interview that process evaluation was not their area of expertise, and they valued and were guided by the expertise of the process evaluation leads. In my observations they

appeared to have less proactive oversight, however were asked to have the final say in complex decisions about the process evaluation without much involvement in the work leading up to the decision. As highlighted earlier, there were also examples of them taking major decisions about the process evaluation without apparently consulting the process evaluation team.

I observed potential differences in power between individual research team actors through differences in how confident they appeared when articulating their ideas and perspectives, and how much they argued for their wishes to be included in the process evaluations. However, as discussed earlier in this theme, these appeared to stem from differences in personality rather than any social structures I could identify. For example, I observed researchers with lower academic seniority appear to argue more confidently and assertively than researchers with higher academic seniority, and no obvious gender differences. It seemed at times like the researchers who argued more strongly had more influence over the final decisions, although there were several examples when the chief investigator decided to or was asked to intervene and make a final decision to prevent a dominant voice establishing the process evaluation direction.

Models of relationships between process evaluations and pragmatic RCTs

O'Cathain et al. (80) identified three models of relationship between qualitative research and RCTs, and these models are useful to apply here to the relationship between the process evaluations and pragmatic RCTs.

In case study 1 it appeared that the chief investigator and all programme grant researchers I observed or interviewed treated the process evaluation as an integral and valuable component of the pragmatic RCT/programme, thus demonstrating the integral-in-practice model (80). Although the timing of this case study means I do not know how the process evaluation knowledge was used in practice, many research team actors spoke enthusiastically of how they envisaged the process evaluation knowledge being applied to inform intervention development and implementation. This fits, at least at the stage I conducted these observations, the definition of the 'integral-in-practice'

model (80) of the process evaluation as impacting the pragmatic RCT to the satisfaction of the process evaluation researchers. The resources identified by O'Cathain et al. as important to the integral-in-practice model were all present in case study 1, namely process evaluation researchers being full team members from the start, appropriate process evaluation researcher expertise, sufficient process evaluation time funded, and integrative team practices.

In case study 2 because I was unable to interview the chief investigator it was less clear whether the process evaluation fitted the integral-in-practice model, however it appeared to a large degree that it did fit this model. The process evaluation aims were explicitly integrated into the pragmatic RCT, the process evaluation researchers also had roles on the pragmatic RCT and had been full team members from the outset, and the process evaluation researchers had appropriate expertise and funded time.

In case study 3 the model appeared to be mostly the integral-in-theory model, characterised by the process evaluation and its aims being considered highly important by the chief investigator and pragmatic RCT and process evaluation teams, however this not being fully realised in practice (80). It seemed as if often when the interest and drive was not realised in practice this stemmed from external factors, such as the challenges of gaining access to recruit process evaluation participants and the pragmatic RCT being delayed, rather than a lack of desire to realise them in practice. The lead process evaluation researchers had been full team members from the outset, however the process evaluation research assistants had joined the team later and it was clear that as they had not been involved from the outset this had created challenges to integration. The researchers I spoke to considered the process evaluation was very well funded, with sufficient researcher time funded and researchers having and having access to appropriate expertise. There had also been efforts to establish integrative team practices to enhance the cohesiveness of the pragmatic RCT and process evaluation teams. However, it appeared that due to the multiple lines of work of the lead process evaluation researchers, chief investigator, and senior pragmatic RCT team, the complex

challenges of articulation work, and the scale and complexity of the process evaluation project and cluster pragmatic RCT it had been difficult in practice to establish the level of team integration that I observed in case study 1. Although I ended data collection for this case study before data analysis and dissemination was complete, it appeared that process evaluation knowledge was likely to not be fully used to the satisfaction of the process evaluation researchers, again fitting the integral-in-theory model (80).

It is possible that the different NIHR funding streams contributed to these differences in models of integration. Case study 1 was funded by the Programme Grant for Applied Research stream, which explicitly states that funded programmes gain added value through the combination of work packages (236). Case study 3 was funded by the HTA stream, which, in contrast, is centred on '*whether it works in the NHS and is cost-effective'* (237).

7.6.3.4 Theme 1 summary

This theme has examined how research team actors shared ideas and made decisions about the process evaluations, and the factors that influenced these processes. It has explored how process evaluations are shaped by:

- The values individual actors bring and are willing and able to share
- How these values are collectively negotiated
- The strategic action fields in which idea sharing and decision-making takes place

Theme 2 now examines the decisions about who participated in the process evaluations, the value participants got from participating, and how the data from participants was valued.

7.6.4 Theme 2 – Participation in process evaluations

This theme considers the people who participated in the process evaluations, and how they shaped the knowledge that was created.

To relate this theme to the research questions of how process evaluations are valued and shaped I discuss:

- ✓ Who participated in the process evaluation and why?
- ✓ What value did participants get from participation?
- ✓ How was the data and knowledge from participants valued?

7.6.4.1 Personal reflections on this theme

While I have experience of being a patient, a nurse, and a researcher I was aware of my tendency to 'side' with patients and clinicians rather than researchers. I therefore paid attention to ensure I did not give undue focus to what researchers were doing 'wrong' at the expense of patients and clinicians. Similarly I realised I felt more drawn to research team actors who took a more patient-centred perspective, so was mindful to not give priority to their perceptions and experiences over those of research team actors who exhibited what I considered to be less patient-centred views.

7.6.4.2 Who participated in process evaluations and why?

Table 7.11 outlines who participated in each case study process evaluation.

Table 7.11 Process evaluation participants in each case study

Case study	Participants
Case study 1	Patients participating in the pragmatic RCT Staff delivering an aspect of the intervention Intervention development team
Case study 2	Patients participating in the pragmatic RCT Patients' partners/carers Staff involved in recruitment to the pragmatic RCT
Case study 3	Patients registered at cluster sites Staff receiving the intervention Research staff delivering the pragmatic RCT

Patients and staff as process evaluation participants

In case studies 1 and 2 all research team actors appeared unquestioningly united in a desire and interest to understand patient and staff experiences and views. It appeared that there were three main factors underpinning this interest.

Firstly, it was recognised that the interventions, contexts of intervention delivery, pragmatic RCTs, and patients' own contexts were all highly complex and therefore qualitative understanding of the views of patients and staff was essential. These interview quotes below from research team actors were representative of the views of all research team actors I spoke to in case studies 1 and 2.

> *"…there is no point of establishing that people didn't get engaged with the intervention if we don't understand the reason behind it."*

> *"I think the process side of things is absolutely crucial to know how best to inform [patients] but at the same time don't scare them so they're traumatised by the thought of [intervention]!"*

The second factor appeared to be deep understanding of the patient populations and health conditions and a desire to improve care and outcomes for them. The process evaluation and pragmatic RCT teams included researchers and clinicians with lengthy experience of research and practice with the patient populations and conditions, and there was strong and historical PPI. The impression I obtained in both case studies throughout the process evaluations and intersecting projects was also that patients were regarded as having an active role in their health and healthcare and as partners in efforts to improve it.

The third factor was that in both process evaluations there was a clear and direct link between how the process evaluation knowledge obtained from patients and staff would be used to improve care and outcomes for patients and enhance conduct of the pragmatic RCT and understanding of its findings. In case study 1 because of the nature of the intervention and programme grant, the team had control over adjusting the intervention after the evaluation and rolling it out into practice. Thus, the potential direct value of the knowledge provided by patients to improve the intervention, its

implementation, and its outcomes was clearly visible, and the team knew they could easily implement findings. Similarly, in case study 2 research team actors knew they could use process evaluation findings formatively to make improvements to pragmatic RCT recruitment and follow-up processes, which had obvious value to facilitating a successful trial. The process evaluation researchers also often enthusiastically discussed in meetings how findings could help them provide a better experience to patients participating in the trial and ensure they were well informed about the interventions and about trial participation. They also discussed how findings could help them improve the experience for staff responsible for trial recruitment.

In contrast, in case study 3 patients appeared to be regarded as having a much less active role in their health, and the target population was defined as hard to reach. The intervention was delivered to staff at cluster sites with the aim to improve services for the patient group, with the primary outcome measured at the patient level using routine care records. Furthermore, in contrast to case studies 1 and 2, many of the core process evaluation and pragmatic RCT teams did not have extensive clinical and research experience of the exact patient population and condition served by the intervention. The chief investigator worked clinically in the same broad field as the intervention but in a different health services setting. Nonetheless an active clinician with a history of involvement in research was heavily involved in the pragmatic RCT and the process evaluation team consulted them on aspects of the process evaluation. While all research team actors expressed and appeared to have a strong interest in improving services, the overall impression I gained in comparison to case studies 1 and 2 was that patients were regarded much less as active partners in their healthcare and in research.

In case study 3 there also seemed to be some lack of clarity about how the knowledge obtained from patients' experiences and views would be used. Because of the nature of the intervention and the variability of its uptake by staff at different cluster sites, it seemed that researchers had less of a direct means of applying findings from patients to make tangible changes than was the case in case

studies 1 and 2. There was concern that findings from patients would get lost in the funder report, and the knowledge written up and disseminated much later and detached from the pragmatic RCT reports.

Additionally, the patient interview subproject of the process evaluation was severely delayed due to researcher employment issues, and challenges to gaining access to cluster sites to invite patients via Clinical Commissioning Groups (CCGs) and Clinical Research Networks (CRNs). In combination with the less active role of patients in both the overall research project and clinical practice, the result of these setbacks was that the value of the entire subproject of patient interviews was debated at times. Some researchers had strong views it should be included, while others appeared less convinced of its importance. Others, including the chief investigator, expressed appreciation of the importance of including patient views in principle, however given all the articulation challenges appeared less motivated to push it forwards.

In case study 3 staff receiving the intervention were the main process evaluation participants. It appeared that all research team actors appreciated the importance of understanding their views and experiences. Most understood that there was likely to be variability in the way staff responded to the intervention and considered it important to explore that. One process evaluation researcher explained:

> *"Trying to capture that kind of hearts and minds aspect of OK, these might be the actual mechanical steps that were taken, but to what extent have you won people over; to what extent do people get what you're trying to do; to what extent are they really engaging with it and feeling like oh yeah, this is something we understand and we want to do and keep doing."*

One process evaluation researcher also commented that compared to most research studies staff were being paid well for their time in this process evaluation which was a sign of how valuable understanding their experiences were to the pragmatic RCT team.

Research team actors as process evaluation participants

In case studies 1 and 3 the process evaluations also involved interviews with research staff. In case study 1 this was with researchers who developed the intervention, and in case study 3 it was with the clinician delivering a component of the intervention to staff and with trial managers. None of these were planned from the outset but over the course of the process evaluation it became clear to researchers that these research staff had important knowledge about how the interventions functioned that was highly relevant to expanding the knowledge being generated.

7.6.4.3 Value placed on participants' voices

In two of the case studies there were some examples of patient experiences in qualitative process evaluation findings appearing to be given less credence by some research team actors when they did not concord with their experiences, or they contradicted experiences of clinical staff.

In one case study findings from patient interviews suggested they had noticed little or no effect from the intervention. There was debate about the significance of this because there was only a small number of interviews, however some researchers were concerned about the potential negative impacts on patients participating in interviews if their data were dismissed as unimportant. In another case study there were occasional examples of qualitative findings from patients being given little attention in meetings when it contradicted the experience of clinicians.

7.6.4.4 What value did participants get from participation?

In all three case studies process evaluation researchers reported to me in interviews that patients who had taken part in qualitative interviews appeared to have a positive experience of the interview. Reasons for this enjoyment included the opportunity for human interaction, telling their experiences, and the desire to help others and improve care and outcomes. In case study 2 the researchers said sometimes patients were very busy, but were still happy to take part. Although measures were in place in case participants became distressed, there were no reports of any participants having any negative experiences of participation. This overall positive experience of

patients of research participation mirrors NIHR survey findings of the patient experience of participating in NIHR funded studies (238).

Similarly, in all case studies process evaluation researchers believed staff participating in interviews and focus groups had generally enjoyed the experience and found it valuable. In all case studies process evaluation researchers said staff appeared generally happy to share their experiences and welcomed the opportunity to learn and contribute. In case studies 1 and 2 staff experiences were able to be used formatively to improve intervention training and recruitment processes, meaning staff saw the impact of their participation quickly. Researchers also felt the staff involved were keen to improve care for patients and saw participating in the process evaluations as opportunities to do so.

In case study 3 the process evaluation researchers had anticipated that staff would be less willing and able to participate due to the demands of their work but had been pleasantly surprised by how many staff members had turned up to the focus groups and engaged in them. They said it had given staff a rare and appreciated opportunity to come together as a multi-disciplinary team and discuss their different viewpoints and practices and consider how they could do things differently.

In case study 3 however researchers also highlighted that staff were very busy and sometimes tired and hungry when they turned up for the focus groups, and that the focus groups took a chunk of time out of their days. However, they felt that providing them with lunch and paying the research sites well for participating helped recruit participants and helped them feel appreciated and engaged.

In case studies 1 and 3 some researchers spoke of the importance of only collecting data from patients that could be meaningfully analysed in the time available, and that to collect data in case it was useful and/or without a clear plan was unethical. They had taken measure to prevent excessive and unfocused data collection.

7.6.4.5 Anticipated negative impacts from process evaluation participation and how these shaped the process evaluations

An important shaping factor in the design and conduct of the process evaluations was, as shown in figure 7.6, what research team actors perceived the values of potential participants would be when making decisions about who to include, how to recruit them, and what to ask them to do.

In case study 1 the process evaluation collected quantitative process evaluation data from patients in online questionnaires. There was debate about how long these questionnaires could reasonably be to not overburden patients and ensure patients would complete them in a considered manner to get the most meaningful data. The programme manager explained that PPI representatives felt the long questionnaires were acceptable, but they also believed that PPI members were generally more motivated and educated than the entire trial population so their views may not be representative. They thought ideally this type of data collection should be piloted to get a true picture how willing patients were to spend time completing it. However, the programme manager also admitted that so far patients had been completing the longer questionnaires without issues.

In case study 3 the process evaluation used questionnaires to collect data from staff cluster sites. When planning these there were numerous concerns, particularly from trial managers, about how much time and effort staff would tolerate spending on these and the meaningfulness of data that would be obtained if questionnaires were too lengthy. These concerns were based on their extensive experience of dealing with sites and working with staff. The process evaluation researchers told me that there had been generally good engagement with the questionnaires, although there were clear differences between those who appeared to give it thought and others who did a quick box-ticking exercise. I did not observe researchers undertake any PPI work with the staff who would be completing the questionnaires although there was an idea to ask a clinician co-applicant to check it would be feasible.

In the case study 3 process evaluation subproject of staff focus group process evaluation, process evaluation researchers were asked not to go to certain sites where there were technical problems

with the intervention and trial data collection because trial managers perceived this could be detrimental to the trial. A process evaluation researcher also told me they had been told they could not recruit sites in Wales unless a translator was present, which they considered strange as all staff spoke English. They felt this had resulted in a missed opportunity to gain a wider range of perspectives in different geographical contexts. In case study 3 research team actors were very concerned with incentivising staff to participate through offering a free lunch, paying sites, and highlighting they would gain CRN accruals and increase their status as a research active clinical area.

In case study 3 research team actors were also concerned about negative impacts to focus group participants from group dynamics. The original protocol, which had been ethically approved, included both patients and staff in the same focus groups. However, some researchers had concerns about the impact this could have on participants so requested to change it, however to my knowledge no patients or staff were consulted about this decision.

In case study 3 patients were also protected by CCGs and CRNs from perceived potential negative consequences of process evaluation participation. As will be discussed in theme 4, there were challenges gaining access to cluster sites via CCGs and CRNs to invite patients to participate. It seemed often these barriers were due to the procedures in place to protect patients by ensuring researchers had undergone adequate checks and were sufficiently trained, mostly with the organising logics of maintaining confidentiality and ensuring patients were sufficiently informed to consent to participate. Similarly, much of the participant information sheets for patient interviews were devoted to data protection, consent, and confidentiality. While the process evaluation researchers understood the need to protect patients, they expressed frustration at what they perceived to be cumbersome and disproportionate processes that caused significant delays and potentially prevented patients from having the opportunity to share their views. They also felt the lengthy information about confidentiality and data protection was confusing to patients. There were however no reports of any patients having concerns about confidentiality or consent issues.

7.6.4.6 Theme 2 summary

This theme has explored the value participants may obtain from participating in process evaluations

This theme has explored how process evaluations are shaped in part by the assumptions research team actors made about the value staff and patients may gain from participation in process evaluations and the potential negative impacts on them. In some cases, concerns about negative impacts on participants played a significant role in shaping the process evaluation, although it seemed at times that researchers made these protective decisions without consulting PPI representatives or similar stakeholders.

This theme has also explored the value participants may obtain from participating in process evaluations and how the knowledge and perspectives from participants was valued.

In theme 3 attention turns to the knowledge being generated by the process evaluations. It explores the characteristics of knowledge being produced, and the value created by the use or planned use of the knowledge.

7.6.5 Theme 3 – Process evaluation knowledge

This theme examines the knowledge being generated by the case study process evaluations.

In theme 1 I analysed how research team actors shared ideas and made decisions, and these decisions often affected the type of knowledge being created. In this theme I therefore consider the factors influencing these decisions in relation to how different types of knowledge were valued.

I also consider how decisions were made relating to how the knowledge should be packaged as an output and disseminated, and values and negative consequences arising from this. I also present examples of how knowledge was or had been already used to create value, and discuss the ways knowledge was planned to be used and the values research team actors considered would arise from this.

7.6.5.1 Personal reflections on this theme

As discussed in chapters 2 and 4, I have strong personal views that it is vital to understand complexity and nuance to inform healthcare practice in a way that takes into account of the differences between patients in how they respond to interventions. I formed my own opinions during the case studies about the extent to which their process evaluation methods adequately addressed complexity, and as in theme 2 was more drawn to researchers who advocated for methods I considered more ethical and appropriate. Again I paid attention to whether I was favouring the views of these researchers.

7.6.5.2 Which processes should be investigated in a process evaluation?

In case studies 1 and 3 there was some debate about what the process evaluations should investigate, in terms of whether certain elements could be classified as process evaluation, and whether certain elements were important.

In case study 1 there was debate about whether a mediator analysis should be part of the process evaluation or part of the pragmatic RCT, with one researcher of the opinion it should be in the process evaluation and another considering the process evaluation should focus more on implementation. I found this debate interesting as the MRC process evaluation guidance (22) stipulates mediators as part of its process evaluation framework, and yet researchers held different opinions about their place in process evaluations. In case study 1 it was also notable that the process evaluation was a distinct project from intervention development work in the programme grant, which was not called process evaluation.

In case study 3 the process evaluation adviser commented in interview that they felt the case study 3 process evaluation focused excessively on implementation at the expense of intervention mechanisms, particularly in terms of how patients interacted with the intervention. In one case study 3 meeting the chief investigator commented that if the pragmatic RCT was positive then knowing how the intervention worked was unimportant. Process evaluation researchers commented to me they had been struck by this viewpoint, and to them it suggested the chief

investigator had a much more medical model perspective of 'does this intervention work or not?'. They felt while the process evaluation was well-resourced and the chief investigator was interested in it, they were coming from a different philosophical position and had not given much thought to the kinds of questions the process evaluation was asking.

It is interesting to note that while case study 1 and case study 3 had process evaluation advisers on their teams, these advisers appeared to have different understandings of the term 'process evaluation' and what its focus should be.

In case study 2 the process evaluation examined trial recruitment and follow-up processes. Within the trial was planned further qualitative interviews about patient experiences which were not considered part of the process evaluation. I asked a process evaluation researcher why this was the case and they explained:

> *"I think they're more like secondary outcomes in terms of experiences, perspectives, satisfaction …, I think. 'cause I think sometimes questionnaires are great if you're collecting hard data, but they don't give you the … if the patients really liked it or not… So that's why it's an important clinical question, really."*

I found this an interesting perspective, as in this study the label 'process evaluation' was taken more literally as an evaluation of (trial) processes, and qualitative exploration of patient experiences, which are often labelled as process evaluation, were considered integral to the pragmatic RCT.

7.6.5.3 Knowledge completeness

Missing voices

In all case studies there were concerns that process evaluation knowledge could potentially present incomplete findings, mostly related to who participated in the process evaluations. In case studies 1 and 2 there were no problems recruiting patients or staff. However, in both case studies research team actors were mindful to not simply recruit all the first patients who agreed to participate,

because they wanted to obtain a sufficiently varied sample. In case study 2 the first patient to be interviewed had expressed satisfaction with the recruitment processes, however the process evaluation researchers were aware this may not be the experience of all patients.

Despite successful recruitment and a planned large number of patient interviews a process evaluation researcher in case study 1 did reflect to me whether this was sufficient to gain a complete picture of the experiences of all patients. They questioned:

> *"…are we asking the right people, what about those that we're not asking? …should we have bigger population? Will our data be better and more comprehensive if we did collect more data and involved more people?"*

In case study 3, as discussed in theme 2, it seemed there were several restrictions placed on the cluster sites from which it was possible to recruit staff and patients. Research team actors were also aware that the more engaged cluster sites may have been more likely to agree to participate. The researchers were aware that the first cluster sites to complete the intervention may not have been representative due to intervention teething problems, so aimed to sample cluster sites that completed at different time points.

In case study 3 despite the differences in opinion about including patient experiences in the process evaluation some research team actors considered not including patients meant there was potentially a very important piece missing from the knowledge generated by the process evaluation. One process evaluation researcher commented to me that they believed it would have been more interesting to understand the patient perspective on current problems with services before the start of the trial. As it stood, they felt the process evaluation, intervention, and pragmatic RCT focused excessively on staff perspectives at cluster sites.

Incomplete integration of process and outcome findings

A delay to obtaining primary outcome data in case study 3 also risked the process evaluation knowledge being incomplete as there may not have been time to complete the planned mixed methods analysis. A process evaluation researcher explained:

> *"And we feel regret, really, that the outcome data, the primary data, has been delayed. It's good to come up with our findings without knowing that, but it would really be great if we'd had an opportunity to be around as that, those findings are presented and we can then think right, what do we do now with the process evaluation? Because that's what we're gonna be missing. It's such a pity. But these things are almost inevitable in trials, that things don't go smoothly and things get delayed, but it has a knock-on effect on what we can provide in the process evaluation."*

There was also resignation that the process evaluation knowledge outputs would potentially become disconnected from the pragmatic RCT. There were discussions about how the process evaluation findings could be presented in the funder report, and all acknowledged how challenging it would be to write up such a large complex process evaluation into a single chapter. There was concern that elements of the process evaluation would get lost in the overall report.

The trial manager acknowledged it was necessary to focus on providing the outcome measure data in the funder report by their deadline, however that also the process evaluation had collated a large amount of valuable and interesting data:

> *"…that when somebody has more time than we do currently, can come back, it's kind of like there's dozens of PhDs sitting there waiting to be written about those aspects."*

I did not observe the same issues concerns about process evaluation elements being incomplete in the other two case studies, although I observed them at different stages. However, it seemed as if it was the iterative design and greater scope of the case study 3 process evaluation and that the

intervention and pragmatic RCT were inherently more complex that led to the process evaluation being perhaps larger than able to be fully captured in the funder report and in knowledge outputs.

7.6.5.4 Knowledge accuracy

In case study 3 some of the process evaluation involved ongoing data collection from cluster sites in the form of questionnaires, and analysis of data collected by the pragmatic RCT team as part of intervention delivery. As will be discussed in theme 4, because the process evaluation research assistants had been employed after some initial data collection systems had set up, there were concerns about whether the data were fit for purpose. The process evaluation research assistants also had concerns that much of the data were incomplete, and cluster sites returned data with varying degrees of comprehensiveness. They were furthermore aware that all the data were subjective, and felt:

> *"…to make comparisons between [cluster sites], quantitative comparisons, on the basis of the responses that people gave to questionnaires and so on, is actually really problematic to do with any kind of confidence that it's an accurate picture of what was happening."*

The process evaluation research assistants also reflected that as they had spent so much of their time on the staff focus groups subproject of the process evaluation, they may be placing more weight on the findings of those. They considered they had perhaps become more invested in the focus group findings and put more confidence and trust in those findings than those from questionnaires because they had heard them directly from staff members and seen their body language.

> *"…in views of the training, when it was very well evaluated in the questionnaires but quite a lot of the focus groups had some quite severe criticisms of it – you say, well how do you reconcile those two? And we could be perhaps led more by what the focus groups said because it's a richer dataset and because we've got this direct experience of collecting the data, but it's a challenge to triangulate that with the findings of questionnaires that are over*

a broader dataset, but which we know some of the questions have been misinterpreted by some people along the way."

The research assistants were similarly reflective about the timing of data collection at cluster sites, reflecting that collecting data on experiences after the end of the year-long intervention period some staff seemed to have forgotten about the initial component of the intervention and may have got it mixed up with other training received at their clinical area. They reflected:

"…you just don't know whether you'd have picked up different things at different times over that year or afterwards."

There was also concern that dynamics between different staff groups in focus groups could result in certain staff members being less willing to share their true opinions, and the process evaluation researchers discussed arranging focus groups in a way that was most likely to enable participants to be willing to share experiences honestly.

In case study 3 all researchers were keen to triangulate findings from the different subprojects of the process evaluation along with primary outcome data because they were aware of the limitations of relying on one data source to gain an accurate representation. However, there were concerns about compromising confidentiality through triangulating data from one cluster site or whether it was possible to obtain data from the database by site. When I completed case study data collection there was doubt about whether there would be time to do this triangulation work before the funder report was due, the primary outcome data became available, and the research assistants' contracts ended.

In all case studies the process evaluation was described as independent from the pragmatic RCT, and the process evaluation researchers who collected and analysed data were not involved in intervention delivery. In case study 3 the trial manager reflected they thought this had enabled the process evaluation findings to be much less biased than if they and the other trial managers had

undertaken the process evaluation. They admitted they were strongly invested in the intervention which would have inevitably biased their interpretation, and that staff would be much more likely to give honest responses to independent process evaluation researchers.

In case studies 1 and 2 I observed fewer concerns about the accuracy of data, which may have been due to there being fewer subprojects and my observations occurring at a different stage of the process evaluations. In case study 1, as previously discussed, the programme manager and chief investigator were concerned that giving patients lengthy questionnaires could result in them not completing them in a considered way and compromising data quality. The programme manager reflected it may be better to ask a smaller subsample of patients to complete long questionnaires and offer a larger payment incentive. In case study 2 a process evaluation researcher reflected on the telephone interviews conducted with patients and wondered if the response patients gave were limited as they did not have a copy of the participant information sheet, which was the topic of the interview, with them.

7.6.5.5 Dealing with complexity

In case studies 1 and 2 all research team actors, including core documents, acknowledged the value of exploring complexity.

The protocols in both case studies underscored the importance of exploring patient and staff perspectives in-depth, and in case study 1 the team had been requested to include a greater number of patient interviews by the funder to increase depth of insight. There were also plans for patients to be involved in data analysis to deepen understanding. In case study 2 the views of patient and staff were considered so important to adding nuance to and thus better interpreting primary outcome findings that the trial protocol stated that a positive primary outcome result was not alone sufficient reason to change practice. This may have been related to the interventions being compared already being in clinical practice and there being existing dilemmas and controversy that all stakeholders were interested to explore in the study.

In case study 1 patient interviews were longitudinal as it was considered important to understand expectations and perceptions at the start as well as experiences and views having completed the intervention. In case study 2, while interviews were conducted on a single occasion, the team were considering extending the process evaluation to interview participants again in the future to find out whether views had changed. This was driven by experiential knowledge of the clinicians involved in the pragmatic RCT and process evaluation of the potentially complex long-term impacts of the interventions.

In case study 1 most team members, including the chief investigator, were qualitative or mixed-methods researchers. They expressed strong interest in the additional depth, detail, and insight that qualitative data from patients could provide to the trial primary outcomes findings, as illustrated by this interview quote from the principal investigator of the pragmatic RCT:

> *"Yeah, I love it, I find it fascinating! I'm very much a mixed-methods researcher so I always enjoy hearing stories from people because I think we learn so much of it and it creates a richness to what we're doing and a different understanding that data just doesn't provide. I think it's really, really interesting work, yeah."*

As well as finding this exploration of complexity interesting, the principal investigator emphasised the value of understanding complexity to support implementation:

> *"…if you just focus on outcome and you're spending three or four years, no, well four years of your life doing it <chuckles> it seems like a small answer – yes it works, no it doesn't. Whereas there's the richness of things that you can find, why does it work, when doesn't it work, who likes it, who doesn't, who does it work for, who doesn't it, if I'm going to actually implement this what are the things that I'm going to need to take into consideration?"*

Nonetheless while there was agreement about the value of understanding complexity, both case studies 1 and 2 employed methodologies and methods such as logic models and testing contextual

moderators, following the predominant lens of complexity set out in the MRC process evaluation guidance. As discussed in the critical interpretive synthesis in section 5.3.3.1, some authors argue do not adequately capture the complexities of how interventions and contexts operate. However I did not observe any disagreements about the perspectives on complexity taken in these two process evaluations.

In case study 3 I had the opportunity to observe meetings in which data and emerging findings were discussed extensively. Due to its iterative design, data analysis methods had not been specified in the original protocol, and therefore researchers were also making decisions about how to analyse data. In this case study it seemed complexity and variability were continuously emerging, and I observed several in-depth discussions of the complexity and variability shown by process evaluation findings, with all research team actors present appeared interested and thoughtfully engaged. Many, including pragmatic RCT team members, considered it to accurately reflect the complexity of real-world clinical practice

There appeared to be several reasons why research team actors were interested in understanding complexity. The process evaluation researchers had background clinical experience and backgrounds in qualitative research, which appeared to help them see and value complexity in the data. From their experience of running the pragmatic RCT and liaising closely with cluster sites, the trial managers appeared to fully understand and have strong interest in understanding the complexity and variability in the way the intervention worked. The clinical co-applicant said they had a strong practical interest in understanding the reasons for variability in intervention implementation and effectiveness as this would help target the intervention better and improve outcomes for patients. They acknowledged that a binary primary outcome result would not reflect the experiences of all sites, and considered it important to explore this variability.

I observed the process evaluation team discussing data analysis methods and theoretical frameworks which did appear to account for complexity more deeply than in case studies 1 and 2,

however it seemed at times this brought up tensions between fully understanding complexity, the pragmatic reality of doing so, and reconciling such findings with the eventual pragmatic RCT outcome result.

The complexity and variability uncovered by the process evaluation about how the intervention appeared to be functioning and implemented at cluster sites was potentially at odds with a statement in the pragmatic RCT funding application about how a positive trial result from this *definitive study* could lead to the intervention being quickly rolled out in the NHS. The funding application implied that findings from the pragmatic RCT could *either* prevent an ineffective strategy being adopted if the primary outcome was negative *or* enable an effective intervention to be rolled out.

Furthermore, while understanding complexity appeared to be valued by most research team actors, it was more difficult in practice to capture that complexity in knowledge outputs. A strong limiting factor in what could be done in terms of analysing and presenting these complex and variable data was time. For example, in one meeting a process evaluation researcher had a fifteen-minute slot to present data, however ran out of time having only covered a small amount but with a lot of detail. They appeared frustrated at having to stop and highlighted there was much more to the data. On a larger scale, it seemed there would likely be insufficient time left in the grant for more complex qualitative analyses to be completed and disseminated, and these would be published separately from the funder report once the funding period was over and if people had time.

It appeared that there was a tension for some research team actors between knowing the data showed considerable complexity, variability, and contradictions and being unable to adequately capture this in outputs. This led to some expressions of frustration, stress, and sadness, showing the potential negative impacts on researchers of seeing the realities of events but not having the resources to fully address them. One researcher commented in an interview with me that in general

they considered it better to employ very pragmatic qualitative researchers for process evaluations who were less interested in using in-depth methods because this fitted better with the goals of RCTs.

7.6.5.6 Dissemination

During the time I conducted the case studies small amounts of conference dissemination had occurred in case study 3, and in all case studies research team actors discussed plans for dissemination.

It seemed at times that the target journal for process evaluation findings was a potential factor shaping the knowledge outputs. In case study 3, when discussing data analysis methods for qualitative data a factor in this decision was the target journal, with certain approaches deemed more suitable if certain journals were to be targeted. The discussion was less about how the knowledge could be used and by whom and selecting data analysis methods on this basis. Also in case study 3, the chief investigator suggested the process evaluation could be submitted to a very high impact journal if findings were presented in a way that showed their wider implications for primary care.

In call case studies researchers were keen to ensure process evaluation findings were also disseminated to patients and professionals in an accessible format with the pragmatic RCT findings. In particular a recognised value of this was to help patients and professionals understand potential benefits of interventions and encourage uptake.

7.6.5.7 Uses of process evaluation knowledge

As already discussed in section 5.6.4.2, having a clear understanding of how knowledge would be used and thus create value appeared an important factor in creating team unity around a common goal and in conducting a cohesive process evaluation.

Formative use

There were examples in the case studies of how process evaluation knowledge had been used formatively and created value. In case study 1 findings from staff interviews had been used to

improve training provided within the pragmatic RCT to staff delivering the intervention, which had supported the success of the trial and helped improve the intervention.

In case study 2 the purpose of the process evaluation was to formatively improve trial processes to support the success of the trial, and, as previously discussed in this chapter, to improve the experience of trial participants.

Two participants commented that they would prefer process evaluations in general to be conducted much more at the intervention development stage so knowledge could be used formatively to develop interventions that were likely to work. They considered it less helpful to focus resources on creating process evaluation knowledge to aid understanding of why an intervention did not work and more helpful to focus resources on making it work.

Summative use

Due to the timing of the case studies, I was only able to collect data about the value case study participants anticipated summative use of process evaluation knowledge would have. Table 7.12 outlines the different suggested summative uses of process evaluation knowledge and gives examples of the value participants suggested this could create.

Table 7.12 Summative uses of process evaluation knowledge suggested in case studies

Suggested summative use of knowledge	Examples of value
Interpreting pragmatic RCT findings	Prevent interventions with negative trial results being 'written off' Understand whether lack of intervention effect due to lack of engagement or ineffective intervention Add nuance to the primary outcome to see if the intervention affected different people differently or people got benefits not covered by the primary outcome Understand impact of contextual factors on findings Understand factors that led to positive trial findings

Suggested summative use of knowledge	Examples of value
	Makes research less reductive and reflects known complexity of patients and condition Understand internal validity of findings Understand proximal changes leading to outcomes or not
Intervention development	Inform strengthening/refining of intervention components Inform potential adjustments to the intervention if certain components shown to significantly contribute to outcomes or not Understand role/significance of intervention components to inform roll-out into practice Inform minor adjustments to make the intervention more user-friendly
Informing wider knowledge	Anonymised process evaluation data potentially used in future research Inform future intervention development and study design – learning from what worked well and what did not work Building the evidence-base for similar interventions Inform development of future interventions Inform wider practice around recruitment to RCTs in specialty Methodological development for process evaluations
Informing implementation of interventions into practice	Inform targeting of intervention/adjustment for different patient groups Understand how the intervention may be integrated into existing care and services Understand acceptability and feasibility of delivering the intervention in the NHS Sharing patient views about the intervention during rollout to encourage others to engage with it Give study findings more traction when implemented – give clinicians and policymakers more encouragement to adopt the intervention

Suggested summative use of knowledge	Examples of value
	Ensure patients are given full information about treatment options Understand potential disadvantages of intervention even if outcome result is positive Understanding which sites tend to get best results from the intervention and why, to inform targeting and development of implementation strategies Understand which sites have the most to gain from the intervention Optimise implementation strategies

7.6.5.8 Theme 3 summary

This theme has considered how different features of process evaluation knowledge were perceived as valuable or potentially detrimental. It has also examined how process evaluation knowledge had been used formatively to create value, and the ways in which case study participants considered it could be used summatively to create value.

The final theme now explores the work involved with getting the process evaluations done in the UK healthcare research organisational contexts.

7.6.6 Theme 4 – Getting process evaluations done in the UK healthcare research context

This theme centres on the TMT mechanism of articulation, described by Allen (107) as the work that makes the work, work. It is the secondary work processes that underpin a project by aligning the resources, knowledge, and actions necessary to enact that project (86). In the case studies, articulation was the work that research team actors undertook to make the primary academic work (for example interviewing a participant or designing a topic guide) and operational work (for example writing an ethics amendment form) possible. Examples of these secondary work articulation processes included the work of ensuring process evaluation data collection aligned with

pragmatic RCT timelines, and the work of organising process evaluation researcher employment contract extensions.

Most of the articulation work on which I collected data related to the work of getting process evaluations done in the multiple organisational strategic action fields of health services research. This included the organisations hosting the research studies, including the funders, universities, NHS sponsors, charity partners, and Clinical Trials Units (CTUs). It also included the organisations which were the gatekeepers to process evaluation participants, including the NHS Health Research Authority (HRA), CCGs, CRNs, and NHS research sites participating in the pragmatic RCTs.

Allen (86) outlines three types of articulation work, and often I observed, or researchers described, more than one of these types occurring concurrently. Table 7.13 defines these three types of articulation.

Table 7.13 Different types of articulation

Temporal articulation	*Aims to guarantee things happen at the appropriate time and in the right order* (86)
Material articulation	*Aims to ensure the availability of the materials to support action* (86)
Integrative articulation	*Aims to safeguard the coherence of different components of project work* (86)

During the periods I spent in the field there were vast differences between case studies in the complexity and volume of articulation work that the process evaluations entailed. The case study 2 process evaluation appeared to need very little articulation work, while in the case study 3 process evaluation there was lengthy and complex articulation work that appeared to take up a great deal of time and cause research team actors considerable frustration. For example, in meetings I observed often half the meeting taken up attempting to find solutions for articulation challenges, rather than discussing the primary academic or operational work. In the case study 1 process evaluation there were also articulation challenges, however these appeared smaller and more manageable than in

case study 3. In the discussion that follows I highlight key differences between the case studies that appeared to influence the articulation challenges that were presented and how they were resolved.

Because the process evaluations and pragmatic RCTs were so closely linked with joint protocols and approvals, articulation work was also often interlinked. It was not always possible to distinguish between the articulation work of the process evaluations and the work of articulating the pragmatic RCTs.

7.6.6.1 Personal reflections on this theme

Having worked as a research nurse and research assistant in the same UK healthcare research infrastructure that formed the context of the case studies, I was aware my own experiences and opinions could influence my interpretations. I have experienced similar frustrations personally to those explored in this theme, and had negative experiences of the same organisations and certain people who work in them. I was therefore aware that I could be wanting to confirm my own negative opinions and use these case studies as a means of validating my experiences by putting undue emphasis on the negative.

Nonetheless through triangulation there was strong agreement between data sources, participants, and critical outsiders that challenges discussed in this theme were common and significant. A few participants and critical outsiders commented to me however that this seemed to be not a process evaluation issue, but rather just the frustrations of doing healthcare research. Nevertheless, it seemed to me that the problems were exacerbated at times for the process evaluations compared to the RCTs, and I also considered even if these were 'just' the problems of doing healthcare research they were so significant in shaping the process evaluations they warranted full exploration.

7.6.6.2 Having actors available to do the work

In case studies 1 and 3 there were significant challenges to aligning research team actors at the right time to do the academic and operational work that was required at each stage of the process evaluations. Because the process evaluations were so closely linked to the pragmatic RCTs, often there was overlap in the temporal and material articulation work required to progress them both,

and articulation issues relating to the pragmatic RCT had a direct impact on the process evaluations. The most significant challenges to aligning research team actors related to cross-organisational working.

In case study 1 both the pragmatic RCT and process evaluation encountered delays due to a requirement for signoffs to all decisions by different actors in different organisation, including the sponsoring NHS Trust's Research and Development department and the CTU. Delays were caused by each organisation having different processes and organising logics, the departments in question being short-staffed, and/or the staff allocated to the pragmatic RCT and process evaluation having multiple lines of work and minimal time available for this particular project. The programme manager summarised the problem as follows:

> *"…and then you had to get it all signed off by the NHS, who have very little understanding of what's going on anyway, and to be honest, don't … they're just very cautious and very risk-aware without actually wanting to get involved in the thing. So essentially it just adds a lot of delays to trying to complete a protocol. If it was just one organisation you'd have one policy, you'd say this is how we're gonna store it and it would go straight forward. Instead you have to bring it up in endless meetings, and when you have people who've only had 5% or 10% of their time in a grant and the only time they really actually address this is in a meeting, you end up spending three or four months just to get a decision on something that was really very simple if it was in its own organisation. So yeah, lots of delays around that point for the process evaluation, having different organisations and different processes."*

A significant impact of delays was a key non-human actor required by the trial and process evaluation, namely the trial database, was not available at the planned timepoint and this led to severe delays in starting the trial and process evaluation.

In case study 1 research team actors did take measures to mitigate the potential disruption related to cross-organisational working. The trial manager described the temporal articulation work

required in managing effective communication of timelines with the CTU, and how they had eased this challenge by basing themselves part-time within the CTU offices and part-time with the academic research team. The chief investigator explained how they had refused to use the CTU's database for storage of qualitative process evaluation data because they had encountered so many articulation challenges with the same database on a previous study, and had instead found an alternative secure data storage solution.

In case study 3 cross-organisational working also caused challenges to aligning research team actors. A process evaluation researcher started a new post at a different university partway through the process evaluation. There were lengthy delays to transferring contracts and funds between the study grant, sponsor, and their new employing university which meant the researcher was unable to undertake the work planned on the process evaluation subprojects allocated to them for several months. This also meant the plan to employ a research assistant to work on the process evaluation was severely delayed. Because of these delays the other process evaluation team began the subproject, which was possible because the research assistants serendipitously had the right skills and experiences to do so. This caused further articulation work as study funds then needed to be transferred again to the other university, and because this took such a long time the lead process evaluation researcher had to find funding to cover costs in the interim.

Transferring research budgets between universities appeared to necessitate a lot of articulation work and cause many delays to the case study 3 process evaluation, often stemming from internal problems and staff turnover in these departments. This quote from a researcher is one example of many similar conversations I observed in process evaluation meetings:

> *"There has been, just to add complications, it seems to be a permanent merry go round of people in our team, so I think [name] has now been replaced with someone called [name], so I'm just sending you.. saying this is the newest newest new person that you've got to talk to about this..."*

Another major cross-organisational issue in case study 3 was severe delays to the pragmatic RCT caused by the length of unplanned time taken to arrange permissions from different NHS bodies to collect primary outcome data from research sites. As this was a cluster RCT with an intervention delivered to staff, patients did not consent as individuals to participate, and their primary outcome data were collected as anonymous routine clinical data. This delay caused major challenges to the process evaluation and required lengthy complex articulation work to address.

Firstly, because the process evaluation researchers were employed on fixed-term contracts at different universities to the pragmatic RCT team, there were many time-consuming and complex issues associated with extending their employment contracts when the pragmatic RCT was delayed. This was further complicated by it being uncertain whether the funder would grant a costed extension and the university employing the process evaluation researchers being unwilling to extend contracts without the extension being agreed. Negotiating these issues appeared to take considerable time away from doing the core process evaluation work, and created uncertainty, stress, and tension about whether the process evaluation work could be completed to plan and whether the research assistants would still have employment.

Secondly, while awaiting a response to the application for a costed extension it was unclear whether the funder would require the process evaluation report to be submitted on the original date, or whether they would also allow this to be extended. A major subproject of the process evaluation was planned to be a mixed-methods analysis of process and outcome data, however without the primary outcome data being available on time it was unclear whether there would be time to complete this. When I completed fieldwork the process evaluation researchers were putting together a report of the process evaluation as it stood in case the funder required it. Several research team actors on substantive contracts commented that they expected they would eventually complete the planned analyses, however in their own time due to their investment and interest in the project, or by finding interested PhD students.

The process evaluation adviser commented that it was a common experience for there not to be sufficient time to undertake a mixed-methods analysis and integration of process and outcome data and usually insufficient time was allocated. I asked a researcher in case study 1 whether time had been allocated to the planned mixed-methods analysis at the end of that process evaluation and they admitted they weren't sure it had been yet. However, a research team member in one case study explained it was very difficult at the funding stage to accurately predict how much time and resource would be required for research programmes lasting several years, and sometimes these were based on educated guesses that turned out to be wrong.

Within organisations it was also clear that articulation work required research team actors to have excellent planning skills to anticipate when people would be needed for each aspect of the process evaluation. This included ensuring enough people on the team were available who could cover crucial timepoints of the pragmatic RCT, for example being available to interview a patient when they were recruited. It also included planning for research team actors to receive training in time to cover specialised aspects of their roles. In case studies 1 and 3 students contributed to process evaluation data collection and analysis of aspects of the process evaluations, and articulation work was involved in aligning their timepoints

In all case studies process evaluation researchers on substantive contracts with time bought out to work on the process evaluations had to manage their time allocated to the process evaluations. Several acknowledged it was difficult to plan specific time to allot to the fluctuating volumes of work required by the process evaluations over the course of the study, and part of articulation work was monitoring how much time they had used of the amount bought by the process evaluations. Nonetheless, all explained that in their academic roles they were used to working flexibly in this way. One qualitative researcher explained however that they had allocated a block of time to qualitative analysis in advance, however when circumstances meant data were not available at the expected time it was difficult to arrange another focused block of time.

Staff turnover during the lifespan of process evaluations and pragmatic RCTs lasting several years also influenced articulation work. In case study 1 the programme manager left post partway through the study, however a researcher commented to me that the chief investigator had taken care to build a strong team from the outset that could cope with such potential disruptions. In case study 3 trial managers in the CTU whose knowledge was important to the process evaluation were redeployed to other studies, however due to their emotional investment in the intervention and overall project continued to share knowledge and insights with the process evaluation team.

In case studies 1 and 3 students participated in aspects of process evaluation data analysis. In both cases this brought benefits for students of educational experiences and to the process evaluation knowledge of different insights. In case study 3 this meant additional aspects of data analysis were able to be undertaken, which would not have been possible otherwise. In both cases this did depend on students' course timelines aligning with the process evaluation timelines, which meant at times involvement was not possible.

7.6.6.3 Recruiting participants

In case studies 1 and 2 recruitment was relatively straightforward because patients were individually randomised to the pragmatic RCT and at the time of consent indicated whether they would be happy to be contacted to take part in interviews. The process evaluation team could therefore simply contact patients who had consented to be contacted. Similarly, recruiting intervention staff, or staff involved in participant recruitment in case study 2, for interviews was straightforward because trial managers or other members of the pragmatic RCT team had existing relationship with them and could contact them on behalf of process evaluation researchers.

A research fellow in case study 1 explained how they felt their role in training intervention staff made them well placed to recruit staff to participate in the process evaluation:

> *"… everything's a bit more smooth I guess. If you're a [staff member] about to take part in this trial and you've met a couple of us and then someone new comes along, it can probably*

seem a bit confusing, but I think for me to be able to say, 'This is our process evaluation team, this how it ties in with what I've talked to you about so far,' it just means that it gives them a bit of context rather than it just feeling like a completely separate study as it were. And I guess operationally it's also made sense for someone in the central team to help with things, 'cause the process evaluation team really deal with process evaluation rather than recruitment and patient pathways and things, so I think it would be tricky for them to step in and get involved in recruitment when it's quite a complicated process when it's such a big trial."

In contrast, recruitment of patients and staff process evaluation participants in case study 3 brought substantial articulation challenges. It seemed that a primary cause was the pragmatic RCT being a cluster design, and a representative of the cluster research sites consented to participate in the pragmatic RCT. The staff receiving the intervention did not give individual consent to participate in the trial, and neither did individual patients as the primary outcome was measured using anonymised routine clinical data.

Although these research sites had consented to participate in the trial, the process evaluation researchers needed to gain separate permissions through regional CCGs and CRNs to approach participating trial sites to recruit staff to participate in focus groups. A process evaluation researcher commented that this was double work as the trial managers had already done this process to recruit cluster sites for the pragmatic RCT, now they had to do the whole process again for the process evaluation. A similar issue arose recruiting patients to participate in process evaluation interviews, which had to be undertaken via the CRNs.

Much time-consuming and complex articulation work was required of the process evaluation research assistants to meet the requirements of the CRNs and CCGs, which caused frustration and diversion of time and energy from doing the process evaluation. A major challenge was that regional CCGs and CRNs had their own rules and requirements, despite being under national umbrella. The

trial managers had built up extensive experiential knowledge of the requirements of different regions and the most helpful individuals to speak to in the organisations. They shared this willingly with the process evaluation researchers, however a process evaluation research assistant explained:

> *"…but a lot of these contacts change over time. So they'd made these initial contacts and put a lot of work into it themselves, and then we had to do it again. I mean we weren't doing it so broadly. We only approached, I think … it may have been more than eight, but eight CRN regions, but that … within those we had to sometimes approach more than one CCG to get approvals and letters of access and that sort of thing. And then sometimes I fell at the first post of actually finding the named person that had a phone number or an email address in the CCG or the CRN, who could actually help us. And you'd be sent from pillar to post and, 'Oh, so-and-so's on maternity leave' and then you'd wait three weeks before someone got back to you, even though you were asking. And then it was the wrong person, so no, no, you need to ask so-and-so. So you go round in these circles and I had big spreadsheets of who might be the right person <chuckles> in the right area. So it took an awful lot of unneeded time really. If someone had been doing that centrally, and keeping it up to date over that time, I think it would have given us more time to do other things and get the focus groups done a lot earlier as well."*

As this excerpt shows, in case study 3 the process evaluation researchers were undertaking this work rather than the trial or programme managers as in case studies 1 and 2. They felt the time taken to do this work should ideally have been factored in, although recognised nobody had anticipated these challenges. However, I found myself questioning whether the issue was less who should do this articulation work and rather why this articulation work needed to be done at all given that cluster sites were already in the pragmatic RCT.

The variability between regional CCGs and CRNs led to certain branches being favoured to approach to support the process evaluation and others being abandoned. The process evaluation team

considered a CRN local to them would be more likely to agree to support the process evaluation as they could present it as a local study. Research team actors spent a lot of time in meetings discussing past experiences with different CRNs being helpful and accommodating or, as one process evaluation researcher put it:

> *"[CRN name] is always a bloody difficult CRN anyway"*

In the minutes of a meeting between the process evaluation and pragmatic RCT team it was even documented:

> *NOTED: [Research assistant] had experienced difficulties with navigating procedures for getting CRN/CCG approvals and letters of access, particularly at [region]. [Trial manager] confirmed they had previously been very difficult.*
> *NOTED: There was no-one at the [name] CTU who had a specific role to support this work though there may be knowledge via other projects of places that were more or less efficient.*
> *ACTION: [Trial manager] to ask around CTU about any further/more recent knowledge of getting approvals in different regions, including [name] (as potential next target for staff FGs).*
> *ACTION: [Research assistant] to liaise with [Qualitative lead] about support with getting approvals for other accessible regions with sufficient [sites] [in another region].*

Process evaluation research assistants described frustration at the lengthy processes required to gain letters of access and research passports from each CCG/CRN region that would permit them to collect data from participants.

> "*You have to get your passport signed by, what are they called? Each of the CRN areas. So, mine's been around four different areas and you have to get it signed off, and then they produce a letter of access, so that gives you permission to work on their patch. Again, even*

though it's only phone calls, I'm never going to go to their patches, it checks out the, you know the DBS check, it checks that I've got no previous history of anything, and gives me permission to work in their area. So, that's all done before I contact the CRNs, that's another whole nightmare that's sort of forgotten now, but yes, that takes several weeks to get that."

The Covid pandemic brought fresh challenges to recruiting patients to participate in the process evaluations as the CRNs introduced a blanket stop to research study recruitment. However, the chief investigator and other research team actors felt this should not stop the process evaluation as the study would not put extra demands on sites and patients would likely welcome the opportunity to participate in telephone interviews while in lockdown. Time in meetings I observed was spent discussing tactics to potentially approach individuals in CRNs who were known to be helpful and flexible to try to gain permission to recruit patients.

As previously stated, case studies 1 and 2 did not experience these problems as process evaluation researchers were able to contact trial participants themselves. Because these issues with CRNs were so prominent in case study 1 I asked in the other two case studies if they had experienced anything similar. In case study 1 there had been a deliberate decision to design the programme so that it would not need to involve CRNs because previous experiences of working with them had been challenging.

7.6.6.4 Data collection

In all case studies articulation work was required to align data collection with pragmatic RCT timelines.

In case study 2 this was straightforward as process evaluation researchers could contact patients after they had received the intervention and arrange an interview at their convenience.

In case study 1 because patient interviews needed to be done after a patient had been consented to the pragmatic RCT but before they knew their randomisation allocation the articulation work was more complex. It needed to align the availability of the process evaluation researcher with when

patients were invited to participate, so that there was minimal delay between the patient agreeing to participate, the interview, and them being randomised and able to start the intervention. Research team actors were mindful that a delay could lead to the patient losing interest in receiving the intervention, and also of the possibility that patients could become lost between the intervention, database, and randomisation computer systems. However, while this was complicated it was resolved fairly easily, seemingly because the research team actors involved all had direct access and control over the different systems and worked directly with the staff recruiting patients. The chief investigator also played an important role, highlighting that they had ensured the process was streamlined to:

> "*…be clear who does what so that we don't miss people but we don't make it too onerous on the team with each recruit needing 15 different emails to actually capture somebody for this.*"

One researcher also highlighted that Covid had facilitated arranging data collection it had normalised online communication, and therefore they conducted interviews online rather than in person. This cut down articulation work considerably as they no longer had to factor in participants' travel arrangements.

In case study 1 the online intervention was being built as part of the programme grant and during this process it was necessary to incorporate the automatic capturing of some process evaluation data. The chief investigator felt this had been positive as it had required the team to consider at the outset the data they would wish to collect, rather than realise later they would be unable to collect an important data point.

In case study 3 arranging focus groups with staff at cluster sites was complex, and research assistants needed to travel to different parts of the UK to fit in with when sites completed the intervention period. Focus groups were sometimes cancelled at the last minute due to clinical

priorities and successfully arranging a focus group seemed highly contingent on offering flexibility to participants, and research assistants being willing and able to be highly flexible with their time.

A further challenge to data collection in case study 3 was that the original process evaluation protocol lacked detail and set out broad aims, and the research assistants employed to undertake the process evaluation were not involved in the initial establishment of data collection systems. This had resulted in the research assistants needing to piece together various data sources to see whether they could adequately address process evaluation aims using those data. As one researcher said:

> *"…that data wasn't necessarily being collected with a view to answering process evaluation questions. It was just collected and we looked at it to say well, does it have any value in terms of answering the process evaluation aims? But as I said, some of those data collection instruments I don't think were specifically designed with process evaluation in mind."*

The trial managers had been responsible for initial data collection, and they also acknowledged their limitations, stating:

> *"…that decision wasn't being made by an expert in the field who is going to be constrained by it now that they're trying to do the analysis."*

The process evaluation research assistants and trial managers spent a considerable amount of time over the whole study on the material and integrative articulation work of ensuring data already collected were fit for the process evaluation's purposes.

In case study 3 the long time period between initial set up of the pragmatic RCT and process evaluation data collection brought further articulation work to ensure data collection was in line with original agreements. When designing the questionnaires to for research sites the process evaluation researchers and trial managers needed to ensure the amount of time staff would need to spend on the questionnaire was in line with what had been agreed with research sites in their

contracts. There were also issues with checking whether data collected from staff at the research sites as part of the trial could be used for the process evaluation under new General Data Protection Regulation (GDPR), as staff had not given individual consent for this specific use of their data. This again involved time-consuming discussions and negotiations of different interpretations of the GDPR.

7.6.6.5 Aligning subprojects and intersecting projects

As described in theme 1, different researchers brought different ideas about what the process evaluations could investigate. Part of integrative articulation work was therefore managing these different elements and keeping the process evaluation on track with its original aims. In some instances, the teams agreed adding new elements to the process evaluations was desirable and sought to do this, for example adding a questionnaire to assess the impact of Covid in case study 1. However, in other instances certain research team actors appeared to play a pivotal role in avoiding mission creep and keeping the process evaluations focused on their original aims. The chief investigator had clear oversight of the process evaluation in case study 1 as they explained:

> *"So I think it was trying to balance between the teams, some wanting far too much, sometimes some feeling that it just needed to be very high level, and trying to negotiate between all the different, I won't call them interest groups but … stances of what was actually … 'cause obviously you could do a whole huge process evaluation, but that wasn't the main point. The point was really to understand what results we got better, but the whole point was not a separate study as a process evaluation. It was so we can interpret our results better by explaining them better, but not to make it a whole industry in its own right…"*

In case study 3 the process evaluation lead researcher took a similar stance and I observed on frequent occasions them steer ideas back to the original aims of the process evaluation. This articulation work appeared more challenging however due to the iterative design of the process evaluation and the large volumes of data being collected.

Another element of this integrative articulation work regarded by some research team actors as important was maintaining a focus on process evaluation outputs, particularly the funder report and publications. In case study 3 a process evaluation researcher commented:

> *"…we could be here for another two or three years analysing all the data, maybe. But we have to get an NIHR report out and some papers written. And so, at some point you have to be disciplined enough to stop doing the data analysis, to make sure that what you do have, does end up as an output and not just a load of data collected that will never be published. Because that's no use to anybody."*

Integrative articulation work was also necessary to keep the process evaluations aligned with the intersecting projects, including the pragmatic RCTs. In case study 3, again as the process evaluation was iterative and the research assistants joined after it had begun, it took time and effort to keep recruitment and data collection in line with the ethics approved protocol and other documents. This included not applying for protocol amendments that had previously been rejected by ethics, and trial managers with their in-depth knowledge of the history of the trial played a pivotal role in this integrative articulation.

In case study 1 several people commented that as the whole programme was so big with multiple intersecting projects, the process evaluation researchers often lost sight of what was going on in the overall programme and how the process evaluation fitted into it. However, I did not observe any problems resulting from this and the chief investigator and programme manager appeared to have strong oversight and kept the whole programme cohesive. In my fieldnotes from a programme management group meeting I noted:

> *People from different work packages comment on and ask questions about each other's work packages – all seem interested, engaged, listening to all bits. [Chief investigator] seems in control of all work packages – as in having a handle on them all and generally directing while*

being very open to feedback - and encourages input from all. Seems discussion trying to take account of all views to make best decision for the programme.

I also noted there appeared to be nobody who had this same level of oversight in the other case studies. In case study 3 the lead process evaluation researcher sought to include pragmatic RCT team members and health economists in the process evaluation discussions to keep oversight of how the projects fitted together, however they seemed to have some difficulties doing so. I also noted that the process evaluation team needed to do considerable articulation work to fit around everybody else's timescales, and very rarely set its own agendas. I reflected that this may be reflective of the value placed upon it in comparison to that placed on the pragmatic RCT.

7.6.6.6 Articulation work in unpredictable and changeable contexts

A key challenge to articulation work was that elements such as time, resources, and the availability and priorities of key actors were often unpredictable and changeable. Within national organisations supporting healthcare research with ostensibly the same goals and policies was significant variation at regional and individual levels. When dealing with departments whose support was needed to progress the process evaluations such as CTUs and university contracts offices, high staff turnover and staff having multiple competing lines of work caused significant delays. Over the course of the process evaluation, local, national, and global contexts evolved, and managing these changing contexts was made more complex by different actors having different interpretations of their implications and how they should be dealt with.

An important means of progressing the process evaluation often appeared to be finding the right person to speak to within a department or organisation. There were examples of individuals within departments or organisations with the right experience or attitudes being able to suddenly move things forwards after lengthy delays and negotiations. Maintaining relationships with these people was also important, and research team actors carefully considered how long to wait before following up requests to maximise the chances of a favourable response.

Often, research team actors needed to find creative ways to present the value of the process evaluation as beneficial to organisations in order to get it approved, for example highlighting that cluster sites would improve their status as research-active through participating. Similarly, when drafting ethics and other regulatory approval applications research team actors shared experiences of wording that had been accepted on a recent study they had been involved in. Research team actors drew on their knowledge and experience of the likely organising logics of the actors who whose approval was needed to frame the process evaluation as a practice object likely to win favour.

In order to successfully navigate this articulation work it was clear, as in theme 1, that research team actors mostly used mindlines (232), drawing on their own and colleagues' tacit and experiential knowledge of how to get things done in complex and at times paradoxically obstructive organisations. The contacts, experience, and sources of tacit knowledge that formed the mindlines were often incidental rather than core to research team actor's role. For example, a trial manager also was a member of an ethics committee, and a process evaluation researcher happened to work in the next office to a senior member of CRN staff. This activity also resonates with Allen and May's (86) description of how within institutional contexts project actors interact with "local stocks of knowledge", and through this are able to assign identities to practice objects that make collaborative action possible.

7.6.6.7 Workarounds and the agency of individual research team actors

There were clear differences in attitudes of research team actors in how they approached the articulation work of navigating organisational structures to get the process evaluations done. Individual willingness to bend the rules and find creative solutions to bypass bureaucratic processes varied, from unquestioning compliance at one end of the spectrum to deciding what they could realistically 'get away with' at the other.

The concept of workarounds (239) appears relevant, particularly in case study 3. Workarounds are defined as:

a goal-driven adaptation, improvisation, or other change to one or more aspects of an existing work system in order to overcome, bypass, or minimize the impact of obstacles, exceptions, anomalies, mishaps, established practices, management expectations, or structural constraints that are perceived as preventing that work system or its participants from achieving a desired level of efficiency, effectiveness, or other organizational or personal goals. (239) p.1044.

As discussed above, research team actors at times needed to find creative solutions to circumnavigate research bureaucracy and often jointly developed and shared workarounds. It is important to highlight that the goals and values of the research team actors using workarounds and those of the organisations whose systems and rules they were attempting to bypass were ostensibly the same – to conduct high-quality ethical healthcare research to improve healthcare and health outcomes. It is therefore relevant to question why research team actors needed to spend time, energy, and creative resources on workarounds rather than on the conduct of research itself to reach this shared goal. It seemed even the chief investigators had limited power to challenge these systems, and at times participated in developing the workarounds.

Research team actors exercised agency in deciding whether to:

- Comply with rules and procedures (as happened mostly in case study 2)
- As far as possible avoid working with organisations where this was likely to be a problem (as happened mostly in case study 1) or
- Find workarounds to multiple challenges (as happened mostly in case study 3).

In case study 1 it appeared that research team actors were able to avoid structural constraints through the deliberate considered action of the chief investigator, resulting from their extensive experience of conducting research in this specific context. In contrast, in case study 3 it appeared that research team actors had not anticipated the challenges that would be encountered as they had

less experience in their context, and some joked they would be unlikely to choose to do research in primary care in the NHS again.

In case study 2 the compliance may have stemmed from the intervention and pragmatic RCT being considered high-risk. I also noted that, likely because the trial was high-risk, representatives from the organisations involved were present at all trial management group meetings I observed, which differed from case studies 1 and 3. This may have led to more efficient communication and processes which negated the need for the degree of articulation work required in the other two case study process evaluations.

It is important to note that although exercising agency in different ways, none of the research team actors did so in a way that challenged the organisational structures and, in some sense, their actions reinforced them.

7.6.6.8 Impact of articulation challenges on research team actors

Articulation work had negative impacts on research team actors at times, with some expressing their frustration and exhaustion with bureaucratic processes, unpredictable factors, and endless delays over which they felt they had no control. These delays and the time spent on articulation work had knock-on effects on the amount of time process evaluation researchers had to undertake the actual research, which in case study 3 brought stress and dissatisfaction to process evaluation researchers at not being able to complete the research in which they had become heavily invested.

Several case study participants reflected the issues experienced in the process evaluations were not unusual, and that doing research in the NHS had become and continued to get more challenging and bureaucratic. One had decided to leave healthcare research altogether and change career. Another joked when I asked if they had any advice for researchers considering doing a process evaluation:

> *"Don't do it in the NHS!"*

Despite the negative impacts of articulation work, working together to attempt to resolve these challenges did appear to facilitate relationships between research team actors in the face

of common frustrations. Some observations particularly in case study 3 seemed to be examples of "*condenser phenomenon*" (240), in which tension is released through sharing of stories of frustration. As Thornton (240) illustrates, while actors may feel powerless to resolve frustrations, through this sharing they may gain a degree of "twisted satisfaction" and a sense of all being in it together.

7.6.6.9 Theme 4 summary

Articulation work appeared to be an important factor shaping the process evaluations, particularly in terms of the amount of time it took away from the primary research tasks, and in some cases determining what was possible to do in the process evaluations. It also highlighted important points about how process evaluations appeared to be valued by the organisations whose role was ostensibly to support research. Furthermore, articulation work had some negative impacts on research team actors, and ultimately on the wider endeavour of healthcare research as some actors were unenthusiastic about conducting similar research in the future.

7.6.7 Summary of findings and recommendations

The cross-case analysis of the three case study process evaluations resulted in four themes of findings addressing the research questions of how process evaluations are defined, valued, and shaped in pragmatic RCTs of complex healthcare interventions. These themes are:

1. How research teams share ideas and make decisions
2. Participation in process evaluation – how participants shape process evaluations, value to participants, negative consequences to participants
3. The knowledge produced by process evaluations – what kind of knowledge is valued and how can the knowledge create value or negative consequences?
4. The articulation work of making process evaluations happen in the contexts of pragmatic RCTs, the NIHR and the NHS

I discuss these findings further in the overall discussion in chapter 8, however, to close this chapter I outline the main recommendations from these case study findings:

1. There should be formal team discussions from the outset of planning a process evaluation among the process evaluation research team, trial team, and any other relevant stakeholders including PPI members to establish:
    a. A common understanding of the definition of the process evaluation
    b. A joint vision of value they wish the process evaluation to create and for who
    c. A clear understanding of how the knowledge being produced will create that value, including dissemination and application to practice
    d. The type of knowledge the process evaluation will create, considering ontology, epistemology, perspectives on complexity, accuracy, completeness – and how this will be integrated with or reconciled with different scenarios of RCT outcome findings
    e. Potential tensions between the conduct of the process evaluation and RCT, and how they will be managed
    f. Ensuring there is sufficient time planned to make decisions and conduct complex analyses at key points in the process evaluation, particularly if it is an iterative design.
2. Process evaluation teams and trial teams, including the chief investigator, should pay attention to the social and organisational processes by which ideas are shared and decisions made – and ultimately which shape the end knowledge that is produced. This includes:
    a. Creating physical, virtual, and social spaces which facilitate the open sharing of ideas and opinions, with sufficient time allocated

b. Establishing positive relationships between team members working across teams and organisations

c. The chairperson of meetings being suitably skilled at managing power dynamics, creating psychological safety, and encouraging participation from all members

3. Address the barriers to getting process evaluations done in healthcare research organisations and contexts:

    a. Ensure sufficient time is factored into process evaluation project plans and researcher contracts to allow for operational delays

    b. Include key organisations and departments in the planning phase to aim to create the most efficient processes, such as for cross-organisational decision making.

    c. Further research exploring the perspectives of people working in the organisations facilitating the process evaluations to address barriers, such as CRNs and university departments – with the aim of finding solutions and changing systems

    d. Researchers report and challenge organisational barriers and their impact on researchers and process evaluations

7.7 Case study strengths and limitations

The focused ethnographic multiple case study approach enabled me to study holistically, in real-time, and in-depth three different process evaluations in different contexts. This approach enabled more closely examine how context shaped the process evaluations than a design focusing on the abstract phenomenon of 'process evaluation', for example through an acontextual qualitative interview study with stakeholders.

Translational Mobilisation Theory provided a novel lens to provide new understanding of how process evaluations are shaped by the mechanisms enacted by research teams to share ideas and

make decisions, and how actors negotiate multiple complex strategic action fields of healthcare research. The concept of organising logics provided a useful proxy for value and enabled me to compare the values that appeared to be influencing different actors' perspectives and actions. Rather than describing a range of different perspectives on the value of process evaluations, TMT aided me to suggest explanations why different actors held different views and examine how these different views were negotiated. However, this analysis also recognised that factors in the strategic action field, such as Zoom technology or the academic title of a researcher, did not themselves determine the course of the process evaluations. Rather human actors interacted with elements of the strategic action field, meaning, for example, factors which were a barrier to some were not to others. Cross-case comparisons enabled understanding of how some actors successfully negotiated barriers, and in some instances, I was able to suggest further concepts, such as psychological safety, to explain differences. These offer possible causal mechanisms at the level of the real in critical realism, and highlight the critical realist perspective on structure and agency as interacting (5). Findings thus provide deeper and more useful insights to inform research practice than, for example describing barriers and facilitators.

Nonetheless, as stipulated in critical realism, it is only possible to gain knowledge of causal mechanisms through human interpretation (5). The causal mechanisms offered in this analysis in the form of TMT mechanisms and others are my interpretations, and there are likely to be others. Furthermore, as acknowledged in section 7.4.1.2, my own understanding of TMT developed significantly over the course of data collection, analysis, and writing up. My own understanding of the scope of the concept of value also expanded, and upon writing the thesis I am still encountering new perspectives I could have included. Findings are therefore limited through my own interpretations of 'value', understanding of TMT, and perspectives on human behaviour. I may have missed relevant objects or events during data collection and analysis, and misinterpreted or given undue emphasis to certain things. Nevertheless, I engaged in reflexivity, and triangulated data, ideas and interpretations with critical insiders and outsiders who offered new perspectives. I sought to

include researchers with from a variety of disciplines and methodological backgrounds as critical outsiders.

As discussed in section 7.6.3.1, I encountered my own feelings of discomfort at times during data collection, analysis, and writing up these case studies. Being a PhD student observing and interviewing senior researchers and chief investigators felt vulnerable at times, although I was aided by my extensive previous professional experience of working alongside professors and consultants on research studies. However, I am conscious that I did not always ask the deep and direct questions that I now realise would have potentially yielded deeper understanding. I also know writing this thesis was influenced by the knowledge it was likely at least some participants would read it and recognise themselves, thus potentially influencing the presented analysis.

While the three case study process evaluations and pragmatic RCTs varied on certain characteristics, all were funded by the UK NIHR, based solely in the UK, reported to be well funded by the researchers involved, and were led by senior and experienced researchers. These similarities allowed for useful cross-case comparison of factors which appeared to influence the process evaluations. Clearly nonetheless, case studies of process evaluations conducted in different countries, with different funders and levels of funding, and led by more junior or inexperienced researchers may yield different findings.

I only collected data on small snapshots of the process evaluations in time and space, and the perspectives of certain actors. Many perspectives are missing from this analysis, including the chief investigator in one case study, and inclusion of these could have led to different and deeper understanding. I was also unable to follow through the impact of events and decisions to see how they may have created value or negative consequences, and therefore can only suggest possible impacts.

Case studies were selected by an element of convenience via introductions by my supervisors to gain access to large pragmatic RCTs. This likely resulted in my being able to access these large high-

profile trials and being afforded a level of trust, however also may have affected what participants said during interviews or conducted themselves during observations. Aside from this my presence as an outsider observing and recording work also may have affected the views and behaviours participants felt comfortable to express or show, although everyone I spoke to was positive about my research and considered it good practice to reflect on their own practices.

7.8 Chapter summary

This chapter has presented the methods and findings of three focused ethnographic case studies of process evaluations conducted within pragmatic RCTs of complex healthcare interventions conducted in the UK and funded by the NIHR.

Chapter 8 now discusses these findings in relation to the findings from the critical interpretive synthesis in chapter 5 and the systematic review in chapter 6 to answer the research questions posed in this thesis. Within this discussion I relate findings to the existing knowledge base and draw final recommendations.

8 Discussion

This chapter synthesises the findings from the three elements of this thesis to answer the research question:

> **How are process evaluations defined, valued, and shaped when conducted in pragmatic RCTs of complex healthcare interventions?**

I discuss findings in relation to the existing knowledge base and draw recommendations for research practice and further research, before considering the overall strengths and limitations of this thesis.

8.1 How are process evaluations defined when conducted within pragmatic RCTs of complex healthcare interventions?

Findings from this thesis clearly show an agreed definition of process evaluation is lacking. The label process evaluation is being applied to evaluations which:

- ✓ Evaluate any intervention or pragmatic RCT process
- ✓ Conceptualise and operationalise these processes in widely different ways
- ✓ Use any non-experimental evaluation methodologies and methods
- ✓ Take any philosophical stance
- ✓ Are any scale or size
- ✓ Address a wide range of different research questions
- ✓ Apply knowledge formatively and/or summatively

Furthermore, evaluations are being conducted which are not labelled as process evaluations, but which share the exact characteristics of evaluations labelled as process evaluations. Findings from the systematic review also showed that pragmatic RCT primary outcome reports include a wide range of data mapping to process evaluation components, which are not called process evaluations.

These findings are unsurprising and fit what is already known. This variability was acknowledged in the MRC's process evaluation guidelines in 2014 (22), and Grant et al. (1) note the inclusion of elements of process data in CONSORT reporting standards for RCTs.

Findings from this thesis also suggest there are some differences in understanding about whether the role of process evaluations is primarily to investigate implementation, or to investigate mechanisms of action. As discussed in section 1.8, process evaluation developed primarily to study implementation processes, however more recently with the publication of the MRC process evaluation guidance (22) its role in testing and developing intervention theory has emerged. The critical interpretive synthesis identified two broad perspectives on the value process evaluations should create, one being supporting a trial to deliver a valid primary outcome result, and the other being to contribute to developing effective sustainable interventions. This resonates with two different research cultures discussed by Mannell and Davis (186), one emphasising the value of understanding how interventions work and identifying potential improvements and better contextual fits, and the other emphasising the importance of ensuring evaluation is rigorous. These also reflect the broader tensions between the knowledge systems of the biomedical model experiential knowledge (241).

These points likely explain some of the inconsistency in how process evaluations are labelled and the lack of clarity about what a process evaluation is. The reporting of process data has become more standard in pragmatic RCTs, the field of process evaluation has evolved beyond implementation to include studying intervention mechanisms, and other theory-based approaches to evaluation are becoming more common. It is therefore understandable that a clear definition of the purpose and scope of 'a process evaluation' is lacking.

Findings also show that as some researchers and other stakeholders appear to have very different understandings of the scope of process evaluations and what may count as a process evaluation,

process evaluations may be limited by these preconceptions, and researchers on the same study teams may have different perceptions of the role of a process evaluation.

In research practice, at the individual study level, this means it is important for researchers considering doing process evaluations as part of pragmatic RCTs to engage in team discussions from the outset to agree on what they fundamentally mean by a process evaluation. It is also important for researchers to critically consider where perceptions about this meaning stem from and whether possibilities are limited by the perspectives presented in different guidance documents or by different experts. Rather than starting from the question 'we need to do a process evaluation, what shall we put in it?' it is likely more helpful to consider the ultimate goals of the overall evaluation of the intervention and the value this is aiming to create, and then consider which processes it is necessary to evaluate and which method is most suitable.

On a broader level critical consideration is warranted about whether or not the label 'process evaluation' is meaningful and helpful. Findings from this thesis show different types of process evaluations are more suited to different types of interventions and contexts, and putting all under the umbrella label 'process evaluation' is of questionable utility. It is also possible that labelling these evaluation components as 'a process evaluation' is part of the reason they become regarded as a separate study, and in publication become divorced from outcomes papers.

It is possible that if these studies were not labelled and categorised separately as 'a process evaluation' they could be regarded as an integral part of a holistic evaluation. This echoes wider calls to move away from conducting trials plus add-on evaluations of interventions to conducting studies of interventions (62, 186). Furthermore, the recent update to the MRC's guidance for developing and evaluating complex interventions (24) uses the broader term 'complex intervention research' and stipulates six core elements to be included at each stage of intervention development, evaluation, and implementation. This shows a strong move in the direction of more holistic

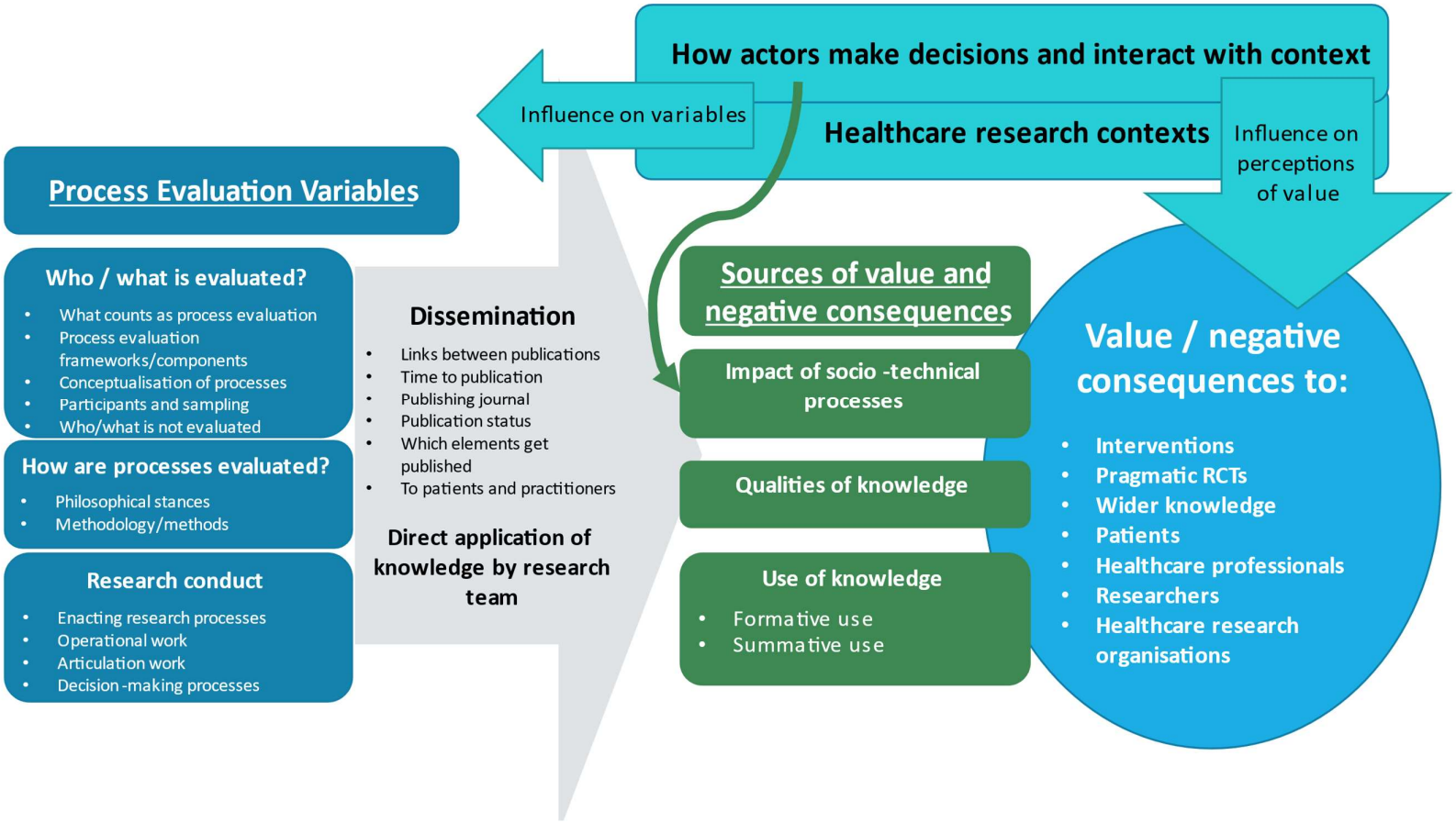
evaluation of complex interventions rather than separation into separate elements. The definition of and role for process evaluation is likely to therefore continue to evolve.

8.2 How are process evaluations valued when conducted within pragmatic RCTs of complex healthcare interventions?

The conceptual framework developed in chapter 5 has been adapted to incorporate findings from the systematic review and case studies and is now presented in figure 8.1 as a conceptual framework of process evaluation value. In summary, this shows that:

- ✓ Process evaluations may bring value and negative consequences through the knowledge they generate and through the socio-technical processes used to create that knowledge
- ✓ Process evaluations may vary widely in what they evaluate, how they evaluate it, and how they are enacted. Therefore, they employ many different socio-technical processes and create many different forms of knowledge, and these affect which values and negative consequences arise
- ✓ Characteristics of the knowledge produced influence its perceived value
- ✓ The value or negative consequence that arise from process evaluation knowledge also depend on dissemination factors and whether the knowledge is used formatively or summatively
- ✓ Value and negative consequences are subjective and context dependent. The same aspects of the same process evaluation may be perceived as valuable by some and negatively by others.
- ✓ There are potential tensions and trade-offs between values

Figure 8.1 Conceptual framework of how process evaluations create value



This framework offers a practical tool for healthcare researchers designing process evaluations to identify the value they wish to create and then plan how to create it, while also understanding and aiming to avoid potential negative consequences.

Starting at the right of figure 8.1 researchers, in collaboration with stakeholders and in conjunction with the aims of the pragmatic RCT, are invited to consider the ultimate value they wish to create for interventions, pragmatic RCTs, wider knowledge, patients, healthcare professionals, researchers, and healthcare research organisations. Moving left along figure 8.1, researchers can consider how this value can be created through the use of knowledge and through socio-technical processes, including the qualities of knowledge required to create this value. These decisions can then inform choices about which processes to evaluate, how to conceptualise these processes, and how to evaluate these processes. It is also recommended that researchers then critically consider whether it is useful to label this as a process evaluation, or whether to consider the evaluation of the different processes identified as integral components of the pragmatic RCT.

To utilise this framework however it is important to critically consider the potential tensions between values, potential negative consequences of decisions, and the subjectivity of what may be considered valuable in different contexts and to different people in the same contexts.

In this section of the discussion, I therefore consider findings in relation to possible tensions and subjectivity in the value of process evaluations to:

- ✓ Interventions
- ✓ Pragmatic RCTs
- ✓ Patients
- ✓ Healthcare professionals
- ✓ Researchers

- ✓ Healthcare research organisations

I also discuss what findings relating to dissemination say about value, and potential consequences of inaccurate or incomplete process evaluation knowledge.

In the discussion on how process evaluations are shaped in section 8.3 I also draw attention to factors which may influence 'open discussion between stakeholders' if using this framework to plan value.

8.2.1 The value of process evaluations to intervention development and implementation

Findings from all three elements of this thesis showed a multitude of ways in which process evaluation knowledge may be used summatively to create value by developing interventions and informing successful implementation into practice. As the critical interpretive synthesis showed, this is not a new finding.

In the case studies it appeared a strong motivator when researchers were able to see clearly how process evaluation knowledge would be used to improve and refine interventions and assist their uptake into practice to ultimately improve patient outcomes. Pragmatic RCT and process evaluation team members often seemed emotionally invested in understanding the intervention and seeing it successfully evaluated and used in practice. This appeared to strongly contribute to research team members being prepared to go above and beyond to ensure the process evaluation was successful, for example completing analyses after the funding period and continuing to provide information after changing jobs. Similarly, this seemed an important factor in the engagement of patients and healthcare staff in the process evaluations.

These findings suggest therefore it is likely to be valuable when planning process evaluations to identify clearly from the outset how the process evaluation knowledge will contribute to making interventions better and enabling their successful implementation into practice to aid clinicians and benefit patients. This value can then be communicated to stakeholders in appropriate formats,

promote engagement, and enable team focus around a common motivator. While this is only one of many values that may stem from process evaluations it appears the most important for many stakeholders and aligns with the mission statements of organisations funding healthcare research (10, 11).

Nonetheless, findings from the critical interpretive synthesis highlighted a divide between perspectives about the value of process evaluation being in its formative contribution to effective sustainable interventions, and its role in supporting the production of a valid primary outcome result. None of the case study process evaluations were designed to formatively adjust interventions during the pragmatic RCT, and none of the process evaluations included in the systematic review were formative. Therefore, findings do not contribute greatly to debates about the role of process evaluations for formative intervention development outlined in the critical interpretive synthesis in section 5.3.6.1. Nonetheless some authors do highlight important issues relating to pragmatic RCTs potentially constraining the improvement and effectiveness of interventions during the trial (63), and debates around conceptualising adaption and fidelity to interventions in process evaluations are covered extensively by the MRC process evaluation guidance (22). A more recent publication by Gray and Shaw (242) argue for a developmental approach to evaluation of complex interventions, arguing that process evaluations conducted alongside even pragmatic RCTs are unable to account for ever shifting contexts, mechanisms, and adaptations.

This thesis also did not examine process evaluations in the intervention development stage, however it is also important to highlight again the comments of a small number of case study participants that it would make more sense financially and in terms of effectiveness to focus much more process evaluation effort to develop interventions that were likely to fit with contexts and be acceptable to patients. This resonates with the MRC guidance (22, 24). A researcher in case study 3 commented that their large and well-funded process evaluation at the pragmatic RCT stage would unlikely

receive the same funding in 2020 that it had several years earlier. Indeed, current HTA requirements for funding pragmatic RCTs of interventions include that the intervention theory is already established and there should already be reasonable expectation of achieving acceptability and fidelity (237).

It is therefore important to acknowledge that the value of process evaluations within pragmatic RCTs for improving interventions is potentially limited, particularly if researchers have limited control in implementing findings to improve interventions post-trial, and its value at the intervention development stage should be giver greater consideration. A recent publication by Brand et al. (243) provides an example of a realist formative process evaluation which authors believe led to the development of an adaptable scalable intervention which was able to fit well into the contexts in which it was then evaluated in a RCT.

8.2.2 The value of process evaluations to pragmatic RCTs

Findings show many ways in which process evaluation knowledge may be used to bring value to pragmatic RCTs. It may be used summatively to explain pragmatic RCT findings, assess internal or external validity, add information, or help make findings more credible and usable. Findings also show a range of ways in which process evaluations may be used to evaluate pragmatic RCT processes to make formative improvements, or provide post-hoc understanding of how these processes were enacted and could have contributed to the effect of interventions observed in the trial.

However, findings also show, despite process evaluations often being integral to pragmatic RCT funding applications and protocols, there is sometimes a disconnect between the aims, conduct, and dissemination of the process evaluation and pragmatic RCT.

Process evaluations may be seen by some at times to threaten the smooth running of pragmatic RCTs. In some instances, concerns about participants finding process evaluation participation burdensome in the case studies related to how this could negatively impact on the pragmatic RCT.

In one case study this led to possibilities for the process evaluation being restricted by concerns about adding burden to trial sites. This issue is well established in the literature, with authors discussing the need to balance obtaining optimal data with potential negative impacts of data collection (22, 128, 151). It is perhaps inevitable that conducing process evaluations with pragmatic RCT will raise methodological and operational challenges and tensions. However, case study 1 showed an example of how this was resolved to the satisfaction of pragmatic RCT and process evaluation teams through shared commitment and the role of the chief investigator. This demonstrates the significance of process evaluations within pragmatic RCTs being overseen by chief or principal investigators who value all elements of the research study, as is recognised in the MRC process evaluation guidance (22).

Findings from the case studies show that there appear to be different views among researchers on the value of different types of process evaluation knowledge to the outcome evaluation. Three important debates are:

- ✓ If a pragmatic primary outcome finding is positive, is it important to understand why the intervention worked?
- ✓ What is the value of understanding complexity and variability alongside a binary pragmatic RCT result?

8.2.2.1 Value of understanding why an intervention works

There are differing perspectives on the value of understanding why an intervention worked alongside a positive pragmatic RCT result. Some have the view that if an intervention works it does not matter why, and others regard understanding why interventions work as vital to implementing interventions successfully, sustainably, and with optimal effectiveness. In one case study the chief investigator commented if the intervention worked knowing how it worked perhaps did not matter, whereas in another the chief investigator was clear that the primary purpose of the process evaluation was to understand the pragmatic RCT results better, whether the intervention worked or

not. This was reflected in general comments from a few case study participants in interviews that often the perceived value of the process evaluation knowledge depended on the outcome result.

Case study 3 also showed a major issue of outcome results not being available to analyse with process evaluation data. This was an operational issue rather than design decision, however it highlights the importance of which data and results from the pragmatic RCT are needed for the process evaluation to produce the required knowledge. Munro and Bloor (57) raise the issue that it may be difficult to collect the most useful process evaluation data without knowing what the outcomes will be, resulting in process evaluation knowledge about reasons for outcomes being speculative.

These findings show it is important when planning value using the framework offered in figure 8.1 to consider different scenarios of primary outcome findings, and what kind of knowledge will be valuable in different scenarios. It is also important to critically consider how to conduct the process evaluation to get that knowledge with or without knowing what the outcome results are.

8.2.2.2 Understanding complexity and variability alongside a binary outcome result

There are potential tensions between the goal of a pragmatic RCT to definitively binarily determine whether an intervention works or not in the real world, and the myriad of complexity and variability potentially revealed by process evaluations conducted alongside them. If aligned with the positivist pragmatic RCT philosophy, process evaluations also should discover linear predicable answers about matters such as intervention acceptability and the influence of context. In case studies 1 and 2 it appeared that the process evaluation designs broadly were aligned with the logic of the pragmatic RCTs. This may have contributed to them being more cohesive and appearing to cause less stress to researchers than the case study 3 process evaluation. In case study 3 it was proving challenging to reconcile the complexity being revealed by the process evaluation with the pressure to produce a definitive pragmatic RCT primary outcome result. This was leading to challenges deciding how to analyse process evaluation data, realisations that different research team actors had different

philosophical assumptions, and the analysis and writing up of complexity potentially being relegated to completion after the funder report when researchers had time or could secure funding.

8.2.2.3 Considerations from the critical interpretive synthesis

The critical interpretive synthesis also identified in section 5.3.3 many debates about how process evaluations should be designed, which were not specific to pragmatic RCTs and healthcare research. These are listed here again in box 8.1 and provide a list of considerations for researchers about how the process evaluation design may align or potentially conflict with the pragmatic RCT.

Box 8.1

Issues for consideration relating to process evaluation design within pragmatic RCTs:

- ✓ Standardisation or tailoring to each study?
- ✓ Pre-planned, or flexible and responsive?
- ✓ Use of theory in process evaluation
- ✓ Studying context
- ✓ Studying implementation
- ✓ Linking process and outcomes
- ✓ Using mixed quantitative and qualitative methods
- ✓ Sampling and obtaining multiple viewpoints
- ✓ Stakeholder involvement in design
- ✓ Evaluating outcome evaluation processes
- ✓ Timing of process evaluations

The aim of this thesis is to highlight the differences between perspectives on the value of different types of process evaluation knowledge, rather than enter debate about whether one perspective is correct. However, these tensions broadly resonate with the wider literature on qualitative research with quantitative outcome evaluation (63, 244, 245) and evaluating complex interventions (24, 186) and findings therefore contribute to these theoretical debates.

Most significantly, in light of differences in perspective about the value of different kinds of process evaluation knowledge to pragmatic RCTs it would appear reasonable to recommend that from the outset of deciding to do a process evaluation researchers and other stakeholders have open

discussions. These discussions could cover how they will study and make sense of complexity, and how they will reconcile process evaluations findings with primary outcome findings in different scenarios. This would logically then lessen the chance of the challenges encountered in case study 3 occurring, likely leading to less stress and more timely integrated process evaluation publications.

However, it is important to critically question this recommendation. Given the multitude of social processes underlying idea-sharing and decision-making in research teams identified in theme 1 of the case studies, there is a possibility these discussions would also be affected by factors such as power dynamics and the social atmosphere of meetings. A researcher in one of the case studies commented that it is better for process evaluation qualitative researchers to be very pragmatic rather than interested in 'hardcore' qualitative methods, a comment I have also heard anecdotally from another researcher during this PhD. Greenhalgh and Papoutsi (246) highlighted in 2018 that despite the MRC's stance on complexity having shifted to a systems perspective which supports non-linear causality, many investigators, journal editors, and health research funders have not in practice followed suit. This suggests there is likely to be an underlying driver for process evaluations to support the philosophical aims of the pragmatic RCT, which may result in this perspective dominating discussions about the stance on complexity at the outset of process evaluations. A recommendation for open discussion about the stance on complexity may result in fewer opportunities for process evaluations to use methodologies considered by some to adequately account for complexity. Therefore, it could be argued that while far from a perfect situation, process evaluations examining complexity using such methodologies in a way that is more disjointed from the pragmatic RCT is better than it not being undertaken at all.

8.2.3 The value of process evaluations to patients

This thesis has not explored the research questions from the perspective of patients who participate in process evaluations. Nonetheless findings from the case studies provide some insight into value and negative consequences they may obtain from them.

Researchers in the case studies reported that patients appeared to enjoy participation and valued the opportunity to contribute to research. In contrast, the value theme of ethics discussed in the critical interpretive synthesis in section 5.3.6.6 mostly identified potential negative consequences.

Nonetheless, findings also show clearly how process evaluations are often shaped by what research team actors assume potential participants value, and that there may be a mismatch between researcher assumptions and the actual experience and perceptions of participants. Researchers in these case study process evaluations often reported that patients who took part were often more willing and engaged than expected, and concerns about negative impacts were unfounded. In some cases, there seemed to be a lack of consultation with PPI about the acceptability of process evaluation data collection methods, with researchers appearing to prioritise their own experience and perceptions of what was acceptable or ethical.

However, it was also highlighted that those who agree to participate in process evaluation and PPI groups may not be representative, an issue that is recognised in PPI (241). It cannot therefore be assumed that all patients value the same things, and all gain the same value or negative impacts from participating in a process evaluation. It is therefore too simplistic to conclude that those with concerns about protecting participants were acting on unfounded concerns, and may be concluded that patient experience of value or negative consequences of process evaluation participation is itself variable and context-dependent. This echoes a paper included in the critical interpretive synthesis which describes how process evaluation participants providing data in groups may benefit from the establishment of group trust and identity however also be potentially negatively affected by status issues and fear of repercussions (121). More widely, negative impacts to patients from participating in RCTs (247) and PPI (248) have been reported.

A further important issue identified in case studies was the potential negative impacts of data from participants being given less credence and of data being collected but not being fully analysed and reported. In all case studies the process evaluation participant information sheets emphasised the

opportunity for participants to have their say, however findings show that how this opportunity is realised by researchers during the data analysis and dissemination processes is far from straightforward. Franzen et al. (167) highlight how the opportunity for process evaluation participants to have their say is empowering only if their views are acted upon. Feeling as if views are not heard can be an emotional toll and disempowering for PPI members (241). As stated by Michaels (249) the knowledge provided by patients through their experience of an intervention being not afforded proper credibility is an example of testimonial injustice. This disadvantages both the patient whose experience is not taken seriously and those of the group to whom they belong through the potential distortion of research findings (249).

8.2.4 The value of process evaluations to healthcare staff participating in them

The case studies did not examine process evaluations from the perspective of healthcare staff who participated in the process evaluations, however findings from this thesis provide some insight into how they may value process evaluations.

The case studies showed how some staff appear to value participating in process evaluation as engaged active partners in the overall endeavour of improving treatments, care, and outcomes for their patients. For other staff process evaluation participation may be more of a burden and in busy clinical environments may involve them using their lunch breaks for example. However, case study 3 researchers reported busy staff still appeared to gain value from participating and reflecting on practice.

Findings from the systematic review and case studies show methods of successfully capitalising on the value healthcare staff may offer process evaluations and enabling healthcare staff participation in real world healthcare settings. Offering a high degree of flexibility in timing and data collection methods is important (200), as is involving staff in the design of data collection methods and ensuring these fit with routine practice (196). Case study 3 researchers also emphasised the importance of adequately compensating staff for their time and showing that their contributions were valued.

Case studies 1 and 2 showed the value to healthcare staff of process evaluation knowledge being used formatively to improve their experience of involvement in the pragmatic RCT. In view of this, it is also important to acknowledge as identified in the critical interpretive synthesis value theme of relationships that if it is not possible to act on participant data formatively this may cause tensions, and therefore clearly informing participants of this is important (138).

8.2.5 The value of process evaluations to researchers

Findings from the case studies enhance understanding of the potential emotional impacts of conducting process evaluations on process evaluation researchers. These included positive impacts such as enjoyment and fulfilling interest in understanding how interventions work and are experienced by recipients.

However, there were also a range of negative emotional experiences, including stress, frustration, sadness, and worry. Sources of negative emotion were the need to deal with NHS research bureaucracy, having insufficient time and resources to satisfyingly complete data analysis and write up process evaluation findings, uncertain fixed-term contracts, concerns about certain findings being dismissed or unwelcome, tensions between teams, and tense or unwelcoming social atmospheres of meetings. These negative impacts on researchers were also potential contributors to researchers leaving the healthcare research workforce or deciding against pursuing research in certain contexts again, although this was an issue not solely related to process evaluation.

The emotional impact of undertaking process evaluations on researchers was not identified in the critical interpretive synthesis, and to my knowledge has not been discussed in more recent literature on process evaluation. However, recent reports on UK research culture commissioned by the Wellcome Trust (250, 251) highlighted widespread concerns affecting researchers, including short-term employment contracts, lack of time for conducting quality research, pressures to produce certain findings, and deteriorating mental health.

Findings therefore show the importance of process evaluation teams (and all research teams) paying careful attention to the emotional wellbeing of researchers. The literature on mixed-methods and interdisciplinary research teams and the Wellcome report cited above provide useful suggestions for how this may be achieved. These include:

- ✓ Clear and open allocation of team roles (252)
- ✓ Regularly *'checking the team's emotional climate'* including 1:1 check ins from the team leader to individual members (252) p.656
- ✓ Regular reflection on how the research group is functioning (253)
- ✓ Training in mentoring and management to promote good research cultures (250)
- ✓ Better mental health provision from universities for the research workforce (251)

In concordance with critical interpretive synthesis findings, case studies showed that process evaluations may provide value to researchers and students in terms of education and career development. O'Cathain et al. (80) similarly identified that undertaking qualitative research with RCTs may be primarily undertaken to provide researchers with opportunities for higher degrees, which brings the benefit of increasing the qualifications and experience of the research workforce and improving future evaluations. However they also highlight that this may mean the qualitative research takes a peripheral role in the RCT, with its aims directed towards the student's interest rather than the trial (80).

Process evaluations also provide value to researchers through gaining publications, although findings highlight this may involve researchers writing papers after the grant funding had ended. This dissemination issue is discussed further in section 8.2.8. Although case study participants did not raise this issue, it is important to note that a recent qualitative study commissioned by the Wellcome Trust found that high-quality research outputs could come at the expense of researcher wellbeing and personal time (254).

8.2.6 The value of process evaluations to healthcare research organisations

In the case studies successful completion of the process evaluations and pragmatic RCTs was dependent on contributions from multiple actors working across multiple healthcare and healthcare research organisations. These may be broadly divided into the organisations hosting the research studies, such as CTUs and university departments and the healthcare research organisations which facilitated research, including the funders, NHS HRA, and CRNs.

The aims stated by the websites of the organisations hosting the case study pragmatic RCTs and process evaluations are essentially to support high-quality efficient research and through this improve care and outcomes. The same aims are broadly stated by the NIHR (11), CRN (255) and CTU network (256). These match the overarching stated aims of the case study pragmatic RCTs and process evaluations.

It would appear logical therefore that the organisations hosting and supporting process evaluations of complex healthcare interventions would value the contributions of process evaluations to their overall endeavours. However, the complex and lengthy articulation work required in some of the case studies to get process evaluations done within and via these organisations suggests a mismatch of priorities in some instances.

Part of the issue appeared to be different organising logics being prioritised to achieve the same thing, for example the organising logic of protecting patient confidentiality and consent by the CRN being perceived as obstructing patient participation in case study 3 process evaluation. Another issue appeared to be, as reported by research team members in the case studies, organisations having multiple studies to coordinate and manage. The process evaluations therefore likely formed only a small component of their lines of work, with many competing priorities. Similarly, many of the process evaluation researchers and the chief investigators had multiple lines of work in their

employing institutions, with other projects and clinical and teaching work often taking priority over working on the process evaluations.

This suggests that process evaluations may have been valued in theory by healthcare research organisations, but this did not always translate into timely action and sufficient resources to enable the process evaluations to proceed smoothly and realise their value. How this shaped the process evaluations is discussed further in section 8.2.3. I did not explore the perspectives of anybody in the healthcare research organisations with whom the case study process evaluations were affiliated, however it would be valuable to explore their perspectives on the value of process evaluations and how they may be facilitated.

8.2.7 Consequences of incomplete or inaccurate process evaluation knowledge

Researchers in the case studies were highly aware of many factors which could affect the accuracy and completeness of process evaluation knowledge, for example the timing of data collection and sampling methods, and often took steps to address these. Many of these factors are well known limitations or considerations of existing research methods which equally apply to when these methods are used in process evaluations.

However, in the context of process evaluations within pragmatic RCTs findings from the case studies show there are often complex and important considerations when evaluating processes such as fidelity and participant responses. In all three case studies there was understanding, for example, that the same participant or intervention deliverer may report different experiences at different times, and that experiences and perceptions could differ widely between participants. In case study 3 some data collection tools had not been designed by the process evaluation researchers and there were doubts over the quality of the data. These issues have been previously noted in the process evaluation methodology literature (22, 56).

Findings from the case studies also showed how knowledge may be shaped by research team idea sharing and decision-making. While it is not possible to follow the consequences of, for example, a

lack of psychological safety leading to ideas not being shared, on the eventual knowledge output, it is reasonable to suggest it may make a difference.

Lack of integration in publishing may also lead to aspects of process evaluation knowledge being separated from each other and from the pragmatic RCT, which may lead to knowledge being presented as not obviously incomplete.

It is important to consider the potential negative consequences of process evaluation knowledge presenting an incomplete or inaccurate picture, and this not being clearly acknowledged in limitations. Process evaluations are considered able to reveal potential inequalities in participant responses masked by binary primary outcome findings (2, 22), however process evaluation findings may also not tell the whole story. As found in the critical interpretive synthesis, some researchers believe that accurate understanding of outcome results requires a holistic approach, requiring investigation of multiple process evaluation components (22, 116, 138, 144) and multidimensional conceptualisations of processes such as implementation (120). Munro and Bloor (57) highlight that in part through narrowing the scale and scope of the process evaluation, a process evaluation is unable to explain unproblematically intervention effects of lack thereof. They point out that process evaluation findings are by nature indeterminate, for example because qualitative findings from one research site cannot be assumed to apply to another.

It is possible that this could lead to injustices through flawed process evaluation knowledge being used to support implementation of interventions which some find unacceptable (249), or a depersonalisation of care (89).

There have been efforts to address these challenges by authors who propose process evaluation frameworks and guidance for specific fields of practice (3, 55) which recommend what process evaluations study and how to obtain a more holistic and accurate view of what went on during the trial.

Reporting guidance for process evaluations (1, 22) also emphasises the importance of reporting design decisions, including rationales for the selection of certain methods and process evaluation components. These findings certainly highlight the critical nature of detailed reporting to enable findings to be thoroughly assessed for relevance and possible incompleteness. In section 8.3.1.6 I also discuss more in-depth reflective reporting and how this may help create more accurate and complete knowledge.

8.2.8 Dissemination and the value of process evaluations

Findings from the systematic review showed the frequent disconnect between pragmatic RCT and process evaluation publications, which, given the value of the process evaluation knowledge to enhancing understanding of the pragmatic RCT results and to informing intervention development and implementation, is a paradoxical finding. This disconnect is clearly a barrier to full realisation of the value of the process evaluation knowledge, however also suggests a lack of valuing of process evaluation knowledge in relation to pragmatic RCT findings.

Similarly, findings show many ways in which process evaluation knowledge can inform the wider knowledge base, including intervention theory, implementation and methodology. This is undoubtedly of value, however it is important to note that findings also show process evaluations may need to emphasise their broader contributions to ensure publication, or to be published in higher impact journals.

This suggests at times a process evaluation's primary purpose in a pragmatic RCT to inform understanding of how the intervention reached its effects may be devalued and deemed less worthy of publication in its own right. Additionally, as seen in the case studies, process evaluations may be shaped around the conventions of a target journal rather than what would most usefully inform understanding of how the intervention achieved its outcomes. That the MRC process evaluation guidance suggested authors may need to emphasise wider applicability of process evaluation results to secure publication is a sign this is a significant issue. As has been observed with qualitative

research with RCTs (186) process evaluations appear at times to be positioned as a secondary output or sub-study, rather than as an integral art of the pragmatic RCT.

Nonetheless, there are examples of journals publishing process and outcomes in the same issue, which was acknowledged to greatly facilitate transfer of research to practice (177). In the systematic review HTA monographs were shown to be a reporting format that allowed process evaluation findings to be reported alongside outcome findings. However, as shown in case study 3, there were challenges to condensing the process evaluation into an HTA chapter, and many aspects of the process evaluation that may have been further analysed and reported after the HTA report was submitted. Therefore, it is important to recognise that these reports may also not include the complete knowledge of process evaluations.

There are clear reporting recommendations to draw from these findings, including to follow reporting guidance already available (1, 22). Specific recommendations are to include process evaluation publications in trial registry entries and mention at least that a process evaluation was undertaken in the main trial publication. The CONSORT extension for reporting social and psychological intervention trials, published in 2018 (257), now includes an item to mention process evaluations in trial reports, which is a positive step towards achieving greater visibility and linkages between pragmatic RCTs and process evaluations. A further recommendation is that even when highlighting broader implications of process evaluation findings in journal articles, authors label the research as a process evaluation and refer to the associated pragmatic RCT in the title or abstract. However, further research exploring the perceptions of journal editors about process evaluation publication is also warranted.

Case studies showed that barriers to timely publishing of process evaluations with emphasis on their contribution to the intervention and pragmatic RCT lie partly at times with researchers lacking time within grant funding to complete publications. This resonates with findings about barriers to researchers publishing findings of qualitative research conducted with RCTs (80), and from findings

on UK research culture (254). This is a problem that is not unique to process evaluation, and likely requires greater system and cultural changes (254).

In the case studies there were examples of anticipated dissemination of process evaluation findings to patient and practitioner audiences about which researchers were enthusiastic. Also in line with the MRC recommendations for dissemination (22), this highlights a useful means of increasing the value obtained from process evaluations.

8.2.9 Summary of the discussion on process evaluation value

It is clear that there is no agreement on the value that process evaluations within pragmatic RCTs of complex healthcare interventions do and should create. There are many tensions and trade-offs, and potential negative consequences of process evaluations which may not always be visible. Before considering how to maximise the value of process evaluations, this shows the critical importance of questioning what value we want to create and why, and how this may be perceived by and impact different people. This also therefore shows the importance of involving stakeholders in discussions about the value aiming to be created.

The framework offered in figure 8.1 and the overview of debates and issues which may affect value are therefore useful starting points for researchers to plan value from process evaluations. However, as will be discussed in the next section, there are many factors which may affect how value is negotiated, and how value is able to be realised in real-world healthcare research settings. These findings therefore inform how stakeholder discussions around the framework in figure 8.1 could be facilitated.

8.3 How are process evaluations shaped when conducted within pragmatic RCTs of complex healthcare interventions?

Findings from the critical interpretive synthesis in section 5.3.5 identified contextual factors which may shape process evaluations, and also identified these contextual factors may be interpreted differently by different people. The systematic review in section 6.4.7 identified barriers and

facilitators to conducting process evaluations in pragmatic RCTs of complex healthcare interventions. These all related to the challenges of conducting process evaluations in healthcare research settings and included suggested solutions, again suggesting different perspectives on contextual factors.

Using the lens of Translational Mobilisation Theory, the case studies examined how process evaluations are shaped in much more depth and detail and findings provide detailed insight into:

- ✓ How researchers share ideas and make decisions
- ✓ How real-world healthcare research contexts shape the possibilities for getting process evaluations done

For both findings show how process evaluations are shaped by what is valued by the multiple actors operating in multiple complex contexts who in some way contribute to enacting a process evaluation, and how this value is negotiated.

Findings also show how the pragmatic RCT design and process evaluations being fixed or iterative are important shaping factors.

8.3.1 How researchers share ideas and make decisions

Figure 8.2 shows an overview of findings from this thesis relating to how researchers share ideas and make decisions. To my knowledge this provides a novel lens to aid understanding of how researchers shape process evaluations and shows how the enactment of process evaluations may also be conceptualised as a complex event in complex systems. Findings thus provide a useful framework to understand and critically analyse the 'black box' of process evaluation knowledge production, and shed light on important factors for process evaluation teams to consider when 'doing' process evaluation.

Figure 8.2 Researcher decision making

8.3.1.1 Sources of guidance and advice for doing process evaluations

Researchers and research staff often use mindlines and experiential knowledge when enacting process evaluations. In the case studies many research team members drew on extensive incidental experience of healthcare and research to help successfully get the process evaluations done. The seeking and sharing of local stocks of knowledge was an important factor in progressing the process evaluations. I was unable to find any previous research exploring the use of mindlines and experiential knowledge by researchers conducting process evaluations or any type of research. However, certainly, some authors consider the lack of an evidence-base to inform the conduct of healthcare research problematic (87), and that a lack of formal consensus processes and systematic searches to develop process evaluation guidance documents makes them lack robustness and renders them liable to an element of subjectivity (55). Nonetheless, similar to critiques of devaluing the experiential knowledge of patients (89), it appears unhelpful to devalue the experiential knowledge of researchers and the use of mindlines when conducting process evaluations. However, it is important to acknowledge the very different perspectives held by researchers about definitions of process evaluation (section 8.1) and the value of different kinds of knowledge (section 8.2), and how these may influence or limit possibilities for what form a process evaluation may take. As highlighted by Masterson-Algar et al. (55), it is important for researchers to be clear about their worldviews and assumptions and the worldviews and assumptions of guidance they utilise.

8.3.1.2 Assumptions about the values of potential participants

Findings from the case studies showed that sometimes process evaluation decisions are based on assumptions what potential participants value, rather than their actual values, as discussed in sections 8.2.3 and 8.2.4. Patient and healthcare professional experience of value or negative consequences of process evaluation participation appears to be itself variable and context dependent. As is recognised in the broader PPI endeavour (248), meaningful involvement of patients (and where appropriate healthcare professionals) in process evaluation design decisions is important.

It would also be useful for future research to examine the value of process evaluations from the perspective of patient and staff participants to help inform researchers planning process evaluations.

8.3.1.3 How individual research team members shape process evaluations

Findings from the case studies show clearly that the values, attitudes, personalities, networks, knowledge, and experiences that individual research team members bring to playing their part in enacting process evaluations are highly significant shaping factors. Findings also showed that individuals rarely expressed stereotypical singular perspectives, and many research team members expressed nuanced and reflective opinions when sharing ideas. For example, in their example applying TMT to a research study (86) Allen and May describe team members in different roles having different interpretive repertoires and organising logics; however in these case studies process evaluation and pragmatic RCT team members often brought, weighed-up, and empathised with a variety of different perspectives. This fits with the critical realist perspective of structure and agency being separate, distinct, and interacting (5) and helpfully shows how the individual who fulfils a role in a process evaluation brings unique perspectives and contributions. I was unable to find any previous research exploring specifically how individual researchers fulfil their roles, although differences in how researchers respond the same pressures in the research environment have been noted (254).

Many research team members in the case studies had a range of experiences, which may also explain this finding. Many process evaluation researchers had experience on trials and pragmatic RCT researchers had mixed-methods backgrounds. This wide range of experience appeared to facilitate team-working, and provided an extensive pool of shared experiential knowledge to design and conduct the process evaluation. This shows the potential value in employing process evaluation research team members with perspectives and experiences which enable them to understand issues pertaining to pragmatic RCTs. However, while this potentially helps avoid issues reported elsewhere in mixed-methods healthcare studies such as methodological disrespect (82) it may also do little to

challenge *'disciplinary comfort zones'* and the more creative and impactful research that may result (252)p. 649. In their reflection on conducting an interdisciplinary process evaluation, Clarke et al. (75) reflect that their process evaluation benefited from researchers having different background knowledge and expectations as this allowed them to uncover meaning in data that likely otherwise would not have been seen.

This individual variability between researchers also however shows the importance of paying attention to the mechanisms by which different values and perspectives are shared by researchers with varying degrees of perceived agency and confidence. The next sections examine these mechanisms.

8.3.1.4 The role of the chief investigator

The role of the chief investigator was shown in the case studies to be very important in shaping the process evaluations, and in achieving or not achieving integration with the pragmatic RCTs. This is acknowledged in the MRC process evaluation guidance, which states that process evaluations should be overseen by a principal investigator who values it (22). Authors on process evaluation have also highlighted this (60, 75), and it is widely recognised in the broader literature on mixed-methods and interdisciplinary health research (80, 82, 252).

It is therefore possible to draw recommendations for chief investigators and principle investigators to reflect on their roles and consider, perhaps drawing on the literature cited above, how to ensure process evaluations are integrated into pragmatic RCTs and thoughtfully and collaboratively create value. It is important to acknowledge however that in the case studies time pressures from multiple lines of clinical, research, and teaching work appeared to be a factor in the chief investigators' abilities to lead and manage process evaluations and make considered decisions. These time pressures have been recognised in relation to problems with wider UK research culture, as have a lack of training and support for PIs on managing research teams (254). Wider cultural changes to research environments, such as improved mentoring and leadership training and support, and

valuing time and space to think (254) may therefore be necessary to allow chief investigators to realise these expectations.

8.3.1.5 Establishing environments conducive to open idea sharing and negotiation of viewpoints

The case studies showed the significance of the strategic action fields in which idea sharing and decision-making takes place as shaping factors in process evaluations. To my knowledge this has not been addressed in process evaluation literature, however is addressed in broader literature on team working.

Recommendations from these findings are that process evaluation (and all) research teams pay attention to nurturing relationships and creating the psychological safety to facilitate free and productive discussions of ideas and perspectives.

Recommendations on this point from the case studies are:

- ✓ Efforts to enable researchers who are unfamiliar with each other to connect via social events and 'small talk'
- ✓ Meeting participants giving meetings their full attention
- ✓ The chairperson ensuring contributions are invited from all participants
- ✓ Clear delineation of roles and responsibilities within the team, including sharing within the team of important contributions by each team member (258)

The wider literature also includes many useful recommendations including:

- ✓ Team members inviting and expressing appreciation for contributions from others, as motivating greater knowledge sharing and a positive cycle of valuing others to enhance team collaboration and creativity (259)
- ✓ Establishing ground rules for online meetings (234)
- ✓ Training for promoting good research cultures (250)

8.3.1.6 Reflective research practice and reporting

It is important to recognise that, in contrast to the methodological issues discussed earlier in this section, these researcher factors shaping the knowledge are often more hidden and unacknowledged.

Reynolds et al. (143) explored the practice of 'doing evaluation' and how evaluation activities may deviate from those set out in protocols, and how these may impact on findings of evaluations of complex interventions. They propose six 'lessons learned' about how to raise awareness of and manage "*the fabric of trials involving the interface of researchers, fieldworkers, participants and data collection tools that may affect the intended production of data and interpretation of findings*" (143) p.1. Their recommendations centre on ongoing reflexivity, collaboration and dialogue between all team members involved in conducting evaluations, and in my observations in the case studies I observed many examples of this occurring. This included from pragmatic RCT team members who often articulated similar concerns and reflections to process evaluation researchers about the potential for process evaluation data to be incomplete or inaccurate, and a desire to understand complexity. Nonetheless there were also times when there seemed to not be optimal open joint reflection and dialogue.

Reynolds et al. (143) recommend that a role for process evaluation is evaluating these (trial) evaluation processes, however findings from these case studies suggest the process evaluation processes themselves also warrant similar dialogue and reflection. Reynolds et al. acknowledge that finding the time and space to apply their 'lessons learned' is likely to be challenging in the context of typical trial cultures, and indeed findings from these case studies showed a lack of time was often a factor already shaping the process evaluations. Nonetheless, Reynolds et al. (143) consider it likely this investment of time and an embedding of such reflective practices as standard in evaluations will result in better understanding of interventions and their implementation, thus ultimately resulting in increased intervention uptake and effectiveness in practice. Given the multitude of factors which

appear to possibly shape the knowledge created by process evaluations, findings from this thesis support these recommendations.

Similarly, Reynolds et al. (143) recommend adapting the CONSORT RCT reporting guidelines to stipulate reporting of reflexive consideration of how evaluation processes as well as intervention processes were delivered, and how investigators' personal experience, knowledge and motivations influenced delivery. This follows recommendations by Wells et al. (85) to report the influence of the trial context on intervention processes, which they argue result in knowledge being more able to inform clinical and policy decision-making. Findings from these case studies suggest reflexive reporting of this nature would be usefully undertaken routinely for both real-world RCT and real-world process evaluation processes to aid interpretation of findings. Nonetheless, the CONSORT extension for social and psychological interventions published in 2018 (257) does not include an item of this kind.

8.3.2 How process evaluations are shaped by real-world healthcare research contexts

Pragmatic RCTs are conducted in the real world, and findings from this thesis show that conducting process evaluations in the real world of healthcare research organisations is often a significant challenge. Findings from the critical interpretive synthesis and systematic review highlighted challenges to recruiting participants and collecting quality data in real-world healthcare settings, and to dealing with regulatory systems. Case study findings greatly expanded on these themes and show how process evaluation researchers often needed to negotiate multiple barriers across multiple complex organisations and spend considerable time and energy on articulation work. These organisations therefore often shaped what was possible to do, and the complex articulation work involved in dealing with them could take time and energy away from the work of conducting the research.

One element of these organisational contexts is healthcare settings in which process evaluation research is conducted. It is already well recognised that real world healthcare settings can be

challenging environments in which to conduct research, with researchers needing flexibility to fit around the demands of healthcare professionals delivering and patients receiving healthcare.

Another element of organisational context is the organisations involved in hosting the pragmatic RCTs and process evaluations, including university departments, CTUs, sponsoring organisations, and partner organisations. The case studies showed significant delays and challenges to process evaluations resulting from cross-organisational working. These included delays to getting decisions signed off by multiple organisations, extending employment contracts, transferring budgets across universities, and departments having high staff turnover.

The final element of organisational context is the organisations who fund, facilitate, and regulate healthcare research. The case studies showed considerable challenges to getting process evaluations done in these organisations, whose aim, as discussed in section 8.2.6, is also to support efficient and high-quality research. An additional challenge was regional variability between national organisations and difficulties finding the right person to speak to in these organisations.

These findings provide new valuable insights into the potential challenges of conducting process evaluations in real-world healthcare and healthcare research contexts. The MRC process evaluation guidance (22) acknowledges the potential challenges of CTU policies being rigid and less suited to flexible process evaluations, although this was not a notable issue in the case studies. To my knowledge these issues are not discussed elsewhere in the process evaluation literature. In their process evaluation framework for cluster RCTs, Grant et al. (1) do not discuss, for example, the practical issues of dealing with multiple healthcare settings and multiple research organisations required in the case study 3 process evaluation.

However, issues of institutional bureaucracy as barriers to efficient research and challenges to researchers have been recognised by the UK government in its *Independent Review of Research Bureaucracy Interim Report* (260). This is aiming to reform UK research systems in a way '*that will*

preserve and enhance the UK's scientific and research strengths, while giving researchers more time to focus on their research' (260) p.5.

This is welcome as case studies showed across organisations successfully progressing the process evaluations often hinged upon finding an individual who had the knowledge and/or willingness to be flexible in the face of bureaucratic procedures and requirements. Similarly, process evaluations were shaped significantly by researchers' ability to navigate the system by finding workarounds or avoiding working with certain organisations. These efforts are certainly commendable, however, it appears absurd to recommend that process evaluation researchers and individuals in organisations become ever more flexible and gain ever more ability to overcome organisational challenges. Rather it seems the barriers arising from these organisations need to be investigated and challenged so that time, energy, and creativity can be spent on core research work rather than secondary articulation work.

It is nonetheless important to acknowledge the time required to progress process evaluations in the case studies, and recommend that process evaluations are planned and funded with sufficient time to allow for delays. This is particularly important when researchers are employed on fixed-term contracts, and the Wellcome reports on research culture have recommended padding on short-term grant contracts (254).

8.3.3 The pragmatic RCT and process evaluation design

Findings from the case studies showed significant differences between individually randomised RCTs and cluster RCTs.

The pragmatic RCT design being a cluster-randomised in case study 3 led to much more complex operational and methodological challenges and decisions than in the individually randomised designs in case studies 1 and 2. This suggests cluster RCTs may benefit from more extensive planning of process evaluations and increased researcher time. However, if the recruitment challenges to process evaluations in cluster RCTs experienced in case study 3, with the double work

of recruiting sites to the trial and then the process evaluation, are reflective of practice elsewhere then consent processes for cluster RCTs should be reviewed as this appeared an absurd waste of effort and resources.

The process evaluation design being fixed or iterative was a key shaping factor, with the iterative design in case study 3 leading to the process evaluation growing and evolving in multiple directions. This again demonstrates the value of clear leadership and oversight, and the need to factor in sufficient time for the multiple decision points that will be reached over the course of the process evaluation.

8.4 Overarching recommendations

Considering the three research questions addressed by this thesis together, the overarching recommendation of this thesis is for researchers to take time from the outset to explicitly, collaboratively, and critically plan the value they wish to create by evaluating process within a pragmatic RCT.

As 'process evaluation' is a broad and subjective label, it is likely more helpful to firstly consider what value is aiming to ultimately be achieved with the overall evaluation of the intervention in question, and then decide which processes to evaluate to help achieve that value. This is in contrast to having the idea to 'do a process evaluation' and questioning what to put in it and how to do it.

The framework offered in figure 8.1 along with the more detailed discussion of its elements in this chapter can then be used to:

- ✓ Question for who and what value is being created for, and how this is prioritised
- ✓ Critically consider the reasons for these choices
- ✓ Consider what process evaluation knowledge would be needed to create this value
- ✓ Consider whether formative or summative use of knowledge is more useful

- ✓ Consider the knowledge that could be required in different scenarios, such as if the primary outcome result is positive or not positive
- ✓ Consider the underlying philosophy of the process evaluation and how if different from the pragmatic RCT this would be integrated or reconciled
- ✓ Consider different possibilities for process evaluation findings and how these would be reconciled with primary outcome findings
- ✓ Use these considerations to inform choices about which processes to evaluate, how to conceptualise these processes, and how to evaluate these processes
- ✓ Consider how the socio-technical processes required to enact the design could create further value or negative consequences, and adjust if necessary
- ✓ Consider and plan for potential challenges of evaluating these processes in real-world healthcare settings
- ✓ Consider which healthcare research organisations will need to facilitate the research and how to best work with these
- ✓ Allow time for real-world delays and setbacks, coordination of approvals across organisations, and to ensure full team input on important discussions and decisions
- ✓ Clearly plan how the knowledge produced by the evaluation of each process will attain its planned value through direct application by the study team and/or dissemination
- ✓ Critically consider whether it is useful to label the study as a process evaluation, or whether to consider the evaluation of the different processes identified as integral components of the pragmatic RCT.

In view of the complexity, subjectivity, and context dependence of process evaluation value identified in this thesis, it is important that these discussions are open, transparent, and involve all

stakeholders. Nonetheless, findings from this thesis also suggest achieving such a discussion is unlikely to be straightforward, and it is therefore important to also consider issues identified in the case studies about the factors influencing idea sharing and decision making to facilitate these discussions.

8.5 Overall strengths and limitations of this thesis

Findings from this thesis provide a novel, detailed, and in-depth perspective on how process evaluations are defined, valued, and shaped when conducted within pragmatic RCTs of complex healthcare interventions. The use of Translational Mobilisation Theory as a lens to analyse ethnographic data from case studies of process evaluations has also provided, to my knowledge, a novel lens on how process evaluations, and any type of healthcare research study, are enacted in real-world contexts.

Because of the broad scope of the research questions, findings are extensive, hawever many findings warrant deeper exploration that was beyond the scope of this thesis.

I have reported my possible biases and been reflective throughout conducting this research about how my own views and perspectives may have influenced the findings. I also engaged in triangulation in the case studies and reflection with my supervisors in the critical interpretive synthesis. Nonetheless the findings I present are my interpretation of what has proved to be a highly complex question, and I acknowledge others may have interpreted aspects of the data and findings differently.

As is the aim of critical realist research, findings show demi-regularities with theoretical generalisability (5), rather than universal generalisations about how process evaluations are defined, valued, and shaped. Findings thus offer a range of considerations for researchers about factors which are likely to shape process evaluations and contribute to the creation of value or negative consequences.

This thesis mostly investigated the research questions from the perspective of researchers, with findings about the value and contributions of patients, professionals, and other stakeholders mostly being secondary reports of researchers. There are therefore many missing voices from the findings presented in this thesis, which should be taken into consideration when applying them.

Findings also mostly relate to the UK context of research conducted in the NHS, although some studies included in the systematic review were from other contexts and countries. Different factors may influence process evaluations in other settings, and findings may not be directly transferable to other cultures.

In summary, findings provide deep, detailed, and extensive answers to the research questions however cannot be considered complete or without potential bias. Other types of value and negative consequences may occur, and other shaping factors may exist which were not identified in this thesis.

9 Key Recommendations and Conclusions

In the context of complex healthcare interventions evaluated in pragmatic RCTs there lacks a clear definition of process evaluation, and the scope of process evaluation is very broad. It is therefore questionable whether the label is always useful.

There is also no simple answer to the question of how process evaluations are valued and the kind of value they create, as value and negative consequences are subjective and context dependent. Even within a single context there are multiple views and interpretations of what is valuable.

Process evaluations are largely shaped by what is valued by researchers and other stakeholders, and how this value is negotiated across multiple complex healthcare research contexts. Conducting process evaluations in the real world of healthcare research is challenging, and getting process evaluations done is highly dependent on the abilities of researchers to negotiate these contexts.

In summary, I draw the following four key recommendations from the findings of this thesis:

- Researchers should plan the value they wish to create from the outset of planning a process evaluation, to then inform decisions about how to design and conduct the process evaluation to create this value. This thesis provides tools and frameworks to facilitate this planning process.
- When planning and conducting process evaluations in practice, and in theoretical discussions of process evaluation, researchers should consider:
    - How they define process evaluation
    - The role of a process evaluation within a pragmatic RCT

    - The kind of knowledge that is perceived as valuable for process evaluations to produce, including ontology, epistemology, and complexity, and how this may be reconciled with different scenarios of RCT outcome results

- Process evaluation teams should pay attention to the social processes underlying their idea sharing and decision-making and the social and physical/virtual contexts in which this takes place, with measures to promote equal and open discussions recommended.

- Barriers to conducting process evaluations efficiently and to their full potential exist in the organisations supporting healthcare research, and these should be further examined and addressed.

These findings contribute to theoretical debates about the role of a process evaluation within a pragmatic RCT and the kind of knowledge that is perceived as valuable, and to broader theoretical debates about the evaluation of complex healthcare interventions. They also contribute practical frameworks and recommendations for researchers to design, conduct, and disseminate process evaluations from a value-informed perspective.

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Appendix 1: Links to publications

Publications

French, C., Pinnock, H., Forbes, G., Skene, I. and Taylor, S.J., 2020. Process evaluation within pragmatic randomised controlled trials: what is it, why is it done, and can we find it?—a systematic review. *Trials*, *21*(1), pp.1-16.

Available from:

https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-04762-9

Submitted for publication

French, C., Dowrick A., Fudge, N., Pinnock, H. and Taylor SJC. What do we want to get out of this? A critical interpretive synthesis of the value of process evaluations with a practical planning framework, 17 May 2022, PREPRINT (Version 1) available at Research Square [https://doi.org/10.21203/rs.3.rs-1616970/v1]

Appendix 2: Papers included in critical interpretive synthesis

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Aarestrup et al. (1)	2014	journal article	Denmark	health	trial	Process evaluation approach / framework / guidance	to present a systematic approach to plan process evaluation of the implementation of randomised multicomponent interventions
Abildgaard et al. (2)	2016	journal article	Denmark	health	trial	Methodological / operational / ethical issues	to shed light on what type of knowledge of the intervention is gained from qualitative and quantitative process evaluation data
Abraham et al. (3)	2014	journal article	UK	health	trial	Process evaluation approach / framework / guidance	This article advances recommendations made by an international group of scholars constituting the Workgroup for Intervention Development and Evaluation Research (WIDER), which has developed brief guidance to journal editors to improve the reporting of evaluations of behavior change interventions, thereby serving as an addition to reporting statements such as CONSORT.
Alia et al. (4)	2015	journal article	USA	health	trial	Process evaluation approach / framework / guidance	to demonstrate how process evaluation is used to assess implementation of, and to provide formative feedback for, a culturally tailored, motivational plus family-based weight loss program
Audrey et al. (5)	2006	journal article	UK	health	trial	Methodological / operational / ethical issues	we describe the extensive process evaluation embedded within the trial and, rather than focusing on resultant data, we consider the potential for such detailed examination of process to affect the intervention's delivery, receipt and outcome evaluation
Bakker et al. (6)	2015	journal article	Netherlands	health	not specified	Methodological / operational / ethical issues	describes the development of a method to concisely summarize the results of process evaluations of complex multi-component interventions
Bakker et al. (7)	2013	letter	Netherlands	health	trial	Process evaluation approach / framework / guidance	n/a

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Baranowski and Stables (8)	2000	journal article	USA	health	trial	Process evaluation approach / framework / guidance	The process evaluation results from the nine 5-a-Day projects were overviewed.
Biron and Karanika-Murray (9)	2014	journal article	Canada	health	not specified	Process evaluation approach / framework / guidance	we discuss how intervention process evaluation (IPE), an emerging field in intervention research, can enhance our understanding of why organizational interventions for stress succeed or fail
Boeije et al. (10)	2015	journal article	Netherlands	health	trial	Methodological / operational / ethical issues	This paper addresses the methodological challenges that accompany the use of a combination of research methods to evaluate complex interventions.
Branscum and Hayes (11)	2013	journal article	USA	health	not specified	Review	reports the use of process evaluations in childhood obesity prevention interventions implemented over the past three decades
Britton et al. (12)	1998	letter	UK	health	trial	Value of process evaluation	n/a
Buckley and Sheehan (13)	2009	journal article	Australia	health	not specified	Process evaluation approach / framework / guidance	sought to provide examples of how to operationalize a process evaluation of an effective programme
Bunce et al. (14)	2014	journal article	USA	health	trial	Methodological / operational / ethical issues	The specific methods used in such ethnographic process evaluations are rarely presented in detail; our objective is to stimulate a conversation around the successes and challenges of specific data collection methods in health care settings.
Butterfoss (15)	2006	journal article	USA	health	not specified	Methodological / operational / ethical issues	This review provides a synthesis of published public health and social science literature to determine how process evaluation has been used to examine community participation and its intermediary role in health and social change outcomes.
Byng et al. (16)	2005	journal article	UK	health	trial	Methodological / operational / ethical issues	This article explores how a relatively low-cost evaluation, using qualitative methods and Pawson and Tilley's realistic evaluation (RE) framework (1997) can both help explain the results of the trial and provide

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
							generalizable conclusions about service development of relevance to practitioners and policy makers.
Byng et al. (17)	2008	journal article	UK	health	trial	Value of process evaluation	This paper builds a picture of how the intervention, as a whole, had its effects and how the process evaluation adds meaning to the results of the trial.
Chandler et al. (18)	2015	journal article	UK	health	trial	Use of a method / theory in process evaluation	To examine the application of core concepts from Complexity Theory to explain the findings from a process evaluation undertaken in a trial evaluating implementation strategies for recommendations about reducing surgical fasting times.
Chrisman et al. (19)	2002	journal article	USA	health	standalone PE	Process evaluation approach / framework / guidance	This article reports the design we constructed and how it hasworked so far
Cornwall and Aghajanian (20)	2017	journal article	UK	health	standalone PE	Use of a method / theory in process evaluation	This article considers the contribution participatory process evaluation can make to impact assessment, using a case study of a study carried out to evaluate
Crutzen et al. (21)	2012	journal article	Netherlands	health	not specified	Use of a method / theory in process evaluation	This study aimed to demonstrate the potential of Google Analytics as a process evaluation method for Internet delivered interventions, using a website about sexual health as an example.
Cunningham et al. (22)	2000	journal article	USA	health	quasi-experimental	Methodological / operational / ethical issues	Included in the paper are the purposes of each process method, problems identi®ed, and their resolution. Suggestions are made for use of process evaluation in community health education programs.
De Silva et al. (23)	2014	journal article	UK	health	not specified	Process evaluation approach / framework / guidance	We propose a theory-driven approach to the design and evaluation of complex interventions by adapting and integrating a programmatic design and evaluation tool, Theory of Change (ToC), into the MRC framework for complex interventions.
Diaz et al. (24)	2014	journal article	USA	health	not specified	Process evaluation approach / framework / guidance	To use a newly devised set of criteria to review the study design and scope of collection of process, outcomes and contextual data for evaluations and implementation

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
							research of integrated community case management (iCCM) in Sub–Saharan African.
Ellard and Parsons (25)	2010	book chapter	UK	health	not specified	Methodological / operational / ethical issues	This chapter discusses issues relating to formative process evaluation and process evaluation; explores the research methods used; and discusses the integration of process and outcome data.
Ellard et al. (26)	2011	journal article	UK	health	trial	Methodological / operational / ethical issues	A process evaluation was commissioned alongside the trial and we report the protocol for this process evaluation.
Evans et al. (27)	2015	editorial	UK	health	pragmatic formative process evaluation	Process evaluation approach / framework / guidance	n/a
Francis et al. (28)	2008	journal article	UK	health	trial	Use of a method / theory in process evaluation	This study illustrates the use of theory-based process evaluation to uncover processes underlying change in implementation trials.
Franzen et al. (29)	2009	journal article	USA	health	standalone PE	Value of process evaluation	The present study illustrates how a systematic process evaluation study can improve program activities.
Grant et al. (30)	2013	journal article	UK	health	trial	Use of a method / theory in process evaluation	develop our own framework for designing process evaluations of cluster-randomised controlled trials.
Grant et al. (31)	2016	editorial	UK	health	trial	Methodological / operational / ethical issues	n/a
Grant et al. (32)	2012	journal article	UK	health	trial	Process evaluation approach / framework / guidance	This paper presents the mixed-method process evaluation protocol of a cluster randomized trial, drawing on a framework designed by the authors.
Griffin et al. (33)	2014	journal article	UK	health	trial	Process evaluation approach / framework / guidance	In this paper, we add to the current literature by describing a comprehensive approach to process evaluation undertaken in a trial of a complex, primary school-based obesity prevention intervention;

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Griffin et al. (34)	2017	journal article	UK	health	trial	Process evaluation approach / framework / guidance	The aim of this paper is twofold: 1) to demonstrate a replicable method of process evaluation data synthesis for use by other complex health intervention researchers, and 2) to present the results of the WAVES study process evaluation, demonstrating how the intervention was delivered and received.
Harachi and Fleming (35)	1999	journal article	USA	health	not specified	Use of a method / theory in process evaluation	This article illustrates the utilization of process measures from a multicomponent school-based prevention program to examine implementation of a teaching staff development intervention, and the program's underlying theoretical basis.
Hatcher and Bonell (36)	2016	editorial	South Africa	health	trial	Value of process evaluation	n/a
Havermans et al. (37)	2016	journal article	Netherlands	health	not specified	Review	This systematic review aimed to explore which process variables are used in stress management intervention (SMI) evaluation research.
Hawe et al. (38)	2004	journal article	Canada	health	trial	Methodological / operational / ethical issues	In this paper, we describe a combination of qualitative and quantitative methods in place to track the unfolding of a large scale primary care and community development intervention in maternal health in Australia. I
Haynes et al. (39)	2014	journal article	Australia	health	trial	Use of a method / theory in process evaluation	This protocol provides a worked example of how to embed process evaluation in the design and evaluation of a complex intervention trial.
Haynes et al. (40)	2016	journal article	Australia	health	trial	Process evaluation approach / framework / guidance	In this paper, we identify and respond to the fidelity assessment challenges posed by novel contextualised interventions (i.e. interventions that are informed by composite social and psychological theories and which incorporate standardised and flexible components in order to maximise effectiveness in complex settings).
Helitzer et al. (41)	2000	journal article	USA	health	not specified	Methodological / operational / ethical issues	In examining this component of the process evaluation, the paper presents the important benefits of monitoring

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
							implementation and providing early feedback to the training process.
Hickey et al. (42)	2016	journal article	Ireland	health	trial	Methodological / operational / ethical issues	In this paper, a process evaluation protocol for an early years parenting intervention, the Parent and Infant (PIN) program, is described.
Hulscher et al. (43)	2003	journal article	Netherlands	health	not specified	Multiple	This paper explores the purpose and value of process evaluation on QI interventions and addresses the issue of what data should be collected ("what to measure") and data collection methods ("how to measure").
Humphrey et al. (44)	2016	online publication	UK	education	not specified	Process evaluation approach / framework / guidance	The purpose of this introductory handbook is to provide guidance to Endowment Foundation (EEF) evaluators (and, indeed, other researchers) on how to conduct high-quality implementation and process evaluations (IPE) at the various stages of intervention development and testing (e.g. pilot, efficacy, effectiveness)
Humphrey et al. (45)	2016	online publication	UK	education	not specified	Review	to draw together existing knowledge regarding the aims, functions and methods of implementation and process evaluation (IPE) in relation to educational interventions, with a view to subsequently informing guidelines for researchers
Irvine et al. (46)	2012	journal article	UK	health	feasibility study	Process evaluation approach / framework / guidance	This study assesses the utility of novel techniques for process evaluation involving no face to face contact.
Jansen et al. (47)	2009	journal article	Netherlands	health	trial	Review	this article aims to review the contribution of qualitative research to developing communitybased interventions in primary care evaluated by means of the pragmatic trial methodology.
Kelley et al. (48)	2001	journal article	USA	health	standalone PE	Value of process evaluation	To use process evaluation methods to describe the development of a hospital-based mental health clinic for children facing medical stressors.
Lee et al.(49)	2013	journal article	USA	health	not specified	Process evaluation approach / framework / guidance	To use and review a conceptual model of process evaluation and to examine the implementation of a nutrition education curriculum,

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Lee et al. (50)	2011	journal article	Canada	health	pilot study	Process evaluation approach / framework / guidance	this article describes a fresh, ethnographically informed approach focused on alignments of project components in a pilot multisite, multilevel community-based falls prevention study in canada
Leeming et al. (51)	2016	journal article	UK	health	trial	Process evaluation approach / framework / guidance	n this paper, we discuss the limitations of evidence gained from measuring large-scale outcomes in RCTs and argue that greater use of qualitative research can enhance understanding of key processes in supporting breastfeeding.
Leontjevas et al. (52)	2012	journal article	Netherlands	health	trial	Methodological / operational / ethical issues	In this article, a model is presented that divides process evaluation data into first and second order process data.
Linnan and Steckler (53)	2002	book chapter	USA	health	not specified	Use of a method / theory in process evaluation	n/a
Liu et al. (54)	2016	journal article	Australia	health	trial	Review	we aim to consolidate the methodology and methods from process evaluations of complex interventions in PHC and their findings of facilitators and barriers to intervention implementation
Lorencatto et al. (55)	2016	journal article	UK	health	trial	Process evaluation approach / framework / guidance	This protocol presents methods for assessing fidelity across five dimensions proposed by the Behaviour Change Consortium fidelity framework, including intervention designer-, provider- and recipient-levels.
Lytle et al. (56)	1994	journal article	USA	health	trial	Methodological / operational / ethical issues	This paper discusses the challenges faced when collecting process evaluation information in a school-based, multicenter field trial.
Maar et al. (57)	2017	journal article	Canada	health	trial	Process evaluation approach / framework / guidance	we present a framework for the process evaluations for mHealth interventions in multiple cultural settings
Manchaiah et al. (58)	2014	journal article	UK	health	not specified	Methodological / operational / ethical issues	The main focus of this paper is to discuss the importance of “evaluating the process of change” (i.e., process evaluation) in people with disability by studying their lived experiences.

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Masterson-Algar (59)	2016	PhD thesis	UK	health	trial	Multiple	The aim of this study is to advance thinking and practice in process evaluation and clinical trial methodology within the field of neurological rehabilitation.
Masterson-Algar et al. (60)	2016	journal article	UK	health	trial	Review	To systematically review how process evaluations are currently designed, what methodologies are used and how are they developed alongside or within neurological rehabilitation trials.
May et al.(61)	2007	journal article	UK	health	trial	Process evaluation approach / framework / guidance	The paper develops this by first discussing the development of the theoretical model, and then applies it to two case studies of complex trials that combine both treatment and organizational interventions in primary care. In the conclusion, the implications of such models for the development of process evaluations are discussed.
Mbuya et al. (62)	2015	journal article	Zimbabwe	health	trial	Process evaluation approach / framework / guidance	n this article, we present the SHINE PIP including definitions and measurements of key mediating domains, and discuss the implications of this approach for randomized trials.
McGraw et al. (63)	1994	journal article	USA	health	trial	Use of a method / theory in process evaluation	The process evaluation system used in the Child and Adolescent Trial for Cardiovascular Health (CATCH) is presented in this paper.
Moore (64)	2010	PhD thesis	UK	health	trial	Process evaluation approach / framework / guidance	This thesis develops a mixed-method framework exploring programme theory, diffusion, implementation, participant experiences and reach, which is applied to the evaluation of the Welsh National Exercise Referral Scheme (NERS)
Moore et al. (65)	2015	journal article	UK	health	not specified	Process evaluation approach / framework / guidance	In this article, we provide an overview of the new framework and summarise our practical recommendations using one of the case studies as an example.
Moore et al. (66)	2014	editorial	UK	health	not specified	Multiple	n/a

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Moore et al. (67)	2014	online publication	UK	health	not specified	Process evaluation approach / framework / guidance	This document provides researchers, practitioners, funders, journal editors and policy-makers with guidance in planning, designing, conducting and appraising process evaluations of complex interventions.
Morgan-Trimmer (68)	2015	journal article	UK	health	not specified	Methodological / operational / ethical issues	This article reflects on the current state of process evaluations of health behavior interventions and argues that evaluation practice in this area could be improved by drawing on the social science literature to a greater degree.
Morgan-Trimmer and Wood (69)	2016	journal article	UK	health	not specified	Use of a method / theory in process evaluation	This article outlines the contribution that ethnography could make to process evaluations for trials of complex health behaviour interventions
Munro and Bloor (70)	2010	journal article	UK	health	trial	Value of process evaluation	not stated
Murdoch (71)	2016	journal article	UK	health	trial	Process evaluation approach / framework / guidance	In this paper I propose an alternative approach to the design, implementation and analysis of process evaluations for complex health interventions through a consideration of trial protocols as textual documents, distributed and enacted at multiple contextual levels
Murta et al. (72)	2007	journal article	Brazil	health	not specified	Review	To conduct a systematic review of workplace stress management intervention studies that have incorporated process evaluation
Murtagh et al. (73)	2007	journal article	UK	health	trial	Methodological / operational / ethical issues	To understand participants' experiences and understandings of the interventions in the trial of a computerised decision support tool in patients with atrial fibrillation being considered for anti-coagulation treatment.
Nagy et al. (74)	2007	journal article	USA	health	standalone PE	Value of process evaluation	In this manuscript we report on the development, implementation, results, and lessons learned from a process evaluation plan initiated during the planning period for the Alabama Racial and Ethnic Approaches to Community Health (REACH 2010) program

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Nielsen and Abildgaard (75)	2013	journal article	UK	health	not specified	Process evaluation approach / framework / guidance	In this paper, we present an evaluation framework based on recent intervention research and process-oriented organization theory.
Nielsen and Randall (76)	2013	journal article	Denmark	health	not specified	Process evaluation approach / framework / guidance	By drawing on existing intervention literature we present an evidence-based model containing three levels of elements that appear to be crucial in process evaluation.
Oakley et al. (77)	2004	journal article	UK	health	trial	Methodological / operational / ethical issues	The article describes the methods used to collect process data, and some of the challenges involved
Oakley et al. (78)	2006	journal article	UK	health	trial	Process evaluation approach / framework / guidance	This paper outlines a framework for using process evaluation as an integral element of RCTs.
O'Cathain et al. (79)	2013	journal article	UK	health	trial	Value of process evaluation	To systematically explore how qualitative research is being used with trials and identify ways of maximising its value to the trial aim of providing evidence of effectiveness of health interventions.
Odendaal et al. (80)	2008	journal article	South Africa	health	trial	Value of process evaluation	this article reviews the methods in a process evaluation of a home visitation programme
Ottoson et al. (81)	2000	journal article	USA	health	not specified	Value of process evaluation	The purpose of this study was to explore process or contextual aspects ofthe work setting and their relationship to learning outcomes following CPE
Palmer et al. (82)	2016	journal article	Australia	health	trial	Methodological / operational / ethical issues	This paper provides a description of a nested process evaluation design using mixed-methods to inform a cluster randomized controlled trial. It builds on current debates about the need to better systematize process evaluation data collection, analysis and reporting.
Platt et al. (83)	2004	book chapter	UK	health	not specified	Methodological / operational / ethical issues	This chapter introduces the purposes, focus, and methods of process evaluation and explores some issues in the application of process evaluation using examples from two research projects

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Raine et al. (84)	2016	journal article collection	UK	health	not specified	Multiple	This collection of essays is intended to address at least the first part of the paradox, the relative lack of consensus about how to evaluate changes in services
Ramsay et al. (85)	2010	journal article	UK	health	trial	Use of a method / theory in process evaluation	To illustrate the applicability of causal methods within randomised trials, we undertook a theory-based process evaluation study within an implementation trial to explore whether the cognitions of primary care doctors' predicted their test requesting behaviours and, secondly, whether the trial results were mediated by the theoretical constructs.
Renger and Foltysova (86)	2013	journal article	USA	health	standalone PE	Process evaluation approach / framework / guidance	The purpose of this study is to report on our efforts at assessing the feasibility of capturing programplanning phase deliberations and using them to design a process evaluation capable of providing information for making decisions about both quality control and quality improvement.
Reynolds et al. (87)	2014	journal article	UK	health	trial	Process evaluation approach / framework / guidance	In this paper, we will draw on our experiences of 'doing' evaluation in a research context to present lessons learned for negotiating the reality of evaluation and reflecting on the subsequent implications for interpreting trial outcomes.
Riley et al. (88)	2005	journal article	Australia	health	trial	Methodological / operational / ethical issues	This paper presents issues which arose in the conduct of qualitative evaluation researchwithin a clusterrandomized, community-level, preventive intervention trial.
Roberts-Gray et al. (89)	2017	journal article	USA	health	trial	Process evaluation approach / framework / guidance	To examine the utility of structuring the trial's process evaluation to forecast use, sustainability, and readiness of the intervention for wider dissemination and implementation.
Roe and Roe (90)	2004	journal article	USA	health	not specified	Process evaluation approach / framework / guidance	This article describes dialogue boxes, a process evaluation tool that has proven extremely useful in diverse health promotion program and planning efforts.

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Saunders et al. (91)	2005	journal article	USA	health	not specified	Process evaluation approach / framework / guidance	The purpose of this article is to describe and illustrate the steps involved in developing a processevaluation plan for any healthpromotion program.
Scott et al. (92)	2014	journal article	Canada	health	not specified	Review	This study focuses on improving process evaluations by synthesizing current evidence on process evaluations conducted alongside experimental designs for evaluating KT interventions.
Sharma et al. (93)	2017	journal article	Canada	health	trial	Process evaluation approach / framework / guidance	Building from previous frameworks, we illustrate a methodology to evaluate implementation processes of the complex CLIP intervention, assess mechanisms of impact and identify emerging unintended causal pathways.
Strange et al. (94)	2006	journal article	UK	health	trial	Methodological / operational / ethical issues	This article has three aims: to outline the methods developed to link process and outcome data in the RIPPLE trial; to present the findings of this analysis; and to explore some of the methodological issues that arose, especially in using the process data to explain the impact on trial outcomes.
Tolma et al. (95)	2009	journal article	USA	health	intervention development	Methodological / operational / ethical issues	In this article, we describe the process evaluation planning that took place during the development of an action plan by a newly developed Turning Point community partnership.
Tolma et al. (96)	2011	journal article	USA	health	intervention development	Process evaluation approach / framework / guidance	To describe the systematic approach to process evaluation of a Turning Point initiative in central Oklahoma during the formation stage
Tonkin-Crine et al. (97)	2016	journal article	UK	health	trial	Use of a method / theory in process evaluation	The current study aimed to follow a triangulation protocol to integrate mixed methods data previously collected in order to see whether such an approach could further inform the findings of the original process evaluation of the trial.
Toroyan et al. (98)	2004	journal article	UK	health	trial	Value of process evaluation	This paper outlines the process evaluation that was conducted alongside the first RCT of day care in the United Kingdom.

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Tuchman (99)	2008	journal article	USA	health	pilot study	Use of a method / theory in process evaluation	This article presents an exemplar of a model-guided process evaluation
Turner et al. (100)	2006	journal article	Australia	health	not specified	Process evaluation approach / framework / guidance	This paper describes the development and implementation of an electronic, web-based application to simplify data collection for this research process
Viadro et al. (101)	1997	journal article	USA	health	quasi-experimental	Methodological / operational / ethical issues	In this paper, we discuss the steps taken to develop a process evaluation plan for an ongoing eight-year, community-based breast cancer screening program (NC-BCSP) for African American women in five rural North Carolina counties.
Wells et al. (102)	2012	journal article	UK	health	trial	Methodological / operational / ethical issues	However, the diverse ways in which context may challenge the central tenets of the RCT, and the degree to which this information is known to researchers or subsequently reported, has received much less attention. In this paper, we explore these issues by focusing on seven RCTs of interventions varying in type and degree of complexity, and across diverse contexts.
Wickizer et al. (103)	1993	journal article	USA	health	standalone PE	Process evaluation approach / framework / guidance	This paper describes an approach developed to analyze community activation for health promotion and presents data on selected measures of activation collected in 28 communities in the western United States as part of the Community Health Promotion Grant Program evaluation.1
Wierenga et al. (104)	2013	journal article	Netherlands	health	trial	Review	The aim of this review was therefore to: (1) further our understanding of the quality of process evaluations alongside effect evaluations for worksite health promotion programs (WHPPs), (2) identify barriers/facilitators affecting implementation, and (3) explore the relationship between effectiveness and the implementation process.

Reference	Year of publication	Type of literature	Country of lead author	Field	Type of accompanying evaluation	Focus	Aim
Wight and Obasi (105)	2003	book chapter	UK	health	trial	Methodological / operational / ethical issues	this chapter discusses four key intervention factors that can be of critical importance in interpreting outcome evaluations. These factors are: (1) the extent and quality of intervention delivery; (2) the mechanism; (3) the context; and, (4) the response of the target group. Finally, the chapter considers some key problems with process evaluations and how process and outcome data can be integrated
Wilson et al. (106)	2009	journal article	USA	health	trial	Value of process evaluation	The purpose of this study was to demonstrate how formative program process evaluation was used to improve dose and fidelity of implementation, as well as reach of the intervention into the target population, in the "Active by Choice Today" (ACT) randomized schoolbased trial from years 1 to 3 of implementation.
Windsor et al. (107)	2000	journal article	USA	health	trial	Process evaluation approach / framework / guidance	To describe and apply a process evaluation model (PEM) for patient education programs for pregnant smokers.
Yamada et al. (108)	2010	journal article	Canada	health	not specified	Process evaluation approach / framework / guidance	To examine the content validity of the Process Evaluation Checklist (PEC), a newly developed measure to assess the fidelity of the EPIC intervention
Yeary et al. (109)	2012	journal article	USA	health	not specified	Review	Thus, a systematic review of the utilization of process evaluation in churchbased health programs was conducted

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Appendix 3: Systematic review trial paper data fields

Data field	Operationalisation	Extract from	Extract as
Funder	Who funded the trial	Trial results paper, or trial registry if not stated	Free text
Publication month	Month the trial results paper was published in print, or online for online only journals	Medline search result	Month
Publication year	Year the trial results paper was published in print, or online for online only journals	Medline search result	2015
Country	The country / countries the intervention was delivered in during the trial	Trial results paper	Country
Journal	The journal the trial results paper was published in	Trial results paper	Journal name
Intervention	Brief description of intervention(s)	Trial results paper	Free text
Comparator	What was received by the control / comparator group(s)	Trial results paper	Free text
Intervention recipients	Who received the intervention	Trial results paper	Free text
Intervention deliverer	Who administered / delivered the intervention(s) during the trial	Trial results paper	Free text
Clinical specialty	The clinical field the intervention was intended for	Trial results paper	Free text
Setting	The setting of intervention delivery.	Trial results paper	Free text
Randomisation level	Whether participants were individually or cluster randomised	Trial results paper	Individual Cluster
Primary outcome result	Whether the primary outcome result was stated as being statistically significant in the abstract of the paper (p value or confidence interval)	Trial results paper – abstract If not clear from abstract class as unclear If classification does not fit e.g. non-inferiority, multiple outcomes, class as n/a	Positive Not positive n/a if does not fit
Trial design	Further details of the trial design	Trial results paper	2-arm 3-arm Non-inferiority Stepped-wedge Crossover

Appendix 4: Systematic review inclusion consensus meeting

My supervisors and I discussed 30 publications which after screening the secondary search results I considered could be classed as process evaluations. This consisted of 25 journal articles and 5 HTA monographs.

We agreed that 21 publications included process evaluation results according to our operational definition. Six studies were excluded as not process evaluations, none of which were labelled as process evaluations. One study was a parallel patient-preference cohort study (1), excluded as we conceptualised it as a separate study with different participants to the main trial, although its aims related to process evaluation. Four studies (2-5) were subgroup analyses investigating the impact of clinical features of disease on outcome, and we felt these addressed questions of clinical efficacy, rather than examining context in a sense implied by process evaluation. The final study (6) was a borderline decision, however on balance we considered the paper appeared to aim to improve practice globally rather than specific to the intervention.

We also excluded three publications which did meet our operational definition. Two used data from a series of trials, rather than solely the trial identified in this review. Another was a methodology paper with no results published, apart from in a PhD thesis.

1. Cooper NA, Middleton L, Smith P, Denny E, Stobert L, Daniels J, et al. A patient-preference cohort study of office versus inpatient uterine polyp treatment for abnormal uterine bleeding. Gynecological surgery. 2016;13(4):313.
2. Horrocks EJ, Chadi SA, Stevens NJ, Wexner SD, Knowles CH. Factors associated with efficacy of percutaneous tibial nerve stimulation for fecal incontinence, based on post-hoc analysis of data from a randomized trial. Clinical Gastroenterology and Hepatology. 2017;15(12):1915-21. e2.
3. Vermeij J-D, Westendorp WF, Roos YB, Brouwer MC, van de Beek D. Preventive Ceftriaxone in Patients with Stroke Treated with Intravenous Thrombolysis: Post Hoc Analysis of the Preventive Antibiotics in Stroke Study. Cerebrovascular diseases (Basel, Switzerland). 2016;42(5-6):361-9.
4. Perl VJU, Leroux B, Cook MR, Watson J, Fair K, Martin DT, et al. Damage control resuscitation and emergency laparotomy: findings from the PROPPR study. The journal of trauma and acute care surgery. 2016;80(4):568.
5. Naslund JA, Aschbrenner KA, Scherer EA, Pratt SI, Bartels SJ. Health promotion for young adults with serious mental illness. Psychiatric Services. 2016;68(2):137-43.
6. Meyer DE, Vincent LA, Fox EE, O'Keeffe T, Inaba K, Bulger E, et al. Every minute counts: time to delivery of initial massive transfusion cooler and its impact on mortality. The journal of trauma and acute care surgery. 2017;83(1):19.

Appendix 5: Systematic review included pragmatic RCT results papers

		MRC process evaluation components reported in index trial results paper(s)											
Reference of index trial results paper *Journal* Country Further references*	**Intervention**	**Reach**	**Fidelity**	**Dose**	**How delivery is achieved**	**Adaptations**	**Contextual moderators**	**Contextual factors that shape intervention theory**	**Causal mechanisms that maintain status quo or enhance effects**	**Mediators**	**Unanticipated pathways and consequences**	**Participant responses**	**Separate process evaluation paper(s)**
Bartels 2015 (1) *American Journal of Psychiatry* USA	Health promotion coaching for obesity in serious mental illness	Y					Y	Y	Y	Y		Y	No (included process evaluation but using data from multiple trials so excluded from review)
Bender 2015 (2) *JAMA Pediatrics* USA	Speech recognition telephone calls to improve adherence to child asthma treatment	Y					Y	Y				Y	No
Boulvain 2015 (3) *Lancet* France, Belgium, Switzerland	Induction of labour vs expectant management for large-for-date foetuses	Y											No
Cooper 2015 (4) *BMJ* UK Clark 2015 (5)	Outpatient vs inpatient uterine polyp treatment	Y					Y		Y		Y	Y	Yes
Curtis 2015 (6) *Canadian Medical Association Journal* Canada	Ultrasound or near-infrared vascular imaging to guide peripheral intravenous catheterisation	Y					Y	Y					No

		MRC process evaluation components reported in index trial results paper(s)											
Reference of index trial results paper *Journal* Country Further references*	**Intervention**	**Reach**	**Fidelity**	**Dose**	**How delivery is achieved**	**Adaptations**	**Contextual moderators**	**Contextual factors that shape intervention theory**	**Causal mechanisms that maintain status quo or enhance effects**	**Mediators**	**Unanticipated pathways and consequences**	**Participant responses**	**Separate process evaluation paper(s)**
El-Khoury 2015 (7) *BMJ* France	Balance training to prevent fall-induced injuries	Y		Y							Y	Y	No
Fortney 2015 (8) *JAMA Psychiatry* USA	Telemedicine-based collaborative care for veterans with PTSD	Y	Y	Y		Y				Y		Y	Yes
Gilbody 2015 (9) *BMJ* UK Littlewood 2015 (10)	Computerised cognitive behavioural therapy for depression	Y					Y		Y		Y	Y	Yes
Hill 2015 (11) *Lancet* Australia	Individualised falls-prevention education for hospital patients, with training and feedback for staff	Y	Y	Y			Y	Y			Y	Y	Yes
Holcomb 2015 (12) *JAMA* North America Baraniuk 2014 (13) Zhu 2016 (14)	Comparison of 2 different ratios of blood products in patients with major trauma	Y	Y			Y							Yes
Honkoop 2015 (15) *Journal of Allergy and Clinical Immunology* Netherlands	Comparison of 3 treatment strategies targeting different levels of asthma control	Y	Y									Y	No
Hui 2015 (16) *Gut* Hong Kong	Comparison of medical and nurse endoscopists performing colonoscopy	Y				Y	Y					Y	No

		MRC process evaluation components reported in index trial results paper(s)											
Reference of index trial results paper *Journal* Country Further references*	**Intervention**	**Reach**	**Fidelity**	**Dose**	**How delivery is achieved**	**Adaptations**	**Contextual moderators**	**Contextual factors that shape intervention theory**	**Causal mechanisms that maintain status quo or enhance effects**	**Mediators**	**Unanticipated pathways and consequences**	**Participant responses**	**Separate process evaluation paper(s)**
Kempe 2015 (17) *JAMA Pediatrics* USA	Collaborative centralised reminder/recall system to increase immunisation rates in young children	Y				Y		Y			Y		Yes
Knowles 2015 (18) *Lancet* UK Horrocks 2015 (19)	Percutaneous tibial nerve stimulation for treatment of faecal incontinence	Y	Y				Y				Y	Y	No
Kutner 2015 (20) *JAMA Internal Medicine* USA	Statin discontinuation in advanced life-limiting illness	Y									Y	Y	Yes
Lamb 2015 (21) *Lancet* UK Williams 2015 (22)	Exercises to improve hand function in rheumatoid arthritis	Y	Y	Y		Y	Y	Y	Y		Y	Y	Yes
Moreira 2015 (23) *Nursing Research* Brazil	Nursing case management for patients with type 2 diabetes	Y					Y		Y				No
Moseley 2015 (24) *JAMA* Australia	Exercise programme for rehabilitation following ankle fracture	Y	Y				Y		Y		Y	Y	No
Mouncey 2015a (25) *NEJM* UK Mouncey 2015b (26)	Early, Goal-Directed Resuscitation protocol for septic shock	Y	Y			Y	Y	Y	Y		Y		No

		MRC process evaluation components reported in index trial results paper(s)											
Reference of index trial results paper *Journal* Country Further references*	**Intervention**	**Reach**	**Fidelity**	**Dose**	**How delivery is achieved**	**Adaptations**	**Contextual moderators**	**Contextual factors that shape intervention theory**	**Causal mechanisms that maintain status quo or enhance effects**	**Mediators**	**Unanticipated pathways and consequences**	**Participant responses**	**Separate process evaluation paper(s)**
Noto 2015 (27) *JAMA* USA	Chlorhexadine bathing in intensive care units	Y	Y				Y						No
Perkins 2015 (28) *Lancet* UK Gates 2017 (29)	Mechanical vs manual chest compression for out of hospital cardiac arrest	Y	Y				Y		Y		Y		No
Rangan 2015 (30) *JAMA* UK Handoll 2015 (31)	Surgical vs non-surgical treatment for adults with displaced fracture of proximal humerus	Y	Y			Y	Y		Y		Y	Y	Yes
Sackley 2015 (32) *BMJ* UK Sackley 2016 (33)	Occupational therapy for care home residents with stroke disability	Y		Y			Y	Y			Y		Yes
Scott 2015 (34) *BMJ* UK Scott 2014 (35)	Tumour necrosis factor inhibitors versus combination intensive therapy with conventional disease modifying anti-rheumatic drugs	Y				Y		Y			Y	Y	No
Semler 2015 (36) *Critical Care Medicine* USA	Electronic sepsis evaluation and management tool in intensive care	Y		Y		Y	Y					Y	No
Smith 2015a (37) *BMJ* UK	Patient-controlled analgesia for patients in emergency department with pain from traumatic injuries	Y									Y	Y	No

		MRC process evaluation components reported in index trial results paper(s)											
Reference of index trial results paper *Journal* Country Further references*	**Intervention**	**Reach**	**Fidelity**	**Dose**	**How delivery is achieved**	**Adaptations**	**Contextual moderators**	**Contextual factors that shape intervention theory**	**Causal mechanisms that maintain status quo or enhance effects**	**Mediators**	**Unanticipated pathways and consequences**	**Participant responses**	**Separate process evaluation paper(s)**
Smith 2015b (38) *BMJ* UK	Patient-controlled analgesia for patients in emergency department with pain from non-traumatic abdominal injuries	Y									Y	Y	No
Stewart 2015 (39) *Lancet* Australia	Standard vs atrial-fibrillation specific management strategy	Y	Y	Y		Y			Y				Yes
Wechsler 2015 (40) *JAMA* USA	Anticholinergic vs long-acting β-agonist in combination with inhaled corticosteroids in black adults with asthma	Y				Y	Y				Y	Y	No
Westendorp 2015 (41) *Lancet* Netherlands	Preventive antibiotics in stroke	Y		Y			Y	Y	Y		Y		No
Williamson 2015 (42) *Canadian Medical Association Journal* UK Williamson 2015 (43)	Nasal balloon autoinflation in children with otitis media with effusion in primary care	Y					Y		Y		Y	Y	Yes

*If applicable - references of additional publications reporting trial results from which we extracted data on process evaluation components

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Appendix 6: Systematic review items mapped to MRC process evaluation components

MRC component	Included items
Implementation	
Adaptations *Alterations made to an intervention in order to achieve better contextual fit*	Trial papers • Time taken to deliver interventions where this was not specified by a protocol • Means through which the intervention was delivered where this was flexible, e.g. qualifications of staff delivering the intervention • Which intervention components were delivered to participants as part of flexible interventions • Description of alternative materials used by sites to trial materials Process evaluation papers • Description of how a flexible intervention was delivered in practice
Dose *How much intervention is delivered*	Trial papers • Numbers of intervention sessions delivered to participants • Numbers of 'occurrences' of optional intervention components delivered to participants • Numbers of times the intervention electronic tool was opened • Time spent by deliverers on intervention components
Fidelity *The consistency of what is implemented with the planned intervention*	Trial papers • Whether or not intervention components were delivered • The quality or standard of (components of) interventions delivered • Reasons for non-adherence or protocol deviations • Fidelity scores, adherence percentages • Whether or not the correct randomised intervention was delivered • Analyses to examine the effect of non-fidelity on the primary outcome – e.g. per-protocol, complier average causal effect analyses Process evaluation papers • Whether and how centres delivered interventions in accordance with intervention protocols
How delivery is achieved *The structures, resources and mechanisms through which delivery is achieved*	Process evaluation papers • Qualitative exploration of perceptions of intervention deliverers • Measures taken to ensure fidelity to intervention and usual care protocols

MRC component	Included items
Reach *Extent to which target audience comes into contact with intervention*	Trial papers • Trial flow diagrams / CONSORT diagrams • Reasons for non-participation, exclusion, drop-out • Participant and site characteristics • Numbers of participants recruited from different sites • Numbers of participants who received the randomised intervention • Comparison of demographics between those who declined participation and trial participants • Characteristics of screened but not randomised patients • Reach of interventions delivered to randomised populations • Comparison of demographics between participants completing and not completing follow-up • Comparison of site characteristics with all departments in the country • Comparison of participant characteristics with national patient population • Length of time sites open to recruitment, length of time between obtaining site NHS permission and opening to recruitment • Independent rating of reasons for patients being judged ineligible by sites • Subgroup analysis comparing outcomes between patients randomised to receive the intervention who answered and did not answer at least one call. • Sample attrition bias • Sensitivity analysis of primary outcome including participants with missing outcomes • Sensitivity analysis excluding participants from 2 poorly recruiting centres • Associations between participant characteristics and the completeness of response to providing follow-up data Process evaluation papers • Interviews with healthcare professionals about the degree to which they targeted recruitment to patients deemed most suitable, and perceptions about which patients were most suitable for the intervention. • Patient motivations for agreeing or declining trial participation • Measures taken to ensure inclusion of intended trial population in pragmatic trial
Context	
Causal mechanisms that act to maintain the status quo, or enhance effects	Trial papers • Details of usual care received by participants • Use of similar interventions by usual care group, impact of use on outcomes • Change in medication use by trial participants during the intervention period • Impact of concurrent interventions

MRC component	Included items
	• Seasonal effects Process evaluation papers • Participant reported barriers and facilitators to engaging with or adhering to the intervention
Contextual factors that shape theory of how the intervention works	Trial papers • Effect of time on effectiveness of the intervention – e.g. cumulative unit level effect of intervention, learning curve effects • Effect of intervention variables e.g. phone calls by answering machine or in person • Ceiling effect of intervention depending on participant baseline level of disability • Comparison of outcomes between participants who kept taking same regime and those who switched partway through Process evaluation papers • Qualitative findings discussing potential factors influencing intervention outcomes e.g. skills, experience, personalities and abilities of intervention deliverers
Contextual moderators *Shape, and may be shaped by, implementation, intervention mechanisms, and outcomes*	Trial papers • Analyses of effect of moderators on outcomes, e.g. participant age, gender, smoking status, cognition, treatment preferences, site characteristics Process evaluation papers • In qualitative studies – findings about factors which could potentially modify intervention effect
Mechanisms of impact	
Mediators *Intermediate processes which explain subsequent changes in outcome*	Trial papers • Effect of participant usage of different intervention components on primary outcome Process evaluation papers • Mediation analysis of proximal intervention effects
Participant responses *How participants interact with a complex intervention*	Trial papers • Uptake and use of the intervention, or components of the intervention, by trial participants, e.g. number of sessions attended • Analyses to examine the effect of adherence to or completion of an intervention or its components on the primary outcome • Subgroup analyses to investigate the effect of certain participant characteristics on level compliance with intervention • Participant satisfaction with treatment • Participant perceptions of which treatment they had received, treatment preferences at end of trial

MRC component	Included items
	• Procedure acceptability to participants • Process-of-care outcome e.g. medication adherence, accessing therapies Process evaluation papers • Qualitative research exploring patient adherence, perceptions, experiences of interventions • Quantitative questionnaire about participant perceptions of the benefits and harms of the intervention
Unintended pathways and consequences	Trial papers • Participant adverse events Process evaluation papers • Qualitative findings included reports of unanticipated consequences

Appendix 7: Case studies participant information sheet and consent form

Participant Information Sheet

Optimisation of the value of process evaluations with pragmatic randomised controlled trials of health services interventions

My name is Caroline French, and I am a PhD student at Queen Mary University London. I am undertaking some case studies of process evaluations as part of my PhD research, and I would like to invite you to take part.

Part 1 – Introducing me and the research

I am a registered nurse, and have several years' experience of working in clinical research as a research nurse and research assistant. My PhD is funded by a studentship awarded by Queen Mary University London, and my PhD supervisors are Professor Stephanie Taylor (QMUL), Professor Hilary Pinnock (University of Edinburgh), and Dr Nina Fudge (QMUL).

My PhD aims to understand the challenges and enablers to achieving optimal value from process evaluations conducted in conjunction with pragmatic randomised controlled trials (RCTs) in health services research. It also aims to explore differences in perceptions of the value of undertaking process evaluations in this context.

As part of my research, I am carrying out **case studies** of current and completed process evaluations carried out with pragmatic RCTs. I am interested in finding out how the process evaluation team, the RCT team, and other stakeholders, understand and realise the value of the process evaluation. The findings and insights from the case studies will help stakeholders gain more value from process evaluations in pragmatic RCTs in health services research.

In the case studies, I hope to gain a detailed understanding of the work involved in the process evaluation and the research context in which it is undertaken. To do this, I would like to collect and analyse data from a range of people, events, and documents associated with the process evaluation. Although each case study will be different, the key data that I will collect and methods I will use will be:

- **Interviews** – these will include questions about perceptions of and experiences of involvement with the process evaluation. I may conduct individual or group interviews as appropriate and convenient. I may interview participants on more than one occasion if they agree to this.
- **Observations** – I will attend and observe meetings and any other events relating to the process evaluation.
- **Documentary analysis** – I will analyse documents associated with the process evaluation and the pragmatic RCT, including protocols, funding applications, meeting minutes and agendas, and correspondence.
- **Informal data** – Informal data that I may obtain opportunistically during visits, such observing or participating in informal conversations, may be used to enhance my understanding of the process evaluation, but I will never record or repeat informal conversations. If it would be useful to explore specific issues raised during these informal episodes, I will ask for a formal interview.

I will ask permission to audio-record interviews, and I will take notes. I will also ask permission from all participants to audio-record formal events that I observe, such as meetings, and I will write fieldnotes during observations.

For case studies of process evaluations which are in progress, I will collect and analyse data about the process evaluation for an agreed period of time, making visits to the research team during this period at times arranged in advance. I will also collect data about earlier stages of the process evaluation by analysing documents, and interviewing relevant people. For case studies of process evaluations which have already completed, I will arrange to collect data and conduct interviews at convenient times for those involved.

I would like to gain a broad range of perspectives on the process evaluation. Therefore, I anticipate involving different members of the process evaluation and pragmatic RCT teams in the case study, and possibly external stakeholders, such as funders or journal editors. I will discuss and agree with the principal investigator who I will invite to participate in each case study.

The study has received ethical approval from Queen Mary University London (ref. QMREC2050a).

Part 2 – Potential Concerns about Participation

I hope that participating in the case study will be an interesting and useful reflective exercise. I have outlined issues that I anticipate might cause concern below, and my proposed means of addressing these. I am very happy to discuss these and any other concerns, and agree how to address these in a way that is satisfactory to everybody involved.

Confidentiality of patients or other participants in the process evaluation / RCT

I will not undertake any observations or interviews involving any participants in the process evaluation or RCT. I will not access any documents containing any data from participants in the process evaluation or RCT.

Confidentiality of information about the process evaluation / RCT

If I publish or present findings from these case studies, I will ensure that they are completely anonymous. It is possible that I will look to publish the case studies before the process evaluation and / or RCT is completed and published. I will use pseudonyms for people, organisations and research studies. I will not give any details or descriptions which would make it possible for anyone to identify the actual research study. I will agree with the appropriate members of the team how best to anonymise the case study, and ensure they are happy with any final drafts before they are submitted for publication. I will anonymise all data in my PhD thesis in the same way as agreed for publications.

All data collected about the process evaluation and pragmatic RCT will be strictly confidential. The only people who will access the data are me and my supervisors.

All data will be stored securely in accordance with Queen Mary University London data protection guidelines. I will remove all identifiable information from the stored data, and store identifiable information separately from the data. I will store audio-recordings securely until I have completed data analysis, and then delete them. If I am given access to any research documents which are not already in the public domain, I will agree with the person granting the access how I will access, store and anonymise these.

The aim of this research is to understand how those involved in conducting process evaluations experience challenges and enablers to gaining optimal value. The purpose of the research is not to inspect or audit the process evaluation, the RCT, or the work of anybody involved.

Confidentiality of views of individual participants

As stated above, I will not name individuals in any write up or dissemination of the study. As is usual with qualitative research, I will use direct quotes to illustrate findings, which will be anonymised. All data from research team members and other stakeholders will be kept confidential and stored securely as described above.

To fully understand the process evaluation, it will be useful for me to discuss issues that people raise in interviews with other relevant people within the case study, to find out how they experience these issues. So, for example, if you mention a problem during an interview which nobody else has mentioned, I would like to ask others within the case study if they have also noted the problem. However, if you do say something I would like to discuss with others then I will always discuss this with you first. I will not quote you directly, and if you wish I will not tell others who mentioned the problem, although it may be obvious in some circumstances. If I note areas of disagreement between people involved in the process evaluation, then I will always explore these sensitively and tactfully.

Interpreting the data

Some people may be concerned that I could misinterpret things that I observe, or things that people say. I will check my interpretation and understanding throughout the study, for example by asking for clarification during interviews. I would also like to feedback and discuss my findings with the teams as the study progresses.

Time and disruption

Exactly what participation will involve for each person will depend on your role in the process evaluation and the timing of the case study. Before you decide whether to participate, we will discuss and agree a level of involvement that you are happy with. You can still change your mind at any time.

I will schedule interviews at a time and place convenient to you, and these may by telephone. I anticipate interviews varying in length from 20 minutes to an hour, but I will always work around your availability.

Part 3 – Consent and Permissions

I will initially discuss the study with the chief investigator of the process evaluation, and anybody else he/she considers appropriate. If we feel that undertaking the case study is feasible, and key members of the process evaluation team are happy in principle to participate, I will seek written permission to undertake the case study from:

- The chief investigator of the process evaluation
- The chief investigator of the associated pragmatic RCT (if this is a different person)

I will ask everybody who participates in the study in any way – taking part in interviews and / or being present when I am observing - to read this information sheet and sign a consent form. You only need to sign the consent form once; however I will check throughout the study that you are still happy to participate.

If you wish to withdraw consent at any time you may do so without giving a reason. I will ask your permission to use the data already collected, but you do not have to agree to this.

Deciding whether to take part

It is important that everybody taking part in the case study feels comfortable doing so. In order to gain the most useful understanding and insight from this research, I would like to be able to include a wide range of perspectives, and explore differences in opinions between people involved in the process evaluation. However, individuals may decide whether (or not) they wish to participate in any aspect of the research.

Please read Queen Mary's privacy notice for research participants[1] for important information about your personal data and your rights in this respect.

Concerns or complaints

If you have any questions or concerns about the manner in which the study was conducted please, in the first instance, contact my supervisors. If this is unsuccessful, or not appropriate, please contact the Secretary at the Queen Mary Ethics of Research Committee, Room W104, Queens' Building, Mile End Campus, Mile End Road, London, E1 4NS or research-ethics@qmul.ac.uk. If you have any questions relating to data protection, please contact Data Protection Officer, Queens' Building, Mile End Road, London, E1 4NS or data-protection@qmul.ac.uk

[1] This is found at: http://www.arcs.qmul.ac.uk/media/arcs/policyzone/Privacy-Notice-for-Research-Participants.pdf

Contact details

If you are interested in taking part in the study, or have any further questions please contact Caroline French by email:

c.french@qmul.ac.uk

My supervisors' contact details are:

Professor Stephanie Taylor: s.j.c.taylor@qmul.ac.uk

Professor Hilary Pinnock: Hilary.Pinnock@ed.ac.uk

Dr. Nina Fudge: n.fudge@qmul.ac.uk

Thank you for taking the time to read this information sheet, and for your interest in the study

Queen Mary
University of London

Consent form

Thank you for considering taking part in this research. Please complete this form after you have read the Information Sheet, and asked any questions about the research. You will be given a copy of this Consent Form to keep and refer to at any time.

Title of Study: **Optimisation of the value of process evaluations carried out in conjunction with pragmatic randomised controlled trials of health services interventions**

Queen Mary Ethics of Research Committee Ref: **QMREC2050a**

Statement	**Circle a response**
I agree that the research project named above has been explained to me to my satisfaction in verbal and/or written form	YES / NO
I understand that if I decide at any other time during the research that I no longer wish to participate in this project, I can notify the researchers involved and be withdrawn from it immediately	YES / NO
I have read both the notes written above and the Information Sheet about the project (V3 17 Jul 2018), and understand what the research study involves	YES / NO
I agree to take part in the study, which will include use of my personal data	YES / NO
I consent to being audio-recorded during interviews and observations	YES / NO

Participant's Statement:

I _____ agree that the research project named above has been explained to me to my satisfaction and I agree to take part in the study.

Signed: Date:

Investigator's Statement:

I _____ confirm that I have carefully explained the nature and demands of the proposed research to the volunteer

Signed: Date:

Appendix 8: Case studies core interview guide

Interview topic guide

Opening the interview

Ensure consent for audio-recording

No right or wrong answers – I'm interested in what you think and why, what kind of challenges you think there are to doing process evaluations, and what we could learn from your experiences and perceptions.

I've also formed some impressions and topics I'd like to follow up from observing the meetings – to ask you more about them and to check out my interpretations.

Part 1 – asking participants about themselves and their role – helps warm up and establish rapport. I'm interested in finding out more about you first.

- Job title and job roles, how PE fits into this
- Professional background – clinical and research, qualifications
- Other current professional roles
- Previous experience of process evaluation and pragmatic trials

Role in the process evaluation

- What is your role in the process evaluation?
- How did you become involved in the process evaluation?
- What do you think you bring to the process evaluation in terms of your skills, experience, qualities?

Part 2 – talking through the process evaluation design, conduct, and dissemination.

Process evaluation design

Did you have any input into the initial process evaluation design in the trial protocol and funding application?

How did the process evaluation design develop from the protocol set out in the trial?

What knowledge did you draw on to design the process evaluation in terms of the questions it asks and the methods it uses?

- MRC guidance
- Literature?
- Initial exploratory work and piloting
- Trial team's experience
- Clinician's experience
- Previous trial

What kind of factors did you have to take into account when designing the process evaluation?

- Trial
- Ethics
- Availability of data and participants
- Costs

How do you reach the key design decisions with the team?

Do you feel the process evaluation design is optimal or is there another design you would have preferred?

Conducting the process evaluation

What issues have you encountered in carrying out the process evaluation in the way you wanted to?

Do you see the process evaluation having any benefits to anyone through the process of conducting it? Or any potential disadvantages?

- The trial
- The intervention
- The practices and staff (ethics of using data without consent)
- Patient participants
- To you personally/professionally
- To other actors (e.g. students doing projects)

Disseminating the process evaluation

Will you be involved in dissemination of the process evaluation? if so how are you planning to disseminate and why?

Do you see any barriers to effective dissemination?

Perceptions of the knowledge generated by the process evaluation

In what ways do you see the process evaluation knowledge being used? What benefits would that bring?

Any ways this knowledge could be harmful or unwelcome? E.g. any tensions between what the process evaluation and trial are trying to achieve?

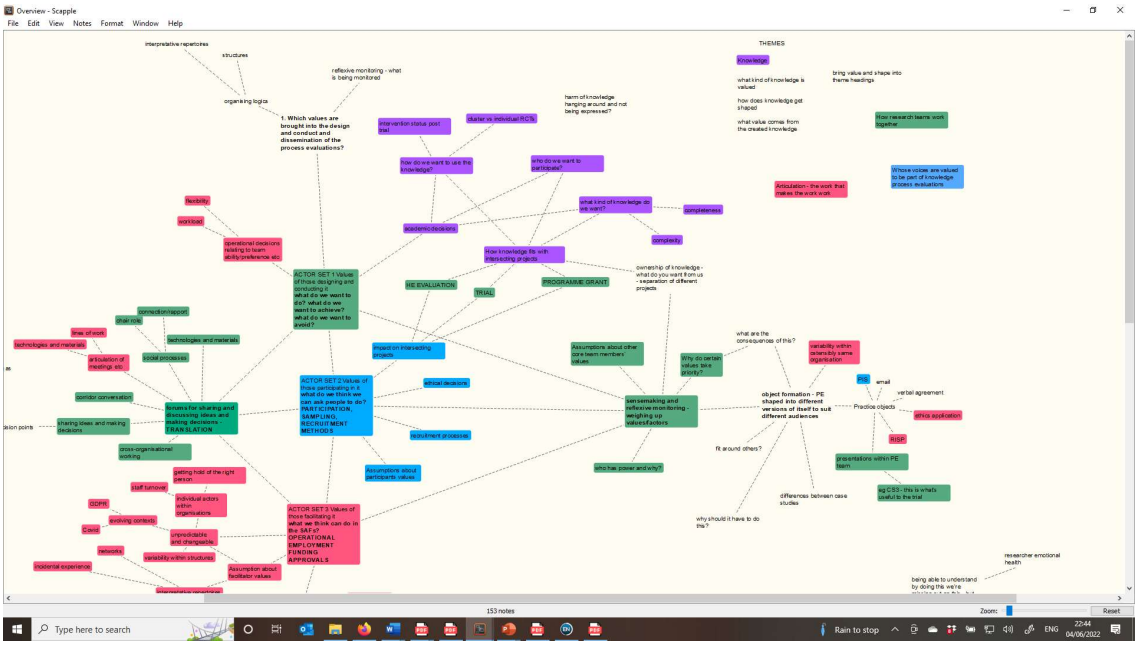
What kind of knowledge do you think the trial wants from the process evaluation?

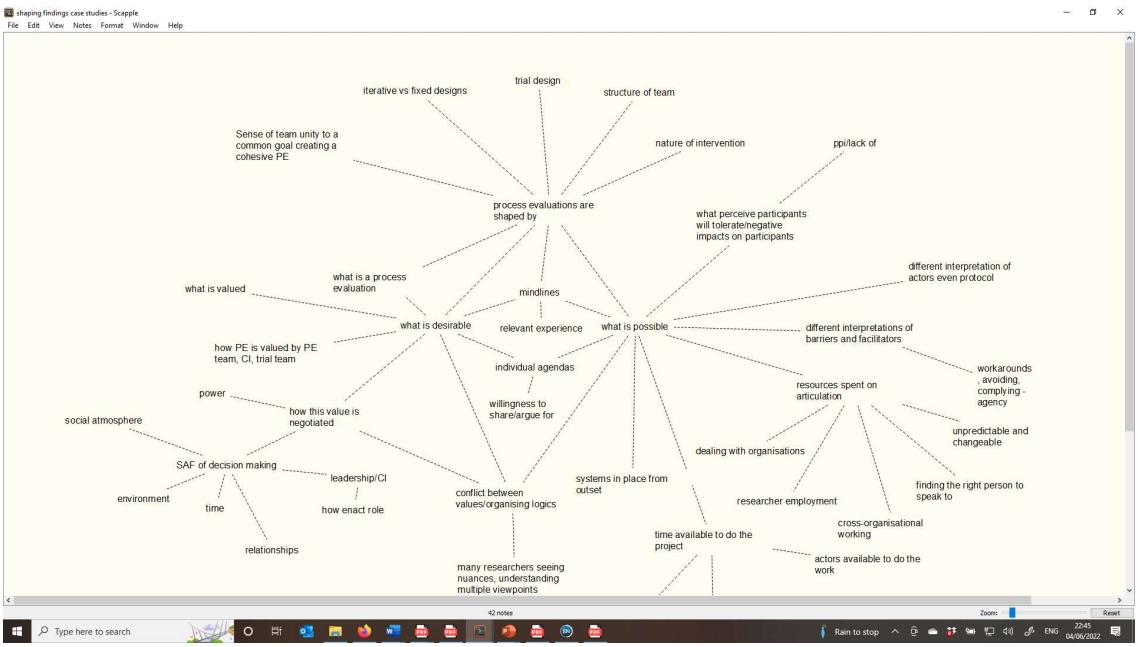
Closing the interview

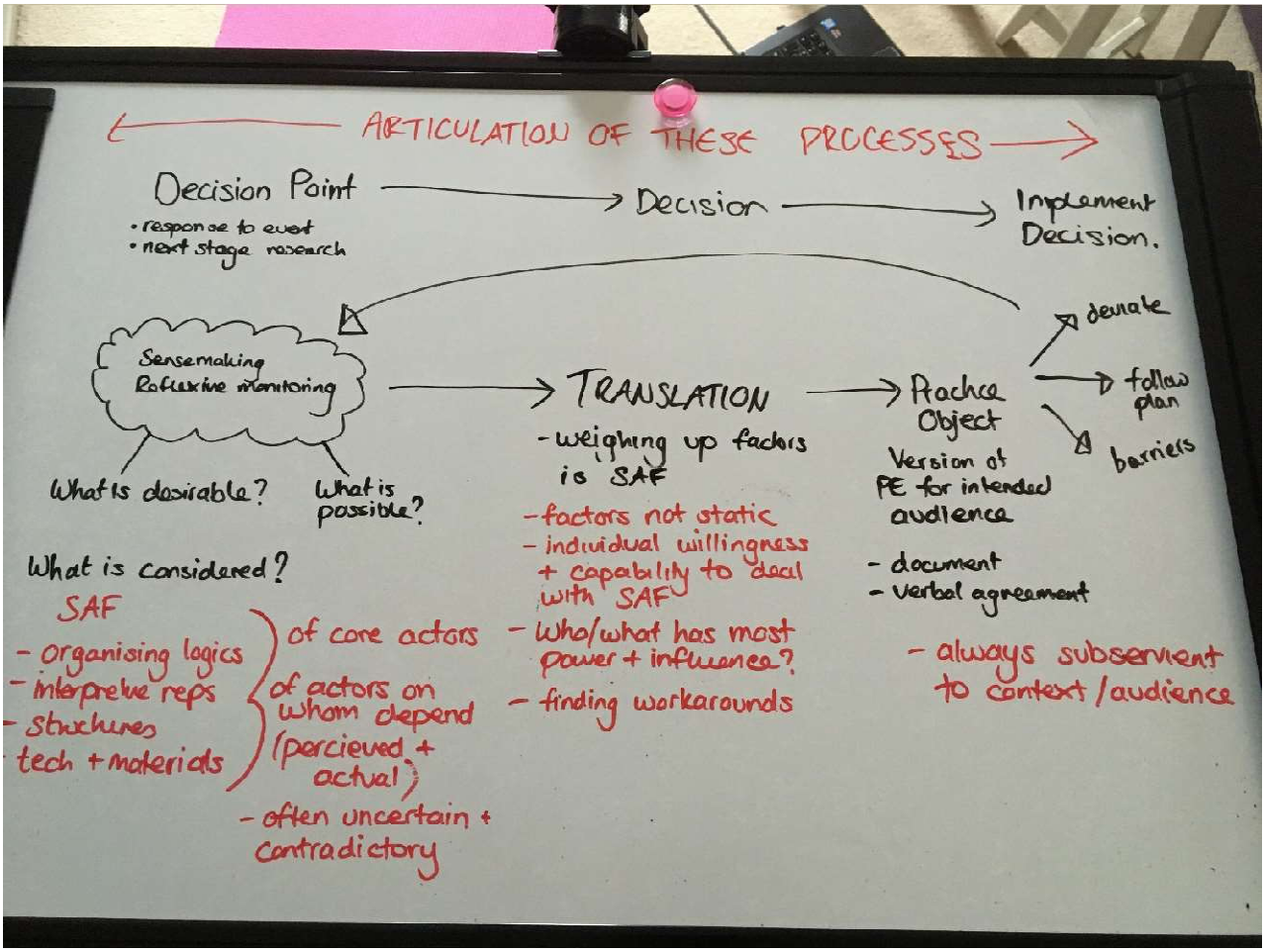
What would you say are the main lessons learned from conducting this process evaluation that you would do differently or advise others to do?

Is there anything else you want to add or think is important?

Appendix 9: Examples of case study cross-case analysis process






ARTICULATION OF THESE PROCESSES
Decision Point
• response to event
• next stage research
Decision
Implement Decision.
Sensemaking
Reflexive monitoring
What is desirable?
What is possible?
TRANSLATION
- weighing up factors is SAF
- factors not static
- individual willingness + capability to deal with SAF
- Who/what has most power + influence?
- finding workarounds
Practice Object
Version of PE for intended audience
- document
- verbal agreement
- always subservient to context/audience
deviate
follow plan
barriers
What is considered?
SAF
- organising logics
- interpretive reps
- structures
- tech + materials
of core actors
of actors on whom depend (percieved + actual)
- often uncertain + contradictory