

How Local Decision Making Works for Adaptations of Health Interventions During Scale-up: A Realist Review

A thesis submitted for the degree of Doctor of Philosophy

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2022

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Declaration

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Signed

A handwritten signature in black ink, appearing to be 'JP' followed by a stylized flourish.

Jessica Power

Acknowledgements

I would like to thank my family for their support throughout this PhD. Their encouragement has helped to keep me going throughout the years it took to complete. In particular thanks to my husband Shane whose support and guidance kept me motivated to continue, and to my sons Aran and Rossa who helped to keep the PhD process in perspective.

I would like to thank my supervisors. Firstly, Dr Fiona Larkan, who sadly left us too soon. She was an inspiration to many of us who got to be part of her circle for the time she was here. As a mentor and friend, she believed in me and encouraged me to apply for this process and for that I will be forever grateful. I would like to thank Dr Frédérique Vallières for taking on my supervision and always making time to provide guidance throughout the process. Her mentorship and friendship over the years has been a huge support. I would like to thank Dr Catherine Darker for coming on board in my final year and her help and encouragement with getting this PhD to its completion. I know I would not have managed the last year without her guidance. I would like to thank Prof. Noel McCarthy for getting me over the final hurdle and arranging the submission and Viva arrangements. I would also like to thank Prof. Eilish McAuliffe from School of Health Systems in UCD who gave her time and support to check in throughout the project and lend her expertise.

I would like to thank the Health Research Board Trials Methodology Research Network (HRB TMRN) for their funding and support throughout the PhD process. They have been a wonderful organisation to be involved and affiliated with. In particular I thank Dr Sandra Galvin and Prof. Declan Devane for all the opportunities that arose through being involved in the network which have been a great learning experience.

I would like to thank my INDIGO PhD colleagues at the Trinity Centre for Global Health. The years of peer support was priceless and whether it was by giving academic or emotional support I was very lucky to have so many wonderful people in my corner. A specific thanks to Dr Brynne Gilmore who was an invaluable sounding board for the realist process and friend throughout the PhD, with a special thanks for her time as a second reviewer for screening for which I am very grateful. I would also like to thank Dr Lauren-Deimling Johns who also gave her time to be a second reviewer for screening in earlier phases which greatly assisted the project. I would like to give thanks to Caitriona Honohan, Dr Elaine Toomey and Dr Ayat Abu Agla for lending their expertise to the searching process. Additionally I would like to thank the stakeholders in scale-up who got involved and gave their time despite being so busy this year. I would finally like to thank the realist community, both in Ireland and internationally for their generosity of time and expertise. The Irish Realist Researcher

Group was a support in early phases of this research and kindly gave their time to troubleshoot early iterations of the project. I would also like to thank the international realist community in terms of the RAMESES forum was a rich source of knowledge and was a great support when learning how to approach this methodology.

Abstract

Introduction: Scaling-up health interventions is a complex process with growing recognition of the need to make adaptations to interventions to address diverse contexts and populations encountered across multiple sites. However these adaptations remain poorly understood with little documentation of what these adaptations are in practice, along with lack of specific guidance on what actions to use to make these adaptations when scaling-up. This leaves implementers with a lack of clarity as to why adaptations may be needed across sites when scaling-up, with minimal guidance on how to undertake the challenging process of adapting health interventions. As a result this may lead to ad-hoc or reactive approaches to adaptations with potential impact on intervention fidelity and effectiveness.

This research set out to uncover (i) what adaptations are made and why, when scaling up health interventions in practice and (ii) what are the actions that can be used to achieve these adaptations when scaling-up health interventions. Furthermore, the specific action of local decision making (LDM) was explored in more detail to discover (iii) how does LDM work (i.e. by what mechanisms, and in what contexts) as an action to achieve adaptations during scale-up of health interventions across diverse contexts.

Methods: These research questions were addressed using realist review methodology. Specifically, Pawson's five stages of realist review of: (Stage-I) clarifying the review and developing initial theory, (Stage-II) developing a search strategy, (Stage-III) screening and appraisal, (Stage-IV) data extraction and (Stage-V) data synthesis and analysis, were utilised iteratively throughout the research process. As a final stage (Stage-VI), key informant interviews with those with experience of scaling-up health interventions were conducted and used to refine the theory for *how* and *why* LDM works for adapting health interventions when scaling-up. There were three distinct phases of this research.

Phase One - A background search was completed to develop an Initial Programme Theory (IPT) framework and focus the research question. The IPT was developed through analysis of previous adaptation, fidelity and scale-up guidance and frameworks, along with the wider implementation literature.

Phase Two - A systematic search was completed to identify examples of scale-up in practice where adaptations of health intervention occurred where the actions used to achieve adaptations were reported. The databases searched were; *PubMed, Cinahl, Scopus, Global Indicus Medicus, Web of Science, EMBASE, and Psycinfo*. Grey literature searches were also completed in *Social Care*

Institute for Excellence (SCIE), Grey Lit and Open Grey. Further to the database searching, the references of identified articles and the *ExpandNet* bibliography were also hand-searched for more case examples. Through the case examples identified in this search, (i) details on the adaptations that were made (i.e. the reasons and type) and (ii) the actions that were used for these adaptations during scale-up were identified - in fulfilment of the first two research questions - and subsequently led to further refinement of the review question. For extracting the type and reasons for adaptations FRAME guidance (1) for adaptation reporting was used. For extraction of actions the IPT framework developed in phase one was used, with the actions headings refined as the review progressed.

Phase Three - The specific action of LDM was explored. IPTs relating to LDM for adaptations to health interventions during scale-up were developed and refined. Screening of case examples for relevance and rigour took place, with additional searching to identify more documents and provide further contextual information on these case examples. Data was extracted in the form of context-mechanism-outcome configurations (CMOCs). These were synthesised for demi-regularities and programme theories were refined. In addition, further searching for relevant substantive theory and interviews with key informants with experience in scale-up were utilised to refine programme theory and aid the development of an Middle Range Theory (MRT). This led to development of programme theories and an MRT on (iii) *how* and *why* LDM works for adaptations of health interventions during scale-up across diverse contexts, in fulfilment of the third research question.

Results

Phase One – An IPT framework was developed. The research question and search strategy for the subsequent phase were developed.

Phase Two - A total of $n=22$ case examples reporting on actions for adaptations made during scale-up were identified as a result of the systematic search in phase two. These were primarily based in Low and Middle Income Countries (LMICs) ($n=19$), with the remainder in High Income Countries (HICs) ($n=3$). The focus of the interventions ranged from: sexual and reproductive health ($n=9$); HIV ($n=6$); maternal and child health ($n=4$), two of which included vaccination programmes; non-communicable diseases (NCDs) ($n=2$); and mental health ($n=1$). Adaptations were primarily reported for the reason of increasing cultural acceptability ($n=15$), notably often to increase cultural acceptability in the wider population and context and not just for specific minority groups within a population. Adaptations were also commonly reported for resource availability ($n=14$), which occurred due to resource shortages at varying levels of the system i.e. at wider socio-political, organisational or recipient levels and were often unavoidable in nature. Proactive adaptations

which were embedded into the scale-up design were reported in the majority of case examples ($n=18$). In addition to this, reactive adaptations also occurred in a number of case studies ($n=11$), these adaptations, although not embedded or planned from the outset, were often reported to serve needs that were identified as the intervention scaled-up. Ad-hoc unplanned adaptations ($n=2$) were also reported, primarily occurring at frontline provider level with a loss to fidelity noted in these case examples. Adaptations were reported at different levels of the system for example at national level ($n=5$); provincial, regional or district levels ($n=6$); organisational levels e.g. health facility or school ($n=14$); for specific cohorts within a population (e.g. based on gender, religion) ($n=6$) and based on individual recipient needs (e.g. literacy) ($n=1$). Fidelity considerations of adaptations and assessments were rarely documented. Adaptations were also often poorly reported. This research reflected and made suggestions for advancement of the FRAME adaptation reporting guidance, in particular for use in LMIC settings, for example suggesting further headings to differentiate resource limitations as a reason for adaptation, and the addition of further guidance on consideration of impact of adaptation on fidelity.

The actions used when scaling-up for adaptations to health interventions were identified with a resulting eight action headings emerging: (i) identification of intervention theory, core elements, components, functions or minimum standards; (ii) providing guidance to sites on intervention theory or components, on how to implement and adapt the specific intervention and/or sharing tried and tested examples of adaptations from other sites; (iii) LDM; (iv) using an adaptive scale-up design; (v) creating peer learning opportunities; (vi) ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations; (vii) the use of data to assess progress and inform or evaluate adaptations and (viii) the use of QI methods. These actions were often used in tandem. 16 of the 22 case examples reported using LDM where autonomy was given to local stakeholders to make decisions on adaptations for local fit within their setting. This occurred at varying levels within the system for example at provincial, regional, district, community, health facility levels, by frontline providers or the recipients themselves. The review was refined at this point to focus on developing theory on *how* and *why* LDM works for adaptations of health interventions during scale-up across diverse contexts.

Phase Three - Eight programme theories and an MRT were developed from the case examples which used LDM ($n=16$) on *how* and *why* LDM works for adaptations to health interventions when scaling-up. These theories were further refined through interviews with key informants with experience in scale-up ($n=6$) and use of substantive theory. Multiple contexts such as: where the intervention does not align with the social norms, values and beliefs of the wider community or the local decision maker; where there is reliance on external funding and poor understanding of the

intervention components from funders; and in resource limited settings where unavoidable adaptations may occur were all identified to impact how LDM works. These circumstances may lead to intra- and person-role conflict for the local decision maker. Mechanisms at the level of the local decision maker of; perception of compatibility, awareness (i.e. of intervention theory), sensemaking, problem-solving, fear of repercussions, feeling valued and respected, were all found to contribute to how LDM works. The use of complementary actions such as provision of accessible guidance and support, for example on intervention components and on how to implement and adapt the specific intervention, can support local sites. Other complementary actions such as peer learning through sharing tried and tested examples from other scale-up sites, and using a data driven approach to inform and evaluate adaptations were suggested to support LDM by reducing the time needed for adaptations in later phases and contributing to buy-in from staff and the target population for the intervention.

Conclusion: Scale-up is complex, with the additional layer of making adaptations during scale-up further adding to this complexity. This research evidenced that adaptations are occurring in practice during scale-up of health interventions and has provided some guidance to implementers on actions that can be used for undertaking these adaptations. Implementers need to examine in advance what contextual challenges may occur in their setting (for example resource shortages, cultural conservatism etc.) that may lead to future adaptations and their potential impact on fidelity. This may assist implementers in considering whether adaptations are unavoidable, and in selecting what actions to embed into the scale-up plan. LDM is a promising approach for adaptations to health interventions during scale-up, however it occurs in complex systems, within a wider cultural and socioeconomic context, with varying levels of capacity, and often in tandem with numerous other approaches. While LDM may support those who know the setting to problem solve based on local knowledge leading to beneficial adaptations within their setting, it may also place local decision makers in a position of intra and person-role conflict leading to adaptations that impact the fidelity and effectiveness of the intervention. Therefore implementers need to consider the complexity of how LDM may work across the diverse contexts they encounter during scale-up.

Acronyms and Abbreviations

ART	Anti-retroviral Treatment
BTS	Breakthrough Series Model
C	Context
CAG	Community Adherence Group
CBITS	Cognitive Behavioural Intervention for Trauma in Schools
CE	Case Example
CFIR	Consolidation Framework for Implementation Research
CHW	Community Health Worker
CMOC	Context-Mechanism-Outcome Configuration
DSF	Dynamic Sustainability Framework
EBP	Evidence Based Practice
EBI	Evidence Based Intervention
FRAME	Expanded framework for reporting adaptations and modifications to evidence-based interventions
HIC	High Income Countries
HIV	Human Immunodeficiency Virus
HRH	Human Resources for Health
IHI	Institute for Health Improvement
IPT	Initial Programme Theory
LDM	Local Decision Making
LMIC	Low and Middle Income Countries
M	Mechanism (Response)
MCH	Maternal and Child Health
MFI	Model for Improvement
MRC	Medical Research Council
MRT	Middle Range Theory
NIH BCC	National Institute for Health Behaviour Change Consortium
O	Outcome
PDSA	Plan-Do-Study-Act
PT	Programme Theory
R	Resource
RE-AIM	Reach Effectiveness Adoption Implementation Maintenance Reach Framework
QI	Quality Improvement
RAMESES	Realist And Meta-narrative Evidence Syntheses: Evolving Standards
S	Stakeholder
SRH	Sexual and Reproductive Health
WHO	World Health Organisation

Glossary of Operational Definitions

This glossary contains operational definitions for specific terms used within this thesis. The terms listed here have multiple definitions within the literature, and while additionally defined within the body of the thesis their presentation here serves as an accessible reference for the reader.

Action	A process used to guide or make adaptations. Can be viewed as a mechanism in the form of a resource (2)
Adaptation	Changes made to the health intervention content which could be planned or occur reactively as needs emerge when scaling-up. Type of adaptations may include adding or removing intervention content, tailoring, tweaking or refining elements, loosening the structure of the intervention etc. (1)
Contexts (C)	Conditions that affect whether mechanisms are activated. A context can act like a dimmer switch for the triggering of mechanism to varying degrees (2)
Context-Mechanism-Outcome-Configuration (CMOC)	Explanation of causation of how a given outcome occurred demonstrated through a relationship between contexts, mechanisms and outcomes (3)
Demi-regularities	Semi-predictable patterns of causation (3)
Health intervention	“An act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions” (WHO online, (4))
Initial Programme Theory (IPT) framework	An initial rough theory in the form of a framework of initial ideas from the literature to guide the following stages of the review
Initial Rough Theory	Initial theory to guide the review. This can be expressed in different ways for example as CMOCs, an ‘if-then’ style statement (5, 6), or a framework (7, 8)
Mechanisms	A mechanism is a generator of change, being the integral link (3) to uncovering the ‘why’ an outcome may have occurred within a context (5, 9, 10). Mechanisms can be in the form of resource or response (2)
Mechanism (Response) (M)	Under certain contextual circumstances, a mechanism in the form of a response gets triggered, generating an outcome (2)
Middle Range Theory (MRT)	Theory at a level of abstraction which is both testable within the data, but also could be applied within wider situations (3)
Outcomes (O)	Intended or unintended consequences in a given context
Programme Theories	A theory of ‘what works for whom in what circumstances’ (5, 6). This is refined as the review progresses

Resource (R)	This is a form of mechanism, when introduced into a context, can trigger a mechanism in the form of a response (2)
Retroduction	Making inference and unearthing the deeper causal mechanisms which may cause a phenomenon to occur (10)
Scale-up	A purposeful expansion of a health intervention to a wider population (11, 12). This could involve expanding geographically, or to a wider population within the same setting
Substantive theory	Also called formal theory, may come from a specific domain e.g. implementation theories. These can assist in explaining CMOCs (3)

Table of Figures

Figure 3.1 Overview of stages of realist review (43), with additional Stage-VI of theory refinement of stakeholders added. Adapted from (44, 158, 159).....	30
Figure 3.2 Overarching phases of the realist review with key outputs from each phase.....	32
Figure 3.3 Overview of stages of realist review (43) and when they occurred in this study. Adapted from (44, 158, 159)	35
Figure 3.4 Searches and sampling strategies for each phase of the review with corresponding component of the realist search based on Booth et al., (45)	36
Figure 4.1 Overview of steps undertaken during phase one search	40
Figure 4.2 Progression from IPT framework, to IPT statements to final Programme Theories within the review.....	43
Figure 4.3 Overview of databases screened and search results.....	45
Figure 4.4 Literature informing the IPT Framework	90
Figure 4.5 IPT Framework with potential actions, contexts, mechanisms and outcomes.....	92
Figure 5.1 Actions identified in the IPT framework used as initial codes	103
Figure 5.2 Flow chart of screening in Phase Two.....	104
Figure 5.3 Level adaptations reported. Adapted from (1)	113
Figure 5.4 Progression of actions headings framework from phase one (IPT headings) to phase two (extraction from case examples)	124
Figure 5.5 Consideration for providing guidance to sites for adaptations when scaling-up	130
Figure 6.1 Overview of stages of the realist review (43, 44) and when they occurred in this study.	164
Figure 6.2 IPTs on How LDM may work for adaptations during scale-up	166
Figure 6.3 Flowchart of screening for further documents on case examples in Phase Three	178
Figure 6.4 IPT refinement to final PTs. Adapted from Gilmore B, McAuliffe E, Power J, et al.(161)	181
Figure 6.5 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works when intervention does not align with Social Norms, Values And Beliefs of the Wider Community	185
Figure 6.6 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker.....	189
Figure 6.7 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How LDM works when there is a Reliance on External Funding	193
Figure 6.8 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works in Resource Limited settings.	197
Figure 6.9 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How LDM Works in the Context of Using Data to Assess Progress and Inform or Evaluate Adaptations.....	201
Figure 6.10 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How Guidance on How to Implement, Adapt and on Intervention Components works when LDM	209
Figure 6.11 Overview of Resources, Contexts, Mechanisms and Outcomes relating to Impact of Who Provides the Guidance on LDM for Adaptations.....	218
Figure 6.12 Overview of Resources, Contexts, Mechanisms and Outcomes of How Peer Learning can Support LDM when Scaling-Up	223
Figure 7.1 Stages of the realist review with overview of steps taken in each phase. Adapted from (43, 44).....	268

Table of Tables

Table 3.1 Definitions of Realist Terms Used For The Purpose of This Review. Adapted from (150, 151)	27
Table 4.1 Example from Research Logbook of Decision Making for Clarifying Scope	43
Table 4.2 Guidance and Frameworks which informed the IPT Framework	46
Table 4.3 Examples from research logbook of decision making for inclusion in IPT	90
Table 5.1 Inclusion Criteria and Definitions for Phase Two	98
Table 5.2 Included Case Examples from Screening: Case Example Reference Number, Topic, Intervention, Location, HIC or LMIC, Reach, and Citations	106
Table 5.3 Purpose & Reasons for Adaptation(s) with case studies who reported. Adapted from (1)	110
Table 5.4 Who Participated in Decisions for Adaptations. Adapted from (1)	115
Table 5.5 Type of Content Adaptations. Adapted from (1)	116
Table 5.6 Consideration of Fidelity for Adaptations Reported in the Case Examples of Scale-Up	119
Table 5.7 Actions for Adaptations during Scale-up Framework, with definition, case examples who reported each action and description of the action in practice	126
Table 5.8 Each Case Example and Actions Coded	129
Table 5.9 Providing guidance to sites: content of guidance and what formats used	131
Table 5.10 QI approaches reported: MFI, BTS, Learning Collaboratives and Driver Diagrams and case examples which reported each method	142
Table 6.1 Conceptual tools for Realist Review with examples in practice. Adapted from (3, 42, 306).	174
Table 6.2 Demographics of who carried out LDM, an overview of the LDM approach, topic of the intervention and location for the case examples	179
Table 6.3 Supporting evidence for PT1 - How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community	186
Table 6.4 Supporting evidence for PT2 - How LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker. Adapted from (305)	190
Table 6.5 Supporting Evidence for PT3 – How LDM works in Contexts where there is a Reliance on External Funding. Adapted from (305)	195
Table 6.6 Supporting Evidence for PT4 – How LDM Works in Resource Limited Settings. Adapted from (305)	198
Table 6.7 Supporting Evidence for PT5 - How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations. Adapted from (305)	203
Table 6.8 Supporting Evidence for PT6 - How Guidance on How to Implement, Adapt and on Intervention Components supports LDM. Adapted from (305)	212
Table 6.9 Supporting Evidence for PT7 - Impact of Who Provides the Guidance for LDM. Adapted from (305)	220
Table 6.10 Supporting Evidence for PT8 - How Peer Learning can Support LDM when Scaling-Up. Adapted from (305)	225
Table 6.11 Resulting PTs and MRT on How Local Decision Making (LDM) Works for Adaptations of Health Interventions during Scale-up	241
Table 7.1 Quality Standards and How the Criteria were Fulfilled in the Review. Adapted from (152, 301)	269
Table C 1 Search Terms and Databases for Initial Background Scoping Search Phase One. Search carried March 2016.	285
Table C 2 Consultation with Experts to Highlight Further Literature Phase One	286

Table D 1 Decision Making from Fidelity and Adaptation Guidance and Frameworks for Inclusion in IPT framework	287
Table D 2 Decision making from scale-up guidance and frameworks for inclusion in IPT framework	289
Table D 3 Decision making from wider literature (including general implementation literature) for inclusion in IPT framework	297
Table D 4 Working definitions for headings in IPT Framework	303
Table E 1 Databases, Search terms and Dates for Systematic Search Phase Two	306
Table F 1 Phase Two Codebook - Extraction of Adaptations and Actions. Adapted from (1, 15, 44, 369)	307
Table G 1 Included Documents for Phase Three: Document types, Primary Focus of Document and Whether Methods Reported on	315
Table H 1 Working Definitions to Assist in CMOC Extraction for Phase Three	326
Table I 1 Publication Standards for Realist Review along with where Standard can be found in Thesis. Adapted from (151)	330

Table of Boxes

Box 6. 1 Example of Extraction at Case Example Level for CE1	171
Box 6. 2 Perception of Compatibility by Local Decision Makers	188
Box 6. 3 Clarity of Intervention Content and Guidance on the Implementation and Adaptation Proces for Local Decision Makers.....	210

Table of Contents

DECLARATION	II
ACKNOWLEDGEMENTS	III
ACRONYMS AND ABBREVIATIONS.....	IX
GLOSSARY OF OPERATIONAL DEFINITIONS.....	X
TABLE OF FIGURES	XII
TABLE OF TABLES	XIII
TABLE OF BOXES	XV
CHAPTER 1. INTRODUCTION.....	1
1.1 AIMS, METHODOLOGICAL APPROACH AND RESEARCH QUESTIONS	2
1.2 FORMAT OF THE THESIS	3
CHAPTER 2. LITERATURE REVIEW	5
2.1 SCALE-UP	5
2.2 ADAPTATION.....	7
2.3 THE NEED FOR ADAPTATION FOR LOCAL FIT WHEN SCALING-UP	10
2.4 ADAPTATION AND FIDELITY	13
2.5 INTERVENTION THEORY, MECHANISMS OF ACTION, CORE COMPONENTS AND ESSENTIAL ELEMENTS.....	15
2.6 ADAPTATIONS IN PRACTICE	19
2.7 EVIDENCE FOR ADAPTATION	20
2.8 GUIDANCE AND FRAMEWORKS FOR ADAPTATION AND SCALE-UP	22
2.9 CONCLUSIONS AND GAPS IN LITERATURE	22
CHAPTER 3. METHODOLOGY	24
3.1 RESEARCH PARADIGMS: ONTOLOGY, EPISTEMOLOGY AND METHODOLOGIES.....	24
3.2 REALISM	24
3.3 IMPLEMENTATION RESEARCH AND REALIST METHODS	25
3.4 REALIST METHODOLOGY	26
3.4.1 <i>Programme and Middle Range Theory</i>	27
3.4.2 <i>Generative Causation and Context-Mechanism-Outcome Configurations (CMOCs)</i>	28
3.4.3 <i>Retroduction</i>	28
3.4.4 <i>Introduction to Realist Review Methodology</i>	29
3.4.5 <i>Selection of a Realist Review Methodology</i>	31
3.5 STUDY DESIGN	31
3.5.1 <i>Phase One – IPT Development and Clarifying Scope of the Review</i>	32
3.5.2 <i>Phase Two – Identification of Adaptations made and Actions Used during Scaling-up in Practice</i>	33
3.5.3 <i>Phase Three – Developing and Refining Programme Theories and an MRT on How Local Decision Making Works for Adaptations During Scale-up of Health Interventions</i>	34
3.5.4 <i>Stages of the Realist Review</i>	35
3.5.5 <i>Components of the Realist Search</i>	35
3.6 CHALLENGES OF REALIST REVIEW METHODOLOGY FOR A PHD	37
3.7 NOTE ON TIMELINE OF REVIEW	38
3.8 ETHICAL APPROVAL	39
CHAPTER 4. PHASE ONE - IPT FRAMEWORK DEVELOPMENT AND CLARIFYING SCOPE OF THE REVIEW.....	40
4.1 METHODS FOR PHASE ONE.....	40
4.1.1 <i>Search Strategy for Phase One</i>	40
4.1.2 <i>Selection Criteria for Phase One</i>	42
4.1.3 <i>Data Extraction for Phase One</i>	42
4.1.4 <i>Methods - Clarifying the Scope of the Review and Developing the Initial Research Question, Aim and Objectives</i>	43

4.1.5 <i>Methods - Developing the IPT Framework</i>	43
4.1.6 <i>Stages of the Realist Review which Occurred in Phase One</i>	44
4.2 RESULTS OF PHASE ONE	44
4.2.1 <i>Literature Identified to Inform IPT and Clarify Scope of the Review</i>	44
4.2.2 <i>Results: Clarifying the Scope of the Review and Developing the Initial Research Questions, Aims and Objectives</i>	87
4.2.3 <i>Results: The IPT Framework</i>	89
4.3 CHALLENGES IN DECIDING ON SEARCH STRATEGY, DEVELOPING AN IPT AND CLARIFYING THE SCOPE OF THE REVIEW	92
4.4 PHASE ONE CONTRIBUTIONS	93
CHAPTER 5. PHASE TWO - ACTIONS USED AND ADAPTATIONS MADE DURING SCALE-UP IN PRACTICE	94
5.1 OVERVIEW OF PHASE TWO	94
5.2 METHODS PHASE TWO	95
5.2.1 <i>Search Strategy for Phase Two</i>	95
5.2.2 <i>Selection, Screening and Appraisal</i>	96
5.2.3 <i>Data Extraction</i>	99
5.3 RESULTS PHASE TWO	103
5.3.4 <i>Results of Screening</i>	103
5.3.5 <i>Demographics of Case Examples (Topic, Intervention Type, Location, Reach of Scale-up and References)</i>	105
5.3.6 <i>Study Types and Quality Appraisal</i>	105
5.3.7 <i>Results: Adaptations</i>	109
5.3.8 <i>Results: Potential Impact of Adaptations on Fidelity</i>	117
5.3.9 <i>Results: Actions</i>	123
ACTION 1. IDENTIFICATION OF INTERVENTION THEORY, CORE ELEMENTS, COMPONENTS, FUNCTIONS OR MINIMUM STANDARDS	125
ACTION 2. PROVIDING GUIDANCE TO SITES	129
ACTION 3. LOCAL DECISION MAKING	133
ACTION 4. ADAPTIVE SCALE-UP DESIGN	137
ACTION 5. CREATING PEER LEARNING OPPORTUNITIES	138
ACTION 6. ONGOING ASSESSMENT OF THE WIDER POLITICAL, SOCIOECONOMIC, CULTURAL AND ORGANISATIONAL CONTEXT TO INFORM ADAPTATIONS	139
ACTION 7. THE USE OF DATA TO ASSESS PROGRESS AND INFORM OR EVALUATE ADAPTATIONS	140
ACTION 8. QI METHODS	141
5.4 DISCUSSION	143
5.4.1 <i>Adaptations Made in Practice During Scale-up</i>	143
5.4.2 <i>Embedding of Processes for Future Adaptations</i>	144
5.4.3 <i>Consideration of Fidelity</i>	146
5.4.4 <i>Identification and Reporting on the Intervention Content</i>	148
5.4.5 <i>Suggested Advancement of FRAME</i>	149
5.4.6 <i>Challenges in Heterogeneity and Quality of Documents Identified</i>	152
5.4.7 <i>Actions used During Scale-up for Adaptations</i>	153
5.5 CLARIFYING THE SCOPE OF THE REVIEW FOR PHASE THREE	158
5.6 METHODOLOGICAL CONSIDERATIONS FOR PHASE TWO	161
5.7 PHASE TWO CONTRIBUTIONS AND CONCLUSIONS	161
CHAPTER 6. PHASE THREE - HOW LOCAL DECISION MAKING WORKS FOR ADAPTATIONS DURING SCALE-UP OF HEALTH INTERVENTIONS	163
6.1 METHODS PHASE THREE	163
6.1.1 <i>Stages of the Realist Review</i>	163
6.1.2 <i>IPTs for Local Decision Making</i>	164
6.1.3 <i>Searching Phase Three</i>	166
6.1.4 <i>Searching for Further Documents on Case Examples</i>	166

6.1.5 Searching for Substantive Theory.....	167
6.1.6 Relevance and Rigour	167
6.1.7 CMOC Extraction	171
6.1.8 CMOC Synthesis – Search for Demi-regularities	172
6.1.9 Programme Theory Refinement and Developing an MRT	173
6.1.10 Stakeholder Involvement.....	176
6.1.11 Middle Range Theory Development	176
6.2 RESULTS PHASE THREE.....	177
6.2.1 Results of Search: Screening and Appraisal.....	177
6.2.2 Demographics of Case Examples Who Used LDM	177
6.2.3 CMOC Synthesis and PT refinement	181
6.2.4 Refinement from IPTs to PTs	181
6.2.5 Stakeholder Involvement for Theory Refinement.....	182
6.2.6 Use of Substantive Theory.....	183
6.2.7 Results: Programme Theories.....	183
PT1. HOW LDM WORKS WHEN THE INTERVENTION DOES NOT ALIGN WITH SOCIAL NORMS, VALUES AND BELIEFS OF THE WIDER COMMUNITY	184
PT2. HOW LDM WORKS WHEN THE INTERVENTION DOES NOT ALIGN WITH SOCIAL NORMS, VALUES AND BELIEFS OF THE LOCAL DECISION MAKER.....	188
PT3. HOW LDM WORKS IN CONTEXTS WHERE THERE IS A RELIANCE ON EXTERNAL FUNDING.....	193
PT4. HOW LDM WORKS IN RESOURCE LIMITED SETTINGS.....	197
PT5. HOW LOCAL DECISION MAKING WORKS IN THE CONTEXT OF USING DATA TO ASSESS PROGRESS AND INFORM OR EVALUATE ADAPTATIONS	200
PT6. HOW GUIDANCE ON HOW TO IMPLEMENT, ADAPT AND ON INTERVENTION COMPONENTS SUPPORTS LDM	208
PT7. IMPACT OF WHO PROVIDES THE GUIDANCE ON LDM FOR ADAPTATIONS	218
PT8. HOW PEER LEARNING CAN SUPPORT LDM WHEN SCALING-UP	223
6.3 DISCUSSION PHASE THREE	227
6.3.1 Weighting of Evidence for CMOCs.....	227
6.3.2 LDM Occurs within a Wider Context.....	228
6.3.3 Consideration of Who is the Local Decision Maker	229
6.3.4 LDM and Unavoidable Adaptations	229
6.3.5 Consideration of Capacity when using Data Driven Approaches to Support LDM	231
6.3.6 Importance of Guidance for LDM.....	232
6.3.7 Sensemaking and Problem Solving as Central Mechanisms to How LDM Works.....	234
6.3.8 Peer-Learning as a Complementary Action for LDM	235
6.3.9 LDM at Different Levels of the System	236
6.4 DEVELOPING AN MRT - HOW LDM WORKS FOR ADAPTATIONS DURING SCALE-UP OF HEALTH INTERVENTIONS	237
6.4.1 Who LDM Works for when making Adaptations during Scale-up	237
6.4.2 Mechanisms that Contribute to how LDM Works for Adaptations during Scale-up.....	237
6.4.3 Substantive Theory to Further Explain and Support Theory	238
6.4.4 Developing the MRT	239
6.5 PHASE THREE CONTRIBUTIONS AND CONCLUSIONS.....	240
CHAPTER 7. IMPLICATIONS, RECOMMENDATIONS, LIMITATIONS, METHODOLOGICAL REFLECTIONS AND CONCLUSIONS.....	243
7.1 CONTRIBUTIONS OF THE STUDY TO THE FIELD OF ADAPTATION AND SCALE-UP.....	243
7.1.1 Reasons for Adaptations in the Context of Scale-Up	243
7.1.2 Actions for Adaptations in the Context of Scale-Up	244
7.1.3 Importance of Knowing the Intervention Theory, Core Elements, Components, Functions or Minimum Standards when Adapting in the Context of Scale-Up	245
7.1.4 Fidelity Considerations	246
7.1.5 Local Decision Making for Adaptations when Scaling-Up	247

7.2 IMPLICATIONS AND RECOMMENDATIONS OF THIS RESEARCH	250
7.2.6 <i>Implications for Theory, Policy and Practice</i>	250
7.2.7 <i>Implications for Research</i>	253
7.3 RECOMMENDATIONS	254
7.4 LIMITATIONS.....	256
7.4.1 <i>Limitations in Search Strategies and Definitions Used</i>	256
7.4.2 <i>Stakeholder Engagement</i>	258
7.4.3 <i>Lack of a Review Team</i>	259
7.4.4 <i>Determining Outcomes</i>	259
7.5 CHALLENGES IN THE TIMELINE OF THE REVIEW	260
7.6 METHODOLOGICAL REFLECTIONS AND CHALLENGES OF THE REALIST REVIEW PROCESS	261
7.6.1 <i>IPT Development and Refinement to PT's</i>	261
7.6.2 <i>CMOC Extraction and Synthesis – Level of Abstraction</i>	262
7.6.3 <i>Heterogeneity of Studies</i>	262
7.6.4 <i>Use of NVivo for Extraction and Synthesis</i>	264
7.6.5 <i>Researcher Reflexivity</i>	264
7.6.6 <i>Challenges of Realist Methods as part of a PhD</i>	266
7.6.7 <i>Flexibility of the Realist Review Process</i>	266
7.6.8 <i>Dissemination of Realist Review Methodological Approach and Reflections</i>	269
7.7 CONCLUSIONS	270
APPENDIX A. STUDY PROTOCOL PAPER	272
APPENDIX B. ETHICAL APPROVAL.....	283
APPENDIX C. PHASE ONE BACKGROUND SCOPING SEARCH DETAILS OF DATABASES AND CONSULTATION WITH EXPERTS	285
APPENDIX D. DECISION MAKING FOR IPT FRAMEWORK	287
APPENDIX E. DATABASES AND SEARCH TERMS USED PHASE TWO.....	306
APPENDIX F. CODEBOOK PHASE TWO	307
APPENDIX G. DOCUMENT TYPES FOR EACH CASE EXAMPLE PHASE THREE	315
APPENDIX H. WORKING DEFINITIONS TO ASSIST IN CMOC EXTRACTION FOR PHASE THREE	326
APPENDIX I. PUBLICATION STANDARDS	330
REFERENCES.....	332

Chapter 1. Introduction

Scaling-up involves the purposeful expansion of a health intervention to a wider population (11, 12). Scaling-up is a complex process, occurring across diverse systems and contexts (12-14). In order for successful implementation, adaptations may be needed to the intervention content, in order to suit local needs across scale-up sites (15), with a necessary trade-off between increasing scale and maintaining local values, local relevance, quality and sustainability (16). How adaptations are occurring in practice when scaling-up, however, is poorly understood within the extant literature. There remains little documentation of what these adaptations are in practice during scale-up (15, 17), nor is there specific guidance on what actions to use to achieve these adaptations, and when to use one adaptation approach over another. This results in a lack of clarity for implementers as to why adaptations may be needed across their sites when scaling-up, and may lead to ad-hoc or reactive approaches to adaptations with potential impact on intervention fidelity and effectiveness (1).

The demand for adaptations to meet local needs has been recognised across the health spectrum, ranging from maternal and child health (MCH) (18), to malaria prevention (19), HIV (20-22), and mental health (23). In addition, given that contexts are continually changing over time, allowing for temporal adaptations with these contextual changes may be necessary to ensure sustainability of interventions (24, 25). When scaling-up often there is an expectation that the effectiveness of an intervention may reduce from pilot to scale-up, referred to as a 'voltage drop' (24). This drop may, in part, be mitigated with these adaptations to suit local settings (24, 25). However, adaptations are poorly described within research (15, 17), with a lack of coherence on what constitutes an adaptation and what classification or taxonomy should be used to report adaptations (26). The adaptation literature it is largely drawn from and conducted in high income country (HIC) contexts (27), with guidance primarily centering on cultural adaptation for minority groups within the wider population (28-36). Therefore this guidance may not be relevant or suitable to when adaptations are needed for the wider population or cultural context, and not just a specific minority group. In addition often this adaptation guidance involves a highly skilled resource heavy process (37), which may include the need for academic partners (33). Thus the relevance of current adaptation guidance may also be limited for low and middle income countries (LMICs), where capacity may hinder the ability to engage in a complex and resource intensive adaptation process.

Despite an abundance of implementation (38) and scale-up (39) models and frameworks, there is lack of specific guidance on *how* to adapt when scaling-up. While many scale-up models and frameworks recognise the need for adaptations (12, 40), they contain minimal guidance on specifically *what actions* can be used to achieve adaptations throughout the course of scale-up,

with even less guidance on how, why and when to choose one action over another across different contexts. Often there is a focus on adaptations in early pilot stages (41), however this may not factor in adaptations that may be needed at future scale-up sites not involved in the pilot, or as changes are needed over time (24). Thus, implementers who recognize the need to adapt when scaling-up within their setting, lack guidance on how to carry out this adaptation process throughout the course of scale-up. This may lead to adaptations not being embedded into scale-up planning and being omitted, or ad-hoc reactive approaches to adaptations that may have an impact on intervention fidelity and effectiveness.

1.1 Aims, Methodological Approach and Research Questions

This PhD study aims to address this research gap by describing what adaptations are occurring in practice when scaling-up health interventions. Furthermore, this research aimed to discover how to achieve these adaptations of health interventions when scaling-up, i.e. what actions can be used by implementers for adaptations during scale-up. This may provide implementers with knowledge on whether adaptations may be needed in their settings and allow for planning and embedding of these actions to achieve adaptations. Additionally, given the complexity of scale-up which occurs across varying diverse contexts, this research aimed to take one of these actions, that of local decision making, to develop theory on how and why it works across different circumstances and settings encountered during scale-up. This may provide implementers with guidance on when and how the action of local decision making specifically may work for adaptations across varying contexts.

A realist review methodology, described in more detail in Chapter 3 (see Section 3.4), was chosen for this research for a number of reasons. In short, realist methods were selected as they focus on developing an explanation of ‘what works for whom in what circumstances’ (5, 6). Moreover, and given that scale-up occurs across diverse contexts, each with differing cultures, needs, capacity, and resources (12), the use of a realist methodology allows for development of theory of ‘what works’ across these different circumstances that may be faced during scale-up, as opposed to developing a one-size-fits-all approach.

The iterative research design inherent to realist approaches (5, 42) led the research questions to be developed and refined as the review progressed. This will be discussed in more detail in Chapter 4 (Section 4.2.2) and Chapter 5 (Section 5.5). The resulting research questions were as follows:

- What adaptations are made and why, when scaling up health interventions in practice?
- What are the actions that can be used to achieve these adaptations when scaling-up health interventions?

- How does *local decision making* work (i.e. by what mechanisms, and in what contexts) as an action to achieve adaptations during scale-up of health interventions?

1.2 Format of the Thesis

This review took a format of three distinct phases, with each phase of the research informing the next. The suggested stages of the realist review (43, 44) occurred iteratively across these three distinct research phases. The format of the thesis therefore reflects this iterative process. Specifically, and to avoid repetition between chapters, the following layout for the remainder of the thesis was chosen;

Chapter 2: Literature Review - presents a review of the extant scale-up and adaptation for health intervention literature.

Chapter 3: Methodology - provides an overview of the realist methodology chosen. It outlines the three overarching phases of the realist review. As the results of each phase of the thesis are used to inform the next however, the clarified scope, focused research questions, objectives and detailed methods for each phase are subsequently presented within their respective chapters.

Chapter 4: Phase One - presents the methods and results for phase one of the review which consisted of a background search to formulate the review question and develop initial programme theory (45), in the form of an initial programme theory (IPT) framework. This involved a background search and analysis of existing guidance and frameworks available for implementers on scale-up, intervention adaptation, and fidelity.

Chapter 5: Phase Two – presents the methods, results, and discussion for phase two of the study. Phase two involved a systematic search to identify empirical evidence (45) and provided a sampling frame of case examples of scale-up. From these case examples, the review identified and described what actions and adaptations were being made in practice during scale-up of health interventions. The scope of the review was then clarified to focus on one of these actions, that of *local decision making*, to explore how this works, for whom, and in what circumstances in the third phase of the research.

Chapter 6: Phase Three – presents the methods, results and discussion for phase three of the study. This involved developing and refining theory on how *local decision making* works, for whom, and in what circumstances, for adaptations during scale-up. This phase utilised case examples identified in the previous phase along with further searches to refine programme theory (45) and to develop an MRT for how local decision making works for

adaptations during scale-up.

Chapter 7: Contributions, Implications, Recommendations, Limitations and Conclusions –

following completion of all three phases of the review this chapter presents an overview of the key contributions of the study to the field of adaptation and scale-up. This chapter then provides a number of implications of the research findings for theory, policy, practice, and research, along with suggested recommendations. In addition to this, the limitations of the research and methodological reflections on the use of realist review methodology are discussed before final conclusions are given.

Chapter 2. Literature Review

This initial literature review chapter introduces the concepts and definitions of scale-up, adaptation, and fidelity used across the literature. It provides an overview of why there is a need to adapt health interventions for local fit across diverse contexts when scaling-up. This chapter then presents what adaptations are occurring in practice when scaling-up and outlines the lack of documentation in this field. A further review of the literature will take place in Chapter 4, where specifically the current guidance and frameworks in the field of adaptation, fidelity and scale-up will be examined and discussed in detail (presented in Chapter 4, Section 4.2.1).

2.1 Scale-Up

Definitions of scale-up vary widely throughout the literature (11-13, 46). More generally, scale-up is described as the expansion in coverage of a health intervention. For example, Mangham and Hanson (11) suggest scale-up as the, “ambition or process of expanding the coverage of health interventions” (p85). Likewise, Milat et al., (47) describe scale-up as the, “the ability of a health intervention shown to be efficacious on a small scale and or under controlled conditions to be expanded under real world conditions to reach a greater proportion of the eligible population, while retaining effectiveness” (p289). However, scale-up has also been discussed as more than expansion in coverage, in recognition of the active process of scale up. Paina and Peters (48), for example, describe scale-up as;

A set of processes that lead to expanded and sustainable coverage of services, and involves strengthening the capacity of delivery organizations, increasing diversity and robustness of funding and management arrangements, and growing the system’s overall capabilities to add more services or to integrate services. (p387)

According to Paina and Peters, scale-up is therefore a complex approach which addresses the diverse system issues of wide scale implementation (13). For this research to recognise both the expansion in coverage, and also the active process involved, scale-up will be defined as *the purposeful active expansion in coverage of a health intervention to serve a wider population group* (11, 12).

Scale-up is time-consuming and challenging due to the complexity of implementing an intervention across contexts with differing populations (49), finances, resources and capacity (50). Accordingly, it is reported that the average time from successful pilot to national scale is 15 years (51). Moreover, demonstrating the effectiveness of a certain health interventions, does not guarantee that the intervention will be scaled-up, and often scale-up of an intervention is restricted due to cost, lack of cohesion with existing infrastructure, and lack of strategic alignment (46). Due to this complexity, scale-up considerations should be embedded during the development and testing of interventions

rather than as an afterthought, or in some cases not explored at all (41). The result is a growing discussion on the need to provide more evidence for how to address this important research-to-practice gap.

The process for scale up is often recognised as being as important as the intervention content itself in part due to the diversity and complexity of health systems in which scale-up occurs (48). Additionally, different processes of scale-up have been suggested in the literature, ranging from horizontal (52) and vertical (52); to expansion (51), replication (51), and collaboration (51), often used in tandem. For example, the concept of horizontal and vertical scale-up is discussed in the 'Nine steps for delivering a scaling up strategy' by ExpandNet (52), whereby vertical scaling-up is described as relating to the political, legal, budgetary, regulatory and health system changes that are needed to institutionalise an intervention at national or sub-national levels. A vertical approach therefore requires specific actions to identify and designate resources and changes in policy or regulations in order to allow for intervention fit. Horizontal scale-up, on the other hand, is described as the expansion or replication of interventions to different sites or user groups. The ExpandNet guidance (52) posits that both approaches need to be considered to scale-up and institutionalise an intervention. The realities of local contexts, possibilities for integration into existing service provision (46), along with the consequences to other elements of the health system all need to be considered for each context when considering the scaling-up strategy. A strength of differentiating across these processes of scale-up is that it allows for the identification of challenges at political and institutional levels and acknowledges that there is sometimes a need to pillar an intervention by supporting it with specific resources, while also highlighting the importance of institutionalising an intervention.

Cooley and Ved (51) suggest there are three main concepts for the original organisation who developed or piloted the intervention to consider when scaling-up. These include *expansion*, where the same organisation expands the intervention within its organisation to a wider population. This could also involve franchising the model to other organisations to roll out in the same way as part of their own organisation. The second method suggested is *replication* involving the use of a process or model of delivery, such as the public sector, for example, where the originating organisation may not be the ones actively scaling the service. This replication can be active, through a planned process, or occur spontaneously. The third method they suggest is collaboration, which could be a combination of the two previous methods. Formal or informal networks can be formed to assist collaboration to divide responsibilities and support scale up. Cooley and Ved (51) discuss how the choice of scale-up method may affect success, and suggest other factors to consider including resources of organisations, capacity of organisations, governance, homogeneity between

organisations and intensiveness of process for scale up. A strength of this conceptualisation of scale-up is that it acknowledges the role of the original developers and how they may influence scale-up, which may be of particular importance when adapting interventions through use of their in-depth knowledge of the intervention.

2.2 Adaptation

Like scale-up there exists a general lack of consensus on the definition of intervention adaptation, ranging from descriptions of contextualising, tailoring and modifying an intervention. Rogers (53), for example, suggests that adaptation is the “degree to which an innovation is changed or modified by a user in the process of its adoption or implementation”(p181). McKleroy et al., (54) describes adaptation as “modifying key characteristics of an intervention, recommended activities and delivery methods, without competing with or contradicting the core elements, theory, and internal logic of the intervention”(p62). Both of these descriptions recognise that an adaptation changes the innovation or intervention, however in the description by McKleroy et al., (54) they suggest that adaptations do not change the theory or core elements of the intervention, while the former does not make this distinction.

It is important to note that in addition to adaptations changing the intervention itself, adaptations can also cause changes (intended or unintended) in the systems and subsystems in which they are implemented (55). Pérez et al., (56) discussed adaptation as it relates to pre-defined changes, as proposed by the intervention designers, or changes that are undertaken by implementers at a contextual level. Broader definitions also recognise the cognitive decision making processes necessary to address issues during implementation of interventions (56). However, there can be a lack of clarity as to whether adaptation includes both the purposeful and also unplanned activities that lead to adaptation (17). The Centre for Substance Abuse Prevention USA et al., (57) (CSAP) classification includes both of these processes and discusses adaptation as “deliberate or accidental modification of a program”(p7).

A seminal paper discussing a classification of elements of adaptation was from Castro et al., (58). This classification focused on cultural adaptations and proposed they occur as surface level changes or as changes to deep structural elements of an intervention relating to core beliefs, norms, values and lifestyles. Castro et al., (58), emphasised that an understanding of cultural nuances and cultural competence is required by the intervention developers, adapters and implementers to achieve adaptations. Dimensions to adaptation suggested by Castro et al., (58) include cognitive information processing, affective-motivational characteristics and environmental characteristics. Here, cognitive information processing refers to the programme being clear and coherent for the

population. On a surface level, this could mean language, whereas on a deeper level this would mean that the concepts make sense or align with prevailing beliefs of recipients. Affective motivational characteristics include gender, ethnicity, religion, and socio-economics, whereby programmes should ensure the intervention does not cause cultural conflicts or a negative reaction to proposed behaviour change. The final heading for consideration is environmental characteristics, which take into consideration the ecological characteristics of the setting. Castro et al., (58), also suggest that two main types of adaptations would occur: adaptations to programme content and adaptations to programme delivery. While Castro et al., (58) laid the foundation for more classifications of adaptations to follow, a key limitation is the focus on cultural adaptation and the exclusion of adaptations for other reasons, such as resources and capacity.

In 2013, Stirman et al., (15) built upon Castro et al's., (58) work by offering a more detailed taxonomy for modifications to assist in categorising adaptations, developed from a review identifying 258 adaptations across 32 studies. This taxonomy compartmentalises adaptations into changes to the: (i) content of intervention, or "changes made to the intervention procedures, materials or delivery" (p6), (ii) context and/or (iii) training and evaluation processes. Stirman et al's., (15) taxonomy also includes a further breakdown of content adaptations. For example, of whether tailoring, i.e. small changes were made, or whether the adaptation caused a larger shift, such as removing elements or drifting from intervention protocol. Contextual adaptations are defined as "changes made to delivery of the same program content, but with modifications to the format or channel, the setting or location in the overall intervention is delivered, or the personnel who deliver the intervention"(p. 6). Training and evaluation process adaptations are defined as "changes made to the procedures for training personnel or evaluation the program....they occur 'behind the scenes' and do not necessarily impact intervention content or context of delivery"(p6). For example, increasing the amount of days of training given (15).

Of these three forms of adaptation, Stirman et al's., (15) review further found that content adaptations were most common, occurring in 84% of studies, with 33% of adaptations made at population level, 33% at network or community level, and 18% at health unit level. In 2019, Wiltsey Stirman et al., (1) expanded this taxonomy to develop the Expanded Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME), which included additional components to describe whether adaptations were proactive, reactive or unplanned; documentation of the reasons and purpose for adaptations; and consideration of whether the adaptation affected fidelity. In this way, FRAME (1) addresses one of the key limitations of Castro et al.'s taxonomy by not solely focusing on cultural adaptations. FRAME (1) also identified different types of adaptations (i.e., content, context and training and evaluation), and also further

differentiates between the types of content adaptations. However, limitations of FRAME (1) include that it was developed for the purpose of reporting adaptations in primary intervention research studies and was developed in High Income Country (HIC) contexts so its utility for use in implementation studies and in LMIC is not known. Furthermore, while Wiltsey Stirman et al., (1) added a section for consideration of fidelity, FRAME gives little information on how to address this. FRAME's utility will be discussed in detail in Chapter 5 (Section 5.4.5).

Published the same year as the original Stirman et al., (15) taxonomy, Moore et al., (59) also made a significant contribution to the classification of adaptations by suggesting three dimensions of fit, timing, and valence. In this classification, fit relates to *logistical fit*, e.g. whether the intervention matches the implementing agencies' resources and capacity, or *philosophical fit*, where the intervention may not fit the belief system or view of the problem the intervention aims to address. Timing relates to *proactive adaptations*, whereby needs are anticipated and adaptations made prior to implementation, and *reactive adaptations*, where needs are identified as the intervention is being implemented. Finally, valence relates to when adaptations could be deemed 'positive', whereby the adaptation is in keeping with the theory and goals of the intervention, 'neutral', where the adaptation did not affect the theory and goals of the intervention, or 'negative', where the adaptation deviates from the theory and goal of the intervention. Like Stirman et al.'s taxonomy, Moore et al.'s taxonomy was also not specific to cultural adaptations and highlights the importance of logistical fit to account for resource issues. However, unlike Stirman et al., (15) and their further updated FRAME (1) taxonomy, Moore's taxonomy lacks some of the detail for reporting. For example, details of adaptations to the content of the intervention.

Chambers and Norton (25) suggest a taxonomy which identifies sources of adaptation as being: cultural adaptations, mode of delivery adaptations, target audience adaptations, and service setting adaptations. Likewise, recent work by Aarons et al., (60) suggests that adaptations could be categorised as process adaptations, referring to how materials are presented (which could include dosage or length of sessions), and content adaptations, referring to adjusting the intervention material itself (for example removing or substituting parts of the intervention). Aarons et al., (60) also propose classifying adaptations as core, where a major component was removed or changed, or as peripheral, where changes did not affect fidelity to the core elements identified. To note, this taxonomy was developed through investigation of one Evidenced Based Practice (EBP) within one health service, where the core elements were known, and thus its use outside of this specific intervention has yet to be examined.

Holliday et al., (61) proposed that adaptations could be classified on a spectrum ranging from avoidable to unavoidable, and acceptable to unacceptable. Thus, an adaptation could be unavoidable but acceptable, whereby the adaptation may necessary to achieve implementation in a local setting but should still remain effective despite this adaptation. However, it may also be unavoidable and unacceptable, thus bringing into question whether this intervention will work in real-world settings should adaptation be unavoidable in some contexts. Additionally, an adaptation may be avoidable and unacceptable, in which case guidance should be put in place to ensure that adaptation does not take place. While this guidance was developed for RCT settings, the concept of looking at adaptations on a spectrum of avoidability and acceptability is also applicable to those scaling-up for local fit given its realistic, practical perspective. A benefit of the Holliday et al., (61) classification approach is its simplicity which would allow busy implementers to quickly and practically determine whether an adapted intervention should and could be used within their setting. However in comparison, with this simplicity, it does not have some of the detail of the types of adaptations that FRAME (1), Chambers and Norton (25) and Aarons et al., (60) discuss in their taxonomies which may be useful to guide implementers when developing more in-depth adaptations.

Overall however, there is lack of coherence on what constitutes an adaptation and what classification or taxonomy should be used to report adaptations (26). Moreover, it has been found that adaptations are often poorly described within research (15, 17), likely partly as a consequence of a lack of consensus on what constitutes an adaptation. For the purposes of the current research, adaptation is understood to be *any changes made to the health intervention content which could be planned or occur reactively as needs emerge when scaling-up* (15). Accordingly, Wiltsey Stirman et al., (1) and their updated FRAME was selected in phase two of this review to further assist in classifying adaptations which occurred during scale-up, and will be described in greater detail in Chapter 5.

2.3 The Need for Adaptation for Local Fit when Scaling-Up

Despite the amount of interventions with demonstrated evidence of effectiveness, the actual impact of an intervention depends on *how* it is implemented across diverse settings (62). Traditional evidence-to-practice research makes assumptions about a loss of effectiveness as an intervention moves along the timeline from efficacy, to effectiveness, to implementation, to wider scale-up and sustainability - known as the 'voltage drop' (24). This trajectory of loss of effectiveness was discussed in a study of policy makers by Milat et al., (63), whereby only interventions with high rates of success in efficacy studies should be used to allow for a voltage drop. However, with limited scale-up and sustainability research this voltage drop is open to discussion (24). Specifically,

Chambers et al., (24) in their proposal of the Dynamic Sustainability Framework (DSF) (more details presented in Chapter 4, Section 4.2.1.2.4) suggest that ongoing contextual changes and adaptations for local fit can work to avoid this loss in effectiveness and achieve implementation and sustainability. A second assumption made about implementation is the concept of 'program drift' which Chambers et al., (24) define as deviation from a manualised protocol during real world delivery. This program drift is expected to have a decreasing benefit from the intervention for patients. Here again, Chambers et al., (24) suggest that continual adaptations for local fit, whereby programme drift, if carried out in a planned way, may not necessarily lead to reduced effectiveness. However, there remains a lack of research into what actions can be used for adaptations for local fit in an ongoing way when scaling up, and the potential impact on voltage drop or programme drift.

Previous efforts to achieve scale-up have often used the approach of replicating what is tested in one off assessments at the start of scale-up in pilot sites (48, 64). However this approach does not account for the diverse social, political and cultural contexts present across scale up sites, prompting the need for more tailored approaches (48). The term 'context heterogeneity' has been used to explain observed differences in treatment effects across sites, due to contextual differences in population or individuals (20). Within complex systems, such as healthcare, a single approach used across all settings is unlikely to be effective, as it does not account for local contextual factors (65). Adaptation and tailoring of approaches may be particularly warranted in later adopting and harder to engage sites, both of which could benefit from more context-specific approaches (66). However, Powell et al., (67) discuss that often implementation strategies do not match the needs of the context itself, and that there is an absence of a scientific and systematic approach for achieving locally tailored strategies. They note that often implementers may become attached to specific strategies, thus applying the same approach across numerous contexts, even if these approaches are not suitable or aimed at the wrong level (e.g., using a provider focused approach for an organisational level factor). In addition, as contexts are continually changing over time, allowing for adaptations within temporal changes is also necessary to ensure the sustainability of interventions (24).

Consequently, a call for adaptations for local fit is being made across the health spectrum (18-23). Reasons for adaptation include: to match interventions to the needs of a more heterogeneous population, to simplify a complex intervention, to focus in on a specific problem, to expand the intervention to address multiple problems, to increase ownership of the intervention, a lack of available resources to carry out the intervention as specified, required changes made by agencies or funders, possible numerous applications of an intervention and lack of knowledge of the

intervention (54). Moreover, Powell et al., (67) suggest that adaptation may be needed to address local fit at patient level (e.g., in ways that are more aligned to a patient's values, culture, buy-in); at provider level (e.g., relating to attitudes towards an EBP); at an organisational level (e.g., to fit with organisational climate); or at system level (e.g., to align with existing policy and funding). Thus the numerous reasons for adaptations at multiple levels adds to the complexity of deciding how and what adaptations to make when scaling-up health interventions across multiple sites.

For example, in the case of reproductive, maternal and child health (RMCH), the need for contextualisation was seen in the scale-up of integrated and community case management services for childhood illnesses Ethiopia (68). Despite scaling-up access, the demand and use of services remained low. Less than 10% of parents were bringing their child to receive services, with individual factors such as perceptions of poor quality of care often cited as the reason (68). Addressing local contextual issues such as previous experience with the health services and perceptions of quality were identified as potential strategies that could have assisted the success of this scale-up. The call to adapt was also found in MCH services in Mauritania where needs differed between regional areas (69). For example, there were different rates of childhood illnesses observed across areas, with higher rates of acute respiratory illness and different health seeking behaviour of parents observed in one area. A contextualized approach to addressing education and recognition of symptoms in areas with greater need could allow for more efficient use of services and reduced morbidity and mortality. Similarly, resources could be directed from better performing areas to those where local need is greatest.

Thus, there is a risk that interventions will not fit local settings or meet needs in these complex and diverse environments (24) and will need to be adapted (70, 71). Consideration of future local fit is needed in intervention design, testing and implementation (61). Despite the recognised need for adaptations for local fit, along with the evidence that this is already occurring in practice, there remains little guidance on how to achieve this when scaling-up health interventions (72). It is challenging to know prior to the commencement of the implementation process how much adaptation will be needed for the intervention to fit local settings, and how to maintain fidelity to elements within a tested intervention (72). Consequently there remain important gaps in the literature on the relationship between local context, scale-up and sustainability (15, 73), and a priority for future research remains the distinction between contextual factors and mechanisms that affect the implementation and sustainability of interventions (73). This research aims to address this gap by exploring *what* actions can be used for adaptations when scaling-up health interventions for local fit.

2.4 Adaptation and Fidelity

Fidelity has been described as the tension between delivering the programme as intended and tested, and adapting to respond to the needs of a target population (58), with both adaptation and fidelity proposed as essential elements to achieve intervention fit (58). Whereas fidelity is often seen as a top-down (researcher, intervention developer) driven approach and adapting seen as more of a community driven bottom-up approach (frontline service providers, community, individuals) (56). Moreover, adaptation can be viewed as negative by intervention developers given that it may undermine intervention effectiveness and can be difficult to measure (74). In contrast, those in favour of adaptation see it as essential in order to match community needs to an organisation's resources and to gain trust and ownership from the community (54).

Bauman et al., (75) traced the history of the adaptation and fidelity debate. In the late 1970's it was proposed by fidelity advocates that alterations to a programme reduces effectiveness and makes evaluation across different contexts challenging. It was later suggested however, that adaptations are acceptable where the underlying programme model and mechanism remains intact, with changes made to match the unique features of the setting. In this way, Bauman et al., (75) discuss that 'reinvention' of the programme to suit local needs can improve the chances of a successful outcome. This opinion is shared in the work previously mentioned by Chambers et al., (24) with their development of the DSF, where adaptations to suit local needs are seen as essential to avoid a voltage drop, i.e. loss of programme effectiveness at scale whereby effectiveness tapers with ongoing implementation. Similarly, Chambers and Norton (25) emphasise that adaptation is necessary and interventions should be fluid by remaining constantly informed by learning and adapted in practice over time. Additionally, this learning in practice over time has also been highlighted in research by Masterson-Algar et al., (76) who found that those who deliver interventions are continually learning and can adapt to work more effectively as experience builds with the intervention.

Considering and assessing fidelity to the original intervention is an important process which is often overlooked (77). Specifically, interventions where fidelity is not monitored are at risk of a Type III error, whereby outcomes are incorrectly attributed to the intervention, when they may instead be due to other circumstances (77, 78). This may lead to the discontinuation of a potentially effective intervention, or the continuation and use of resources for an intervention which is responsible for the observed outcomes. Assessing fidelity can help explain what changes were made and what effects this had on the programme (77). Importantly, the level of fidelity (e.g. dose of components of an intervention) can give information on how feasible it is to deliver the intervention as intended (77). However, there is no clear guidance on fidelity measurement (77, 79) and there is a general

lack of consistency in terms of what constitutes fidelity across the literature.

Haynes et al., (80) differentiate between 'implementation fidelity' and 'theoretical fidelity', whereby implementation fidelity is the "extent the intervention-as-delivered matched the intervention-as-planned" (p2). They discuss theoretical fidelity as the "extent to which the intervention-as-delivered was congruent with the intervention theory (the logic and hypotheses that underpin the intervention design)" (p2), with the intervention theory, 'essential elements' and 'active ingredients' identified which are required for the intervention to be effective. With theoretical fidelity achieved it will allow for adaptations outside of these identified 'essential elements' or 'active ingredients'. Being able to make this distinction may assist implementers in distinguishing between what is central to the intervention itself and what is central to implementation in order to achieve effectiveness. However, it relies on the intervention theory and essential elements of the intervention both being known, while in reality these are often poorly described (80).

Overall, there is lack of guidance for implementers on what fidelity is, what elements constitute fidelity, and how to assess it. Dusenbury (77) reviewed 25 years of fidelity literature in 2003 and found, at that time, fidelity was measured in terms of adherence, dose, and quality of programme delivery, participant responsiveness, and programme differentiation. For concepts of fidelity in behaviour change interventions, the National Institute of Health (NIH) Behaviour Change Consortium (BCC) (81) propose using the five concepts of: design, training, delivery, receipt, and enactment. Reviews of how fidelity is assessed within the field of behaviour change interventions suggests however, that fidelity is often not studied, and that where it is studied, a range of dimensions are often not assessed (82-87). Where fidelity is evaluated, the concept of delivery is a common metric used to assess fidelity, with other concepts such as treatment receipt or enactment by the patient much less often studied (79, 88, 89). Therefore elements such as whether the intervention was received and given in a way that was understood by recipients is often not known. Moreover, within trials there is often less emphasis on discovery of essential components, and more on whether the intervention as a whole was delivered as prescribed (82-87). The majority of guidance for fidelity comes from the field of behaviour change interventions, including within the aforementioned NIH BCC guidance (81). However, this NIH guidance suggests that fidelity is assessed across multiple concepts, which in practice, could take up a lot of time and resources within programme implementation. Indeed, fidelity assessments are known to be challenging and resource intensive (89, 90), with practitioners citing having minimal time to complete these assessments, while also balancing clinical caseloads (91). Thus the findings of minimal fidelity assessments, with lack of consistency in what is assessed, could be considered unsurprising in

practice.

2.5 Intervention Theory, Mechanisms of Action, Core Components and Essential Elements

Trials for health interventions often test the content, number of sessions, activities and procedures; however in practice there can be a need to deviate from or consider additional elements to the intervention (62). This can be in order to ensure fit within diverse and ever changing settings, or to reach new target populations not originally included in the trial (62). A significant challenge for practitioners remains to be able to identify when adaptation is needed, and whether adaptations may affect how an intervention works and change the impact of an intervention (62). RCTs often do not provide sufficient information, as their purpose is to discover whether an intervention works in a given setting, but often not *why* and *how* it worked (92). Such information would be particularly helpful to implementers when introducing interventions into varying sites and areas encountered during scale-up.

Knowing the intervention is critical to be able to implement an intervention with fidelity and to allow for adaptations (93). Knowing an intervention can include understanding the theory behind the intervention and the mechanisms of action central to its effectiveness (93). Similarly, it has been noted that adaptation and the reliability of replication of an intervention is often linked to how well the theory and mechanism of operation of said intervention is described and articulated (93). Where the theory and mechanism of operations are not clearly described and articulated, components can be misunderstood, and the functions overlooked or not prioritised (93). Accordingly, Bauman et al., (75) initially suggested that fidelity should be maintained to the 'causal mechanisms of operation' of the intervention, whereby following this, reinvention of elements outside of causal mechanisms can be permitted. This approach is also supported in Haynes et al., (80) definition of theoretical fidelity (Section 2.3). In addition, Anyon et al., (74), in their work in youth violence prevention, promote that understanding the theory and principles of an intervention will allow for adaptations that ensure fidelity to these principles are enacted. Further to this Perez Jolles et al., (94) support the concept of 'core functions' of an intervention that can allow for autonomy and flexibility to adapt the intervention once fidelity to these 'core functions' remain in place. In recent work by Wight et al., (95) on intervention development for public health interventions, they suggest when developing and testing an intervention to identify what it is that you want to change, then identify what the active ingredient or mechanism would be to accomplish this, and how that can be delivered.

The importance of knowing the casual mechanisms of operation of an intervention along with the 'core elements' which need to be enacted to achieve this is also central to Aarons et al., (49) and

their concept of 'scaling-out'. The idea of an intervention having active mechanisms is also shared by realism itself, as reflected in realist methodology, developed by Pawson and Tilley (6), which views an intervention as having an underlying programme theory (how it is thought it should work). Programme theory can be achieved through mechanisms, which, when activated under certain circumstances, can achieve a given outcome. Realist methods further suggest that resources inputted into a context and contextual factors can either trigger or dampen these mechanisms, thus resulting in whether an outcome is achieved (2).

Thus, within intervention design and testing, further identification of the elements central to enacting intervention theory and mechanisms of action is required. To note the language to describe these elements central to an interventions effectiveness varies, and has been used interchangeably in the literature, often termed 'active ingredients', 'essential components', 'core components', or 'essential elements' (54, 75, 80, 96). However, identifying these essential components is challenging, with little guidance on how to complete this (56). Moreover, this approach assumes that mechanisms of action and essential components are known prior to adaptation (80), which often is not the case (17).

Accordingly, Harshbarger et al., (62) advocate that researchers need to better articulate what components of interventions are essential, and should therefore not be adapted, and which are amenable to adaptations to fit local settings and needs. There exists some guidance for intervention developers to assist in this, however the categories and parameters for consideration vary between guidance, with no consensus as to what to assess and evaluate. For example, Bauman et al., (75) suggest programme developers should: (i) provide a causal model of how a programme works, (ii) how to achieve meaningful outcomes within the client group (i.e. demonstrate effectiveness) and (iii) discuss how programme parameters may interact with implementation parameters, as well as what elements are key to successful implementation. Here, programme parameters for consideration include: the technology and content of the intervention (the casual mechanism from which the outcome will be achieved, which will be the least amenable to future adaptations), complexity of intervention, programme ambiguity (lack of clarity on how it works and how to deliver), intensity of the intervention (both to achieve desired effect and be replicable in with available resources in real world settings), and sponsorship (and incentives or impacts from this). Similarly, Rolleri et al., (97) discuss three categories of core components including: (i) content (knowledge attitudes, norm skills), (ii) pedagogical (relating to how it is administered including methods, strategies, interactions, theories) and (iii) implementation (logistics, resources, staffing). Likewise, Lara et al., (71) suggest a conceptual model for translating Evidence Based Interventions (EBIs) into community settings, whereby an EBI will have both structural elements and process

elements, and core component identification and maintenance of fidelity in both of these elements is needed to allow for effective adaptation. An example of structural elements includes: the framework for the intervention, the setting, the resources available and level of qualification of providers. On the other hand, process elements refer to how the intervention was meant to be delivered (i.e., what was the protocol for the intervention) for who, and how the intervention would be carried out, and by what activities. Further to this, the Medical Research Council (MRC) UK created an evaluative framework for process evaluations of trials for interventions (98), building on its 2008 guidance which focused on outcomes (99). Notably, this process evaluation framework (98) promotes explicitly stating causal assumptions of an intervention and testing these in each context. This process evaluation framework (98), recognises the importance of mechanisms of impact, which involves testing of assumptions of causal pathways, through which mechanisms the intervention will achieve its effect. However, while this guidance is welcome, its use within RCTs is not part of routine practice, with many RCTs failing to adequately describing what the intervention entails (28, 100), let alone providing a comprehensive process evaluation alongside the trial.

Carroll et al., (101) proposed that understanding the fidelity of an intervention can help to uncover the 'core components' of an intervention. Accordingly, Carroll's conceptual framework for implementation fidelity (101) suggests that in addition to the evaluation of outcomes, *moderators*, such as facilitation strategies, should also be evaluated alongside *adherence*, or details of content, coverage, frequency and duration. In doing so, Carroll et al. (101) argue that both fidelity to the original intervention and how moderators influenced fidelity can be described for each setting. They suggest participant responsiveness to the intervention should also be observed to evaluate how acceptable and willing the target population was to adopt the intervention. Putting forward these findings may help to further explain and unpack the core components of the intervention in question which would provide useful information for implementers.

More recently, Pérez et al., (56) using Carroll's conceptual framework for implementation fidelity (101) to explore adaptation and fidelity suggested further modifications to the framework (56). Namely, they added a component analysis where the essential elements of an intervention are identified. Pérez et al., (56) suggest that to complete a component analysis there needs to be a clear idea of expected outcomes and theory of how the intervention will work. With this theory in place, the identification of the specific descriptors of fidelity (i.e., what elements of the intervention will feed into and are necessary for this theory to work) is needed, along with how moderators in the context may affect fidelity. In addition, recent guidance by Anyon et al., (74) suggests that fidelity could be measured in terms of adherence to principles of the intervention, rather than to a set of manualised indicators. This guidance provides some support for those trialling interventions

in terms of what elements to assess for fidelity, however fidelity measurement remains a challenging and time consuming process.

An example of where essential components of an intervention are articulated is in the trial by Holliday and colleagues (61) who used a 'traffic light system' when testing a complex intervention for smoking cessation in schools, where red indicated an activity that was essential and could not be omitted, amber an activity that was important as it could consolidate or link skills but if there were serious time constraints could be omitted, and green represented activities that were enjoyable for participants, or linked sessions together, but could be omitted if needed. Thus, there are some examples in practice of how articulation of core components can be achieved, however consensus on a best practice method to use to identify intervention components and assess for fidelity has yet to come to the fore.

Another consideration is that while some essential elements of an intervention may be proposed, the validity of what is deemed an essential element may need to be reconsidered in the context where an intervention is being scaled. A study by Haynes et al., (80) for example, explored the validity of what had been suggested as 'essential elements' in practice by assessing how well these elements embodied the theory of the intervention, and to the extent to which they were essential in each setting. Their results suggested that some elements deemed essential in some sites were not in others. The authors further went on to categorise these potential differences of what was deemed essential under six headings, depending on whether the essential element was 1) redundant (e.g., where a facilitator to ask questions was not needed if natural discussions were occurring); 2) poorly articulated (i.e., lack of certainty on what the essential element was); 3) infeasible (e.g., due to organisational policies or lack of trust participants who may not feel open to state a change goal in a first session); 4) ineffective (e.g., while provider has experience presenting to policy makers, this may not actually be correlated with success); 5) paradoxical (i.e., essential elements contradicted each other); and 6) absent or suboptimal (e.g., participants make a commitment to change, however if instead participants have already taken actions and therefore further commitment not needed). Another consideration is that within complex interventions, components may be active at different times, and also be interdependent of each other (102). Thus, distinguishing what is essential at all times, to all sites can be challenging for implementers. However, when what is essential is not known and shared with local sites, multiple adaptations may occur in practice without consideration for whether essential elements of the intervention for each context are also being changed.

2.6 Adaptations in Practice

Adaptations are often naturally and commonly occurring in practice once programmes are scaled-up outside of a research setting (59, 103-105). For example, within 44 preventive interventions in a Substance Abuse and Mental Health Services, USA (SAMHSA) national database in the USA, over half of these had been adapted, evidencing that adaptation was more common than not (58). Likewise, a nationally representative study of 195 health facilities in Uganda accredited to provide anti-retroviral treatments (ARTs) conducted by Zakumumpa et al., (106) found that 95% of health facilities reported adaptations, with 81% of facilities reporting these adaptations as 'major' in nature, and mainly due to resource considerations. Adaptations made related to: the format (e.g., reducing frequency of clinic appointments), the setting (e.g., providing home-based care), to personnel (e.g., task-shifting to alternate cadres), and relating to the population group. Similarly, Moore et al., (59) looked at the adaptation of ten evidence-based programmes designed to reduce delinquency and violence in Pennsylvania, USA, which had resulted in over 200 replications across the state. A total of 44% of these replications reported making adaptations. Most common adaptations included: changing of procedures (e.g., survey instruments, recruitment process, location, timings); change in dosage (number and/or length of sessions; changes to the population targeted; changes to content (e.g., adding elements) and adaptations for cultural relevance. The reasons given for adapting included: difficulty engaging or retaining participants - reported by over 60% of those who made an adaptation - difficulty finding intervention staff, lack of resources, lack of time, resistance from implementing staff, and requests from participants for changes. Lack of time and resources however, was the most commonly cited reasons. Most adaptations were noted as being reactive in timing as needs emerged during implementation. Further to this Cooper et al., (103) documented adaptations in a family substance abuse presentation programme across 167 sites in Washington State, USA, citing adaptations in practice were in majority reactive in response to logistical constraints encountered during implementation with a negative impact on fidelity to the intervention.

Aarons et al., (60) interviewed 138 providers of a Self-Care intervention, where adaptations to the content and process of the intervention were occurring in practice. This included adaptations to address recipients' needs (e.g., parent's literacy levels) as well as based on provider factors (e.g., available resources, provider level of efficacy and comfort with the intervention, and provider judgement on what was important to focus on). It was reported some adaptations would have affected the core components of the intervention, while others were deemed as peripheral and would not have affected fidelity to the original model. Likewise, Sampson and Torres (107) in their experience of evaluating a five-year national Hispanic healthy marriages programme in the USA, found that adaptations occur naturally by professionals - as those individuals working in and deeply

embedded in the context, and who therefore understand the nuances - either consciously or subconsciously, to meet the needs of their individual clients and population group. While systematic adaptations to address issues such as cultural contexts are at times the most suitable approach, they further found that this is not always feasible or realistic in busy settings. However, this ad-hoc reactive approach to adaptation is rarely discussed, documented, or evaluated and therefore longer-term effects of this approach remain unknown. Thus, while adaptation is happening in practice, including in ad-hoc unplanned ways, there is a need to build scientific evidence on how to approach adaptations during scale-up.

2.7 Evidence for Adaptation

Comparing effectiveness of adaptations across studies is challenging due to limited or mixed evidence of adaptations for intervention or implementation strategies, in addition to adaptations being rarely reported and poorly described in research (15, 17, 25, 107, 108). Moreover, some adaptations may have large, deep modifications whereas others may have smaller, surface-level changes with different study designs and reporting. Additionally, intervention and implementation studies when they do explore adaptation more often focus on fidelity, as opposed to exploring the evidence for adaptation (25). It is also important to consider when studies do look at the evidence of effectiveness of adaptations whether the approach used is an appropriate fit for the study. For example, a Cochrane review of tailored approaches to increasing professional practice uptake conducted by Baker et al., (109) demonstrated an overall positive outcome for adapting intervention strategies, however the review did not detail *how* and *why* these adaptations were made. Moreover, the review only included RCT evidence, and only assessed whether changes made were effective or not in terms of outcomes in each setting.

Sundell et al., (17) completed a meta-analysis exploring the effectiveness of programmes that were adopted in their original form to those with adaptations or novel development. Within the identified studies of psychological and social interventions from Sweden (n = 139 studies), adapted and novel programmes were shown to be more effective than adopted programmes, proposing the importance of addressing adaptation as a way to maintain programme effectiveness. However, it is important to note that there may have been other contextual factors other than adaptation causing outcomes, which were not examined or isolated within this review, and so results should be interpreted in light of this.

A barrier to evaluating adaptations is that the length of time it takes to adapt, implement, review, revise and repeat (75). As noted by researchers in the Prevention Intervention Research Centre in the USA, clinical and Community-based Organisation (CBO) settings may not have the time or

resources to complete such an evaluation (62). Additionally with contexts continually changing, frequent and recurrent adaptations may be needed (24). Therefore, although there have been reviews looking at effectiveness of adaptations and use of tailored interventions or implementation strategies, there is little information on *how* and *why* these adaptations were made, thereby limiting the applicability of their findings for future implementers. Moreover, there remain concerns that adapting programmes may affect programme integrity, however, and given the dearth of research within adapted programmes this concern warrants further exploration (17).

Some studies have suggested that in addition to ensuring that the intervention has appropriate local-fit, a potential benefit of adaptation is the creation of local ownership and buy-in (17, 56, 62). For example, frontline staff feeling they can adapt an intervention to suit the needs of their setting has been positively associated with believing in the positive effects of the intervention, and fostering a sense of ownership (62). Likewise, programmes adapted with community support are more likely to be sustainable and institutionalised (54). However, while some positive benefits are highlighted throughout the literature, adaptations can also lead to negative outcomes. For example, Solomon et al., (110) explored a HIV and STD sexual risk reduction intervention was adapted for rural youth in West Virginia, whereby consultation with key stakeholders including community members, teachers, school county representatives and the target youth group, reduced and replaced the original intervention's emphasis on condom use with messaging on abstinence. This adapted version was found to be less effective than the non-adapted programme. Therefore, guidance for implementers making adaptations is essential to ensure that the theory of intervention, as well as the mechanisms central to its effectiveness, are retained. Likewise, and as previously outlined in Section 2.2, Holliday and colleagues (61) noted that adaptations could be categorised on a spectrum from avoidable to unavoidable and acceptable to unacceptable. Thus, highlighting when an adaptation may be detrimental to the effectiveness of the intervention, and whether it may be avoidable or not.

Chambers and Norton (25) have called for more evidence for adaptations occurring in practical settings. Evidence for adaptations can build on an intervention efficacy or effectiveness RCT studies, by also learning *how* the intervention works in practice when adaptations are made (25). Taken together, it is clear that evidence for adaptations is lacking, and despite the fact that adaptations are occurring in practice, there is a gap in the literature with adaptations being reported and described poorly, with a lack of research as to how and why adaptations are occurring thus making it challenging for researchers to systematically address adaptations when scaling-up interventions.

2.8 Guidance and Frameworks for Adaptation and Scale-Up

While there are guidance and frameworks in the field of adaptation, these are not specific to scale-up with some of this guidance requiring highly skilled, and resource heavy processes (28, 33, 37, 54, 57, 111-116) which may not be feasible at multiple diverse sites when scaling-up. Additionally some guidance suggests involving the original intervention developers (57), and at times promotes redesign and testing of the intervention (28, 33, 37, 111, 114, 117), which may not be feasible within the resources and timelines of scale-up across multiple diverse sites. Current adaptation guidance is primarily from HIC settings (28-34, 54, 57, 110, 114, 118-121), with a large number focused in the field of substance abuse prevention and HIV behaviour change interventions (35, 54, 57, 110, 114, 120, 121), and/or for cultural adaptations for minority groups within the wider population (28-34, 112, 118, 119). There is a gap within this adaptation guidance, specifically for adaptation in the context of scale-up, and for adaptation within LMIC contexts, where feasibility and capacity may strongly influence the process, along with minimal guidance for interventions adaptations for the wider population as opposed to for specific minority groups. A large number of scale-up guidance and frameworks recognise the need to adapt for local fit when scaling-up (12, 24, 40, 41, 49, 51, 52, 122-134), however, there remains a lack of consensus on how to achieve these adaptations, with no specific guidance on what actions to use for adaptations when scaling-up across multiple heterogeneous contexts, along with what resources need to be in place for this to occur. Thus, leaving implementers without support for this challenging process. As part of the background search in phase one, this review examined the existing guidance and frameworks in relation to adaptation and scale-up. To avoid repetition, the adaptation and scale-up guidance and frameworks identified will be presented and discussed in detail in Chapter 4 (Section 4.2.1).

2.9 Conclusions and Gaps in Literature

Scale-up is a complex process, occurring across diverse systems and contexts (12-14). This chapter has highlighted that when scaling-up adaptations may often be made to the intervention content, in order to suit local needs (15). This literature review has highlighted the lack of clarity in the concepts of scale-up, adaptation, and fidelity, and while there is evidence that adaptations are occurring in practice, adaptations are poorly documented and evaluated across the literature. Moreover, this chapter has discussed that despite an identified need for adaptations for local fit when scaling across multiple sites and diverse contexts, there is a lack of guidance on how and when to complete this, resulting in a lack of clarity for implementers as to why adaptations may be needed across their sites when scaling-up, and may lead to ad-hoc or reactive approaches to adaptations with potential impact on intervention fidelity and effectiveness. This literature review will be continued in Chapter 4 (Section 4.2.1), as part of the background search that occurred for phase one of this review, where in-depth exploration of existing guidance and frameworks takes

place, which will further demonstrate the lack of practical guidance for implementers for adapting health interventions when scaling-up.

There is a growing call in the literature to provide more evidence for *how* to scale-up in order to reduce the research-to-practice gap (7, 73, 124, 135). Whereas previous studies in the field of scale-up focus on barriers and facilitators to scale, evaluation of coverage rates, or wider health outcomes, less explore the process of scale-up itself (39, 136). Moreover, there is a need explore how to adapt interventions for local contexts when scaling-up (7, 24, 39, 49). Given the lack of guidance in this area, it is therefore unclear what actions are being used, and what adaptations are being made during scale-up. In light of these existing gaps, this research aims to discover *what adaptations are being made, and why, in practice during scale-up*. Specifically, and due to the lack of guidance in this area, this study aims to discover *what actions can be used for adaptations when scaling-up health interventions across diverse local settings*. In the later phase of this research, one specific action will be selected to be explored in detail to uncover *how and why (i.e. by what mechanisms) this specific action works across diverse contexts that occur during scale-up* in order to develop theory on how this action can be used to make adaptations to health interventions for local fit during scale-up across diverse contexts. In doing so, this body of work will make an important contribution to existing knowledge in the field of scale-up and adaptation and may assist future implementers in selecting a successful approach when scaling-up and making adaptations. The research questions, aims and objectives will be discussed in more detail as the scope of the review is clarified throughout phase one (presented in Chapter 4, Section 4.2.2) and phase two (presented in Chapter 5, Section 5.5).

Chapter 3. Methodology

This chapter provides a general overview of the research paradigm and methods used across each of the three phases of the research. A realist review was chosen as the overall methodological approach. Given the iterative research design of this methodology (6) the scope of the review and steps for each phase were refined as the review progressed with each phase informing the next. As a result, refined research questions and objectives, along with specific steps followed within each phase will be detailed in each of their respective empirical chapters (Chapters 4-6). A research logbook was used to allow for transparency throughout the realist review process and relevant sections will be referenced and appended throughout the thesis. To note a description of the research methodology is also available in the published study protocol (44) (see Appendix A). A summary of the steps taken across all three phases is also summarised at the end of the thesis in Chapter 7, Figure 7.1.

3.1 Research Paradigms: Ontology, Epistemology and Methodologies

Research paradigms are a set of beliefs around ontology, epistemology and methodologies (137, 138), whereby ontology describes the nature of being or reality (137), epistemology describes the nature of knowing or how we can learn, and methodology describes how we can find it out (137). These elements together constitute a paradigm and can inform a researcher in their choice of methods of inquiry.

3.2 Realism

Largely viewed as a third paradigm, realism sits between the largely popular paradigms of positivism and interpretivism (3). From an ontological standpoint, and more aligned to positivism (137), realism believes that a reality exists independent of our knowledge of it (3, 139). Williams (139) discusses; “The ontological core of realism is that the real, whether physical or social, exists independently of our knowledge of it.” (pg.2). From an epistemological standpoint however, and more aligned to interpretivism (137), realism proposes that we experience and learn of this reality through our interpretations of it (3, 139). Therefore, though one may never truly know the reality as it is viewed through the human senses, we can gain and accrue as much knowledge as we can on reality over time (3, 139). Bhaskar (140) discussed; “Things exist and act independently of our descriptions, but we can only know them under particular descriptions. Descriptions belong to the world of society and of men; objects belong to the world of nature “ (pg.242).

Much of the seminal work in realism came from the field of critical realism, for example through the work of Bhaskar and Archer (141, 142). A key concept in realism is that of ‘generative causation’ (3, 9), described by Bhaskar (141) as the underlying mechanisms that could be hypothesised to

cause an expected outcome, given a certain set of conditions (9, 141). This concept served as a building block for further realist thinking (9). As discussed by Williams (139), a realist may view the ontology of a mechanism of what actually exists in nature (or society), and the epistemology of mechanisms as to what we propose or believe to cause the outcomes, i.e. mechanisms are heuristics based on what we think or can find out (139). Archer (142) suggested the concept of morphogenesis and how causation may work within the social world, whereby choices and decision making at an individual level are the mechanisms which cause outcomes. These choices and decisions are shaped by society (i.e. culture, norms), but may also alter society (9). Thus, society is seen as fluid and ever changing (9). Within realism, a belief exists that programmes and interventions can, by the generation of mechanisms, not only change outcomes but also change the micro, meso or macro level contexts (3, 6).

Developed by Pawson and Tilley, a further branch of realism, often coined scientific realism, holds similarities to critical realism and the work of Archer and Bhaskar (6). While an in-depth discussion on similarities and differences between critical realism and Pawson and Tilley's realism is beyond the scope of this thesis and can be found elsewhere (2, 9). In short, the overarching paradigms of both critical realism and Pawson and Tilley's realism are proposed to overlap with the belief of complexity of social systems, the importance of mechanisms, and the existence of deep layers of stratified reality (2, 9). However, Pawson and Tilley's realism suggests a pragmatic viewpoint that systems do not need to be closed in order to be meaningfully evaluated (2, 9), and the use of 'demi-regularities' (semi-predictable patterns) can assist in the discovery of how and why an intervention or programme may work (or not) in a given setting (9). The current research aligns with the epistemology and methodology of Pawson and Tilley's realism (6) and therefore any reference to realist methods hereto refer to Pawson and Tilley's realist methods.

3.3 Implementation Research and Realist Methods

Implementation Research (IR), also known as implementation science (143), has been described by Peters et al., (144) as "any aspect of implementation, including the factors affecting implementation, the processes of implementation, and the results of implementation, including how to introduce potential solutions into a health system or how to promote their large scale use and sustainability" (p.1). IR therefore aims to address the research-to-practice gap by developing knowledge on how to improve and support implementation (143, 144). Moreover, and whereas healthcare research tends to be dominated by the paradigms of positivism or interpretivism (145), IR has no clear preferred paradigm and research design (143, 144, 146, 147). The current research could be classified as IR as it examines the *process of implementation*, specifically of how to scale-up and adapt health interventions.

An abundance of theories, models, and frameworks exist within the field of implementation science, with no agreement reached on which approaches are best to use (148). This presents a challenge for implementers deciding on how best to go about the process and evaluation of implementation and scale-up, which can be messy, non-linear (13, 41), and have multiple outcomes both intended and unintended (55). This may, in part, explain why research in scale-up (7, 135) and sustainability (24) has been far less frequent than other areas of implementation. Scale-up and sustainability research is rendered more challenging to complete without a clear preferred design or framework (135), with longer timelines needed acting as an additional barrier (24).

Within positivism, the epistemology takes an objective standpoint (137) where this reality can be examined, measured and viewed with neutrality (145). This lends itself to more experiential methodologies, such as RCTs, which allow for controlling of context and reducing perceived researcher bias (137, 145). However, these types of methodologies may miss key contextual factors resulting in an inability to adequately capture the complexity of issues within implementation (55). In contrast, realism encourages the consideration of context and how it may influence mechanisms and outcomes to occur (6). Therefore, a realist paradigm could be argued as a good fit within the field of implementation science, given that IR aims to address the complexity of real world implementation, including the central role of context and how this may influence implementation processes (143, 144). Specifically, a realist paradigm allows one to research the complexity faced in the process of implementation and scale-up, towards learning what works across diverse settings. Realist methods and their focus on theory generation is also in keeping with a call in the field of IR for theory based approaches to develop knowledge applicable across contexts (149). Accordingly, and though initially situated within social policy interventions (42), realist approaches have gained popularity across disciplines, including within health and implementation science research (7, 8).

3.4 Realist Methodology

Pawson and Tilley's seminal text, 'Realistic Evaluation' (6), first proposed a methodology for realist evaluation in 1997. Within realist research, a theory (i.e. an explanation) of how a programme or intervention may work within a given setting is developed, tested, and refined (3). The phrase 'what works for whom in what circumstances' (5, 6) has become the banner for the realist approach, encompassing the importance of how context may affect causation (5) (i.e., generative causation (6)). An overview of the realist terms and definitions used in this research are provided in Table 3.1.

Table 3.1 Definitions of Realist Terms Used For The Purpose of This Review. Adapted from (150, 151)

Term	Definition for the Purpose of this Review
Mechanism	A mechanism is a generator of change, being the integral link (3) to uncovering the “why” an outcome may have occurred within a context (5, 9, 10). Mechanisms can be in the form of resource or response (2) (see below)
Resource (R)	This is a form of mechanism, when introduced into a context, can trigger a mechanism in the form of a response (2)
Mechanism (Response) (M)	Under certain contextual circumstances, a mechanism in the form of a response gets triggered, generating an outcome (2)
Contexts (C)	Conditions that affect whether mechanisms are activated. A context can act like a dimmer switch for the triggering of mechanism to varying degrees (2)
Outcomes (O)	Intended or unintended consequences in a given context
Context-Mechanism-Outcome-Configuration (CMOC)	Explanation of causation of how a given outcome occurred demonstrated through a relationship between contexts, mechanisms and outcomes (3)
Initial Rough Theory	Initial theory to guide the review. This can be expressed in different ways for example as CMOCs, an “if-then” style statement (5, 6), or a framework (7, 8)
Initial Programme Theory (IPT) framework	An initial rough theory in the form of a framework of initial ideas from the literature to guide the following stages of the review
Programme Theory (PT)	A theory of “what works for whom in what circumstances” (5, 6). This is refined as the review progresses
Middle Range Theory (MRT)	Theory at a level of abstraction which is both testable within the data, but also could be applied within wider situations (3)
Demi-regularities	Semi-predictable patterns of causation (3)
Retroduction	Making inference and unearthing the deeper causal mechanisms which may cause a phenomenon to occur (10)
Substantive theory	Also called formal theory, may come from a specific domain e.g., implementation theories. These can assist in explaining CMOCs and PTs (3)

3.4.1 Programme and Middle Range Theory

Realist methodology lends itself to multi-method research based on what will hold value to theory building, testing, and refinement for the research question (5). Beginning with an initial ‘rough’ theory, this is subsequently refined throughout the course of the review, in response to emerging findings (3). This process generally leads to refined ‘programme theory’ (or theories) which aims to explain *how* a programme or intervention works (3). Ultimately, programme theory may be comprised of, “multiple context-mechanism-outcome configurations (describing the ways different mechanisms fire in different contexts to generate different outcomes) and an explanation of the pattern of CMOCs” (p.4) (152). Substantive theory can also be used to support programme theory refinement (3). In some cases, a ‘Middle Range Theory’ (MRT) may also be developed, described as a theory at a level of abstraction that is detailed enough to be testable, but also generalisable enough that it potentially could be applied in other situations (3).

3.4.2 Generative Causation and Context-Mechanism-Outcome Configurations (CMOCs)

As previously mentioned, a key focus of realist methods is that of generative causation (3, 9), which refers to providing an explanation of how an outcome was caused, through generative mechanisms (3). Within realism, mechanisms may only be triggered during certain circumstances, known as contexts (3). In other words, contexts are conditions that affect whether mechanisms are activated, whereby context can act like a dimmer switch for the triggering of mechanism to varying degrees (2). Mechanisms are therefore the generators of change, acting as the integral link (3) to uncover the 'why' an outcome may have occurred within a certain context (5, 9, 10). This focus on complexity is central to a realist approach, and allows for a greater understanding of how and why an outcome occurs across different contextual circumstances (6, 43, 153). Dalkin et al., (2) further suggest that mechanisms could be viewed as either 'resources' or 'reasoning' (2). Resources, for example elements of a programme or intervention, when introduced into a context, can trigger an individuals' reasoning (or response) to this resource, which in turn can generate an outcome. For this research, this concept of a mechanism in the form of resource and response was adopted (2). Specifically, actions carried out to achieve adaptations when scaling-up (e.g., generation of evidence or participation of stakeholders) were considered resources (7). These resources, under the right contextual conditions, were thus considered to fire a mechanism in the form of response (e.g., awareness or trust), which in turn may generate the outcome of interest (e.g., buy-in for an intervention).

The units of contexts, mechanisms and outcomes, which together form 'context-mechanism-outcome configurations' (CMOCs) (6), serve as a heuristic tool to explain generative causation and aid in theory building, analysis, testing and refinement. In other words, realist methodology focuses on exploring if an intervention (or action (7)) under a set of contextual conditions (C), triggers a mechanism (M), to cause an outcome (O) (2, 43). Following development of CMOCs, demi-regularities (i.e. semi-predictable patterns of causation (3)) can be sought across these CMOCs to guide synthesis and analysis for theory building, testing and refinement (3). In addition substantive theory can also be used to guide and support the findings (3).

3.4.3 Retroduction

'Retroduction' can also be used to guide realist thinking for theory development and refinement (3, 5). Whereas induction is considered as the generation of theory from evidence, and deduction the testing of theory against evidence, retroduction involves making inference and unearthing the deeper causal mechanisms which may cause a phenomenon to occur (10). Retroduction therefore suggests the existence of latent mechanisms that may activate under certain contextual conditions to generate an outcome (10). Once mechanisms are activated they may or may not be possible to

capture empirically, however, proxy equivalents can be used to approximate mechanisms or outcomes and an accumulative approach to generation of evidence can be used (10). While retroduction is often linked to abduction, there are differences. Jagosh (10) for example, describes retroduction as “inference to theorize and test hidden mechanisms” and abduction as “the inventive thinking required to imagine the existence of such mechanisms” (p122).

3.4.4 Introduction to Realist Review Methodology

Following realist evaluation, realist methodology was further developed to include another methodology known as the realist review, or a realist synthesis (43, 153). Whereas realist evaluation relates to completion of primary research on a programme or intervention, a realist review relates to an evidence synthesis of existing research and documentation (43, 153). Aligned to realist methods, a realist review begins with an initial rough theory, which could be expressed in different ways, for example as CMOs, an “if-then” style statement (5, 6), or can take the form of a framework to guide the review (7, 8). This initial theory is then refined throughout the review, as learning occurs with the purpose of providing explanation of generative causation. The final outcome of a realist review is programme theories, and in some cases an MRT (3). Retroduction and abduction can also be used to guide this process. These are then synthesised based on demi-regularities seen to aid refinement of theories (3). Realist review methodology has gained popularity in recent years, leading to the development of the Realist and Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) guidance materials (3), quality standards (152) and reporting guidelines (151) in 2013. Aligned to these standards and reporting guidance (3, 151, 152), the current research is a realist review, which aims to synthesise existing evidence to advance our understanding of the process of how to scale-up and adapt health interventions.

Pawson et al., (43) suggest five key stages to a realist review. The first stage begins with clarifying the scope of the review and developing an initial rough theory (Stage-I) (43), i.e. a theoretical framework (7, 8) or initial programme theories (IPTs) (5, 6). This stage can then be re-visited and the scope clarified throughout the review as learning occurs. A search strategy, or multiple search strategies are then developed to find evidence (Stage-II) (43). This can be a search to (i) *formulate the review question*, to complete a (ii) *background search*, (iii) *search to identify initial programme theory*, (iv) *search for empirical evidence* and/or (v) *search to refine programme theory* (45). Different searches can be carried out iteratively in response to needs identified and can take many forms, including a systematic search with further complementary searches as required, for example a search for empirical studies, followed by an additional search to identify substantive theory (45).

A realist review does not follow a typical hierarchy of evidence, allowing for the inclusion of multiple evidence sources and for learning to emerge from all relevant sources (154). Instead, documents are selected and appraised based on the criteria of relevance and rigour (Stage-III) (43). Specifically, the RAMESES realist review quality standards suggest that selection and appraisal of documents should “demonstrate sophisticated judgements of relevance and rigour in the domain” (p.6) (152), whereby relevance is “whether [the document] can contribute to theory building and/or testing” (p.34) (3) and rigour is “whether the methods used to generate the relevant data are credible and trustworthy” (p34) (3). Explained in greater detail in Chapter 6 (Section 6.1.6), consideration of rigour in realist reviews is complex and there is no one-size-fits-all approach to assessing it. In practice, appraisal of rigour is applied to each piece of evidence, with consideration made of whether it appears to be trustworthy, coherent or plausible, depending on what it is contributing to programme theory (155). Data is then extracted from these sources in the form of CMOCs to provide an explanation of what works, for whom, in what circumstances (Stage-IV) (42). Data synthesis and analysis then takes place, whereby demi-regularities in the CMOCs are sought to see if any patterns in contexts and mechanisms are seen across the data to inform programme theory refinement (Stage-V) (43). More recently, some have suggested an additional stage, whereby stakeholders are involved to clarify the scope of the review or assist in theory refinement (156, 157). A realist review is thus an iterative process that progresses as learning occurs (3). Important to note is that these steps are not necessarily carried out linearly, and can be revisited multiple times throughout the review process to address the research question. Figure 3.1 offers an overview of these stages.

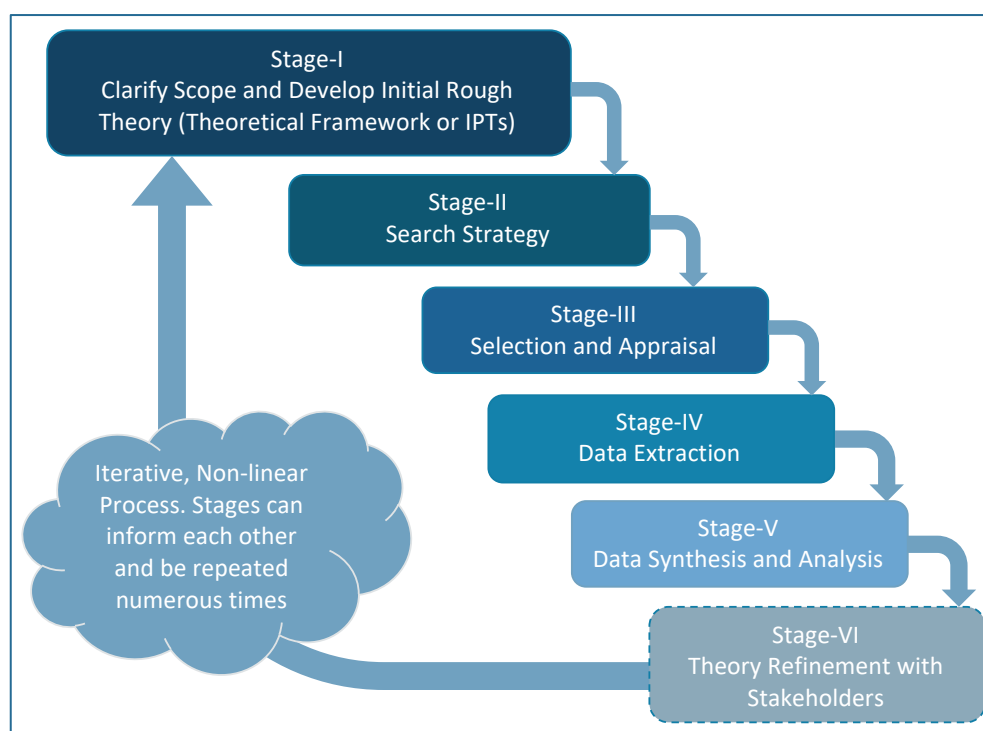


Figure 3.1 Overview of stages of realist review (43), with additional Stage-VI of theory refinement of stakeholders added. Adapted from (44, 158, 159)

3.4.5 Selection of a Realist Review Methodology

A realist review methodology was chosen for this research for a number of reasons. Firstly, a synthesis methodology was selected due to an identified need in the literature (see Norton et al., (135), for example) for synthesis of evidence and practical findings to advance our knowledge of scale-up. Second, unlike more traditional evidence synthesis methods, realist reviews allow for the inclusion of any documents that meet the criteria of relevance and rigour. This was considered particularly important given that existing scale-up and intervention adaptation literature includes a range of documentation, such as programme reports and other forms of 'grey' literature. Third, and given that scale-up occurs within complex systems, the use of realist review methodology allows for the capturing of complexity across multiple contexts, mechanisms and outcomes, considered at different levels of the system (3, 150, 151). In keeping with calls by Norton et al., (135) and Proctor et al., (73), a realist review thus allows for a greater understanding of the respective roles of context and mechanisms, which may impact scale-up and spread and affect implementation and sustainability. Fourth, the use of realist review methods allow for the identification of mechanisms involved in scaling-up interventions, as a step beyond the identification of commonly identified barriers and facilitators (7). Fifth, the realist review approach, which is iterative and non-linear, allows for the option to consult stakeholders as the study progresses. The utilisation of stakeholders, for example to refine theories (153), has been suggested by Brennan et al., (156) as offering a 'reality check' as to whether the theories may be of relevance to real world practice (153). Such pragmatic and practical findings within IR for the process of scale-up was also found to be of importance to stakeholders in a consultation by Willis et al., (7). Finally, the use of realist review, as a theory-driven approach, was chosen for its potential to provide findings that could be applied outside of the study (151), and the methodology has previously been successfully utilised for IR (8) and scale-up research (7).

3.5 Study Design

This study has three overarching phases (see Figure 3.2). The first phase (detailed in Chapter 4) involved a scoping search to focus the realist review question and develop an initial theoretical framework. The second phase (detailed in Chapter 5) involved a systematic search for case examples of scale-up in practice. Specifically, this phase identified what adaptations were being made and actions being used in practice when scaling-up and adapting health interventions for local fit and allowed for further focusing of the review question. In addition to this, the second phase generated a sampling frame of case examples of scale-up for the following phase. The third and final phase (detailed in Chapter 6) involved the exploration of 'what works, for whom in what circumstances', with the extraction and synthesis of CMOCs relating to the action of *local decision*

making for adaptations during scale-up. Through learning from what happened in practice when scaling-up, and with further support from substantive theories, programme theories were refined and an MRT also developed in this phase. The final phase also involved consultation with stakeholders to refine theories related to their experience in practice. A general overview of the three phases is described below. As realist approaches lend themselves to an iterative design, phases two and three were reliant on the results of the previous phase. Therefore, the clarified scope with research questions, aims and objectives for each phase are detailed in each of their respective empirical chapters as the review progresses (Chapters 4-6). To avoid repetition, greater detail on the specific methods used for each phase are provided within each respective chapter, with a general overview given below.

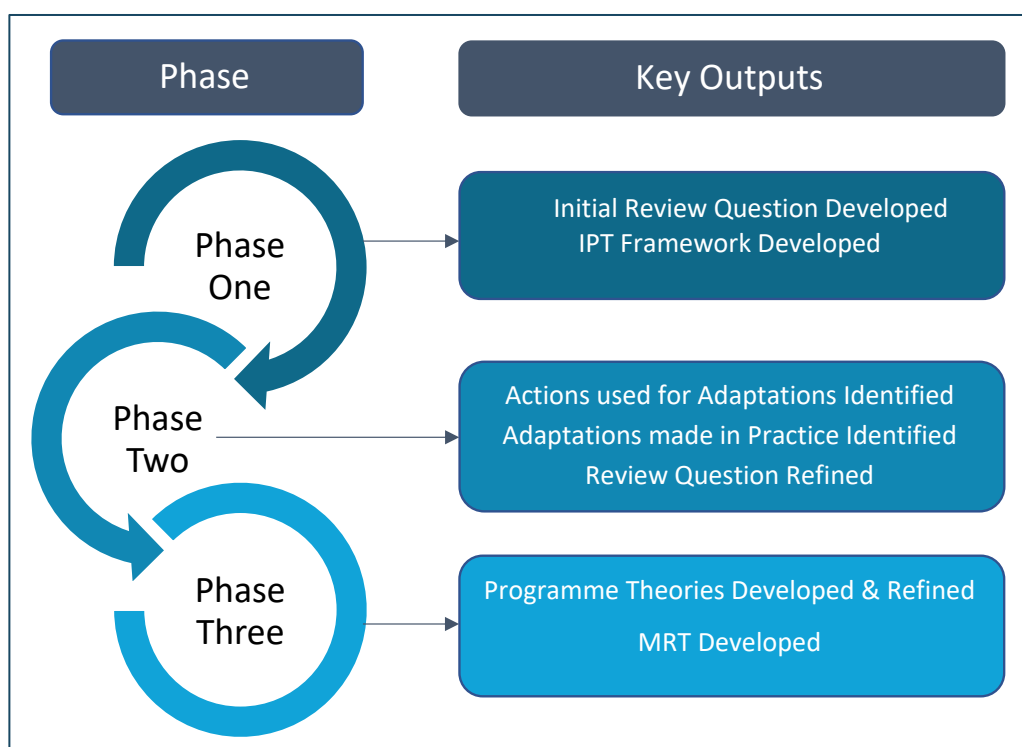


Figure 3.2 Overarching phases of the realist review with key outputs from each phase

3.5.1 Phase One – IPT Development and Clarifying Scope of the Review

Described in detail in Chapter 4, the first phase of the realist review begins with clarifying the scope of the review and the elicitation of initial rough theory in the form of an initial programme theory (IPT) framework (43). This phase involved an initial background scoping search on the scale-up, fidelity and adaptation literature, including available guidance and frameworks. The objectives for phase one were therefore to:

- 1.1 Develop the initial research question, aims and objectives through an in-depth literature review (presented in Chapter 4)

- 1.2 Develop an IPT framework identifying potential actions (resources), contexts, mechanisms, and outcomes that may be of relevance to scale-up and adaptation to support later phases of the review (presented in Chapter 4)

Results of phase one were subsequently used to clarify the scope of the review for phase two.

3.5.2 Phase Two – Identification of Adaptations made and Actions Used during Scaling-up in Practice

Findings from phase one identified a need to better understand what adaptations were made, in addition to what actions are being used for these adaptations, during scale-up in practice resulting in the following initial research questions:

- What adaptations are made and why, when scaling up health interventions in practice?
- What are the actions that can be used to achieve these adaptations when scaling-up health interventions?

Therefore, phase two focused on three main objectives:

- 2.1 Identify and describe what adaptations are made and why, when scaling up healthcare interventions in practice (presented in Chapter 5)
- 2.2 Identify and describe what actions are used to achieve these adaptations in practice when scaling-up health interventions (presented in Chapter 5)
- 2.3 Identify one action for adaptations of health interventions during scale-up to explore in detail in phase three (presented in Chapter 5)

Phase two involved a systematic search for case examples of scale-up and adaptation in practice, detailed methods of which are described in Chapter 5. Initial documents were identified and adaptations made in practice were extracted with coding guided by use of the FRAME (1) adaptation taxonomy. Following this, the actions used for adaptation during scale-up were captured and mapped onto the IPT framework developed in phase one. Addressing this research gap in phase two provided a foundation for phase three of the review by becoming more familiar with the literature to further clarify the scope of the review, through the identification of one specific action to be explored in greater detail. The outputs for phase two included: (i) the identification of what adaptations were made and why in practice (objective 2.1), (ii) the identification of what actions were used to achieve these adaptations when scaling up in practice (objective 2.2), (iii) a more focused review question based the emergence of *local decision making* as the specific action to be explored (objective 2.3). In addition to these outputs, phase two yielded (iv) the identification of a wider sampling frame of case examples of scale-up for use in phase three.

3.5.3 Phase Three – Developing and Refining Programme Theories and an MRT on How Local Decision Making Works for Adaptations During Scale-up of Health Interventions

Phase three provided more in-depth exploration of one identified action, that of *local decision making*, to discover how and why it works for adaptations across different circumstances encountered during scale-up. This led to the following remaining research question being developed:

- How does *local decision making* work (i.e. by what mechanisms, and in what contexts) as an action to achieve adaptations during scale-up of health interventions?

Based on learning from phase one and two, specific IPTs relating to how local decision making may work for adaptations during scale-up were developed. These programme theories were subsequently refined through data extraction of CMOs, synthesis, and analysis, including the identification of demi-regularities (42). All suggested stages (I-V) of the realist review therefore took place in phase three (43). The focused research question, aims and objectives, along with methods for phase three are described in detail in Chapter 6. Phase three had two key objectives:

- 3.1 Discover how *local decision making* works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit through generation of CMOs (presented in Chapter 6)
- 3.2 To develop and refine programme theories and propose an MRT on how *local decision making* works to achieve adaptations when scaling-up health interventions for local fit, by identifying demi-regularities within the uncovered contexts and mechanisms (presented in Chapter 6)

Phase three ultimately led to the development of five IPTs specific to local decision making for adaptations during scale-up of health interventions. Following this, further screening and appraisal of the case examples identified in phase two took place based on criteria of relevance and rigour. Data extraction occurred in the form of CMOs relating to local decision making which were synthesised and analysed. From this, the programme theories were refined. These findings were additionally refined through engagement with stakeholders in the field of scale-up. Further to this, substantive theory guided programme theory refinement and assisted in development of an MRT. The key outputs of this phase were: (i) eight programme theories on how local decision making works for adaptations during scale-up (objective 3.2) and (ii) an MRT on how local decision making works for adaptations during scale-up (objective 3.2).

3.5.4 Stages of the Realist Review

The five stages of realist review suggested by Pawson et al., (43) occurred throughout the three phases of the review to varying degrees. In addition to this a further stage of stakeholder involvement for theory refinement (Stage-VI) was incorporated into this study as suggested by previous reviews (156, 157), as part of phase three. An overview of these stages and which phase they occurred in can be seen in Figure 3.3.

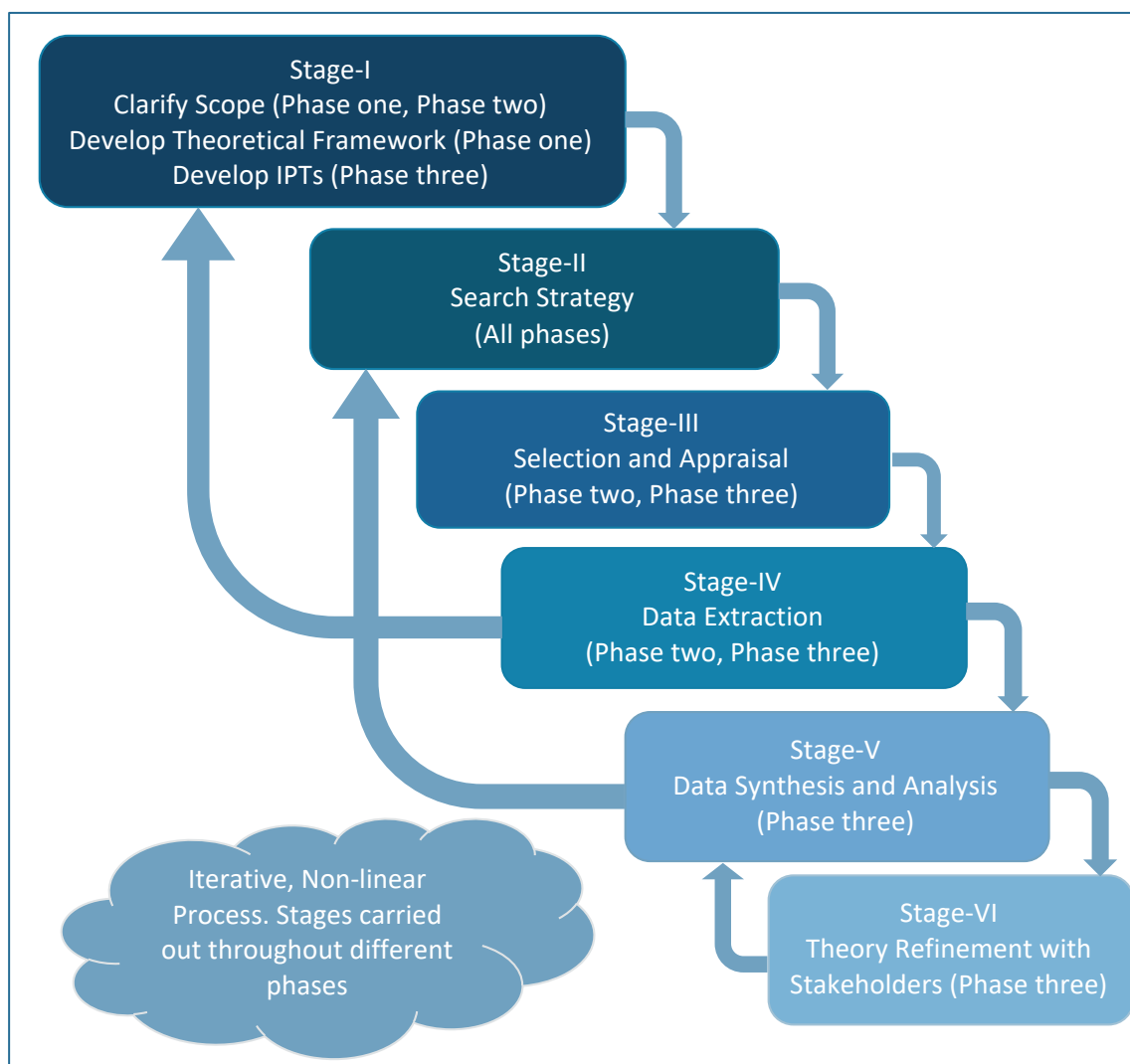


Figure 3.3 Overview of stages of realist review (43) and when they occurred in this study. Adapted from (44, 158, 159)

3.5.5 Components of the Realist Search

In the interest of transparency for the realist search, the framework by Booth et al., (45) was used for the reporting of the search components for Stage-II of Pawson's stages of a realist review (43) (figure 3.3). This framework discusses the components of a realist search as: (i) *formulating the review question*, (ii) *background searches*, (iii) *searches to identify programme theory*, (iv) *searches to identify empirical evidence* and (v) *searches to refine the programme theory*. These should be followed by (vi) *search documentation*. An overview of the search and sampling strategies used in each phase, and their corresponding component of the realist search is presented in Figure 3.4. To

reduce repetition, a broad overview is introduced in this figure with more specific details relative to the searches completed in each phase introduced in their respective chapters (Chapters 4-6).

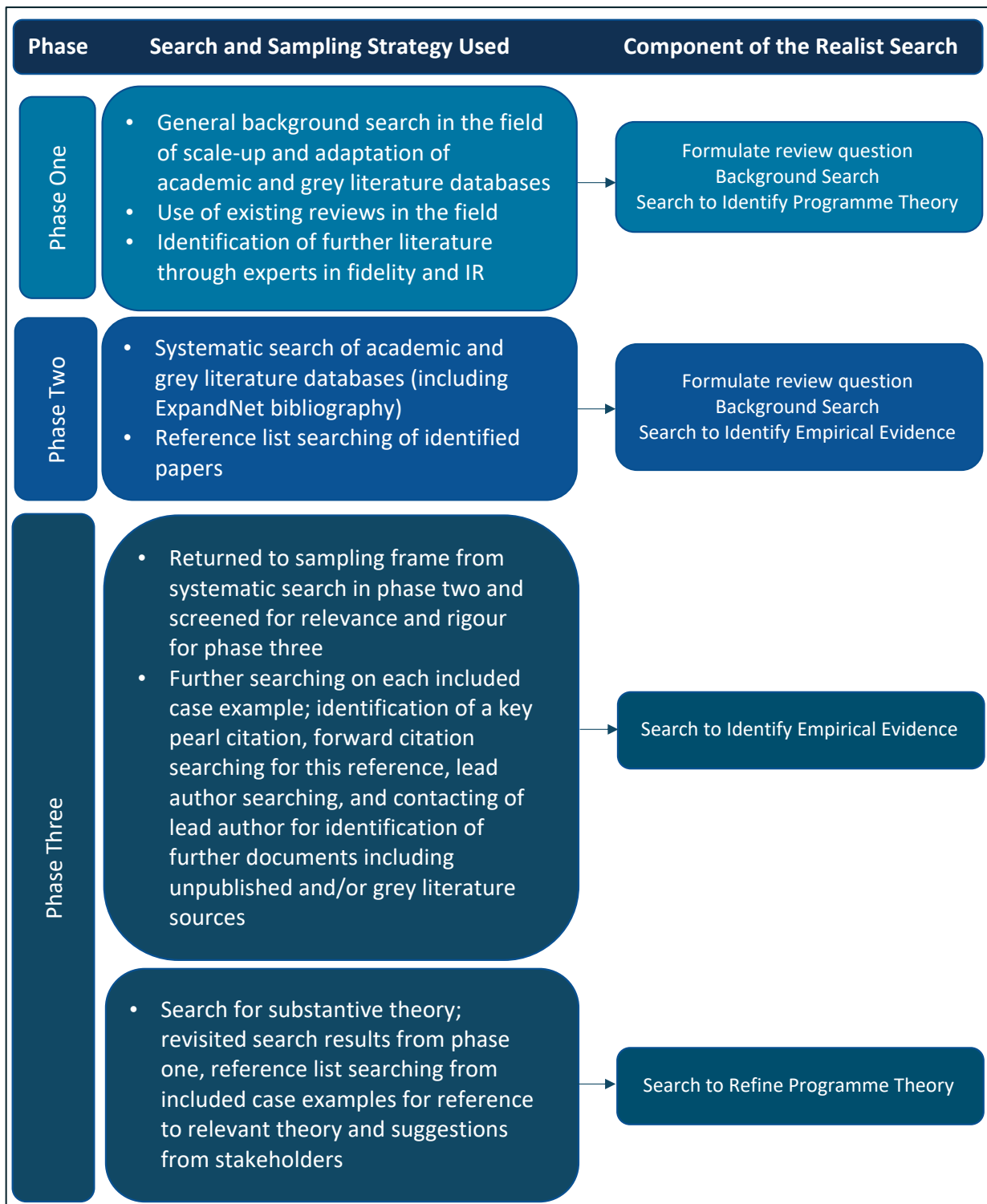


Figure 3.4 Searches and sampling strategies for each phase of the review with corresponding component of the realist search based on Booth et al., (45)

As can be seen in Figure 3.4., there was considerable overlap as the components of the realist search were addressed iteratively throughout multiple phases of the review. For example, *formulating the review question* took place in phase one through: a general background search, use

of existing reviews, and input from experts to identify papers. The question was then further refined in phase two following a systematic search of academic and grey literature databases where case examples of scale-up in practice were identified and the question narrowed to one action to explore further. Additionally the component of *searching for empirical evidence* occurred primarily in phase two, through this systematic search. This search further served as a sampling frame for phase three. Where further information was needed in phase three this was supplemented by forward citation searching, lead author searching, and by contacting authors for more documents for the included case examples. Additionally, phase one completed a *search to identify programme theory* scoping for theories and frameworks in the field of scale-up, fidelity and adaptation. These results were returned to in the *search to refine programme theory* to identify substantive theory which could aid programme theory refinement in phase three. While the figure gives an overview, more details on each of the phases, and how they iteratively informed the next phase is provided in the respective chapters (Chapters 4-6).

3.6 Challenges of Realist Review Methodology for a PhD

As noted by Jagosh et al., (160) the underlying logic of a realist review does not lend itself to standardised or prescriptive application. This can lead to confusion and challenges in how to practically apply the methodology to a given research question. While the overarching methodology has been well described in the literature, much of the published realist research offers little guidance of the specific steps that can be taken when using this challenging methodology (161). The RAMESES guidance published in 2013 (3), and quality standards (152), while providing a framework to work from, purposefully leaves the methodology open with flexibility of application.

This review commenced in 2016, prior to publication of many of the newer practical guidance materials (45, 162). While the newer guidance materials and papers were useful in the later stages and for reporting, many were not available at the outset. Throughout this research, while the overarching logic for the realist review approach was understood, with each step of the review new questions presented themselves and had to be worked through in how to practically complete the review to answer the research question both as efficiently and as transparently as possible. Such questions included: *how to approach the literature? when and how to clarify the scope of the review? when and how to involve stakeholders in a meaningful way? how to screen and appraise? when does screening complete and appraisal begin? and how to extract and refine CMOCs and maintain a logical and transparent thought process throughout?* A further challenge of completing this as part of a PhD is that it takes place as largely a solo venture. Many paths were taken, reversed, circumducted and refined throughout the course of this research as learning of how best to practically approach this realist review progressed. The review used the available guidance and

quality standards (3, 152), in addition to the RAMESES mailing list for support. Realist methods are evolving, and expertise is developing, however, there is often a need for further support for researchers in this process. As a result, in the earlier phases of this study the Irish Realist Researcher Support Group was utilised as a peer support mechanism which allowed for discussion of processes used for the review with feedback given.

As there is no prescriptive or standardised approach that will fit all realist reviews, this research aimed to be as transparent as possible about the methods chosen. To this end, a research logbook was used throughout (44) and referenced with relevant sections appended throughout the thesis. Realist reviews are complex, iterative and approaches taken will be dependent on the question itself, capacity of the review, and the available literature. A reflection on the use of realist review methods and the learning that took place is thus included as part of Chapter 7. It is hoped these reflections, along with the approaches used, may be of use to others conducting a realist review for developing methods for their own studies.

3.7 Note on Timeline of Review

This realist review took place from 2016-2020. Phase one took place in 2016 and 2017, which also involved development of the study protocol (44). To note - I took maternity leave of 18 months from February 2018 – July 2019; and the review was placed on hold during this time. The systematic search in phase two commenced on my return in 2019, and phase three took place in 2020. This study was completed in November 2020, with a break for a further maternity leave before submission in October 2021. In addition to this, there were three changes in primary supervisor throughout the PhD due to illness and staffing in 2016, 2017 and 2019, with further interim periods without supervision while supervisors were on their own maternity leave. Thus the timeline for the review reflects the above circumstances.

The challenges of this timeline were multifaceted. The field of scale-up is evolving at a rapid pace, and multiple papers had emerged in the period of the initial maternity leave that had not been included in the original IPT. As each phase informed the next, incorporating this recent literature into phase one which was already completed and published (44), did not feel organic to this review. Therefore, relevant literature which emerged, for example new reviews of adaptation guidance (27, 163, 164) are discussed in Chapter 5 (Section 5.4.7) in terms of how they relate to the findings of the study. Similarly, the evolving nature of the field of scale-up resulted in the search strings for the systematic search for phase two (which had been developed prior to maternity leave) yielding considerably higher results in 2019, than the test searches carried out in 2017. To address this, the

search strings were further refined to ensure that returned results were both manageable within the resources available and also remained sensitive and specific to the needs of the review.

As realist reviews are iterative in nature, decisions were made in 2016 and 2017 on clarified scope and what to include for the IPT framework. Recalling these thought processes after returning from maternity leave was a challenge. A further break in the review occurred from March – July 2020 during the global COVID-19 pandemic as there were no childcare services available during this time. Thankfully, the research logbook used to record decision making and thought processes as they occurred assisted in ensuring transparency. This served as an invaluable tool to support the return to this review on these occasions and assist in recalling and reconnecting with the previous work. In order to share the success and learning from use of a research logbook approach, I presented at the Realist Research, Evaluation and Synthesis Conference in Dublin (February 2021) on how research logbooks may be beneficial for other realist reviews for recall of decision-making and to ensure transparency.

Stakeholder involvement was also due to take place in 2020, however due to the onset of the global COVID-19 pandemic this made recruitment of those involved in health implementation and scale-up a challenge. Pragmatism had to take place in terms of numbers and format for consultation as a result, and this is reflected on in Chapter 7 (Section 7.4.2).

Overall, while the timeline of this review led to challenges, there were also a number of benefits. For example, the timeline and chosen methodology allowed for inclusion of case examples and developments in the rapidly evolving field of scale-up to be included as part of phase three. Additionally a longer timeline allowed for inclusion and use of realist practical guidance developed during this time to support reporting of the review. For example, the use of the new framework for components of the realist search (45), which greatly assisted in transparency of searching within the review process.

3.8 Ethical Approval

Ethical approval for this research was received from Health Policy and Management and Centre for Global Health Research Ethics Committee, Trinity College Dublin (please see Appendix B).

Chapter 4. Phase One - IPT Framework Development and Clarifying Scope of the Review

Phase one of the realist review began with clarifying the scope of the review and the development of an initial programme theory (IPT) framework. This chapter presents a detailed description of the methods and the results from this phase. In summary, phase one involved an initial background search of the scale-up and adaptation literature. Following this, a search and comparison of guidance and frameworks for fidelity, adaptation and scale-up was completed (presented in Section 4.2.1 below). This served to generate the initial review questions and inform the IPT framework for the review. The objectives for phase one were to develop: (i) the initial realist review questions, aims and objectives (presented in Section 4.2.2 below) and (ii) the IPT framework (presented in Section 4.2.3 below). Phase one is also described in detail in the published study protocol (43) (Appendix A).

4.1 Methods for Phase One

4.1.1 Search Strategy for Phase One

Phase one of the review consisted of a background search. The search strategy emerged as learning progressed and took place across five steps (an overview of these steps can be seen in Figure 4.1). To begin with, an initial background search took place in the field of scale-up and adaptation (Step 1). As learning occurred and the initial review question, aims and objectives were developed, a decision was made to direct the search towards guidance and frameworks in the field of adaptation, fidelity and scale-up (Step 2). These were identified through the initial background search results (Step 3), reference list searches and use of previous reviews in the field (Step 4). Further to this subject experts were consulted to further highlight literature (Step 5). More details for each step are outlined in Section 4.1.1.1 below. Consistent with Booth et al., (45) components of a realist search, this phase one (and the steps outlined below) served to *formulate the research question*, complete a *background search* and *identify programme theory*.

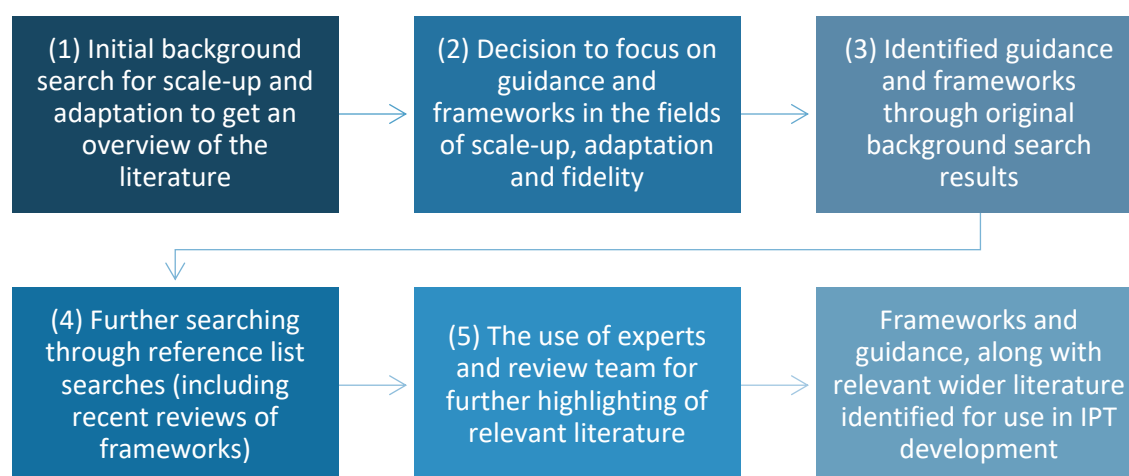


Figure 4.1 Overview of steps undertaken during phase one search

4.1.1.1 Steps Undertaken during Phase One Search

The steps undertaken during the phase one search were as follows:

Step 1 - An initial background search on scale-up and adaptation in healthcare was undertaken in March 2016 to get an overview of the available literature and as an introduction to this field (7). The following databases were searched: PubMed, Cinahl, Scopus, Global Indicus Medicus, Web of Science, EMBASE, and Psycinfo. Grey literature searches were also completed in Social Care Institute for Excellence (SCIE), Grey Lit and Open Grey. Subject headings of: (i) scale-up and (ii) contextualise were used and adapted for each database for example with MeSh terms used where appropriate (see Appendix C, Table C1 for full details of search terms for each database).

Step 2 - Following this, while a large volume of articles were returned, with many articles discussing the need to adapt for local fit, none specifically offered guidance for how, why or when to complete adaptations when scaling-up. Thus leaving implementers with no specific process or actions to follow. Step 2 then focused the scope of the review to explore what actions could be used to make adaptations when scaling-up. As a result, a decision was made to identify guidance and frameworks relating to scale-up, adaptation and fidelity, in order to better prioritise identification within the literature of what actions could be taken for adaptations when scaling-up.

Step 3 - Initial frameworks and guidance documents relating to scale-up, adaptation and fidelity were identified through the search results from the original background search, as described above.

Step 4 - Additional documents and guidelines were further identified through reference list searching of identified papers and reviews completed in the field. Of particular relevance were the reviews of scale-up frameworks by Milat et al (47), and Subramanian et al (39); and the review and taxonomy of implementation frameworks by Nilsen (38).

Step 5 - Results of this search was complemented by the involvement of two experts (one fidelity researcher and one implementation researcher) and the review team (with backgrounds in global health and health systems), as well as through consultation with eight global health researchers attending the International Doctorate in Global Health (INDIGO) research seminar at Trinity College Dublin, which assisted in the identification of further relevant literature. This approach is consistent with use of experts to supplement searching for IPT development within realist reviews (7), the process of which was documented in the research logbook and can be seen in Appendix C, Table C2. Consequently, this stage yielded additional information, such as fidelity guidance from the field of education, also considered of relevance to this research (61).

4.1.2 Selection Criteria for Phase One

As this was a background search, in order to clarify the scope of the review and for IPT development, only broad criteria to inclusion was applied at this stage, with an emphasis on whether the guidance, framework or study could be relevant to identify actions for adaptations when scaling-up and assist in IPT development and/or to clarify the scope of the review. The key areas of literature identified of relevance from the results of the background search and included were: (i) fidelity guidance and frameworks (e.g. comprehensive intervention fidelity guide (165)), (ii) adaptation guidance and frameworks (e.g. ADAPT MAP draft guidance for adapting HIV interventions (54)), (iii) scale-up guidance and frameworks (e.g. AIDED model (40)). Specifically due to the volume of implementation and scale-up guidance and frameworks a focus for inclusion was placed on whether *actions for adaptation* during scale-up were present, rather than to focus on actions that may be more relevant to scale-up more generally. A number of scale-up frameworks were examined in greater detail which were selected based on this relevance to adaptation and scale-up (e.g. scaling-out framework (49)) and also due to popularity of framework (e.g. ExpandNet (166, 167)). In addition to this, wider literature which could inform potential mechanisms or theories relating to adaptation and scale-up (e.g. Rogers' diffusions of innovations theory (53)) were included. Learning from this phase and clarification of the scope of the review were then taken forward during a more targeted systematic search, with defined inclusion and exclusion criteria, as part of phase two (described in detail in Chapter 5, Section 5.2).

4.1.3 Data Extraction for Phase One

The fidelity and adaptation guidance were examined and compared for any key actions of relevance to adaptation and scale-up, with some commonalities across these guidance documents found and discussed in Section 4.2.1.1. Key scale-up guidance and frameworks were then examined and the findings are discussed individually in greater detail in Section 4.2.1.2 below. Following this the scale-up guidance and frameworks were collectively examined and any key actions were identified for adaptations and are discussed in Section 4.2.1.3. Further to this, the wider implementation literature was examined to highlight potential relevant mechanisms and theory for scale-up and adaptation, and will be discussed in Sections 4.2.1.4 and 4.2.1.5 respectively. The above literature guided and informed the development of the initial research question and informed the initial programme theory (IPT) framework, which are presented in Sections 4.2.2 and 4.2.3 below.

4.1.4 Methods - Clarifying the Scope of the Review and Developing the Initial Research Question, Aim and Objectives

Following the background search gaps in knowledge were identified which focused the review. Decision making processes for clarifying the scope of the review were documented in the research logbook, with an example provided in Table 4.1 below. Clarifying the scope of the review ultimately led to development of: (i) the initial review questions, aims and objectives and (ii) the search strategy and inclusion criteria for phase two (presented in Chapter 5, Section 5.2).

Table 4.1 Example from Research Logbook of Decision Making for Clarifying Scope

Source: Scale-up and wider implementation literature	Thought process, decision making	Clarified scope
Many theories and frameworks in implementation are untested. They are aspirational but may not reflect what is happening in practice.	Scale-up is often carried out within the limited resources that are available in real world settings, particularly in LMIC contexts. Theories and frameworks that are aspirational or developed from smaller scale implementation or pilot studies where more resources are available may not reflect what is happening in practice during scale-up.	Decision to focus on examples of scale-up and adaptation in practice Inclusion criteria for stage two developed

4.1.5 Methods - Developing the IPT Framework

The format of the IPT framework was informed by Willis and colleagues' (7) realist review, which focused on the process of scale-up of complex interventions and which identified actions, contexts and outcomes in their IPT framework. Following analysis and synthesis of three case studies they further identified what mechanisms were triggered to achieve scale-up of complex interventions and what contexts influenced this. Informed by this method, the current study developed an IPT framework identifying potential actions, contexts, mechanisms, distal outcomes and proximal outcomes that may be of relevance to scale-up and adaptation. A particular focus of this IPT framework was the identification of potential actions (e.g. definition of roles, use of feedback loops etc.), and how these can achieve the outcome of adaptation for local fit during scale-up. This IPT framework provided a theoretical map (7) for further exploration in the following stages of the review. As the review progressed, in phase three it was later refined to five IPT statements specific to one action (Chapter 6, Section 6.1.2). These were then further refined into programme theories (see Figure 4.2).



Figure 4.2 Progression from IPT framework, to IPT statements to final Programme Theories within the review

Rycroft-Malone et al., (8) note that “the challenge of developing a framework for a realist synthesis is in finding a level of abstraction that allows reviewers to stand back from the detail and variation in the evidence, but that is also specific enough to meet the purpose of the review” (p.3). Due to the broad nature of the topic, with multiple potential actions affecting contexts and resultant mechanisms and outcomes, this challenge was also shared during the development of the IPT framework in this review. Specifically, it was difficult to decide upon a level of abstraction that allowed for recognition of the demi-regularities and variation within the evidence, while also being specific enough to assist in answering the research question. To assist in this process, the IPT was presented to the Irish Realist Researcher Group for feedback, which led to further refinements, including bringing it to a higher level of abstraction than what was originally presented in order to allow for future comparison between studies.

4.1.6 Stages of the Realist Review which Occurred in Phase One

This first phase laid the initial foundation for the phase two and three of the review. Under the stages of the realist review (43, 44) (Chapter 3, Figure 3.3), phase one primarily aimed to *clarify scope and develop a theoretical framework* (Stage-I). To achieve this it developed a *search strategy* (Stage-II). On reflection, it could also be argued that phase one carried out elements from the stage of *selection and appraisal* by deciding on guidance and frameworks to incorporate in the IPT framework. However, the latter stage was not as systematic and formalised in this phase as it is within phases two and three. Instead, the searching carried out in this phase was based on Booth et al., (45) components of the realist search for the purpose of: *formulating the research question, completing a background search and identifying initial programme theory*. These searches provided a rich literature review from which the IPT framework was developed and which could also be drawn upon again when refining theory in phase three.

4.2 Results of Phase One

4.2.1 Literature Identified to Inform IPT and Clarify Scope of the Review

The previous literature review presented in Chapter 2 offered an overview of the concepts of scale-up, adaptation and fidelity (Sections 2.1, 2.2 and 2.4), identifying a lack of clarity within definitions, a lack of consensus of what elements constitute these concepts, and a lack of guidance on how to assess adaptation and fidelity. Chapter 2 provided evidence that while adaptations are occurring in practice (Section 2.6), these adaptations are generally poorly documented and evaluated. Together, these gaps in the literature suggest the need to better define, document, and implement adaptations for local contexts when scaling-up. Accordingly, there is a need for stronger guidance for implementers on *how* to adapt for local fit when scaling-up health interventions. In an effort to start to address this gap, the following section provides an overview and highlights some of the

guidance and frameworks, along with some of the relevant implementation literature, identified through the background search for phase one which is currently available for implementers in the fields of fidelity, adaptation and scale-up. A flow chart of the search and screening process for this background search can be seen in Figure 4.3 below.

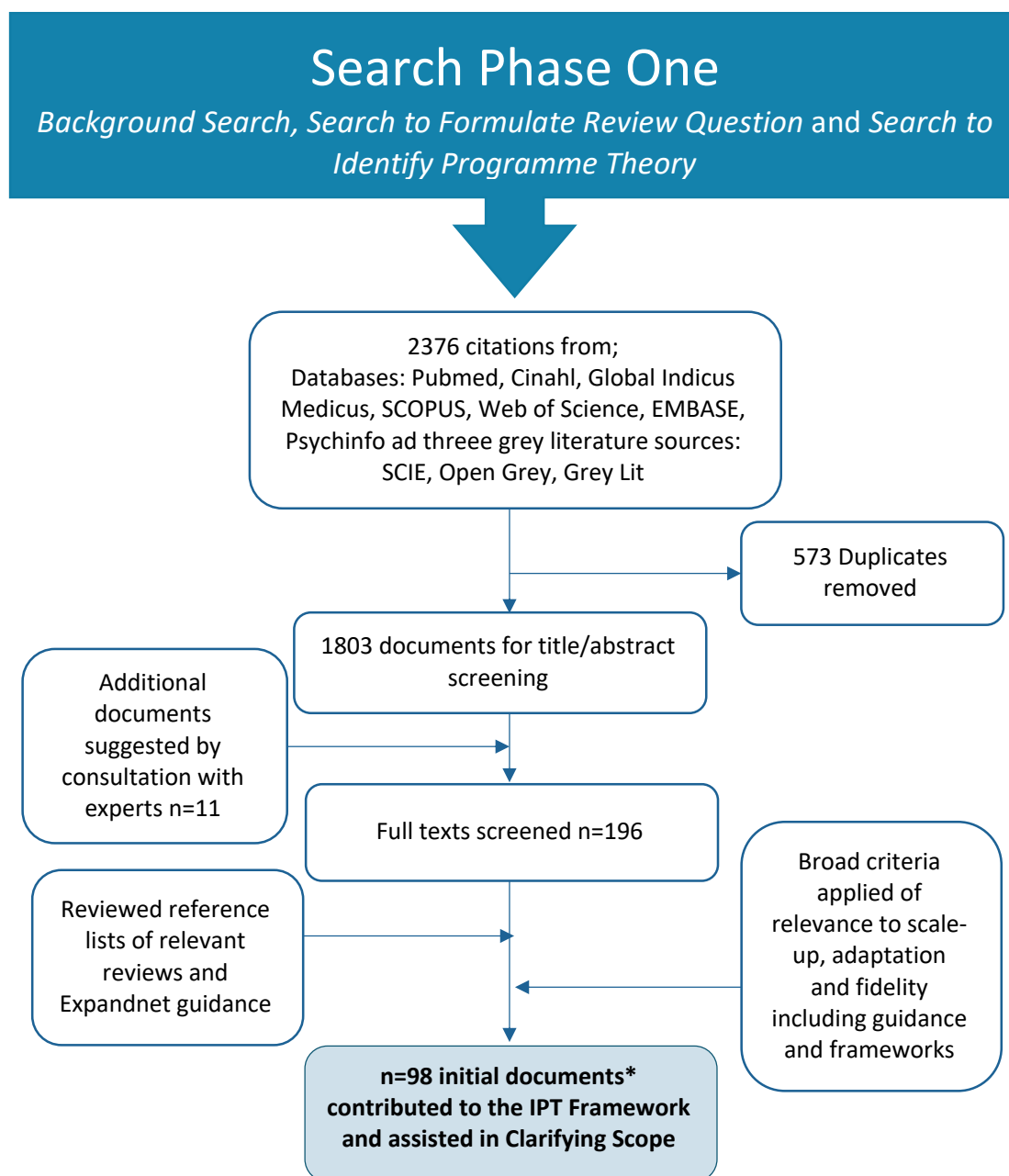


Figure 4.3 Overview of databases screened and search results.

*Documents which contributed to IPT framework & clarifying scope are referenced in Appendix D

The guidance and frameworks identified through this initial background search can be seen in Table 4.2 below. These were examined collectively and some potential key actions of relevance to adaptation and scale-up were identified across the fidelity and adaptation guidance documents and are presented in Section 4.2.1.1. Following this, a number of the dominant scale-up guidance and frameworks are individually discussed in greater detail (Section 4.2.1.2). Furthermore, the scale-up

guidance and framework literature was collectively examined for any key actions on how to make adaptations when scaling-up and these findings are presented in Section 4.2.1.3. Wider implementation literature, with relevant mechanisms (Section 4.2.1.3) and theory (Section 4.2.1.4) for scale-up and adaptations are then identified and discussed. The literature presented was then used to guide and inform the development of the initial research question and to inform IPT framework, which are presented in Sections 4.2.2 and 4.2.3.

Table 4.2 Guidance and Frameworks which informed the IPT Framework

Guidance and Frameworks Identified which informed the IPT Framework	
Adaptation and Fidelity	• ADAPT MAP draft guidance for adapting HIV interventions (54) • ADAPT-ITT model for adapting EBI for HIV (114) • ADAPTE guidelines (168) • Bauman's parameters for consideration in intervention development (75) • Carroll's conceptual framework for implementation fidelity (101) • Comprehensive intervention fidelity guide (165) • Contextualised Interventions (55) • Elements to consider in cultural programme adaptation (58) • Fidelity variation concepts from ASSIST RCT (61) • Figuring out fidelity (80) • Finding the balance program fidelity and adaptation in substance abuse prevention (57) • Hasson's modified conceptual framework for implementation fidelity (169) • Intervention mapping to adapt an effective HIV, sexually transmitted disease, and pregnancy prevention programs (120) • Key principles for adapting research based interventions in HIV (110) • Medical Research Council (MRC) guidance for process evaluations (98) • NIH Behaviour Change Consortium (BCC) fidelity concepts (81) • RE-AIM framework (170, 171) • Replicating effective programs (REP) framework (121) • Template for Intervention Description and Replication (TiDiR) guidance (100) • The conceptual framework for adaptive interventions (172) • The modified Carroll's fidelity framework (56)
Scale-Up *	Determinant frameworks • A framework for understanding the constraints of scaling up (123) • Conceptual framework for priority setting in health (127) • Dynamic Sustainability Framework (DSF) (24) • Scaling up health service innovations: a framework for action, ExpandNet (12, 122) • Scaling up; A proposed framework for success (124) • The learning process approach (LPA) (126) • The non-adoption, abandonment, scale-up, spread, and sustainability (NASSS) for patient facing health and care technologies (125) Process Models • A guide to fostering change to scale up effective health services (131) • A guide to scaling up population health interventions (130) • AIDED model for dissemination, diffusion and scale up of family health innovations in LICs (40) • Beginning with the end in mind, ExpandNet (41) • IHI framework for going to full scale (13) • MuSCLE framework (134) • Nine steps for delivering a scale up strategy, ExpandNet (52) • Practical guidance for scaling up health service innovations, ExpandNet (129)

Guidance and Frameworks Identified which informed the IPT Framework	
	• Program assessment guide for scaling up nutrition interventions (132) • Scaling up breastfeeding (133) • Scaling up Management (SUM) Framework (128), updated by (51) • SEED Scale (173) Evaluative Frameworks • Scaling-out (49) Not specific to scale-up but highlighted to be of relevance to implementation and adapting for local context were: • Consolidated Framework For Implementation Research (CFIR) (174, 175) • Implementation Research (IR) Toolkit (147) • Integrated i-PARiHS Framework (176) • Knowledge to action framework (177) • Methods to Improve the Selection and Tailoring of Implementation Strategies (67) • Promoting Action on Research Implementation (PARiHS) Framework (178) • RE-AIM (Reach, Effectiveness, Adoption, Implementation and Maintenance) Framework (170, 171) • Taxonomy of implementation outcomes (179)
Some examples from the wider literature	Some examples of wider literature used to also inform IPT Framework (please note this is not comprehensive and all wider literature for IPT decision making is referenced in Appendix D): • Barriers and facilitators to scale-up, by Norton and Mittman (180) • Diffusions of innovation theory, Rogers (53) • Mechanisms for scale-up by Willis and colleagues (7) and large system transformation in healthcare by Best and colleagues (181)

*Scale-up frameworks are categorised into: determinant frameworks, process models and evaluative frameworks (depending on their primary focus) as per Nilsen (38)

4.2.1.1 Fidelity and Adaptation Guidance and Frameworks

Guidance and frameworks in the field of fidelity and adaptation that were identified and utilised in this study can be seen in Table 4.2 above. It is important to note that none of these are specific to adaptation and scale-up, for example with the guidance in the field of fidelity often developed for intervention design and testing (e.g. Medical Research Council (MRC) guidance for process evaluations (98)), however some elements were deemed of relevance to inform the IPT framework. To note across the identified fidelity guidance there is also no consensus on what fidelity is, and on how to evaluate it, thus it is confusing for those implementing interventions to decide on what to consider and how to measure fidelity when scaling-up. From the guidance and frameworks identified in the field of adaptation most are in the area of substance abuse prevention and HIV behaviour change interventions (35, 54, 57, 110, 114, 120, 121), or focused on cultural adaptation for specific minority groups (28-34, 112, 118, 119). The majority of the guidance is based in HIC settings (28-34, 54, 57, 110, 114, 118-121), with some of this guidance requiring highly skilled, and resource heavy processes (28, 33, 37, 54, 57, 111-116). Additionally, some guidance suggests involving the original intervention developers (57), and at times promoting redesign and testing of the intervention (28, 33, 37, 111, 114, 117), which may not be feasible across multiple diverse sites

when scaling-up. While the target audience is primarily those involved in intervention implementation, the adaptation guidance was also not specific to scale-up.

Despite the above, through examination and comparison of the adaptation and fidelity guidance and frameworks some common actions were seen of relevance to adaptation and scale-up that could be considered by implementers when scaling-up. These actions were: (a) the identification of the theory of the intervention, mechanisms, core components or essential elements, (b) identifying the 'level' of components needed to enact intervention theory (for example the dose), (c) evaluation of fidelity and adaptations to the intervention, (d) gaining knowledge of the local context, (e) involvement of the community/end users in the development or review of adaptations, and (f) use of technical assistance (e.g., having intervention developers review adaptation plans). These will be each be discussed in more detail in below.

4.2.1.1.1 The Identification of the Theory of the Intervention, Mechanisms, Core Components or Essential Elements

Central to both the fidelity and adaptation guidance and frameworks was the concept of identifying the theory of the intervention, mechanisms, core components or elements (28, 33, 35, 54-57, 61, 71, 75, 81, 90, 98, 100, 101, 110, 114, 120, 121, 165, 169, 182-184). However the language used i.e. of intervention theory, mechanisms, core components, elements or internal logic varied within the guidance. Additionally, how to achieve an understanding of intervention and the active ingredients and components also varied between the guidance. An example of a method suggested can be seen in the CSAP guidance (57) where they suggest the use of core component analysis, logic model or intervention developer consultation as a way to deepen understanding of how the intervention works. A number of frameworks and guidance identified were originally developed for evidence-based HIV interventions (54, 114, 121), supported by the Centre for Disease Control (CDC). Here however, the intervention theory and core components were already known thus negating the need to complete further analysis to discover them. The importance of intervention theory, mechanisms, components or essential elements in the literature was discussed in Chapter 2 (Section 2.5). However, and as discussed previously, there is no set criteria for what this entails and ambiguities remain as to whether it relates to the *content* or to the *implementation* of the intervention, or both (97). It is also important to note, that while identifying the theory of the intervention, its' mechanisms, core components or elements was identified as key within the adaptation and fidelity guidance and frameworks, often an interventions' components are not known (115), or are poorly articulated (17), making this step challenging and time consuming for implementers during scale-up (17).

4.2.1.1.2 Identifying the 'Level' of Components Needed to Enact Intervention Theory

Identifying the level of components (e.g., amount, dose) needed to enact an interventions' theory was found across many of the guidance and frameworks (61, 75, 81, 98, 100, 101, 165, 169, 172). For example, Collins et al., (172) proposed the concept of 'adaptive interventions' and the conceptual framework for adaptive preventative interventions to assist in intervention development and adaptation. They suggest that pre-prescribed changes to the intervention should be considered and applied based on an individual's needs. This framework further theorises that treatments may not have the same effects and outcomes on all individuals. Therefore, variables in the intervention (e.g., dose) can be adapted during the testing phases and rules made as to when and how much of an intervention to apply. These rules then form part of the intervention itself. To note this framework focuses on adaptations on an individual recipient level. Collins et al., (172) gives the example of the FastTrack intervention for prevention of conduct disorders among 'at risk children', where some components were given to all participants. Other components, such as reading tutoring, were only given to those children displaying academic difficulties. Additionally, the number of visits to families varied depending on parental functioning. The chosen intervention and 'dosage' was adapted three times a year at pre-determined time points. Results from this study suggest that adaptive interventions may increase compliance, as the intervention may be more suited to the individual, thus reducing negative effects arising from disengagement with programme as elements are seen as irrelevant or intrusive by the recipients, etc. They may also reduce waste as not all elements need to be provided to everyone, thus saving resources and cost. Consideration of the level of each component and whether it is needed may also enhance potency of intervention as interventions are made more specific to individual needs. However, and while considering the need for future adaptation and embedding adaptations within testing is welcome, it is important to note that Collins et al., (172) model centres on an individual's need and may therefore be less relevant for population-based adaptation. Collins et al., (172) model also involves a complex RCT design to test the different dosages and rules, which may not be feasible for all interventions.

4.2.1.1.3 Evaluation of Fidelity and Adaptations to the Intervention

Within the guidance two key actions relating to evaluation were seen. Firstly, the need to evaluate and consider elements affecting fidelity to the interventions theory, mechanisms, core components or essential elements (56, 61, 81, 100, 101, 165, 169, 171, 172, 185). This was primarily seen in the fidelity guidance (56, 61, 81, 100, 101, 165, 169, 171, 172, 185). Secondly, the need to evaluate the effectiveness of adaptations made. This was primarily seen in the adaptation guidance (28, 37, 54-56, 61, 90, 98, 100, 110, 113, 117, 119-121, 171, 172, 182, 183, 186).

An example of guidance for evaluation of fidelity includes the MRC UK evaluative framework for

process evaluations of trials for interventions (98), which promotes looking at *what* was delivered in practice including: fidelity, dose, adaptations and reach. Further to this, Gearing et al., (165) developed the comprehensive intervention fidelity guide to identify the key components of fidelity, their characteristics, and to provide guidance to researchers on how to measure fidelity. Specifically, they propose that the key components of fidelity include design, training, intervention delivery, and intervention receipt. They further suggest items to enhance fidelity in each of these areas such as training protocols, details of intervention components, participant adherence and potential threats. Similarly, Carroll's conceptual framework for implementation fidelity (101) proposes that in addition to the evaluation of outcomes to explore 'adherence', which includes details of content, coverage, frequency and duration, 'moderators', such as facilitation strategies, should also be evaluated. In addition, the TiDieR reporting guidance (100) was developed to promote clarity and specificity in reporting of the intervention rationale and theory, what was carried out, who provided it, how this was done and in what setting. This reporting guidance further includes consideration and reporting of whether intervention fidelity was measured and whether fidelity was maintained (100). However, as discussed in Chapter 2, Section 2.4, there is no agreement on what constitutes fidelity. Therefore, and while existing guidance frequently mentions the need to evaluate fidelity, there is currently no consensus on what to measure and how to measure it (89). Additionally it is important to note that the above guidance is not specific to scale-up where fidelity assessments may not be feasible or cost-effective use of resources.

Evaluating the effectiveness of adaptations was seen across numerous frameworks (28, 37, 54-56, 61, 90, 98, 100, 110, 113, 117, 119-121, 171, 172, 182, 183, 186). For example, the suggested steps of the ADAPT MAP model (54) specify the use of built-in feedback loops and checkpoints, advocating for formative research and evaluation throughout the assess, select and prepare stages, and ongoing outcome monitoring and evaluation in the pilot and implementation phases. Throughout all phases, the ADAPT MAP model further advocates for process monitoring and evaluation, supervision, and quality assurance. Likewise, the key principles for adapting interventions relating to HIV guidance by Solomon et al., (110) also emphasises the importance of documenting and evaluating the adaptation process. Similarly, with Tortolero (120) and their intervention mapping for adaptation of evidence based interventions in the field of HIV, STIs and pregnancy prevention programs suggests that the next stage after adaptation of the intervention is considerations for evaluation and whether the evaluation measures are relevant for the population and intervention objectives. Finally, the Replicating Effective Programs (REP) framework (121) for HIV interventions for use in community non-academic settings (121) also promotes evaluation in the third implementation phase. Taken together, the above suggests that the need to evaluate adaptations, which could include embedding feedback loops, was identified across a

number of guidance materials. The considerations for when evaluation was needed and the timepoints to embed evaluations of adaptations however, (i.e. piloting vs later stages of implementation) varied across the guidance. Thus it remains unclear for implementers as when may be best to carry out this step and where and when to direct resources towards these evaluations. Additionally these evaluations must consider the capacity and resources available in local sites when scaling-up.

4.2.1.1.4 Gaining Knowledge of the Local Context

The need to gain knowledge and understand the local setting, including the population group and their needs was frequently suggested across existing guidance and frameworks (28-30, 35, 37, 55-57, 71, 75, 90, 98, 101, 110, 113, 115, 117, 119-121, 169, 182, 186-189). For example, in the parameters for consideration in intervention development by Bauman et al., (75) propose that a programme interaction with implementation parameters in the local setting is an important consideration. Suggested implementation parameters to assess include: site characteristics (e.g., features of human resources for health (HRH) or organisation that may affect implementation), the political and social context, and population characteristics. Hasson (169) built upon Bauman's parameters in their modified conceptual framework for implementation fidelity, adding two further moderating factors to Carroll's conceptual framework for implementation fidelity (101), the effect of context and of recruitment. Likewise, Pérez et al., (56) with their more recent modified Carroll's framework for implementation fidelity, propose the need to have a clear idea of expected outcomes and theory of how the intervention will work. In addition to this, Pérez et al., (56) model includes the evaluation of setting (or situation) specific moderators, which are similar to the idea of context moderators presented in Hasson's framework (169). Another example of a framework recognising the importance of context and its role in shaping intervention theory and assumptions is the MRC evaluative framework for process evaluations of trials for interventions (98). Specifically, this latter framework discusses a need for the identification of contextual factors that may affect implementation, the intervention, its mechanism, and/or outcomes. Thus, across numerous fidelity guidance there is a recognition of the importance of the context and how it may affect the implementation fidelity and intervention effectiveness.

Further to this, selection of the intervention based on local needs i.e., selecting the intervention that would be best fit and therefore may have less need for adaptation, was also identified as a commonality across frameworks (54, 110, 114, 120, 121). For example, the ADAPT-MAP guidance for HIV intervention adaptation by McKleroy et al., (54) suggests five steps for adaptation which include 'assess' to look at the fit of the intervention for the local setting for example its fit with the target population and organisational capacity. Another step, 'select' refers to deciding whether to

adopt, adapt, or select another intervention. This includes consultations with communities and experts to determine what changes need to be made within selected interventions. Similarly, the ADAPT-ITT model (114), which followed this guidance, consists of eight sequential phases. The first phase suggests assessment to find out who is the target population and what are the needs, risk factors, and behavioural characteristics relating to HIV within this population group. The ADAPT-ITT model suggests this first phase can be completed through formative research, including focus groups and interviews with the target population and other key stakeholders. Once this is complete EBIs most relevant are selected and a decision made on whether to adopt or adapt the HIV EBI. Thus it is suggested that taking time to match the intervention to the setting may reduce or negate the need for multiple future adaptations, however with the multiple heterogeneous sites encountered during scale-up this may be challenging to complete in this context with no one intervention matching all sites.

Solomon et al., (110) also discuss key principles for adapting interventions, again relating to HIV. These include: knowing the target population and community context, selecting the programme which best matches population and context, retaining fidelity to the core programme, and documenting and evaluating the adaptation process. The authors also note that while there are multiple value sets that will be shared across population groups, these are not necessarily shared by all, and stress the importance of not oversimplifying culture with it being viewed as a race or ethnicity. Further to this, Tortolero (120) proposes the concept of intervention mapping for adaptation of evidence based interventions in the field of HIV, STIs and pregnancy prevention programmes – which encourages reviewing the literature to demonstrate what has worked in previous settings. Following a needs assessment of the new population, Tortolero (120) suggest that intervention implementers should review key outcomes, determinants, and objectives. This includes reviewing behavioural outcomes (for this population group), specifying performance objectives for the specific and determinants for this population, along with the development of proximal programme objectives. Tortolero (120) further promotes identifying the theoretical foundation of the intervention, selecting methods and strategies, and developing programme content based on these new population determinants and objectives. Similarly, the Replicating Effective Programs (REP) framework (121), developed by the CDC for HIV interventions for use in community non-academic settings (121), also promotes the importance of identifying pre-conditions (need, target population, suitable interventions), including through the use of community needs assessment. However, this guidance is primarily focused on adaptations for minority groups within a wider population and is designed for use within primarily HIC contexts. Thus use of the REP framework for wider population adaptations, or for within LMIC settings, where resources are limited, is unknown. While some guidance was developed for community-based, non-

academic settings (e.g. the REP framework), the majority involve resource-heavy processes that may not be feasible across multiple scale-up sites.

4.2.1.1.5 Involvement of the Community/End Users in Development or Review of Adaptations

Participation of the community and/or end users was central to many of the guidance and frameworks (29, 37, 54, 57, 90, 113-115, 119, 121, 168, 186). However, the stage wherein this involvement is suggested, or the format this takes, varies across guidance and frameworks. For example, early in the process the ADAPT-ITT model (114) supports putting the original EBI to the target group in the form of a “theater test”, which has also been used in marketing research. The EBI is presented to the target population and reactions and feedback are recorded through open and closed survey questions which are then analysed. It suggests using this approach as it is time sensitive. Likewise, the ADAPT MAP draft guidance (54) also suggests early participation with community and expert consultations to select and determine what change(s) need to be made to selected interventions. The REP framework (121) suggests involvement of the community for input in the pre-implementation and planning phase. The CSAP guidance (57) also suggests taking plans to the community for feedback to assess for feasibility, acceptability, build support and highlight any barriers to implementation at a later stage, after reviewing plans with the programme developer. However Chen et al., (115) advocate that more specific guidance is needed for implementers if recipient input is to be used, and describe the importance of recipients having some prior exposure to the EBI before it is adapted in order to make judgements on what may need to be changed. An example of this, as outlined by Kumpfer et al., (186) is the use of weekly feedback gathered from recipients throughout implementation to allow for continuous adaptation during piloting, which would be later evaluated. Taken together, and while the inclusion of community and end users was commonly suggested, when and how to include end users varied across guidance and frameworks.

The ADAPTE guidelines (168) provide a resource for adapting guidelines to the context in which an intervention will be delivered, instead of de novo (from scratch guidelines development). The ADAPTE guidance recommends involving participants who will be affected by the guidelines at later stages through their inclusion in feedback in the finalisation phase. While the ADAPTE guidance and attention to the need for adaptation is welcome, it is important to note that the ADAPTE guidance is specific to guideline adaptation and not guidance for active implementation. Guidelines can often be poorly implemented and with active deliberate activities also required (12, 190). The lack of focus on guideline implementation was identified as a failing in the original ADAPTE guidance (191). Accordingly, Amer et al., (191) at the Alexandria Centre for Evidence Based Clinical Practice

Guidelines (CPG) built on the ADAPTE guidance to include a section for dissemination and implementation considerations. This added the consideration of dissemination and implementation strategies and use of implementation tools: including monitoring and evaluation, action plans and organisational interventions. Further adding to the ADAPTE guidance, Gagliardi et al., (190) developed a checklist to support those implementing guidelines including which elements to consider and suggested tools. Gagliardi et al., (190) version further includes considerations for the dissemination and implementation strategies, based on local needs, along with what barriers may be present, as well as considerations for the development of an implementation plan for the guideline.

4.2.1.1.6 Use of Technical Assistance

Use of technical assistance (e.g., getting intervention developers to review adaptation plans) was also discussed across several frameworks and guidance documents (37, 54, 57, 113, 114, 182, 183). For example, the CSAP guidance (57) noted as one of six stages, if available, to get technical assistance and review plans and/or changes with the programme developer. Here, the programme developer could also assist in identification of intervention theory or core component, if previously unknown (57). The ADAPT MAP draft guidance (54) also suggest early expert consultations to select and determine what changes are needed for a selected intervention. Likewise, the ADAPT-ITT guidance (114), developed following the ADAPT-MAP model (54), for use by HIV intervention providers (i.e., CBOs), also suggest use of technical assistance. Specifically, the fifth phase of the ADAPT-ITT guidance suggest involvement of topical experts for their input into the adapted EBI plans.

While technical assistance was identified as a commonality across guidelines and frameworks, it is important to note that use of technical experts or original intervention developers may not be feasible across multiple diverse sites when scaling-up. The ADAPT MAP model (192) was put to practice in the adaptation of the HIV 'Community PROMISE' intervention in two CBOs for use among a target population of HIV positive African American men who have sex with men (MSM) in Boston and Minneapolis-St.Paul, USA, in partnership with a research organisation (192). While the CBOs reported that the ADAPT MAP model was helpful in guiding the adaptation process, they also reported a number of challenges. For example, they reported that the assess section contained insufficient information on how to understand the EBIs. In this case, the CBOS had contact with the original developers to clarify issues, however this may not be the case for other interventions in the future. CBOs also had the support of research institutions, without which the MAP guidance may not have been as effective due to its complexity and time needed to complete. Thus, technical

assistance for adaptations in scale-up may not be possible if there are no links with the original intervention developers or support of a research institution for local sites.

In summary, despite a number of common actions and overlap present within existing fidelity and adaptation guidance and frameworks, including the importance of identifying intervention theory and intervention components, there was also a lot of variation and not all guidance mentioned all of the common actions identified. Therefore, and while the above guidance can provide implementers with some structure on how to adapt interventions for local fit when scaling-up, several gaps in knowledge remain. Specifically, there is no clear agreement of what and when to take each action. For example, in the identified action of evaluating adaptations there was variance in what and how to evaluate, and at what timepoints during the implementation process. Additionally, much of the above guidance is focused and tested within HIV and substance abuse prevention interventions (35, 54, 57, 110, 114, 120, 121), or focused on cultural adaptations for minority groups in a HIC setting (28-34, 112, 118, 119), calling into question the applicability the guidance outside of these settings. The guidance was also not specific to scale-up, which faces many challenges including multiple heterogeneous sites and differing resources and capacity for implementation, evaluations and adaptations. Furthermore, much of the guidance suggested a resource heavy and skilled process (28, 33, 37, 54, 57, 111-116), including engaging with original intervention developers, which may be difficult to carry out across the multiple local sites required in scaling-up. Thus, further exploration and guidance on how to scale up-and carry out adaptations within these circumstances, to embed adaptations in a thoughtful and effective way within the complexity of scale-up is warranted.

4.2.1.2 Scale-Up Guidance and Frameworks

Guidance and frameworks relevant for adaptation and scale-up were also identified in the background search however given the volume of implementation guidance and frameworks, Nilsen's categorisation was used to organise this literature. Nilsen (38) categorised implementation theories and frameworks into: process models, determinant frameworks, evaluation frameworks, classic theories, and implementation theories. Process models (also called process frameworks) focus on guiding or describing the process or steps of implementation. Determinant frameworks identify factors that may influence implementation, whereby factors can be categories or domains. According to Nilsen, determinant frameworks are not meant to show causal links and therefore are not theories, but rather are intended to assist in guiding explanation. Evaluation frameworks can be used to structure the evaluation of implementation. Classic theories can be from any discipline, for example behavioural sciences theories, and then applied to implementation, whereas implementation theories are specific to elements relating to implementation (e.g. organisational

readiness). Further to the above, many guidance and frameworks not specific to scale-up were also identified from the field of implementation as relevant to scale-up and adapting for local context. The guidance and frameworks for scale-up and implementation relevant to adaptation utilised in this study were presented in Table 4.2 above. A number of these scale-up guidance and frameworks are discussed in greater detail below (Sections 4.2.1.2.1 - 4.2.1.2.7). Following examination and comparison of the above scale-up and implementation guidance and frameworks, key common actions in relation to adaptation and scale-up were identified and are discussed in Section 4.2.1.3 below.

4.2.1.2.1 ExpandNet

ExpandNet is a WHO led global network founded in 2003 to expand the practice and science for scale-up (167). As part of this initiative, they have developed multiple guidance documents for the purpose of scale-up, ranging from the determinant framework of 'scaling up health service innovations: a framework for action' (12, 122) in 2007; to process models such as the 'strategic approach for scaling-up reproductive and family health interventions' (122), 'practical guidance for scaling up health service innovations' (129), 'nine steps for delivering a scale up strategy' (52) and 'beginning with the end in mind' (41), developed in 2007, 2009, 2010, and 2011, respectively. The initial guidance of 'scaling up health service innovations: a framework for action' (12) highlights the key elements affecting scale-up of (i) the innovation itself, (ii) the resource team of those involved in development, testing or promoting use of the intervention, and (iii) the user organisation of those adopting the intervention. This guidance suggests they are all encompassed by the wider environment including policy, bureaucracy, the health sector, sociocultural context, and people's needs and rights. The guidance further highlights the choices to be considered in the scale-up strategy, including the type of scale up, organisational choices (e.g., participatory or top down/expert driven), costs and resource mobilisation, dissemination, and how to monitor and evaluate the scale-up and intervention outcomes. The ExpandNet 'scaling up health service innovations: a framework for action' (12) can be used as part of the 'strategic approach for scaling-up reproductive and family health interventions' (122), which was also developed in 2007 and provides steps to follow including three stages of (i) strategic assessment, (ii) developing and testing the interventions, and (iii) scaling up the successful intervention. It proposes these steps are done through a staged implementation process, use of a systems framework to highlight relevant factors, a rights-based approach to reproductive health, a focus on equitable access and quality, a participatory process with stakeholders, and country ownership of process and results.

The 'practical guidance for scaling up health service innovations' (129), 'nine steps to delivering a scale-up strategy' (52) and 'beginning with the end in mind' (41) scale-up guidance were also

developed by ExpandNet to provide support on processes of scale-up. The ‘practical guidance for scaling up health service innovations’ (129) provides suggested steps for the addressing the concepts identified in the original framework. In addition to this practical guidance, a process framework nine steps for developing a scaling up strategy was developed to provide a step-by-step guide towards the development of a scaling-up strategy (52), including four overarching principles to help enact the ExpandNet ‘scaling up health service innovations: framework for action’ (12, 122) and to achieve successful scale-up. Overarching principles include use of systems thinking; a focus on sustainability; enhancing scalability by use of the attributes to success previously identified in the framework for action; and respect for human rights, equity and gender. The ‘beginning with the end in mind guidance’ (41) was developed to provide those piloting and testing interventions with steps to take to increase the chances of successful future scale-up. These build on concepts in the ExpandNet scaling-up health innovations framework. Suggested steps include: using a participatory process, ensuring relevance of the intervention, expectation setting among stakeholders, testing under different contexts and routine resources. A strength of the ExpandNet guidance is therefore that it provides both determinant frameworks and process models to follow, and within the scale-up field, could be considered one of the more comprehensive forms of guidance for implementers. It also has specific guidance for those piloting and testing interventions to address future scale-up, along with guidance for those completing scale-up itself. However, it is focused on scale-up more generally and is not specific to scale-up and adaptation. Moreover, and while ExpandNet recognises the need for local fit, it does not give specific adaptation steps and guidance during the course of scale-up, with guidance being focused on changes during piloting and testing, such as in the ‘beginning with the end in mind guidance’ (41). Another limitation stems from its development in the field of Sexual and Reproductive Health (SRH), and therefore several examples given lessons learned focus on SRH-related issues such as cultural acceptability, which may not be relevant to all scale-up projects.

4.2.1.2.2 AIDED Model

Developed in 2012 by Bradley et al., (40) the AIDED model is another process model for scale-up. The AIDED model explores dissemination and diffusion for scale-up in the field of maternal and reproductive health, with a focus on LMIC contexts. Within this model there are five non-linear steps: (i) assess, (ii) innovate, (iii) develop, (iv) engage, and (v) devolve. The ‘innovate’ step relates to adaptation for local context. This includes redesigning and packaging of interventions so that the user groups will engage with the intervention and view them as relevant and advantageous within their context. This also includes consideration for what Bradley et al. call “non-technical” aspects of an innovation, including HRH etc. This stage encourages user engagement to ensure matching of the user needs and the innovation (40) and promotes local devolvment of the intervention for

sustainability. The simplicity of this model could be argued as both a strength and a weakness for implementers. The five steps appear simple and are therefore appealing, however there is little guidance on how to complete them, and so lacks some of the specificity seen in the ExpandNet guidance above. Another drawback of this model is that while it promotes devolvement for sustainability, it does not have specific steps for consideration of ongoing sustainability of local fit following initial adaptation, and at time of development had yet to be empirically tested.

4.2.1.2.3 A Guide to Fostering Change to Scale up Effective Health services

A third process model is the guide to fostering change to scale-up effective health services, developed by the WHO (131) in 2013. Focused on achieving buy-in and support in local contexts for an intervention and implementation, the guidance is heavily underpinned by theory of change. The guide also contains suggested key clusters for consideration, which include the characteristics of the potential adopter, perceptions of the innovation and contextual factors. It uses Rogers' diffusion of innovations theory (53) to explore perceptions of innovation and suggests the need to consider whether an intervention is credible, observable, relevant, relative advantage, ease of transfer, compatible and testable.

To identify characteristics of potential adopters, the guide highlights the need to consider who is affected and will be involved with the intervention, what would their perceptions be, and how their perceptions could be addressed. This guidance further highlights recognising the response of potential adopters (e.g. denial, commitment, exploration or resistance), and how to mitigate or enhance these responses. For denial, they discuss that people often do not want to change what is familiar and suggest mitigating this by providing clear information on when and how the change will take place and to offer coping mechanisms. For resistance, for example that people may question future success of the intervention and worry about their job and coping with change, the guidance proposes to mitigate this by creating opportunities for people to express any anxieties and listen to concerns. The authors maintain that the supporting and persuading people is aided by showing respect for feelings over defensiveness, and that creating networks of people to support change and listen to concerns may alter levels of resistance. To support exploration, the authors suggest giving people the opportunity to express any concerns, such that they are more likely to engage with exploring change. Use of a change agent to support people in discovering how they may enact change and involving the change agent in planning, providing any required training and goal setting, may also assist. According to this guidance, commitment is most likely to occur when people can see the potential benefits of the change. Once acceptance occurs, they may be more likely to commit, allowing for less hands-on management and allowing people to manage themselves, with support as needed.

For the creation of a supportive context the guidance applies the principles that: change must matter to those making it, a change agent is vital, support of a change agent gives the change agent legitimacy and confidence, change most likely succeeds when leadership is present at all levels support, the benefits are clear, and staff must be motivated and supported through the change process. In order to complete the change process the guidance proposes a clear definition of the team, a definition of the problem, change needed, its purpose and expected outcomes. Following this, the guidance outlines the need to plan for demonstration and scale-up through use of change agents and monitoring at test sites, creation of a supportive environment, and evaluation and consolidation of demonstration site outcomes prior to going to full scale to decide if the practice warrants scale-up. If the choice to scale-up is made, the guide promotes using a participatory process. A strength of this guidance is that it recognises the need for local fit and buy-in for an intervention and implementation and emphasises a participatory process to achieve this. However, it is not focused on specific steps to adapt an intervention, but rather it is focused on how to develop buy-in and support. For example, the guidance has a step to “choose and adapt a proven practice that is appropriate for the service delivery context and the needed change.” (p17), there is no specific guidance within this step relating to how to adapt, and it appears more focused on selecting an appropriate intervention for the setting over adapting one. Thus it leaves busy implementers without specific guidance on how to complete this and may lead to ad-hoc adaptations.

4.2.1.2.4 Dynamic Sustainability Framework

Published in 2013, the Dynamic Sustainability Framework (DSF) (24) identifies that change is constantly happening with the need for intervention, practice setting, and broader ecological system fit at different time points. Therefore it supports ongoing data gathering, evaluation and decisions based on this data. Adaptation is seen as inevitable and encouraged, while guided by evidence. The DSF suggests that a static intervention which is ‘optimised’ at outset will not have ongoing fit within dynamic changing contexts. A key strength of this framework is that while looking at scale-up it also focuses on long-term sustainability following a high-resource implementation phase. Specifically, it highlights the final stage of implementation as institutionalisation, where new practice becomes usual care. Another strength is the recognition of adaptation and the need to address fit of intervention within the context, as key for this to occur. However, whether this focus on ongoing need for local fit is happening in practice needs to be considered. For example, a review of psychological interventions over ten years by Prowse and Nagel (86) found the concept of ongoing fidelity overtime was found to be rarely mentioned or assessed in practice. Therefore, the DSF could be considered to be aspirational. This framework could be also considered as primarily a

determinant framework, identifying factors to consider (i.e., the practice settings and broader ecological fit), as opposed to providing specific actions or steps to achieve adaptations. To compare with the ExpandNet frameworks above, a strength of ExpandNet is the volume of guidance for both determinants and process. However, from an adaptation perspective, ExpandNet lacks the focus on the need for ongoing local fit, and how needs may change over time, which the DSF promotes.

4.2.1.2.5 IHI Framework for Going to Full Scale

A further framework, the IHI Framework for Going to Full Scale (13), was developed in 2016 and combined several previous frameworks and theories (13). It describes one of its three main components as articulating contextual and environmental factors that will allow for scale up, recommending a formative exploration of context. It proposes identifying a 'scalable unit' as its own microsystem that is replicated or adapted multiple times to take an innovation to scale. The IHI framework also recommends an embedded adaptive design at each stage to learn and fit to diverse contexts as scale up occurs. There are four steps in this framework. 'Set-up', which includes initial testing and entry point. In this stage the purpose is to provide clear outline of what is intended for scale, with early adopters and champions identified. 'Develop a scalable unit', or a subsystem of the wider scale aiming to be representative. In this stage, the purpose is to test local ideas and generate context-sensitive strategies (in the form of a change package). Context sensitive strategies will be further refined in broader scale-up through further Plan-Do-Study-Act (PDSA) cycles. During 'test of scale-up', these context sensitive strategies (in the form of change packages) are tested at wider range, HRH capacity is built, and monitoring and evaluation and supply chain systems are tested. In the final stage, 'going to full scale', wide scale implementation occurs, including use of reliable data feedback systems and focusing on replication while allowing for some adaptation. Strengths of this framework include the suggested practical methods that can be used to achieve each stage (e.g. via site visits, QI methods). The framework further promotes knowledge sharing between sites and the use of change packages to support already tested changes from similar contexts, thus reducing the need for new innovation and adaptation across more sites. It was also developed through both a literature review and experience in South Africa and Ghana. However, the experiences used were based on projects which had significant IHI support and at times used resource heavy approaches such as a Breakthrough Series Model (BTS), which sets up and supports learning collaboratives and needs to build capacity at local sites for use of QI methods. Therefore, a potential weakness is the utility of aspects of this framework in the absence of additional resources, for example external partners for technical support, in future scale-up projects which needs to be considered. Additionally, the framework relies on there being some universality of context and homogeneity between sites (193), with changes in past sites being relevant and useful

for future ones, which may not always be the case where there are high levels of context heterogeneity (193).

4.2.1.2.6 Methods to Improve the Selection and Tailoring of Implementation Strategies

In 2017, Powell and colleagues (67) suggested four actions for the tailoring of implementation strategies which included concept mapping, intervention mapping, conjoint analysis, and group model building. All methods are participatory and involve creating a shared vision, or consensus building. A benefit of these suggested actions is the transparency of their approach, as well as allowing and accounting for the complexity of implementation. However, it is apparent these actions were not specific to scale-up, as these methods all involve resources that may not be available at multiple local scale-up sites. For example, some of these actions would require specialist skill sets to complete, including complex statistical modelling. To note, these actions are mainly untested approaches for tailoring for implementation strategies and are not specific for adapting the intervention content itself, so their utility in practice for adaptation of health interventions during scale-up remains unknown.

4.2.1.2.7 Scaling-Out

The concept of 'scaling-out' and the resultant framework was proposed by Aarons et al., (49) and could, along with the DSF, be argued to be one of the first to truly combine scale-up and adaptation within a single framework. It suggests that adaptation of EBIs can be required when the intervention is introduced to new populations or new delivery systems, or in some cases both. Built on the commonalities across the Exploration, Preparation, Implementation, Sustainment (EPIS) framework, the DSF and the Consolidated Framework for Implementation Research (CFIR), scaling-out identifies that an EBI is influenced by the delivery system, population, and community setting. The framework further maintains that an understanding of causal mediating mechanisms, and how and why they cause effect, may assist in adaptation and implementation across diverse settings. Use of this framework involves the assumption of knowing the intervention's core elements, along with the causal mechanisms of actions of these elements and an assumption that these will remain the same in each context. As mentioned previously often these core elements in reality are not known or can be poorly described (80). This is in addition to having a delivery system with enough support to deliver the intervention as intended to sufficient population numbers.

The evaluative domains for consideration with the scaling-out framework are implementation fidelity, intervention fidelity, uptake, proximal and distal outcomes. Aarons et al., (49) propose four levels of evidence depending on the level of adaptation needed for the setting. Level 0 would develop and consider minimal new evidence and assume the intervention would be delivered as

intended by the original trial, thus resting proof of efficacy with the original study. Level one would involve proxy indicators of implementation based on the RE-AIM framework of intervention fidelity, implementation fidelity, reach and exposure, sustainment and adoption and effect on health outcome. Level two would involve a more considered evaluation of indicators to ensure the theory, mechanism and mediators work in the setting. Level three would be the need for a new randomised empirical study. Aarons et al., (49) also suggest domains that would need to be considered as a mediating model, with the clinical intervention situated in the delivery system and wider context, which includes the population and community. These domains include the evaluation of intervention fidelity (relating to programme content etc.), implementation fidelity (in terms of supervision, training etc.), uptake by the population, proximal outcomes (e.g. behaviour change which could be parents feeding practices) and distal outcomes (e.g. nutritional health outcomes in the child). They further advocate that if causal assumptions hold (from original empirical research) that full assessments (e.g. distal health outcomes) may not be required if the proximal outcome has been achieved. These causal assumptions could hold if the context contains the relevant properties relating to that causal assumption. Scaling-out could be considered to be primarily an evaluative framework providing guidance to implementers on when a new evaluation is required after an adaptation is made. However, its purpose is not to provide prescriptive steps for making these adaptations in the first place, and as a result there is a remaining gap in the scale-up literature for specific steps or actions. The scaling-out framework also works off an assumption that the intervention theory or core components are known and well-described, which in practice is often not the case (17, 115). Despite this, this framework provides a key piece of knowledge for when a new evaluation may be required.

4.2.1.2.8 Previous Reviews of Scale-up

From the above guidance for scale-up, many promote the need for local fit. However, for implementers looking at these guidance documents in isolation, and while there are actions and steps to follow for scale-up more generally, there is no specific guidance for how to adapt interventions during scale-up. Further to the above, two reviews of scale-up frameworks were identified by Milat et al., (46) and Subramanian et al., (39). The first, a review of concepts, processes and frameworks for public health interventions for scale-up by Milat et al., (46) identified seven frameworks. Common themes found across the frameworks included understanding the intervention to be scaled (i.e., acceptability, potential reach, and effectiveness); identifying and supporting implementers; selection of appropriate strategies for delivery; understanding and accommodating the adopting community's characteristics; considering the broader socio-political context; the need for use of research and monitoring and evaluation data to inform and feedback into the process (46). The review by Subramanian et al., (39) identified six theoretical models

relevant to scale-up in LMICs scaling-up. A common theme across these theoretical models included that approaches need to be adapted for different contexts rather than assuming a 'one-size-fits-all' approach. The review further suggested that strategies specific to each setting need to be developed with buy-in and involvement from the adopting organisations and communities (39). Some processes identified that may assist scale-up included stakeholder consultation, identification of barriers, ongoing feedback mechanisms to allow for adaption based on needs and use of multiple strategies (39). While these two reviews provide some insights for scale-up, Milat et al., (46) review was based on only on public health interventions and the review by Subramanian et al., (39) focused only on theoretical models in LMICs. Both were focused on scale-up generally and not specifically on actions for adaptations during scale-up, therefore further exploration of commonalities relating to actions for scale-up and adaptation within available guidance is needed.

4.2.1.3 Actions Relating to Adaptations Identified in Scale-up Guidance and Frameworks

A persistent gap in the literature relates to what specific actions can be taken for adaptations during scale-up. As mentioned above, each scale-up guidance explored in isolation offers no clear actions or steps to be taken for adaptations, with guidance being based on scale-up more generally, or, if focused on scale-up and adaptation, are primarily focused on determinants, such is the case of the DSF (24), or are focused on evaluation of scale-up such as the scaling-out framework (49). Therefore, process guidance of actions for adaptation during scale-up is lacking. To address this, the guidance and frameworks identified through the background search (and listed in Table 4.2) were further examined to identify any key actions for adaptations during scale-up. Despite the many common general barriers and facilitators to scale-up across the frameworks, the focus of this research is on *how* adaptations are made for local fit when scaling-up. Therefore, the decision was made to focus on specific *actions for adaptation* during scale-up, rather than to focus on actions that may be more relevant to scale-up more generally. The following actions were identified across the scale-up guidance and frameworks that may be of relevance: (i) creating and using knowledge, (ii) use of feedback loops, (iii) identifying intervention theory and components, (iv) determining intervention fit within the context, (v) providing guidance to sites, (vi) communication, (vii) create opportunities for learning, (viii) participation, (ix) supporting community driven interventions, (x) community based participatory research (CBPR), (xi) local decision making, (xii) considering future adaptations and sustainability, (xiii) systems thinking and (xiv) consideration of resources and capacity building for adaptations. These will be discussed in detail in Sections 4.2.1.3.1 to 4.2.1.3.12 below.

4.2.1.3.1 Creating and Using Knowledge

A number of actions within the scale-up guidance and frameworks considered relevant to adaptation centred around the need to create and use knowledge. The importance of understanding the wider context such as environmental, political and socio-cultural factors (12, 13, 24, 40, 52, 123-127, 129, 133, 134, 147, 174, 176, 194); consideration of attributes relating to the community, or population to which the intervention will be scaled (40, 49, 123-126, 131, 132, 134, 173, 176); organisational factors and needs (12, 24, 41, 49, 51, 52, 123, 126, 127, 129, 131, 132, 134, 147, 174, 194, 195); along with the need to assess the intervention itself, which could include evaluating it under real world resources (129), the intervention effectiveness, feasibility and acceptability (194) and in multiple contexts where the intervention will be scaled was seen (13, 41). For some frameworks, specific approaches were suggested, for example a situational analysis, stakeholder mapping (194), embedding monitoring and evaluation (131, 132), or operations research (132).

The importance of awareness of the wider contextual factors such as environmental, political and socio-cultural came across strongly in the scale-up guidance (12, 13, 24, 40, 41, 52, 123-127, 129, 133, 134, 147, 174, 176, 178, 194). This included highlighting that an assessment of the wider context could span multiple levels from local to global (40). Identified as important was political interest and will, which may affect the scale-up, with a need to look at the political environment, current priorities, integration into government plans and resources in early stages of planning suggested (196). It was also highlighted that political environments can be a challenge, particularly when there is change of leadership, and in areas where leaders may hold more traditional or conservative views (197). In addition to the wider political context, the influence of socio-cultural factors such as local beliefs, values and practices that may influence the intervention and uptake was noted (133). For example, the scaling up breastfeeding guidance (133) suggested completing formative research to gain an in-depth understanding of the specific contextual factors that may directly affect the intervention, such as HIV and breastfeeding (133). Therefore, the importance of the wider context can be seen throughout these frameworks with the need to understand the policies, resources and socio-cultural factors that may influence the need to adapt the intervention (41, 129). This also needs to be considered over time as political will and contexts can change, affecting scale-up and sustainability (24).

The importance of considering attributes relating to the community, or population to which the intervention will be scaled, was made by numerous frameworks (40, 49, 123-126, 131, 132, 134, 173, 176). Attributes could be related to the specific needs of the community (40, 126), the values and beliefs within the community (176) and/or the capacity of the community or the individual to

implement the intervention (125, 173, 176), or express their needs (126). Placing value on those who know the context was also highlighted (124, 126, 132), with an engaged and active community where the community are seen at the experts, identified as a success factor (124). Thus, learning about community needs, values and beliefs may be an important consideration for implementers.

Specific characteristics of the adopting organisations that were frequently highlighted include: capacity of the organisation to implement the intervention (12, 13, 24, 52, 123-126, 129, 174, 194); leadership (12, 13, 123-127, 174, 176, 178); supervision (24, 123, 133); and infrastructure and resource availability (12, 13, 24, 123, 125-127, 132, 174, 176, 178). The need to assess and consider the delivery system (24, 49, 123, 127, 132), which could include logistical issues such as transport and cold chain storage, presence of health facilities etc., was also found (123, 127). In addition to consideration of the capacity and infrastructure, the motivation and will of the adopting organisation was also highlighted as needing to be considered, with the perception of the need or value of the intervention by the adopting implementers frequently noted (12, 40, 125, 126, 174). Thus, assessment of the organisational capacity, delivery system, and motivation may all need to be considered at multiple sites where an intervention is to be scaled, as potential adaptations and strengthening of organisations may be required depending on needs identified (51, 194).

The need to assess the intervention itself was also highlighted, which could include assessing under real world resources (129), its outcomes, feasibility and acceptability (194) and in multiple contexts where it will be scaled (13, 41). One of the key pieces of guidance available relating to scale-up, adaptation, and intervention evaluation was the recent scaling-out framework (49). As mentioned previously, this evaluative framework suggests criteria for when new evaluations of the intervention may be needed for new populations or delivery systems. This framework also proposes that a fidelity assessment for the implementation process and intervention may need to be completed, however details of how to approach such a fidelity assessment is not given (49). A framework which provided some process guidance for assessment was the IHI framework for going to full scale (13). The testing of local ideas was emphasised, as was the development of context-specific strategies that could be tested and further shared with local sites through learning networks and change packages. However, and as noted in the wider implementation literature, assessment of adaptations may not be frequently occurring in practice (198). For example, a study of 40 scaled-up public health interventions by Indig et al., (198) found only 55% were comprehensive in developing and using evidence for their setting. The study further notes that there is often pressure to scale rapidly before evidence is produced, with one-in-four examples moving straight from development to full scale-up. This pressure to scale rapidly was also reported in the ExpandNet guidance (12), with there often being inadequate time for planning and building

capacity. Thus, guidance which promotes ongoing assessments may be aspirational for many scale-up projects and sites.

4.2.1.3.2 Feedback Loops

Ongoing assessment (24) and the embedding of feedback loops was discussed in several frameworks (24, 51, 131-133, 194). Feedback loops can assist in creating and using knowledge by the embedding of mechanisms to assess the context, the intervention and any changes made over time. A suggested specific action for this could include the Knowledge To Action (KTA) framework (199) which is in itself a feedback cycle where actions are selected, adapted and tested and their sustained use or further adaptation determined through evaluation. Other specific actions which were reported included embedding of monitoring and evaluation mechanisms (131, 133) and use of QI methods such as use of Plan-Do-Study-Act (PDSA) cycles (13). The DSF (24) also noted that ongoing learning and feedback is essential for future adaptations and sustainability, with feedback needing to be both practical and relevant. Embedding of feedback loops is a way that this can be achieved, however there was no one process suggested to follow within the frameworks to support this. Some did give guidance on concepts that could be assessed on an ongoing basis, for example the guide to scaling population health services (194) suggest the need to assess performance and efficiency during scale-up including: reach, fidelity, acceptability, cost and delivery to inform programming. Thus, the importance of consideration of multiple factors, on an ongoing basis, through embedded mechanisms can be seen, however what exactly to consider and how to approach it is open to debate.

4.2.1.3.3 Identification of Intervention Theory and Core Components

As discussed above with the adaptation and fidelity guidance in Section 4.2.1.1.1, a few scale-up frameworks also did emphasise the importance of knowing the intervention components in terms of those that are essential and those that are flexible to adaptation (24, 49, 147, 174). This could include using a logic model (147) or the intervention design being guided by programme theory (132) to identify the active components for the setting. The scaling-out framework (49) for example, proposed evaluation of intervention and implementation fidelity for these components, with suggested criteria for when evaluation may be necessary. With the knowledge of intervention theory and components central to its effectiveness coming across so strongly in the fidelity and adaptation literature (Section 4.2.1.1.1), it was surprising that so few scale-up frameworks mentioned or focused on this. A potential factor influencing this may be that often the intervention theory and core components are unknown (17, 115), and therefore unavailable to implementers, or they may be unfeasible to discover without returning to an RCT or full-scale evaluation studies.

4.2.1.3.4 Determining Intervention Fit Within the Context

While the importance of knowing intervention theory and core components was only mentioned by a few guidance and frameworks, a large proportion did recognise and promote the need to consider elements of the intervention and its fit within the context (12, 24, 49, 52, 53, 125, 127, 132, 134, 147, 174, 176, 178, 194). This included considering the resources needed for an intervention (50, 196) and the value of keeping an intervention as simple as possible (41, 50, 194, 196, 200). However, it is important to note that even simple interventions are introduced into complex social systems (48). For example, Oral Rehydration Therapy (ORT), which would be considered a simple intervention is still not being successfully implemented at scale, with only an estimated two-in-five children in need receiving ORT (201). Given the complexity of scale-up, and the systems in which interventions are implemented in, two frameworks promoted the use of multi-criteria complex systems thinking for selecting an intervention or alternative based on the context (132, 134). In addition to this, the ExpandNet guidance (129) highlighted the importance of ensuring that elements of the intervention that may be easily lost in implementation, such as those most different to current practice, are protected during scale-up.

Specific reference to elements of Rogers' diffusions of innovation theory (53) was made by many frameworks (12, 13, 52, 124, 131, 174). Rogers (53) proposed that certain characteristics of the innovations will influence adoption. These include *relative advantage*, *compatibility*, *complexity*, *trialability*, and *observability*. Relative advantage has been described as the level to which use of this innovation may be better than current practice. This could relate to cost, effectiveness, resources needed etc. Compatibility relates to how the innovation may align with current values and norms within the social system, whereby those that fit with current beliefs may be more readily adopted. Those that do not, may fail to be adopted or the value and belief system may need to change before the innovation is the right fit in this setting. Complexity relates to how difficult the innovation is to use and understand by the potential adopters, with simpler easier to understand ideas being preferred. Trialability relates to the ease with which adopters could try out the innovation, for example on a short-term basis. This allows for adopters to see the results of the innovation within their setting and to test ease of use. Observability relates to how visible the results of the innovation are to potential adopters, thus stimulating discussion and sharing of practice. Consequently, these characteristics have been widely cited and influenced many implementations and scale-up frameworks (12, 13, 52, 124, 131, 174).

An important factor for consideration when addressing intervention fit in the context when scaling-up is the concept of readiness (197). Projects that address an area of great need can be rushed to scale up before effectiveness is determined or proper planning has taken place (202). Rushing to

scale before readiness in local sites may lead to core components, in particular those most different to current practice, being omitted or improperly delivered. Accordingly, care must be taken to expand at a pace that ensures the quality of intervention (197). One identified reason for failure of scale-up was noted as 'misjudged readiness', with differences in context between the pilot and future settings causing loss of fidelity (50). The meta-narrative review of diffusions of innovation in service organisations by Greenhalgh and colleagues (203) identified system readiness as a key factor, noting that where support for the intervention, capacity to evaluate and dedicated time and resources are in place, these may facilitate adoption. Thus, ensuring time to consider needs and future adaptations and avoidance of rushing to scale may facilitate success.

4.2.1.3.5 Providing Guidance to Sites

Weak technical guidance was noted as a negative determinant for scale-up (123), with availability of programme materials reported as a facilitator to scale-up (180). Some frameworks that specifically referenced giving guidance included the ExpandNet guidance (129), which noted that testing of innovation, under real world conditions, and identifying key features for success to share with future sites could facilitate scale-up. The IHI framework for going to full scale (13) also described the use of change packages to share learning from past sites. Further to this, the AIDED model (40) recommended the need for clarity of the intervention, which could include provision of guidance and materials for those adopting the intervention. They also noted that how the intervention may fit the context, for example within current religious beliefs and practices, could be highlighted in this guidance to facilitate local adoption, thus demonstrating intervention fit within a context within the materials themselves. A further consideration is that end users could be involved in the development of easy to use programme materials such as: training manuals, guides, planning tools, estimation of costs etc., which may assist in local implementation (180). Thus, guidance to sites has been identified by a number of frameworks as important, however the content of what guidance to share is not clear, with some supporting identification of key features following testing (129), others the clarity of intervention (40), or others sharing learning from past sites (13). Further considering that the intervention content, such as the intervention theory, active mechanisms and essential elements, may not be known or poorly described in research (17, 192), giving clear guidance to local sites poses a challenge.

4.2.1.3.6 Communication

Communication was highlighted within several frameworks however, its importance was described within different contexts (12, 13, 24, 40, 123, 126, 127, 173, 174). The IHI framework for going to full scale (13) for example, proposes communication as a key adoption mechanism, and advocates for data, including real-time data, to be used both in the early demonstration phase to show

evidence of effect, which could include of adaptations, and also communicating results in later phases to gain support of the majority. The DSF (24) also noted that early and ongoing stakeholder involvement will help highlight issues as they arise. The importance of communication with the community (173), along with ensuring the beneficiaries have capacity to express their needs, has also been highlighted (126). Other frameworks noted the need for communication as a facilitator or barrier to scale more generally (12, 40, 123, 127). For example, the CFIR notes the importance of networks and communication for implementation within the inner setting of the adopting organisation (174). The importance of communication was also discussed in Rogers' diffusion of innovation theory (53), whereby diffusion is proposed as the communication of a new idea (innovation) through channels within a social system. This communication is two-way process where information is shared to achieve mutual understanding. Communication was suggested as more effective when the individual's sharing information are more homogenous, leading to greater understanding, attitude changes, and potential behaviour change. Diffusion can further be centralised, where it is led by a small often top-down team driving change. However, it can also be decentralised with social change occurring through horizontal networks as the mechanism. Thus, the use of communication channels can be considered by implementers, along with who needs to communicate with each other, with the need for specific actions to achieve still needed.

An outcome of communication appeared to be the development of consensus and a shared vision. The importance of clarity of what is to be scaled (13, 52, 132, 133, 194) which may include developing consensus and agreeing on a shared vision for the intervention and scale-up (41, 51, 52, 132) was seen across some frameworks. Specific actions suggested in the frameworks included multi-stakeholder learning cycles used for participation in strategic planning (134), or Powell and colleagues (67) suggested concept mapping, intervention mapping, group model building and conjoint analysis, all of which encompass elements of creating an agreed vision or problem statement. Clarity with a consensus and shared vision may contribute to buy-in and support for the intervention and implementation (131). One framework which clearly focused on developing buy-in and support for scale-up, as mentioned previously, was the guide to fostering change in health services (131), which provided some steps to follow for this. The framework proposes that clarity of purpose, benefits and results are necessary in order to create a supportive context for change (131). This included defining the need for change by defining what is the problem, an agreed change idea, and expected outcomes (131). Thus, communication and developing consensus could be seen as important, but communication between who, in what way and for what specific purpose varied across the guidance and frameworks.

4.2.1.3.7 Create Opportunities for Learning

The need to support opportunities for learning was noted in a number of frameworks (13, 41, 129, 173, 176). The benefit of using a phased or cascaded approach was also highlighted as ways to allow for learning and refinement throughout scale-up (124). A phased approach could include planning how to promote and create opportunities for learning during scale-up (41, 129), including peer learning approaches, which could be facilitated by the use of formalised learning systems to share ideas and knowledge such as learning networks (13, 176), or change packages (13), or through less formal channels such as site visits (173). The DSF (24) further noted that organisational learning should be a core value, with capacity built for learning cycles, problem solving, adaptations and feedback. The importance of ongoing learning was also noted in the wider implementation literature. For example, the meta-narrative review of diffusions of innovation in service organisations by Greenhalgh et al., (203) discussed the use of formal network initiatives citing QI initiatives. However, they also noted that these are not a guaranteed success and that motivation, capacity and receptivity to change, along with quality of facilitation can play a role in effectiveness. Thus the literature identifies that peer learning may facilitate sharing of ideas and scale-up, however with no one approach of completing, barriers to formal approaches such as motivation and capacity to be considered by implementers.

Rogers influential work on diffusions of innovations (53) suggests five adopter categories of: innovators, early adopters, early majority, late majority, and laggards. Innovators could be considered the risk takers and are able to deal with the uncertainty of the innovation success. They are gatekeepers of new ideas into the social system. Early adopters are often opinion leaders, with their endorsement of an innovation promoting its use by others. Early majority adopters adopt before the majority however may still deliberate for some time before adoption. They form the link between early and late adopters. Later adopters are after the majority, often adopting out of necessity through pressure or economic reasons. Laggards are the latest adopters who are slow to adopt and change from past practice, they are often not well networked by communication channels and may be suspicious of new practices. The importance of change agents as a link between change agency and the unit of adoption was also highlighted in this work (53). Rogers' diffusions of innovations theory has been widely influential in the field of implementation and scale-up and informs many of the frameworks discussed above. Thus, the diffusions of innovations theory offers insight into how different adopters and opportunities to communicate and share learning may be beneficial in scaling an intervention across different contexts.

4.2.1.3.8 Participation

The importance of participation of stakeholders was noted in most frameworks (12, 13, 24, 40, 41, 46, 52, 124, 126, 129, 131, 132, 134, 173, 174, 178). There were multiple potential benefits of participation cited such as the development of leadership and champions (46) (13, 129, 131, 174, 203), which may assist in buy-in, support (40, 41, 51, 129, 194) and commitment (132) to the intervention, along with participation of end users leading to a better understanding of the needs of local contexts (40, 126). However, who would be involved, in what capacity and for what purpose varied throughout the frameworks. The importance of partnerships was identified in numerous frameworks (24, 129, 132, 173). For example in the SEED-Scale (173), one of seven tasks is determining the direction and the partners involved in the three-way partnership needed between the community working from the bottom up, officials working from top down, and support from experts coming in from outside. Who to include was also discussed in the PAG (132), which suggests involvement of three types of stakeholders: those with contextual knowledge from all levels of the delivery system, experts in the subject area, and any other stakeholders who can help to advocate and build support. ExpandNet guidance (129) also suggested involvement of those who developed and tested the innovation. However, ExpandNet also noted the need to weigh the potential drawbacks and benefits of adding partners (129).

The need to identify stakeholders and define roles and responsibilities was further noted in several frameworks (52, 131-133, 194). In terms of specific actions suggested, the PAG (132) advocated for a definition of clear roles and responsibilities for stakeholders with accountability, which could be completed in a planning workshop. The guide to scaling up population health services (194) advocated for completing a detailed agreement on who will complete actions and mobilise resources within an agreed timeline. In addition to this, the IHI framework for going to full scale (13) proposed the involvement of local stakeholders through the specific action of participatory QI methods for driving local change, and the MuSCLE framework (134) recommended the importance of multi-stakeholder engagement in a learning cycle for active planning and participation. Thus, while the importance of participation was noted in a number of frameworks, who is involved and what how to select those involved varied among the guidance.

The involvement of end users in the design and delivery of interventions was promoted by senior researchers and policy makers in scale-up (47). Thus allowing for acceptability to be tested in the design phase, whereby interventions deemed unacceptable would not make it past this point (at least theoretically). The co-production of research between researcher, practitioners and end users from the inception of the research process for public health interventions also contributed to successful scale-up in a study conducted by Milat et al., (63), with research findings deemed more

relevant to practice. However, it is important to note that engagement took part in the early stages and not necessarily throughout the course of the scale-up, whereby needs may change over time.

The involvement of user groups to identify needs and assist adaptations was seen across numerous scale-up frameworks and models (40, 50, 67, 125, 126). For example, the AIDED model (40) spoke of the involvement of stakeholders early in the process when innovating the intervention for local fit. The scaling-up a proposed framework for success (124) also suggests the need for adaptations for local context, highlighting the importance of engagement of the local community along with valuing the experience of service users. Along with this, the LPA (126) proposes that there needs to be fit between the programme, beneficiaries and the organisation. The programme should be based on, and match local beneficiaries' needs, as well as the local organisation's capacity to implement, with local beneficiaries needing the capacity or be supported to express their needs. The NASSS framework (125) noted the importance of considering the value the service user may (or may not) place on the intervention. The importance of community involvement was also noted in the wider implementation literature. Lack of engagement with adopting organisations, local implementers and community can affect buy-in and demand for the intervention (50). A review of sustainability of health interventions in sub-Saharan Africa by Iwelunmor and colleagues (204) for example, found that community ownership and mobilisation was crucial to intervention sustainability, with buy-in being achieved through participation. This can be viewed as ensuring that the intervention is relevant and guided by needs of community (196).

Programmes which are adapted with community support are suggested as more likely to be sustained and institutionalised (54). Community engagement can also achieve ripple effects across other local areas (i.e., via diffusion) through getting opinion leaders on board (196). The involvement of communities in planning and implementation is further supported by the World Health Organisation (205) recommendations for health promotion interventions for maternal and newborn health. Their recommendation package discusses that strategies pre-determined and implemented for (as opposed to with) communities run the risk of lack of ownership and buy-in. Similarly, organisations with strong community links were more suited to implement and adapt programmes for their settings (180). Consequently, partnering with community organisations that have the infrastructure to reach local populations has been reported as a factor to successful scale-up (180). Castro et al., (58) also discussed that adaptive approaches have a history in community-based health promotion, with community-based participation in planning, evaluation and research identified as key to this process. A mixture of top-down and bottom-up approaches can also be used (58), with experts in design or policy supporting initial programme design or decisions, and grassroots, bottom-up approaches informing programming to ensure the intervention meets needs

of the community, the right fit, along with local ownership, buy in and enhanced chances of sustainability (58). It is also in keeping with the adaptation guidance, with many supporting the use of the community and end-users for adaptations (29, 37, 54, 57, 90, 113-115, 119, 121, 168, 186).

4.2.1.3.8.1 Supporting Community Driven Interventions

The SEED-Scale noted the need to support a community's success (173), which could be in the form of supporting scale-up of a community-driven intervention, or implementation strategies. This was also discussed in the implementation (180) and adaptation literature (54). For example, the challenge for CBOs in having the capacity, time and resources to scale community-driven interventions was discussed by McKleroy et al., (54) and Norton and Mittman (180) in US contexts. In their study of programmes in the US, Norton and Mittman (180) found that interventions driven from the bottom-up, while not following traditional evidence-to-practice pathways, could be faster adopted and often received positive attention and feedback from participants, community leadership, and implementers. The importance of supporting communities was also supported by Binswanger-Mkhize et al., (206) in bringing HIV/AIDS interventions to scale. Binswanger-Mkhize et al., (206) discussed the potential success achievable from building on available local models (those that have worked locally and at scale), community involvement, building upon local capacity, use of participatory approaches, and making funds available locally with flexibility based on local needs. They proposed that phased implementation by starting scale-up to one district or region, before national implementation, may support this driven approach.

4.2.1.3.8.2 Community Based Participatory Research (CBPR)

Actions for community engagement such as community based participatory research (CBPR) (also called participatory action research (PAR)) have also been used to achieve intervention fit (71, 207). Reinschmidt et al., (208) discussed the use of a CBPR approach for local cultural adaptations of a diabetes public health programme to incorporate norms and social values into the programme. Originally developed for Mexican-American communities in southern Arizona, the programme was further adapted for other communities. Reinschmidt et al., (208) report that CBPR assisted with community engagement, ownership, and local buy in. Insight was also gained from the community as to health disparities and engagement with health services. Promotors (community health workers; CHWs) were based in this community and were a key part of CBPR for programme adaptations. Acting as key links between the families, community and organisations, CHWs were identified as a key component of the SBPR and programme success. However, CBPR can be a resource heavy and skilled process and its role in scale-up across multiple sites may need to be considered with this in mind (207).

4.2.1.3.8.3 Challenges with Community Engagement when Scaling-Up

While not a simple process, community participation and approaches greatly assist in ownership and making a programme sustainable, whereby the absence of community participation can lead to disempowerment of communities and local organisations (39). However, it is important to note that community participation does not guarantee success (39), nor does it guarantee buy-in from community. A fidelity study of the scale up of strategies to improve dengue management in 16 districts in Cuba by Pérez et al., (56) for example, found that community participation components were not consistently occurring. For example, and while there was good community involvement for risk mapping and problem identification, over half of groups did not generate an action plan or actions. Similarly, while there was also a component for community to modify or tailor messaging to their local area, which was rarely done (56).

Additionally, while community involvement can occur at initial stages of implementation, involvement can diminish as the intervention is scaled. An example of this can be seen in the scale up of Community Health Planning Services (CHPS) in Ghana (209, 210). While community participation had been encouraged for local contextualisation, the use of community entry points were not always used at national scale. Community participation had previously included community dialogue, consensus building with community leaders, use of naturally occurring events to link in with community and identification of change agents from within. Within the original model, the community funded and built centres themselves, creating ownership. In districts where the steps to include community were rushed or skipped, for example in a district where building occurred before community entry dialogue was complete, local ownership was hard to gain afterwards. With national scale, there was external funding for centres which at times were built before this community buy-in and consensus was reached. Thus, making the intervention a more top down rather than bottom up approach which in some areas led to reduced support for the intervention.

As seen above, community engagement is complex, can utilise numerous resources, and be time-consuming. There is therefore a need to ensure that actions selected foster genuine participation, commitment and participation of stakeholders (129), and that participation is not just tokenistic (131), with care that participation does not unintendedly taper overtime (209, 210). In terms of guidance available for community engagement, nine principles of community engagement have been proposed by the Clinical and Translational Science Awards Consortium (CTSA) (211) which are: (i) being clear on the communities to be engaged and what the goals are, (ii) developing knowledge of the community including values, norms, history and experience with community engagement, (iii) respecting the needs and cultures of communities and being flexible to design and adapt

approaches for this, (iv) ensuring the right for self-determination, (v) taking time to build trust and to build both formal and informal leaders, (vi) recognition of the diversity of the community, (vii) to achieve sustainability, community capacity building should be prioritised and resources and assets mobilised, (viii) being open to hand over control to the community and to be open to changing needs, and (ix) committing to a long-term partnerships. These principles could therefore be considered by implementers if choosing to use a community involvement for adaptations during scale-up.

4.2.1.3.9 Local Decision Making

Policy makers and practitioners need to make decisions on priorities for their context based on best available evidence. However who makes decisions and how decisions are made for scale-up has not received much attention (63). A qualitative study by Milat et al., (63) of policy makers and practitioners involved in scale-up found that research that was locally made and contextually relevant was highly valued. However, they noted there was often a lack of data on intervention effectiveness relevant to their setting and a lack of data on cost effectiveness (63). Policy makers reported they often used evidence both in the traditional scientific (i.e. in RCT and systematic review formats) but also expert opinion, local knowledge, etc. (63). The CDC guidance on use of evidence (212) highlighted the importance of the use of a mix of evidence types. While it acknowledged the importance of best available research evidence, it also advocated for experiential evidence and contextual evidence as key for decision-making. Experiential evidence being based on professional expertise, skill, judgment and insight that has been accumulated over time (212). Contextual evidence being when there is evidence around feasibility, usefulness and potential acceptance in the community where the interventions would be delivered (212). Therefore, who is making decisions and what evidence (i.e. contextual, experiential, and from available research evidence), along with documentation of this decision making are important considerations for implementers, though very little guidance for this decision making is currently available.

Decentralising decision making to local levels is suggested by several frameworks (13, 124, 129, 132, 134, 173), with the use of local knowledge and involving those who know the context being highlighted as an important factor when scaling up. The involvement of local decision makers, for example government, in programme design, identifying policy champions and networks, harmonising with external programmes, and aligning with current health system innovations and priorities was found to facilitate successful scale-up (12, 196). Health interventions need local buy-in to be successful (213). Adaptations that are made in conjunction with the local agencies who will adopt the practice have a higher rate of institutionalisation (54). External imposed planning may

lead to programmes which are unsuitable, ineffective, and that are not fully implemented (213). Byrne et al., (18), looked at context specific strategies to address scale-up of reproductive and MCH initiatives, and found that context specific plans could be made at regional and local levels addressing factors affecting implementation. It further reported that national strategies cannot allow for differences in supply and demand of health services, and local uptake, and that contextualised approaches are therefore needed (18), especially since lack of demand has continually been reported as a problem, for example for MCH interventions (214).

In terms of specific actions or approaches for local decision making in the scale-up guidance, the IHI framework for going to full scale (13) advocates the concept of a “scalable unit” which could be a health facility, or sub-district/district, that is representative of other smaller units, where local change ideas can be generated, tested and then shared with other similar units. The PAG (132) promotes implementation at all levels including at local level, where learning and adaptation through feedback can take place. Within the SEED-Scale (173), community involvement is central to the concept with a three-way partnership at local level, from the top down, and from experts. In addition, the MuSCLE framework (134) mentions the need to build social capital locally to sustain and adapt interventions, through HR training, infrastructure, data capturing systems, promotion of local enterprise. Thus, while the importance of local decision making can be seen across the literature, the level at which this occurs, what approach to use, and the capacity required varies between the guidance, with no clear guidance on how best to achieve local decision making in various contexts.

4.2.1.3.10 Considering Future Adaptations and Sustainability

Given the dynamic and heterogeneous nature of contexts when scaling-up, the need for consideration of future adaptations and sustainability is highlighted across the literature (12, 13, 24, 125, 131, 134, 194). This includes the embedding of thoughts of scale-up in intervention design, trial and piloting (12, 41, 75, 202, 215, 216), and that during scale-up, actions are embedded to allow for local fit (12, 13, 24, 40, 49, 124, 125, 131-133). From an intervention design and selection perspective, this can include the purposeful design of scalable interventions (196), or the embedding of future adaptations in the design (75, 107). Interventions that reach effectiveness trials, or pilot studies, are often resource intensive without consideration of future implementation and scale-up (50, 196). Their scalability may thus need to be considered, as these resource heavy innovations are less likely to be appealing and implemented at scale (50, 196). An example of this can be seen in Type 2 Diabetes Mellitus (T2DM) interventions. An article by Yates et al., (217) discussed the volume of resource heavy behaviour change interventions often trialled for this condition which would put a large strain on health systems resources. In reality, the feasibility of

these being taken to scale is low, with only some very well resourced HIC contexts managing to implement them at scale, if at all (217). This was also discussed by Edwards and Barker (55) for HIV interventions that were developed and tested without consideration of the wider infrastructure and resources that would be available to implement the intervention across diverse contexts where HIV is prevalent. For example, if task-shifting is likely to occur when implementing due to HRH shortages, this method could be embedded into initial intervention trial and design and may speed up implementation and scale-up (47). It has been advocated that it is the researchers' role to embed future implementation and scale-up into design and not leave as an afterthought (12, 41). In terms of guidance for this, ExpandNet produced the beginning with the end in mind guidance (41) for the purpose of supporting thoughts of future scale-up. While this guidance is not specific to scale-up implementers, with its focus on earlier phases of design, testing and piloting, it nonetheless provides valuable consideration of future challenges an intervention may face when being implemented across multiple heterogeneous sites with varying resources.

Within the scale-up literature there is growing recognition of the potential need to embed actions to continually adapt as contexts change over time (13, 24, 125, 132-134). However, there was no consensus on what actions to use to complete these continual adaptations. While there was recognition that adaptations need to be carried out in real-time, as needs emerge (132, 133), capacity needs to be in place to achieve this (134). As discussed previously, the DSF (24) was central to this call, highlighting that the intervention should not be optimised prior to implementation, with the need for ongoing feedback and an embedded ability to adapt over time, as needs change. This approach is echoed by Jenal and Cunningham (218) who discussed that contexts are constantly changing and what might be appropriate at one point in time, may not remain the case at later stages of implementation. Therefore, there is a need to embed actions for ongoing assessment and consideration of contexts for adaptations and sustainability as they naturally change over time (24), which requires constant checking in, probing and exploring to ensure right fit. However, what specific actions that can be used to achieve embedding of adaptations in varying contexts are not clear within existing guidance.

4.2.1.3.11 Systems Thinking

There is an identified need to assist governments in the development of general health systems and HRH, in particular in LMIC settings (196). Consequently, it is proposed that using a more systems thinking approach, looking holistically at the health system, may assist successful scale-up, such as addressing HRH training, supervision, attitudes towards intervention and supply chains (11, 12, 41, 52). The use of systems thinking for scale-up has also been discussed in the ExpandNet framework and guidance documents (12, 41, 52, 122). While systems thinking was not specifically

mentioned by Powell and colleagues (67), they promoted the use of group model building to identify complexities within the system and using stakeholder experience to map and suggest strategies for each setting. In the wider implementation literature, the potential benefits of using systems thinking was also discussed by Best and Saul (219), who promote the consideration of complex systems that are adaptive and changing overtime, as unpredictable and non-linear, with many interactions and relationships between components. They suggest that consideration of local context and its complexity requires engagement with local stakeholders along with experts to clarify the problem and participate in the generation and testing of solutions. Therefore, systems thinking may be an important tool for scale-up and adaptation that warrants further exploration.

4.2.1.3.12 Consideration of Resources and Capacity Building for Adaptations

While not specific actions, two areas which came across strongly within the scale-up literature was consideration of the resources (12, 13, 24, 46, 55, 75, 123, 125-127, 132, 174, 176, 178, 180, 203) and capacity (12, 24, 49, 123-125, 127, 174, 176, 178) available for intervention scale-up and potential need for adaptation. The effectiveness of an intervention can be affected by resource availability at scale, whereby instances where the resources present at initial research or pilot were no longer available at scale were identified as a key barrier (180). Programmes and interventions are often developed and tested in conditions with several resources favourable to their success, such as funding and highly motivated and skilled staff in the area (75). Consequently, the implementation approach taken when piloting and evaluating an intervention may be unfeasible to be taken to scale within existing country resources (55). For example, the accelerating contraceptive use (ACU) project, which was implemented across three districts in Afghanistan and showed increased uptake of contraceptives, was subsequently endorsed for scale-up by the Ministry of Health (MoH). The implementation approach however, involved in-depth community dialogue with religious and community leaders, health committees, Community Health Workers (CHWs) and service users. It also required technical expertise and skilled coaching for development of supervision skills and training for community. A key limitation for national scale-up was therefore the resources and time required for this in-depth dialogue, technical expertise and skilled training (220). To mitigate this barrier, it is suggested that evaluation and piloting of programmes in resource constrained settings emulate existing resources prior to scale-up to, such that adaptations can be made to programming at this stage in order to facilitate implementation at scale (180). There may be a need to realign and mobilise resources for the intervention and scale-up (51, 128, 129, 133, 194). Failure to take into account available resources may result in loss of effectiveness when the same programme is taken into real world settings.

The funding mechanisms in place for testing and implementation of an intervention is identified as another significant barrier to scale, with ongoing access to funding a factor influencing successful implementation (203). Specifically, the discontinuation of funding once an intervention has been 'proven' to work, but before it has been implemented at scale, was identified as contributing to failure to scale (202). Similarly, awareness of funding needs has been identified as assisting successful scale-up, with costing and economic modelling of an intervention (i.e. having a strong idea of what it will cost and cost effectiveness identified) as factors for success (46). The role of funding in sustainability, particularly in low resource settings, was highlighted as important and was cited as a common reason for de-adoption of a practice. Despite this, funding was rarely reported in studies (73).

Capacity building of the adopting organisation or the community was noted in a number of frameworks, with the need to assess (12, 24, 49, 123-125, 127, 174, 176, 178) and build capacity of the adopting organisation frequently highlighted (13, 51, 52, 129, 133, 134, 194). Capacity building could include developing capacity to complete a specific action for adaptation and evaluation, for example to use QI methods at local sites (13). A key barrier to scale-up was lack of availability and capacity of HRH needed for scaling-up health interventions. This includes lack of availability and capacity of human resources, leadership, management and health system capacity (50, 196, 201, 221). High staff turnover was noted as a barrier leading to lack of trained staff members and organisational memory (180). Leadership change was also noted as a barrier, with loss of champions potentially detrimental to a programme's success (180). Resistance to scaling-up and implementation was also noted as being caused by HRH constraints, with difficulty in recruiting and retaining staff (46). Gaining an understanding of priorities of health workers, rather than imposing an intervention for which they have no buy-in, was also noted as important (196). In many LMICs, a 'technical capacity gap' was noted by Kruk et al., (201) where through understaffing or lack of expertise, organisations may have challenges in decision-making, exploring evidence and making plans for their setting (201). Thus, consideration of capacity and competing interests for time and resources is needed, particularly in LMIC settings.

The capacity of the organisations implementing the intervention has also been discussed from the perspective of grassroots CBOs. For example, when an intervention is developed or piloted by grassroots organisations, CBOs may lack the networks, skills or motivation to take the intervention to scale outside of their local area (128). Having adequate infrastructure for HRH, training, delivery, technical resources to support scale-up, along with flexibility to address HRH constraints, were therefore all identified as success factors for scale (46). The need to build capacity for adaptations at service provider level was also noted by Solomon et al., (110). Specifically, they advocate for the

need to build service providers' capacity to collect and use needs and assessment data and capacity to use theory-based approaches. They support that researchers need to provide information on intervention core components which are efficacious, and to collaborate with service providers to support practitioner-driven adaptation. However, in addition to organisational capacity, the capacity of the beneficiaries in their ability to articulate their needs (126) and that of the patient, and if relevant the carer, to engage with the intervention (125) also needs to be considered. Without this, there implementers may not get an understanding of recipient needs and adaptations may not occur or may not fully address these needs. Therefore, capacity from both an organisational or community perspective appears central to the success, or failure, of scale-up at local or wider levels, with further consideration of capacity at individual recipient levels also needed.

The central resource team can act as a support for organisations and communities. The concept of a central resource team, as referenced in the ExpandNet framework (12, 129), includes those who may be involved in developing and/or initial pilot testing of the intervention prior to scale-up, but who may not necessarily be a part of the implementing organisation. The central resource team also includes those that may be interested in facilitating implementation (12, 129). The role of facilitators of implementation was also highlighted in the PARIHS and i-PARIHS frameworks (176, 178). Likewise, the PAG (132) and TDR IR toolkit (147) both discussed facilitation workshops as part of the process, where planning can be supported by those with experience in implementation and scale-up, but who may not necessarily be part of the adopting organisations. Rogers' diffusions of innovations (53) discusses both centralised diffusion and decentralised diffusion. Centralised diffusion is led by a change agency and is often top-down or expert driven, and can be led those who are not necessarily part of the adopting organisation. In contrast, decentralised diffusion occurs in a more horizontal fashion, potentially without resource team support. Thus, the concept of a central resource team may offer support to local agencies implementing the intervention during scale-up, in the form of supporting issues with capacity for adaptations across sites.

4.2.1.4 Mechanisms for Scale-Up

While scale-up literature and frameworks often report on barriers and facilitators to scale and propose steps to be followed, there is less information on what mechanisms are necessary for successful scale-up (7), with even less information on mechanisms for scale-up and adaptation. Correspondingly, a realist review completed by Willis et al., (7) explored the scaling-up of complex interventions focusing on identifying the mechanisms triggered. Prior to this review, some mechanisms had been identified in a realist review of large-scale change initiatives by Best et al.,

(181), and while not specific to scale-up, the mechanisms could be hypothesised to have relevance for the field.

Willis et al., (7) realist review of scaling-up complex health interventions used a literature search to first generate an initial programme theory. They then identified and analysed three case studies of complex interventions scaled-up within community settings in Canada, synthesising the findings from these three case studies to find common mechanisms and patterns of activation across studies. The theories generated were then further refined in a workshop conducted with 20 participants with experience in scaling-up complex interventions. Ultimately, this review identified four mechanisms relating to scale-up of: awareness, confidence, trust, and commitment. Awareness was noted in several ways, for example the awareness of community and stakeholders that efforts had reached a plateau of effectiveness, awareness of leadership of the need to adapt for local settings, and awareness of the need for collaborative action to regain lost momentum. Confidence was viewed as the feeling of reliability or assurance on their own abilities or qualities. This was viewed as different to trust as there was a focus on self-assurance. Three forms of confidence were identified: local stakeholders being confident that the intervention was effective for the community's needs, confidence from leadership that the community had the relevant capacity to implement the intervention, and confidence from the local stakeholders that leadership could implement the intervention in their setting. Trust was viewed as the "firm belief in the reliability, truth, ability or strength of someone or something" (p9) and was found to often precede the mechanism of confidence and commitment. All these mechanisms were influenced by the context in which the scale-up took place. In particular, the mechanisms of awareness and commitment were activated when efforts to renew and regenerate the intervention were made. For example, when evaluations were made, this triggered a mechanism of raising awareness of the challenges and need to further plan and adapt the scale-up strategy. This planning led to secured funding and engagement of local partners. In contexts where success of the intervention was demonstrated, this assisted in firing of the mechanisms of confidence and trust, which assisted in continued participation of communities and recruitment of new communities for scaling-up. The review of three case studies further found that the planned incremental approaches put forward in many scaling-up frameworks were often not seen clearly in practice. While this review by Willis et al., (7) is a welcome contribution to the field of scale-up, it is important to note that these mechanisms and theory were identified for the process of scale-up more generally, and not specifically related to scale-up and adaptation for local fit. Of particular relevance to this study, within the workshop Willis et al., (7) completed with participants involved in scaling-up complex interventions, they noted the gap in research on processes for adaptation of intervention and contexts over time to ensure best fit, thus highlighting the need for future research in this area.

Another consideration of this review and its findings was that it was developed from case studies and participants based in HIC settings, which may differ from circumstances in LMIC with further resource shortages and challenges with capacity.

The mechanism of trust was also identified in a review by Bell et al., (222) which looked at replication and adaptation of six programmes for HIV risk reduction in youth in the US. They found that community support and trust was integral for the programme's success and noted that there could be several reasons for a mismatch. This included the issue of HIV not being a priority for programme beneficiaries, for example alcohol use in youth was more of a concern than HIV. Issues of trust also emerged where people external to the community were responsible for the design or were involved in rollout of the intervention. Distrust was particularly found in rural communities, where those who developed and implemented the intervention were viewed as 'outsiders'. The community also needs to be ready for the intervention. As was discussed by Bell et al., (222) for example, some schools or communities were not open to HIV prevention for youth at the time of implementation.

Best et al., (181) completed a realist review exploring large scale change in healthcare. While not specifically exploring scale-up of new interventions, the review by Best et al., (181) can be seen to hold relevance for scale-up where change is needed to implement an intervention. This review further identified five simple rules for achieving change, which also identified mechanisms and contextual factors that influence these. They firstly found that attending to the local history was of importance. This was not seen necessarily as the past would repeat itself, but more so as a way for learning from past experiences in order to address and avoid any potential issues. This was assisted by the mechanisms of education of leadership at all levels about previous past efforts for change and building on shared ideas and values for the future change. The establishment of feedback loops was also of high importance, and was proposed as influenced by the quality of the infrastructure to measure and report this feedback, along with leadership's commitment to reporting findings. Mechanisms which were identified to attribute to success included active participation of stakeholders in determining what is to be measured, their confidence and trust in the accuracy and validity of measurement, the level of understanding of the measures, perceptions of consistency of measurement across the system, the ability to adapt the measurement systems as needs or issues emerge, and inclusion of incentives (or negative consequences) for lack of action from measurements.

Greenhalgh et al., (125) also found that engagement of stakeholders at all levels led to a change effort, through both designated and distributed leadership, and that building social capital was

important. The contextual factors that were identified to affect this were: a transparent and clear mission, vision and strategies, HR capacity for change, flexible values and norms, funding availability and consistency, and how integrated the health system was. Mechanisms to support the alignment of top down and distributed leadership included explicit alignment of vision and goals (which may reduce cognitive dissonance towards the change), active management of the change (which may involve change agents), demonstrating proof of concept through smaller scale pilots, and providing assurance that change will not be penalised. Another factor highlighted was engagement of all team members, including physicians in the change. This could be encouraged through the mechanisms of examples of past engagement of physician leaders, facilitation and guidance, incentive structure and alignment of professional drivers. Engagement of patients and families on an ongoing basis was also highlighted and marked as important in order to increase awareness among decision makers of the priorities of patients, a sense of validity of the approach, and feelings of equity by staff and patients. However, there remains a lack of examples of successful practice in this area.

4.2.1.5 Theories Relating to Scale-up and Adaptation

Further to the above, some formal theories were considered within this review as useful to our understanding of scale-up and adaptation. This includes Rogers' diffusion of innovation theory (53), which was discussed previously in Sections 4.2.1.3.4 and 4.2.1.3.7, and also includes complexity science (213) and complex adaptive systems theory (48).

Lanham et al., (213) proposed that complexity science can help us in understanding how complex systems can impact scale-up. They discuss this under the concepts of self-organisation, inter-dependencies, and sense-making. Self-organisation describes how people inter-relate and act in each context. Often people organize by trying to work as effectively as possible given their resources and setting. Multiple factors will influence this self-organisation. Importantly, self-organisation is seen as a ground level approach based on needs within a setting and the nuances of this often may not be recognised by top-down decision makers and implementers. To this end, Lanham et al., (213) suggest that understanding and working with self-organisation in a given context can facilitate scale-up. To achieve this, interdependencies and sense-making can be used, whereby interdependencies is the interaction between the complex systems and its parts. This includes interactions and relationships between people. People will then self-organise because of these inter-dependencies. Sense-making is where people give meaning to experiences. How an individual views experiences can be affected by their inter-dependencies. For example, the attitudes of those around them and how these attitudes influence them. Sense-making will therefore influence action or inaction.

Complexity science can be combined with diffusion theory (53), where the implementation of an intervention is diffused into a complex social system. Therefore, while interventions and implementation can be explored at an individual level it is important to also look at the complex system and interdependencies around the individual, which will in turn affect sense-making and self-organisation and adoption (or non-adoption) of interventions. Complex systems are also always changing and thus what 'worked' at one point in time might change and shift over time, impacting on the sustainability of an intervention (213). Therefore, complexity science aligns with some of the guidance supporting the ongoing consideration of adaptations and sustainability within dynamic contexts (24) and can aid in the potential explanation of how scale-up may work in complex systems.

Among a growing literature on scale-up, there remains a call to look at new and innovative ways to guide this process. Paina and Peters (48) propose that the phenomena within complex adaptive systems (CAS) theory could also assist in the explanation of complex systems and help to guide implementation at scale. They specifically discuss that the use of theory on path dependence, feedback loops, scale-free networks, emergent behaviour and phase transitions could help explain and inform health scale-up. They propose that CAS can explain how small inputs may cause large change in health systems, while sometimes costly resource inputs may cause little change or unexpected consequences. CAS theory has been used in other fields but within health has received less attention. The use of this theory takes a system thinking approach which values the interconnectedness of elements. This builds upon complexity theory where components within health systems can self-organise, adapt and build on experience (48, 213). Similarly, CAS theory focuses on the complexity and non-linearity as core to its idea (48). The non-linearity of elements has been discussed in previous scale-up frameworks with steps or processes overlapping or occurring in tandem (40).

4.2.1.6 Summary of Scale-up Guidance and Frameworks in Relation to Adaptation

A large number of the scale-up guidance and frameworks recognise the need to adapt for local fit when scaling-up (12, 24, 40, 41, 49, 51, 52, 122-134), with some suggesting determinants that could be considered when adapting, or guidance on embedding adaptations into design. However, there remains a lack of consensus and guidance of what actions to use to adapt when scaling-up across multiple heterogeneous contexts, along with what resources need to be in place for this to occur. Thus, leaving implementers without support for this challenging process. Interestingly, elements which were of central importance in the fidelity and adaptation literature, such as knowing the intervention theory and components central to its effectiveness (as seen in Section 4.2.1.1.1), was notably not present in many of the scale-up frameworks. Potentially this is due to the fact that

often intervention theory and core elements are often not known or as poorly articulated and in practice implementers when scaling-up may have to work with imperfect information on an intervention. However, addressing the intervention fit for the local setting was mentioned in most frameworks (as seen in Section 4.2.1.3.4), many of which were informed by Rogers' diffusions of innovation theory (53) and the compatibility, trialability, relative advantage, complexity and observability of the intervention within the setting.

When comparing the guidance and frameworks from scale-up, a number of key areas were identified that may provide some assistance to implementers. For example, the need to understand the context came across strongly, with assessments, where needed (51, 132), and participation of those who know the context (40, 124), including the community and user groups identified. Both creating knowledge to fill these gaps in knowledge, but also ensuring this knowledge is used and informs the process and planning were noted (51, 132). Understanding the context also came across in the adaptation and fidelity guidance, including the need to understand contextual factors that may affect how the intervention may work (28-30, 35, 37, 55-57, 71, 75, 90, 98, 101, 110, 113, 115, 117, 119-121, 169, 171, 182, 186-189, 223). The wider contextual environment including political, socio-cultural and environmental factors, was also discussed in the majority of scale-up frameworks (12, 13, 24, 40, 52, 123-127, 129, 133, 134, 147, 174, 176, 194), including the potential need to adapt for fit within this environment. The organisational context (12, 24, 49, 123, 126, 131, 132, 134, 147, 174, 178, 194, 195) and its readiness in terms of human resource availability, capacity to scale-up and adapt (12, 13, 24, 52, 123-126, 174, 194), and leadership (12, 13, 123-127, 174, 176, 178) was also commonly noted. Opportunities for learning was mentioned in several frameworks (13, 41, 129, 173, 176), which included formalised learning networks (13, 176) and learning from other sites (13, 173). Although there was no consensus on specific actions to use to achieve this learning. Additionally, the embedding of feedback mechanisms (24, 131-133, 194) to inform the scale-up process was mentioned across numerous frameworks, with the need to be flexible and responsive to needs in real time as contexts adapt and change (24). It is important to note that for implementers however, and while there was no clarity on which specific actions to use, some approaches mentioned could be considered, such as the use of QI methods (13). The need to embed and plan for sustainability (12, 13, 24, 125, 131, 134, 194) was also noted by several frameworks. However, again, there was no consensus on what specific actions to take to achieve this, with notable variance across the frameworks.

Participation also came across strongly as beneficial to adaptation and scale-up (12, 13, 24, 40, 41, 52, 124, 126, 129, 131, 132, 134, 173, 174, 178). This could be in the form of local decision making at multiple levels within the health system (13, 124, 129, 132, 134, 173), involving the community

and user groups in innovating and making adaptations (40), partnerships (173), or through consultations (194). Participation could potentially assist in buy-in (131), commitment and creating a shared understanding (132). The benefits of local champions (13, 129, 131, 174) and building of support (40, 41, 51, 129, 194) for the intervention was also highlighted. However, the extant literature also highlights the challenges of community engagement, including the tapering of engagement over time (209, 210), and the potential for tokenistic engagement (131). Thus, community engagement needs to be a thoughtful process, with resources allocated to the same, to ensure that the complexities of this participation can be addressed throughout the course of scale-up, as opposed to it being an add-on or 'tick-box' action.

The potential for power imbalances (126, 173) was identified within guidance. In addition to address this imbalance an emphasis on developing a culture of respect with value was placed on those close to the context, for example the community, has also been identified as important when scaling-up (131). The importance of communication at an organisational level (13, 123, 127, 174), through social networks (40) or inter-personal levels (12) was also highlighted. This communication at organisational level could include clarity and definition of roles (52, 131-133, 194) or the development of an agreed vision or consensus (41, 132, 134)(4)(13, 51, 131, 133, 194), which in turn may support buy-in. Guidance to sites both in the form of technical guidance (40, 123, 129) and ideas for changes to the intervention and implementation (13) tested at other local sites was also mentioned by some frameworks. However, there was no agreement what type of guidance should be given, and in what format this should be, leaving this unclear for implementers.

While a large volume of guidance and frameworks exist, there remains no clear frontrunner used within the field of scale-up. This results in a vast, intimidating field for implementers to select from, as well as no clear process model offering specific guidance for the purpose of scale-up and adaptation. Scale-up however, is an evolving field, and over time, we may see greater effort to consolidate the aforementioned guidelines and/or identify one as being more useful than the others. In relation to adaptation and fidelity guidance these were not specific to scale-up and often focused on cultural adaptation for minority groups, or resource heavy highly skilled processes for adaptation that may not be feasible at multiple sites when scaling-up. This results in implementers not having clear guidance on what actions to use when making adaptations when scaling-up. This literature review examined and consolidated the available guidance with some potential key actions, contexts and mechanisms. These findings informed the IPT framework for the review which will be presented in Section 4.2.3, Figure 4.5 below. These findings also assisted in clarifying the scope of the review, presented in Section 4.2.2 below.

4.2.2 Results: Clarifying the Scope of the Review and Developing the Initial Research Questions, Aims and Objectives

Through reviewing the literature there were numerous gaps identified which clarified the scope of this review. As discussed in Chapter 2 (Section 2.6), while adaptations are commonly occurring in practice, they remain poorly documented and understood. This leaves implementers facing scale-up without information of what type of adaptations may be beneficial or necessary, and for what purpose they may be needed, to achieve local fit in their setting. This leaves planning and embedding for adaptations challenging and may lead to reactive ad-hoc adaptations as needs arise, potentially affecting intervention fidelity and effectiveness. Thus, there is a need to discover what type of adaptations are occurring during scale-up in practice, and the reasons for these adaptations, which may guide future implementers when planning within their own settings.

The above literature presented in this chapter (Section 4.2.1) evidences a variation of approaches exist across adaptation and scale-up guidance and frameworks, with no clear path or process to follow when it comes to adapting and scaling-up interventions. Discussed in detail in Section 4.2.1.1, adaptation guidance was not specific to scale-up, and largely centred in the field of substance abuse prevention and HIV behaviour change interventions (35, 54, 57, 110, 114, 120, 121), or focused on cultural adaptation for specific minority groups (28-34, 112, 118, 119). Moreover, existing guidance material was mainly developed in, or catered to HIC settings (28-34, 54, 57, 110, 114, 118-121), with some of this guidance requiring highly skilled and resource heavy processes (28, 33, 37, 54, 57, 111-116). Some suggested approaches within the adaptation guidance, such as liaising with original intervention developers or re-evaluations, may not be feasible across multiple sites and resources at scale. Thus, there are numerous gaps identified such as the need for specific guidance for adaptations in the context of scale-up that incorporate the challenges faced, such as adapting for wider population groups, across various intervention types and implementing in multiple diverse sites with limited resources when scaling-up, in particular in LMICs where feasibility and capacity may strongly influence the process.

As seen in Sections 4.2.1.2 and 4.2.1.3 above, while there was some overlap between the scale-up guidance and frameworks relating to fidelity and adaptation, there was also variation and no clear set of actions or steps for implementers to take when attempting the complex task of adapting during scale-up across multiple sites and diverse contexts. Where consensus exists within the fidelity and adaptation literature, for example, in terms of the importance of identification of intervention theory and components, this consensus was not as frequently evident in the scale-up guidance. In addition, it is noted that intervention theory and components often go unreported when interventions are developed and trialled (17, 100). Therefore, even when some agreement is

seen in the guidance, steps may not be pragmatic or possible to put into practice when adapting and scaling-up. The most specific guidance available in terms of combining scale-up and adaptation was seen in the scaling-out framework (49), and while this is a welcome addition, it also does not provide specific actions to follow to complete adaptations. More so, it highlights the need for adaptation and consideration for when new evaluations are needed. Therefore, what actions can be used to support adaptations during scale-up, and how and when to choose one approach over another in varying contexts remains a key gap in the extant literature.

As a result of the above, the scope of the review was clarified for phase two to focus on examples of scale-up and adaptation in practice, drawing on real-world examples. Within these case examples, this research set out to discover and document *what adaptations were made and why* when adapting health interventions in these practice settings. Further to this, a focus was placed on the process of scale-up in identifying *what actions* were used (for example local decision making) to make adaptations when scaling-up in practice settings. A further focus was to identify one action to explore in detail to discover through what mechanisms this action worked (for example by building trust within the local community), and how the context may have influenced this. This resulted in the following initial research questions, aims and objectives:

Initial Research Questions

- What adaptations are made and why, when scaling up health interventions in practice?
- What are the actions that can be used to achieve these adaptations when scaling-up health interventions?

Initial Research Aims

The aim of this research is to discover what adaptations are being made in practice during scale-up for local fit across diverse contexts, in addition to discovering what actions are being used to make these adaptations. Further to this, the research aims to focus on one of the identified actions to develop theory on how this *one selected action* works to make adaptations to health interventions for local fit when scaling-up that will have practical application for implementers involved in scale-up across diverse contexts.

Initial Research Objectives

1. Develop an IPT framework identifying potential actions, contexts, mechanisms, and outcomes that may be of relevance to scale-up and adaptation to support later phases of the review

- 2.1 Identify and describe what adaptations are made and why, when scaling up healthcare interventions in practice (presented in Chapter 5)
- 2.2 Identify and describe what actions are used to achieve these adaptations in practice when scaling-up health interventions (presented in Chapter 5)
- 2.3 Identify one action to explore in detail in phase three for adaptations of health interventions during scale-up (presented in Chapter 5)
- 3.1 Discover how this *one selected action* works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit through generation of CMOCs (presented in Chapter 6)
- 3.2 To develop and refine programme theories and propose an MRT on how *one selected action* works to achieve adaptations when scaling-up health interventions for local fit, by identifying demi-regularities within the uncovered contexts and mechanisms (presented in Chapter 6)

As a result, the research was divided into two remaining phases. Phase two focuses on answering objectives 2.1 and 2.2 of identifying actions used to make adaptations during scale-up, and identifying what adaptations were being made in practice. To achieve this a systematic search for case examples of scale-up in practice took place and is described in detail in Chapter 5. The scope of the review including the research question and objectives continued to be clarified as the review progressed (objective 2.3) and will be discussed again following learning from phase two in Chapter 5 (Section 5.5). Further clarifying of the review led to one action selected for phase three, where theory was developed for on how and why the selected action works, in fulfilment of objectives 3.1 and 3.2. This will be presented in detail in Chapter 6.

4.2.3 Results: The IPT Framework

An overview of literature which informed the content of the IPT framework can be seen in Figure 4.4 and was presented in detail in Section 4.2.1 above. In summary, the literature included adaptation, fidelity and scale-up guidance and frameworks, and was complemented by the inclusion of the wider implementation literature, including two previous realist reviews, one of which focused on scaling-up complex healthcare interventions (7), and the other on large systems change in healthcare (181), both of which were thought to be of relevance and assisted in identifying further potential mechanisms. Theories from inside and outside the health field were also sought. Overall, a total of n=98 documents informed the IPT framework and are referenced throughout Appendix D.

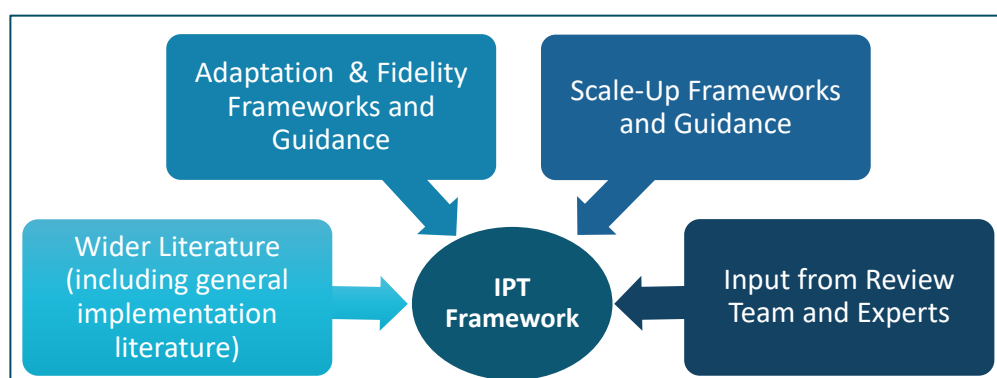


Figure 4.4 Literature informing the IPT Framework

Many barriers, facilitators and actions were identified within the literature that may influence scale-up in general, however, these may be of less relevance to adapting when scaling-up. Therefore, the IPT framework went through revisions to simplify the findings to ensure utility of the framework. Specifically, it aimed to focus on the potential actions, contexts, mechanisms and outcomes most relevant to adaptation and scale-up, rather than those relating to scale-up in general. Decision making for the IPT framework was recorded in detail as part of the research logbook in Appendix D, Tables D1-3. In these tables, key findings from the literature from the fidelity and adaptation frameworks and guidance (Table D1), scale-up frameworks and guidance (Table D2), along with the wider implementation literature (Table D3), were captured and the thought process/decision making regarding whether to include elements in the IPT framework transparently discussed. Some examples taken from the research logbook can be seen in Table 4.3 below.

Table 4.3 Examples from research logbook of decision making for inclusion in IPT

Source: Scale-up Frameworks and Guidance	Thought process, decision making	Inclusion in IPT
Decentralization - The decentralization of decision making to local levels (13, 124, 129, 132, 134, 173) - Build social capital locally to sustain and adapt interventions, this can be through HR training, infrastructure, data capturing systems, promotion of local enterprise (134)	The transfer of decision making to local levels was discussed in many scale-up frameworks. This could include transfer of decision making to local district level, frontline professionals or to communities and service users. The heading of local decision making was included as a potential action. This heading was thought could capture when autonomy was given to local level to make decisions about best fit.	“Local decision making” included as a potential action.
Source: Fidelity and Adaptation Frameworks and Guidance	Thought process, decision making	Inclusion in IPT
Fidelity is often seen as a top-down (researcher, intervention developer) driven approach and adapting more of a community driven bottom-up approach (frontline service providers, community, individuals) (56)	Fidelity and adaptation discussed as top down and bottom-up in their approach. With community and service level providers more engaged with adaptation, and top-down intervention developers or researchers driving fidelity. This suggests a power imbalance may exist among the two. The issue of	As a result, “power imbalance” was included in the IPT under contexts.

	power imbalance came up in the context of the scale-up literature also.	
Source: Wider Literature (including general implementation literature)	Thought process, decision making	Inclusion in IPT
Political context Political interest and will to scale up (47, 50), enabling policy environment (180)	The wider context, in particular the political context came up in this literature. It was decided to keep this heading broad at this stage to keep the IPT framework as simple and useful as possible. This also allows for variation in what may emerge and for this heading to be refined.	An overarching heading of “ political, socio-cultural and environmental factors ” was added as potential contexts.

A decision to use distal and proximal outcomes within the IPT was taken. For example, an action may be attributed directly to a proximal outcome e.g. involvement of community in decision making for adaptation (action), through a formalised community partnership (context), leading to community building trust (mechanism - response), generating buy-in and local ownership for intervention (proximal outcome). This may, in turn, lead to successful scale up with local fit and sustainability (distal outcome). However, multiple other actions may also assist in delivering the distal outcomes of scale-up and sustainability. Therefore, the use of proximal outcomes may assist in providing more specific insights addressing this complexity. Causation between the potential actions, contexts, mechanisms and outcomes were not made at this stage and will be added iteratively as the review progresses and further scope is refined. Contexts were further placed under headings adapted from the socio-ecological model (224) to aid in organisation. More details on this decision making for inclusion in the IPT framework can be seen in Appendix D provided.

The IPT framework is presented in Figure 4.5 and lists the potential actions, contexts, mechanisms and outcomes identified in phase one (working definitions for each heading can be seen in Appendix D, Table D4). To note, these actions would be introduced within differing contexts, which may influence whether a mechanism is triggered generating an outcome. As mentioned above, causation between them was not sought in this early stage. Instead, this IPT framework provides a theoretical map (7) for exploration in the following stages of the review. Specifically, it assisted in: (i) providing a framework for initial coding of actions for phase two (which will be discussed in Chapter 5, Section 5.2.3.3), and (ii) was used to support the development of specific IPTs related to the specific action taken forward in phase three of the study (presented in Chapter 6, Section 6.1.2).

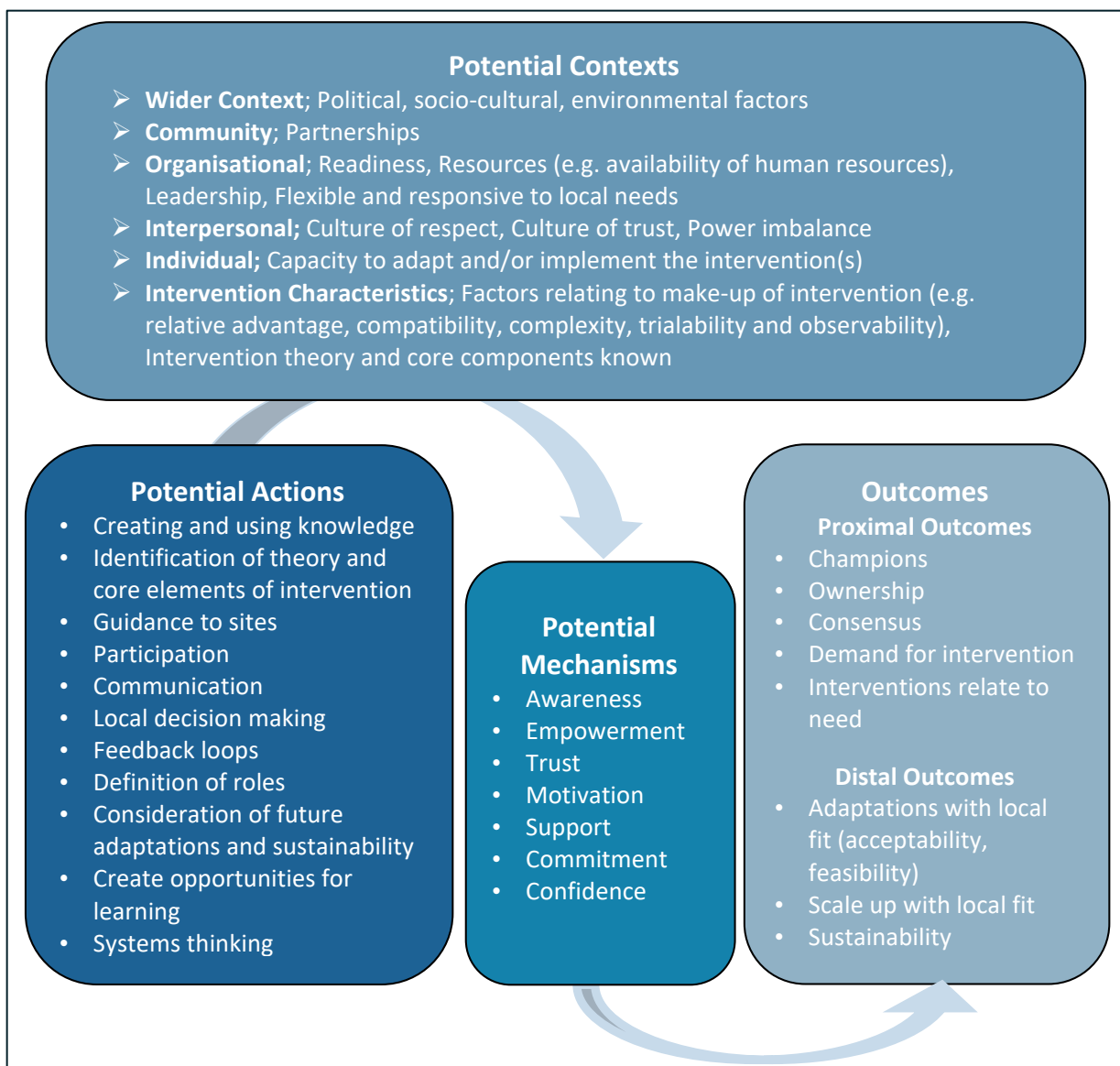


Figure 4.5 IPT Framework with potential actions, contexts, mechanisms and outcomes. To note actions are introduced within a context, which may influence whether a mechanism is triggered generating an outcome.

4.3 Challenges in Deciding on Search Strategy, Developing an IPT and Clarifying the Scope of the Review

While a decision was made for this phase to learn from frameworks and guidance in the field of adaptation, fidelity and scale-up, it was decided that it was not necessary to run a new search for this. Instead, the decision was made to use the results generated by the general background search, reference lists from previously identified reviews in the field, along with linking in with researchers in the field of fidelity and implementation to identify further resources. This approach is consistent with the realist review process, which allows for this flexibility and prioritisation of resources and time for subsequent searches and phases. With that said, a limitation of the approach chosen is that the guidance and frameworks identified may not be as exhaustive as a systematic search. Additionally while this phase made use of experts to complement this search, consulting a subject

librarian in addition to this in phase one (in addition to their consultation phase two) may have also saved time. Future reviews may therefore want to consider involving a subject librarian from the outset to guide planning of the review searches. However, for the purpose of this phase, the guidance and frameworks identified served as a sufficient source of knowledge to inform and build an overview of the field, and inform the IPT framework and future direction for the study. It also allowed for resources to be directed towards the systematic search for case examples in practice during phases two and three.

The dearth of research into what actions were used to support adaptations when scaling-up health interventions made it challenging to choose one action to focus on at this early stage. Therefore, identifying a range of potential actions from the theoretical literature, which could then be built upon through practical examples, was deemed most appropriate to address the research question and aims and allow for further focusing of the IPT framework. By not focusing on one action at this stage, the IPT framework was kept open, however, leading to more literature to review and incorporate, requiring a significant amount of additional time to go through this literature. However, progression in advance of a sensitised foundation of knowledge from the literature was deemed not to be a prudent approach.

As mentioned previously, there was a challenge in developing a review framework that both allowed for a level of abstraction to synthesise between documents, while also remaining specific enough to address the purpose of the review. Consequently, there were many iterations of the IPT framework of varying levels of detail and completion of these took up valuable time, which in hindsight could have been better applied during later phases of the review. This extensive use of time and resources for an IPT was also reflected on by Flynn et al., (225) during their realist review. In our case the IPT framework acted as a starting block, open to ongoing refinement, including progressing to five IPT statements at a later stage, as the review progressed. On reflection, future realist reviews should consider thinking about the future use of the IPT framework from the outset keeping in mind that it is open to refinement as learning progresses and so only using resources as needed for this purpose.

4.4 Phase One Contributions

Phase one ultimately resulted in an IPT framework of contexts, actions, mechanisms and outcomes identified in the literature that may support adaptations for health interventions during scale-up. In addition to this, phase one resulted in the development of a protocol paper (44), which outlines the steps taken in this review and which may help guide future realist reviews. This protocol paper is available in Appendix A.

Chapter 5. Phase Two - Actions used and Adaptations Made During Scale-up In Practice

Phase two sought to address the gap in knowledge identified as part of phase one. Namely, to discover what adaptations are made and why, when scaling up health interventions in practice. In addition to this, this review set out to explore what actions implementers can use to achieve these adaptations. Correspondingly, the research objectives for phase two were to:

- 2.1 Identify and describe what adaptations are made and why, when scaling up healthcare interventions in practice
- 2.2 Identify and describe what actions are used to achieve these adaptations in practice when scaling-up health interventions
- 2.3 Focus the review question by identifying *one* action to explore in detail in phase three for adaptations of health interventions during scale-up

5.1 Overview of Phase Two

In order to achieve the above objectives, phase two of the study involved a systematic search and screening for case examples of scale-up in practice, where health interventions had been adapted for local fit. First, a systematic search (Sections 5.2.1 and 5.2.2) was used to identify case examples of scale-up in practice. Second, included case examples were examined to identify adaptations made and actions used during scale-up. Based on these results, the scope of the review was one again clarified to focus on *one* specific action and how this action works for adaptations during scale-up to be explored in phase three.

Extraction of the types of adaptations used was guided by the FRAME expanded framework for coding of modifications (1). Described in greater detail in Section 5.2.3 below, adaptation extraction included details on the type of intervention content adaptations made, cited purpose and reasons for adaptations, whether adaptations were planned or unplanned, and the potential impact of the adaptation on fidelity to the intervention. The extraction of the types of actions used was informed by the initial IPT framework ‘potential actions’ headings, as derived in Chapter 4 (Figure 4.5), with additional actions added and original headings refined throughout the extraction process.

Consistent with the stages of a realist review by Pawson et al., (43) (Chapter 3, Figure 3.3), phase two of the research primarily included elements of Stage-I (clarifying scope) and Stage-II (developing the systematic search strategy). Phase two also included elements of Stage-III (selection and appraisal of case examples to use in this and future phases) and Stage-IV (data extraction of actions used, to build upon those presented in the initial IPT framework). Similarly, and consistent with Booth’s realist search components framework (45), phase two could be

considered primarily part of the *background search*, search to *formulate the review question* and also completed a *search to identify empirical evidence*.

The principal outputs of this second phase therefore included: (i) a description of what adaptations were made when scaling-up in practice (objective 2.1) and (ii) a description of what actions were used to guide adaptations when scaling up in practice (objective 2.2). Taken together, phase two thus provided a foundation for phase three by describing the actions and adaptations used in practice. These descriptions are then used to further clarify the scope of the research and to identify (iii) one *specific action* to be carried forward for further exploration in phase three, in fulfilment of objective 2.3. Phase three (Chapter 6) will then explore this action in-depth, identifying how this action works, through the examination of contexts and mechanisms and resultant outcomes. Phase three therefore serves to meet the remaining two objectives of the thesis:

- 3.1 To discover *how* the selected action works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit (presented in Chapter 6)
- 3.2 To develop and refine programme theories and propose a Middle Range Theory (MRT) for *how* the selected action may work to achieve adaptations when scaling-up health interventions for local fit, by identifying demi-regularities within the uncovered contexts and mechanisms (presented in Chapter 6)

Phase two further provided (iv) a sampling frame for case examples of scale-up in practice, which was revisited in phase three of the review in order to achieve objectives 3.1 and 3.2.

5.2 Methods Phase Two

5.2.1 Search Strategy for Phase Two

The search strategy was adapted from the initial background search completed in phase one of the review (Chapter 4, Section 4.1.1.1). Specifically, databases were identified with search strings developed for each database. Depending on the database, the use of MeSh terms, subject headings, and truncation aided the development of the search strategy. These were then reviewed by a subject librarian and further reviewed by a realist researcher with experience in systematic searches. As per the published study protocol (44) the databases searched were: PubMed, Cinahl, Scopus, Global Indicus Medicus, Web of Science, EMBASE, and Psycinfo. Grey literature searches were also completed in Social Care Institute for Excellence (SCIE), Grey Lit and Open Grey. Further to the database searching, the references of identified articles and the ExpandNet bibliography were also hand-searched for more case examples.

Following test searches, and in order to increase the specificity of the search, two refinements were made. First, and following the advice of a subject librarian, search strings were developed for the subject heading of 'health' in order to ensure that returned results were restricted to case examples within the field of health. Therefore, unlike phase one which also included case examples from other fields, such as education, the search strategy in phase two was restricted to the health field and to the scale-up of healthcare interventions. In total, three subject headings were developed: (i) scale-up, (ii) contextualise and (iii) health.

The second refinement of the search strategy occurred by using the subject headings of 'scale-up' within title only. The decision for this second refinement was based on results of the initial test searches using title and abstract, which returned a high volume of results, with the majority of articles unrelated to scale-up. More specifically, many articles reported the results of an RCT, pilot study or single case of implementation, only making reference to scale-up as part of their discussion or conclusion in the abstract. This refinement greatly increased the specificity of the search, restricting results to case examples of scale-up and returning a more manageable and relevant number of results. To ensure the search strategy still remained sensitive, key known citations were identified and checked for in the search results (e.g. Svanemyr et al., (197), Bergh et al., (226), Billings et al., (227) and Keyonzo et al., (228)). Assured that these documents were also identified after implementing these search refinements, the search strategy was deemed to have reached an acceptable level of specificity, without compromising sensitivity. Search terms used within each database are presented in Appendix E. These searches took place in June and July 2019.

In keeping with a realist review, and in contrast to a traditional systematic review, the goal was not necessarily to focus on exhaustive searching, but rather to systematically identify a sampling frame of examples of scale-up in practice from which further theory building, testing, and refinement could be drawn (3, 229). Further searches, and re-visiting of documents from this sampling frame, were completed iteratively, as required, based on clarified scope of the review and relevance to theory building and refinement and will be further discussed as part of phase three (Chapter 6, Sections 6.1.5 & 6.1.6).

5.2.2 Selection, Screening and Appraisal

5.2.2.1 Development of Inclusion Criteria for Phase Two

While it is acknowledged that many adaptations may occur in the RCT or pilot stages, these adaptations are often aided by extra resources (e.g. financial, academic research partners, staffing) that may not be available during a wider scale-up. Additionally, the needs identified in RCT and pilot sites may not represent those experienced by future sites targeted during scale-up. Therefore, and

given that the purpose of this study was to identify how to support adaptations that occur *during scale-up* (i.e., with usual resources available, where needs may emerge over time as contexts change (24), and where intervention fit may be need to be addressed across multiple heterogenous sites), examples where the adaptation(s) occurred during an RCT or pilot stage, and the same intervention was then scaled-up without further adaptations during the rollout of scale-up were excluded.

Accordingly, included documents initially had to meet all of the following criteria: (i) be an example of scale-up of a healthcare intervention(s) in practice, (ii) describe adaptations that had been made to a health intervention(s) to fit local settings during scale-up, and (iii) discuss 'in detail' the actions taken to adapt the health intervention(s) at scale. However, following test screening it was found there was a need to clarify this latter criterion further. Specifically, the inclusion criteria of discussing 'in detail' actions for adapting health interventions was found to be hard to quantify. As objective 2.2 of phase two was to identify and describe the actions used (with phase three focusing on a further in-depth analysis of one specific action), it was decided that excluding papers based on level of detail was not necessary at this point. Therefore, this third inclusion criterion was clarified to specify the description of an action as sufficient for inclusion, with no documents excluded due to a lack of detail of the specific action(s). Instead, results were screened again in phase three for relevance to the specific action ultimately chosen to be carried forward for further exploration in phase three, and based on whether the document could contribute to theory building or refinement.

Further clarity on the wording and definition was also needed for what constituted an adaptation to the health intervention. As objective 2.1 of this phase focuses on adaptations made to health interventions themselves, this criterion's definition was clarified to specify adaptations to the *content* of the health intervention using the FRAME (1, 15) guidance. Specifically, the FRAME guidance was used to assist in defining the types of content adaptations that could be made to a health intervention (e.g. tailoring the content by using relevant cultural references, or adding or removing elements of the intervention content). Consequently, and while adaptations to the wider context, the training of providers, and to the implementation process (1, 15) were all viewed as important, they were considered beyond the scope of this study, on the basis that they did not describe adaptations made to the content of the health intervention(s).

Studies that described scale-up at national and/or regional levels were included. In addition, adaptations described as positive and/or negative (e.g. where a loss to fidelity or local fit was not achieved) were included. Health interventions were limited to those where the direct target was

the individual as opposed to those directed at wider implementation interventions for example capacity building of human resources to deliver intervention. As scale-up occurs over a long-time period of time (with an estimated 15 years to reach national scale (51)) no time limit was placed on the search. Searches were carried out in English and included languages limited to those spoken by the review team: English, Spanish, Portuguese, and French. The final inclusion criteria and operational definitions used within phase two are summarised in Table 5.1.

Table 5.1 Inclusion Criteria and Definitions for Phase Two

Inclusion criteria	
1. Be a case example of a scale-up of a health intervention 2. An adaptation was made to the content of the health intervention 3. Adaptation(s) were made during the scale-up 4. The action used to guide or support this adaptation was described	
Exclusion Criteria	
1. Did not report adaptation to the content of a health intervention 2. Adaptations occurred prior to scale-up and no further adaptations were reported 3. Did not describe how adaptations were made i.e. did not describe actions used	
Definitions	
Scale-up	Scale-up was understood to be a purposeful expansion of a health intervention to a wider population (11, 12). This could involve expanding geographically, or to a wider population within the same setting. Both scale up at national and sub-national levels were included once the intervention was being purposefully expanded to a new geographic area or to a wider population group. If an article or study was not based on a real-world case example but put forward guidance, framework or aspirational steps these were excluded.
Health intervention	“An act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions” (WHO online, (4)). For this study, it was limited to interventions where the direct target was the individual. An example of this would be provision of nutritional supplements, vaccines or medication (e.g. vitamin A, polio vaccine etc.) and/or educational or behaviour change interventions directly delivered to the individual (e.g. breastfeeding education, safe sex promotion etc.). This could include interventions delivered in a group format, for example community education interventions. If the primary intervention was capacity building of Human Resources for Health (HRH), where the target beneficiary was the staff and not the end user, this was considered indirect and not included. As scale-up often occurs as a package of interventions, case examples of this were included if a specific direct health intervention was identified as a primary part of this package. Where case studies were general service delivery for example provision of mental health services at scale but did not identify a specific health intervention these were excluded.
Adaptations	Changes to the health intervention content. These could be planned or occur reactively as needs emerge. Type of adaptations may include adding or removing intervention content, tailoring, tweaking or refining elements, loosening the structure of the intervention etc. (1). For inclusion these adaptations needed to have occurred during scale up. If the adaptations occurred during the RCT or pilot stage and the same intervention was rolled out nationally (or sub-nationally) without further adaptations to the content, these were excluded. Adaptations could be reported as positive (achieving local fit with fidelity) or negative (where a loss to fidelity occurred).
Actions	An action was understood to be a process used to guide or make adaptations. For example, if core components of the intervention were identified and shared with sites to assist in making adaptations. Documents describing adaptation(s) without discussing what action(s) were used were excluded.

5.2.2.2 Screening and Appraisal

As per RAMESES guidance (3) for realist reviews, the application of relevance and rigour were used to guide screening and appraisal throughout the review. Title and abstract screening was completed based on the above inclusion criteria for phase two (table 5.1). The full texts were screened by two reviewers, including myself, with a third reviewer available to discuss inclusion or exclusion as needed. Documents were considered relevant where the document met all the inclusion criteria, as stated above. Any discussions between reviewers to clarify inclusion or exclusion were recorded in the research logbook. Notes were also taken on full texts which did not meet the criteria, but which were deemed to have some potential future value for theory refinement. Consistent with the RAMESES training materials (3), notes alongside the reasons for exclusion ensured a good data management system, and allowed for article retrieval if needed at later stages. Consistent with realist methods, no documents were excluded based on a hierarchy of evidence (3, 154). As this review is focused on scale-up, the inclusion of grey literature sources (e.g. reports on the scale-up), in addition to inclusion of peer reviewed articles, was considered important given their rich insights into the process of scale-up.

5.2.3 Data Extraction

5.2.3.1 Methods: Identifying Adaptations Made when Scaling-up Health Interventions

Initially, and as outlined in the published version of this study's protocol (44), it was planned to use Stirmans' 2013 classification of modifications (15) to guide data extraction for adaptations. However, Wiltsey Stirman et al., (1) had since published an update of their framework 'FRAME: an expanded framework for reporting adaptations and modifications to evidence-based interventions'. An improved version of their 2013 classification, FRAME provided further classification of adaptations, including whether adaptations were planned, proactive, or reactive, who made the adaptations, the reasons for adaptation and an additional section for consideration of fidelity. It was therefore decided to update the data extraction tool to reflect any additional relevant headings identified, based on this updated FRAME.

The chosen headings for data extraction for adaptations were: (i) description of adaptation, (ii) code assigned for type of content adaptation (e.g. adding or removing elements), (iii) at what level adaptation was made (e.g. individual, cohort), (iv) who made decision to adapt, (v) was adaptation planned (proactive or reactive) or unplanned, (vi) description of reason(s) for adaptation, (vii) with corresponding FRAME code assigned for reason(s) for adaptation, (viii) purpose of adaptation if stated or known, and (ix) consideration of fidelity. More details for each of these headings are provided below and are also detailed in the research codebook (Appendix F).

All reported adaptations were coded, such that a case example could have more than one adaptation code. Data extraction was completed using Microsoft Excel. A column for notes was also added to the data extraction tool to allow for quick note-taking on any details that could aid future screening, use, and identification. This process also helped to focus the review question and to easily recall a document, should it be relevant again in phase three.

An initial round of coding was completed for the adaptations across all case examples. Following this, additional reviewers were familiarised with the updated FRAME (1) and the codebook during a research seminar with seven other doctoral researchers in Global Health, each of which agreed to undertake a subset of case examples for coding. Therefore, each case example was coded by myself and then underwent a second independent review of adaptation coding from an additional reviewer who had been familiarised in FRAME and the codebook. Any difference in coding occurring as a result of this process was discussed and consensus agreed between the reviewers (106).

5.2.3.1.1 The Reasons and Purpose for Adaptations

The FRAME (1) identifies two distinct headings with the ‘goal’ of adaptations and the ‘reasons’ for adaptations. Here, the goal of adaptations relates to the overarching purpose of the adaptation, for example improving feasibility or increasing reach and engagement. For clarity however, the current study uses the terminology of ‘purpose’ instead of goal, as the case examples often used the term goal for other meanings such as improving overarching health outcomes. The original FRAME headings for *the purpose* of the adaptations were therefore to: ‘improve feasibility’, ‘increase reach or engagement’, ‘improve fit with recipient’ (with a sub-heading ‘to address cultural factors’ to improve fit with recipients), ‘increase retention’, ‘reduce cost’, ‘increase satisfaction’, and ‘improve effectiveness/outcomes’ (1). Each case example could have one or more purposes coded, as needed.

FRAME *reasons* for adaptations were organised under four headings including, the wider socio-political level, the organisational level, the provider level, and at recipient level (1) (see Table 5.3). While some reasons coincided with only one of these headings, for example, ‘adapting to fit within the current political climate’ occurred only under the socio-political level heading. Others were cross-cutting themes across all levels. For example, adapting for cultural norms was present under all four levels of socio-political, organisational, provider, and for the recipient. Of note, a case example may have described adapting for cultural norms at each of these levels, or only one. Each case example could also have multiple reasons and/or levels coded as needed. The reasons headings from FRAME (1) thus provided more specific codes than that of the purpose. For example, to address available resources at organisational level or address literacy/education at recipient

level, which, in turn, would assist in achieving the overarching purpose of improving feasibility or increasing reach and engagement.

5.2.3.1.2 Planned (Proactive/Reactive) or Unplanned Adaptations

Case studies were also examined for whether adaptations were planned proactively, planned reactively, or unplanned (1). *Planned proactively* was understood to be where planned processes for adaptations throughout scale-up were embedded from the outset (e.g. Quality Improvement (QI) methods) (1). *Planned reactively* related to adaptations which may not have been planned at the outset, however, were made in a systematic way in response to circumstances and learning as scale-up progressed (e.g. component added during scale-up in response to new national policies) (1). Finally, *unplanned adaptations* captured when ad-hoc adaptations were reported without thoughtful processes or were unsystematic in nature.

5.2.3.1.3 Level of Adaptation(s)

At what level the adaptation was made was coded based on the FRAME headings of: individual recipient, target intervention group, cohort/individuals that share a particular characteristic, individual practitioner, clinic/unit level, organisation and/or network system/community (1). Where an adaptation occurred at one or multiple levels, it was coded for all relevant levels.

5.2.3.1.4 Who Made Decisions for Adaptations

Where stated, the type of stakeholder who participated in decisions for adaptations was also extracted. The following FRAME headings were initially used to categorise different stakeholder groups: political leadership, funders, administrator, intervention developer, researcher, treatment/intervention team, individual practitioners, community members, recipients, and other/unclear (1). As decisions could be made by multiple stakeholders, one or more codes were used, as required.

5.2.3.1.5 Type of Adaptations

The type of content adaptation was also coded based on the following suggested FRAME headings (1): (i) tailoring, tweaking, refining, (ii) changes in packaging or materials, (iii) adding elements, (iv) removing/skipping elements, (v) shortening, condensing (pacing/timing), (vi) lengthening, extending (pacing/timing), (vii) substituting elements, (ix) re-ordering elements, (x) spreading (breaking up session content over multiple sessions), (xi) integrating parts of intervention into another framework, (xii) integrating another treatment into intervention, (xiii) repeating elements, (xiv) loosening structure, (xv) departing from the intervention (i.e., drift) followed by a return to protocol within encounter, and (xvi) drift from protocol without returning. More details on each of these types of adaptations are described in Table 5.5 and the FRAME guidance (1). An adaptation

could be coded under more than one heading. For example, if an element was removed to allow for a shorter intervention both 'removing elements' and 'shortening/condensing' were coded for.

5.2.3.2 Methods: Potential Impact of Adaptations on Fidelity

The potential impact of the adaptations on fidelity to the intervention was also considered. This was easiest to examine where a fidelity assessment was described and reported as having taken place. However, where no fidelity assessment was present a note was made and an estimate produced as to whether the adaptation(s) appeared consistent or inconsistent to fidelity, based on available information. These estimates were determined based on whether the intervention was adequately described, including whether explicit theory, functions, core components or minimum standards were identified. Reported adaptation(s) were then considered in terms of whether they were likely to have changed a this reported theory, functions, core components or minimum standards of the intervention (56). Instances where the intervention or adaptation(s) were not reported in sufficient detail to estimate their impact on fidelity were also noted.

5.2.3.3 Methods: Identifying Actions Used to Support Adaptations of Health Interventions during Scale-up

The actions used in adaptations were extracted using the potential actions headings from the IPT framework generated in phase one, as the initial codes (see Figure 5.1). These action headings from the IPT were subsequently refined, removed or added to, based on findings from the case examples. A description of each action reported for adaptations during scale-up from the case examples was extracted into the Excel file and placed under the relevant heading. A case example could have one or more actions extracted. If an action was described that did not fit under the original headings, a new heading was created. Headings could also be refined to be more specific as the extraction progressed, or removed if found to be no longer relevant. The code book (see Appendix F) was also updated to reflect any changes and each case example was reviewed again following updates to the codebook. Actions and refined actions headings were discussed with thesis supervisors. Once all the actions were extracted, the scope of the review was once again clarified to identify one action to carry forward for in-depth analysis in phase three, in fulfilment of objective 2.3 and with a view to advancing and developing theory on how this specific action works and in what circumstances.

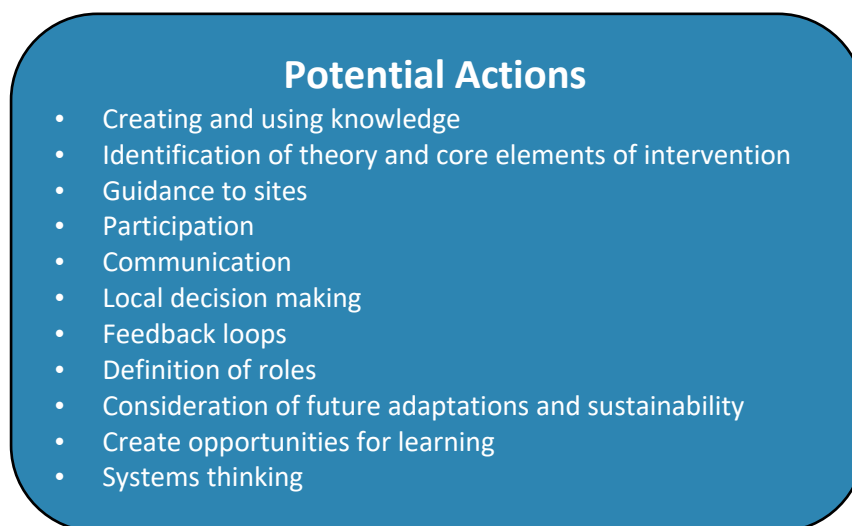


Figure 5.1 Actions identified in the IPT framework used as initial codes

5.3 Results Phase Two

5.3.4 Results of Screening

Searches were run between June and July 2019. However, one site (Grey Lit) was down during this time and therefore had to be revisited for a search in February 2020. A total of $n = 571$ records were returned from database searching, $n = 320$ of which remained after duplicates were removed. These were subsequently screened at title/abstract level, with $n = 33$ full texts identified. Following screening by two reviewers, $n = 23$ full texts were excluded with reasons for exclusion described in Figure 5.2. A challenge in screening for this phase of the study was the poor reporting of adaptations, along with the difficulty in distinguishing between adaptations to the implementation process and adaptations to the *content* of the health intervention itself, as the primary area of interest, and as per the aforementioned inclusion criteria. Four of the case examples required further discussion between reviewers before a decision was made as to whether to include these documents. This discussion was documented for transparency in the research logbook and is available on request. A total of $n = 10$ case examples were ultimately included from this initial search.

Following this, the ExpandNet bibliography was hand-searched and a further $n = 5$ case examples identified. Reference list searching on full texts was also completed, leading to the identification of a further $n = 7$ case examples, and bringing the total number of case examples for inclusion to $n = 22$. Through this reference list searching an additional 27 documents, providing more information on the resulting 22 case examples, were also identified. This therefore resulted in a total of $n = 22$ included case examples, described across a total of $n = 49$ documents. The screening process is summarised in Figure 5.2.

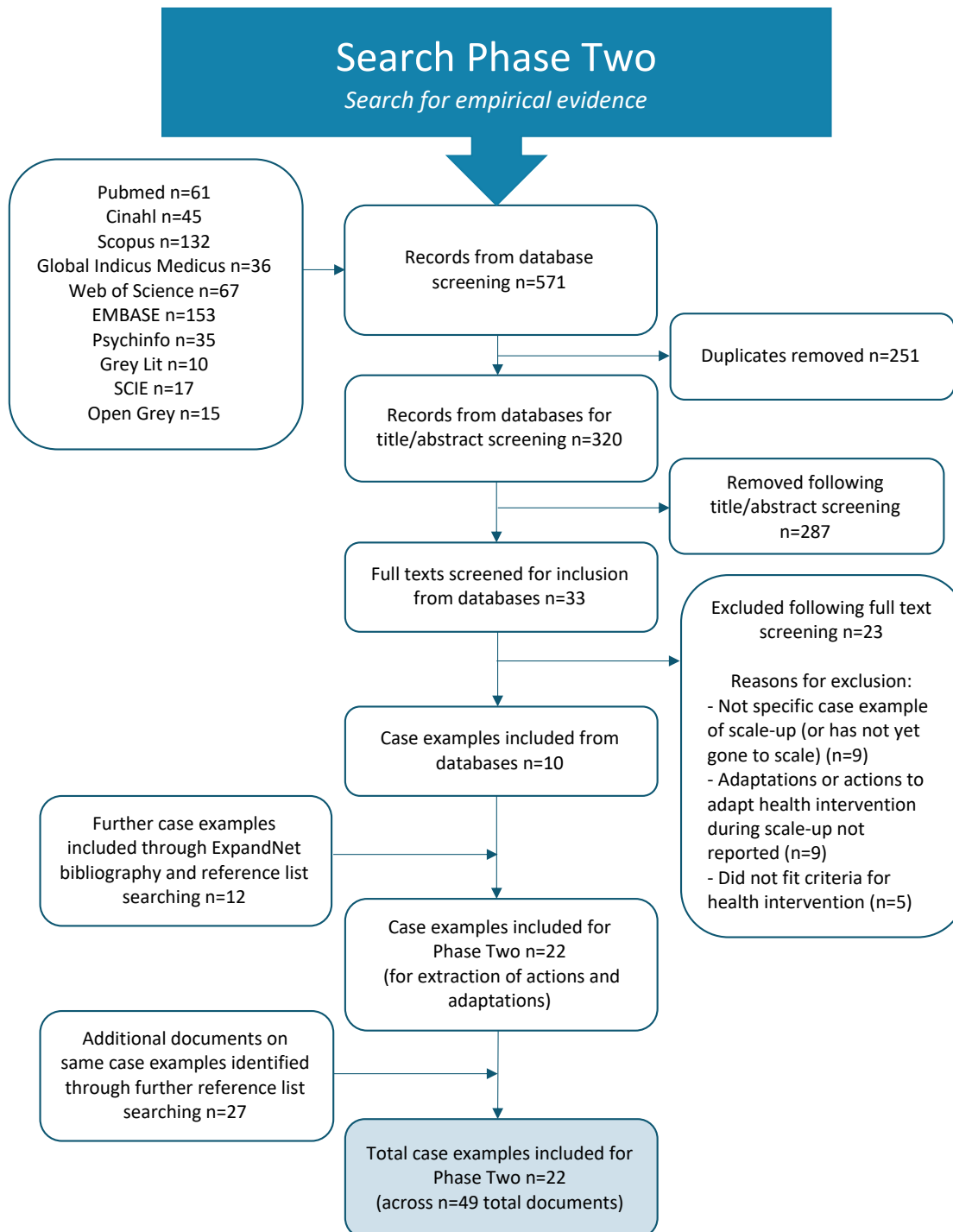


Figure 5.2 Flow chart of screening in Phase Two

5.3.5 Demographics of Case Examples (Topic, Intervention Type, Location, Reach of Scale-up and References)

Three of the 22 case examples were based in HICs (CE14, CE16, CE17), with the remainder based in LMICs. Nine case examples described scaling interventions in the field of sexual and reproductive health (SRH) (CE1-CE9), including two in sexual health education (CE1, CE2), two in post abortion care (PAC) (CE3, CE4), and five related to increasing contraceptive choice and provision of family planning counselling (CE5-CE9). Four case examples scaled-up maternal and child health (MCH) interventions (CE10, CE11, CE12, CE13), two of which included vaccination programmes (CE12, CE13). Two further case examples were related to non-communicable diseases (NCDs), with one scaling a physical activity and healthy eating intervention (CE14) and another a cervical cancer screen and treat approach (CE15). There was one case example scaling a mental health intervention (CE16). Six case examples related to HIV, which included scaling of interventions relating to prevention (CE17, CE22), treatment (CE18-CE21), and antiretroviral therapy (ART) adherence support groups (CE18, CE19). Twelve case examples reported on a national scale-up, with a further two reporting national scale beginning after a provincial scale-up. The remainder of case examples described health interventions scaled at city, district, provincial or regional levels. The included case examples with the topic, intervention type, location, reach and references are summarised in Table 5.2 below.

5.3.6 Study Types and Quality Appraisal

A range of documents including peer reviewed articles (62, 197, 207, 227, 228, 230-256), reports (257-261), newsletters from the scale-up (262-267) and ExpandNet publications (16, 129, 268-270) were included. Given the large variation in the types of study design and reporting for the case examples across documents, each case study was reviewed individually and notes taken on potential issues related to methodological quality and reporting, depending on the document type. The primary focus of the documents also varied. Whereas a number of documents primarily reported on an evaluation of the outcomes of the intervention or implementation, with some additional information on the process of scale-up or adaptation, others primarily focused on the process of scale-up, with or without an evaluation. Only two documents were specifically focused on assessment of adaptations and fidelity (CE17; (239, 240)).

Reporting and the level of data used to report on the process of scale-up across the documents also varied. For example CE3 (227) reported completing site visits, document analysis (including project reports), completing in-depth interviews (n = 49) with relevant key stakeholders (including

Table 5.2 Included Case Examples from Screening: Case Example Reference Number, Topic, Intervention, Location, HIC or LMIC, Reach, and Citations

Ref	Topic	Intervention(s)	Location	HIC/ LMIC	Reach (if reported)	Citations
CE1	SRH	Comprehensive Sexuality Education for schools	Senegal	LMIC	30% schools Senegal, 90% schools in two focus regions of Tambacounda and Kolda	(230)
CE2	SRH	Sexual and Reproductive Health “Life Skills” Education for schools	Pakistan	LMIC	National across 1,188 schools and 312,807 students. Including use of a boardgame which reached 250,000 girls in the community	(197)
CE3	SRH	Post Abortion Care (PAC) which included: (i) emergency care post complications of abortion and (ii) family planning counselling and methods	Bolivia	LMIC	National, services available in all nine regions, including across 8 tertiary hospitals, 53 second level hospitals, and 57 primary healthcare centres with further expansion expected	(227)
CE4	SRH	Post Abortion Care (PAC) which included: (i) emergency treatment of incomplete or spontaneous abortion complications, (ii) psychological support, (iii) family planning counselling and services, (iv) referral to other reproductive health services where needed and (v) community and service provider partnerships	Senegal	LMIC	23 districts, covering half of the country	(261)
CE5	SRH	Family planning package of interventions including increasing range of contraceptives offered and community education activities	Kenya	LMIC	Five cities; Nairobi, Kisumu, Mombasa, Machakos and Kakamega with total population 4.4. million	(228, 267)
CE6	SRH	Family planning package of interventions including increasing range of contraceptives offered and referral pathways to centres where contraceptives are assured to be available	Brazil	LMIC	National, with over 5,500 municipalities (administrative divisions)	(129, 270)
CE7	SRH	Family planning package of interventions including introduction of injectable contraceptive (DMPA) and wider quality of care strategies for counselling and education on family planning methods	Vietnam	LMIC	National, commenced with scaling to 21 of 64 provinces, however by 2002 all 64 had begun programme	(268)
CE8	SRH	Family planning package of interventions including increasing range of contraceptives offered	Zambia	LMIC	Copperbelt region in rural and peri-urban areas (8 districts), with 48 service delivery points and population of 1 million.	(16)
CE9	SRH	Family planning package of interventions including increasing range of contraceptives offered and improved quality of counselling and education on available methods	Bangladesh	LMIC	National	(269)

Ref	Topic	Intervention(s)	Location	HIC/ LMIC	Reach (if reported)	Citations
CE10	MCH	Kangaroo Mother Care (KMC). A method of care for pre-term infants which focuses on positioning of infant with skin to skin contact, nutrition with breastfeeding and follow-up care	Ghana	LMIC	Four regions, which included 52 districts and 38 hospitals (note total of ten regions in Ghana).	(231)
CE11	MCH	Project <i>Fives Alive!</i> , which included multiple maternal and child health interventions	Ghana	LMIC	National	(232, 233, 257, 262-266)
CE12	MCH	<i>Child Health days (CHD)</i> , Package of child survival interventions including supplemental vaccination activities (SIAs) e.g. deworming with vaccination programme	Somalia	LMIC	National, with some areas not covered due to insecurity/lack of consent by local leadership	(234)
CE13	MCH	Vaccinations, including pneumococcus, human papillomavirus (HPV), rotavirus, and measles & rubella	Rwanda	LMIC	National, 93%-98% vaccination coverage post scale-up	(235)
CE14	NCD	<i>Action Schools!</i> , a physical activity and healthy eating intervention for schools	Canada	HIC	All school districts (>60) totalling 1,474 schools in British Columbia Province	(236)
CE15	NCD	Cervical cancer single visit screen and treat, or two visit screen-refer-treat with electrosurgical excision procedure at specialist centre (as needed)	Zambia	LMIC	National, 33 government health clinics in all 10 provinces	(237)
CE16	Mental health	<i>Cognitive Behavioural Intervention for Trauma in Schools (CBITS)</i> , a mental health intervention for schools	USA	HIC	National, however unclear what the total reach was from these articles. Of examples discussed reach of 30 schools in Jersey city and 18 schools in New Orleans	(207, 238)
CE17	HIV	<i>Diffusion of Effective Behavioural Interventions (DEBI)</i> project, HIV prevention interventions for community settings	USA	HIC	National, >300 CBOs implementing nationally	(62, 239, 240)
CE18	HIV	Community Adherence Groups (CAG) for ARTs for HIV	Mozambique	LMIC	Provincial, Tete province with population 2.1million, 7.5% HIV rate, 5782 registered CAG members in 2012 data. National scale-up has commenced i	(241-243)
CE19	HIV	Adherence club (AC) for ARTs for HIV	South Africa	LMIC	Initially Western Cape and Cape Town, South Africa. Progressed to national scale. 400 AC's, with 30,000 patients in the Western Cape. Nationally 5,931 AC's, in 8 provinces with ongoing scale-up	(244-249)
CE20	HIV	ARTs for treatment of HIV, including individual education and adherence interventions along with community demand creation interventions	South Africa	LMIC	Three provinces of Western Cape, Free state and Gauteng with approximately 120,000 patients on ART in 2007 data	(250, 260, 271)

Ref	Topic	Intervention(s)	Location	HIC/ LMIC	Reach (if reported)	Citations
CE21	HIV	Prevention of Mother to Child Transmission of HIV (PMTCT) interventions, including treatment with ARTs and education and adherence interventions	South Africa	LMIC	National	(251-255, 258, 259)
CE22	HIV	<i>Avahan</i> programme, a HIV prevention intervention package including peer-led education, condom, needle and syringe distribution along with community education interventions	India	LMIC	83 districts across six states, delivered to 300,000 people at risk of HIV	(256)

ARTs Antiretrovirals, CE Case Example, HIC High Income Country, HIV Human Immunodeficiency Virus, LMIC Low and Middle Income Country, MCH Maternal and Child Health, NCD Non-communicable Disease, SRH Sexual and Reproductive Health

MoH, NGO, health providers, advocates and researchers), along with use of health service statistics, policies and guidelines. In contrast, one of the documents in CE17 (240) was an editorial style reflection on lessons learnt, where the perspective was solely from one authors' experience in the community-researcher partnerships with minority groups.

Methodological reporting gaps were identified in a number of peer-reviewed articles. For example, CE16 (238) discussed reflections on the process and lessons learnt when scaling-up, however they failed to clarify the role of the authors in the scale-up, leading to a lack of transparency. Other articles presented both outcomes of the intervention (or implementation), and also presented details on the process of scale-up. While some included details on how the outcome data was collected, there was a general lack of reporting on how the information was gathered to report on the process elements of scale-up up (e.g. CE12 (234), CE13 (235), CE15 (237)).

While the lack of reporting on the *process* of scale-up was discouraging, this was somewhat expected given the general lack of guidelines for reporting on IR and for the process of scale-up, which has been identified within the broader literature (see Chapter 3, Section 3.3). However, and given that Pawson (154) promotes that useful information can arise from studies which would otherwise not be prioritised using a traditional hierarchy of evidence, valuable information was successfully identified from documents that may otherwise have been considered of low quality. Therefore, and after reviewing all documents, a decision was made not to exclude any documents on the basis of their quality at this stage. This decision allowed for the inclusion of documents, such as newsletters - some of which described adaptations which occurred at local levels. Further consideration of potential methodological issues within the included documents, as well as their usefulness for the purpose of theory development, refinement and testing is explored further in phase three, when the included documents are appraised for relevance and rigour, based on their use for programme theory development (3, 155).

5.3.7 Results: Adaptations

5.3.7.1 The Reasons and Purpose for Adaptations

The reasons and purpose for adaptations, as identified in the included articles, are presented in Table 5.3, with adapting for *cultural acceptability* and *reduced resource availability* most frequently cited.

Table 5.3 Purpose & Reasons for Adaptation(s) with case studies who reported. Adapted from (1)

Purpose of Adaptation(s)		Case Examples who Reported
Purpose of Adaptations	Improve feasibility (n=11)	CE1, CE2, CE5, CE8, CE14, CE15, CE17, CE18, CE19, CE20, CE21
	Increase reach or engagement (n=11)	CE2, CE4, CE8, CE10, CE11, CE16, CE17, CE18, CE19, CE20, CE22
	Improve fit with recipients (n=11)	CE5, CE8, CE9, CE13, CE16, CE17, CE18, CE19, CE20, CE21, CE22
	Improve fit with recipients by specifically addressing cultural factors (n=10)	CE2, CE5, CE9, CE10, CE11, CE16, CE17, CE19, CE21, CE22
	Improve fit within the wider community or sociocultural context (n=15)	CE1, CE2, CE3, CE4, CE5, CE6, CE7, CE8, CE10, CE11, CE13, CE14, CE16, CE18, CE22
	Improve effectiveness/outcomes (n=10)	CE5, CE10, CE11, CE12, CE15, CE16, CE17, CE20, CE21, CE22
	Increase retention (n=7)	CE15, CE16, CE17, CE18, CE19, CE20, CE22
	Reduce cost (n=3)	CE5, CE17, CE19
Level	Reasons for Adaptation(s)	Case Examples who Reported
Socio-political level	Existing laws, mandates, policies, and regulations (n=2)	CE2, CE17
	Political climate (n=5)	CE1, CE2, CE6, CE17, CE22
	Funding Policies (n=1)	CE17
	Historical context (n=4)	CE2, CE5, CE6, CE7
	Societal/Cultural Norms (n=15)	CE1, CE2, CE3, CE4, CE5, CE6, CE8, CE10, CE11, CE13, CE14, CE17, CE18, CE19, CE22
	Funding and Resource Allocation/Availability (n=2)	CE10, CE15
Organisational level	Available resources (n=13)	CE1, CE5, CE7, CE8, CE10, CE12, CE14, CE15, CE17, CE18, CE19, CE20, CE21
	Competing demands or mandates (n=2)	CE10, CE17
Organisational level	Time constraints (n=3)	CE1, CE2, CE5
	Service structure (n=2)	CE15, CE17
	Location/accessibility (n=1)	CE15
	Regulatory/compliance (n=1)	CE17
	Billing constraints (n=0)	n/a
	Social context (culture, climate, leadership support within organisation) (n=4)	CE6, CE7, CE10, CE17
	Mission of the organisation (n=2)	CE17, CE21
	Cultural or religious norms within organisation (n=2)	CE4, CE6
Provider level	Race/gender/ethnicity/sexual orientation or gender identity (n=0)	n/a
	First/spoken languages (n=0)	n/a
	Previous Training and skills (n= 2)	CE8, CE15
	Preferences — relating to their level of interest and comfort in delivering intervention (n=2)	CE1, CE2
	Clinical Judgement (n=3)	CE12, CE17, CE22
	Cultural norms and competency (n=3)	CE1, CE10, CE22
	Perception of intervention (n=1)	CE10
Recipient factors	Race, gender, ethnicity, sexual orientation or gender identity (n=4)	CE2, CE16, CE17, CE22
	Cognitive capacity (n=0)	n/a
	Physical capacity (n=0)	n/a
	Literacy and education level (n=5)	CE2, CE11, CE13, CE20, CE21
	First/spoken languages (n=2)	CE2, CE17
	Access to resources (n=5)	CE11, CE17, CE18, CE19, CE20

	Cultural or religious norms (n=13)	CE4, CE5, CE6, CE8, CE9, CE10, CE11, CE13, CE16, CE17, CE18, CE19, CE22
	Comorbidity/Multimorbidity (including HIV status) (n=4)	CE18, CE19, CE20, CE22
	Legal status (n=1)	CE22
	Immigration Status (n=1)	CE16
	Crisis or emergent circumstances (n=2)	CE16, CE22
	Motivation and Readiness (n=3)	CE17, CE19, CE20
	Occupation (n=2)	CE17, CE22

Firstly, adapting for cultural acceptability cut-across the four levels of socio-political, organisational, recipient, and to a lesser extent, at provider level. Adapting for cultural acceptability was most commonly cited at the socio-political level ($n = 15$), where adaptations were seen as necessary in order to align to the societal/cultural norms of a community or the wider national context. It was also reported frequently at recipient level, with adaptations seen as necessary to address an individual's cultural or religious norms and values ($n = 13$). The case examples reporting adaptations 'for cultural fit' as the reason and purpose are presented in Table 5.3. These include where there was international guidance on an intervention, for example for skills-based sexual health education from the WHO (272), which was adapted for cultural fit in respective countries (CE2).

Secondly, resource availability was mainly identified at organisational level ($n = 13$) with access to staffing, funding, medication and facilities often listed as limiting factors. However, adapting due to resource availability also cut-across other levels, with an individuals' access to resources ($n = 5$), such as recipients unable to afford time off work or pay for the transport to facilities (CE17), cited as a reason to reduce the length or number of intervention sessions. Additionally, adapting for funding and resource allocation ($n = 2$) or for funding policies ($n = 1$) at the wider socio-political level were specifically reported. Of note, adapting for funding policies may not relate to the needs of the beneficiaries and local context, but could also depend on the beliefs and agenda of the funding agency (CE17).

5.3.7.2 Results: Proactive, Reactive or Unplanned Adaptations

A large number of case studies reported on proactive adaptations whereby processes for future adaptations were embedded into the scale-up design (CE2, CE4, CE5, CE8, CE9, CE10, CE11, CE12, CE13, CE14, CE15, CE16, CE17, CE18, CE19, CE20, CE21, CE22). This included having an adaptive scale-up design (CE22), embedding quality improvement (QI) methods (CE11, CE16, CE21), and building community partnerships (CE16).

Reactive adaptations also occurred in a number of case studies (CE1, CE2, CE3, CE6, CE7, CE14, CE15, CE17, CE18, CE19, CE20). These adaptations, although not embedded or planned from the

outset, often served to adapt the intervention as needs were identified. For instance, in Pakistan, and due to time constraints, the volume of content of sexual health education was reduced to be completed within one year (CE2). As another example, a lack of resources which emerged when ‘treatment buddies’¹ (273) were unavailable, led to the removal of this element in some sites so as to avoid delays in starting ARTs in South Africa (CE20), thus making the intervention more pragmatic to the available resources in the context. Reactive adaptations also occurred in response to a recognised need to address acceptability. For example language was adapted from post abortion care to “care for haemorrhage during first half of pregnancy” (p2216) (227) to emphasise lifesaving elements and reduce emotive and stigmatising language being used in during the scale-up of PAC in Bolivia (CE3), thus reacting to ensure the intervention was more acceptable within the organisational and wider cultural context.

Reactive adaptations could also be negative. For example, with local leadership removing elements of family planning interventions based on cultural norms and religious beliefs in their area (CE6). In another example, some provinces in the scale-up of family planning methods in Vietnam reacted to time constraints by not waiting for the results of an evaluation of effectiveness and removing quality of care elements of the intervention prior to implementation (CE7). In this case, both authors of these scale-ups reported that this decision had a negative impact on implementation, whereby women did not necessarily receive an acceptable range of contraceptive options or informed education on family planning options, as per international guidance and standards (274-277).

Unplanned adaptations were noted in the scale-up of Comprehensive Sexuality Education (CSE) in Senegal (CE1), with teachers omitting core topics citing discomfort with topics considered sensitive or taboo. Another adaptation coded as unplanned was a provider dropping parts, or whole sessions, of a group-based HIV prevention intervention (CE17, (239)) in response to recipients not engaging with or walking out of particular sessions. Both of these examples reported an impact on intervention fidelity with an unknown impact on intervention effectiveness.

5.3.7.3 Results: Level of Adaptations

Adaptations varied from changes made for an individual recipient, to changes made at national level, with some case examples reporting adaptations occurring at multiple levels within their system, depending on the adaptation (see Figure 5.3). New headings were therefore added to the existing FRAME headings to specify at national level; provincial, regional or district levels; and for

¹ Treatment buddies (also known as treatment supporters) can be used as a strategy where a person provides support for adherence to ART medication

local community level in order to delineate the differences and enhance specificity. A challenge in synthesising these international examples, however, was the variation in terminology used to delineate levels below national level across countries. Consequently, a heading of ‘provincial, regional and/or district’ was developed to capture levels below national, but above levels of community, or the health facility.

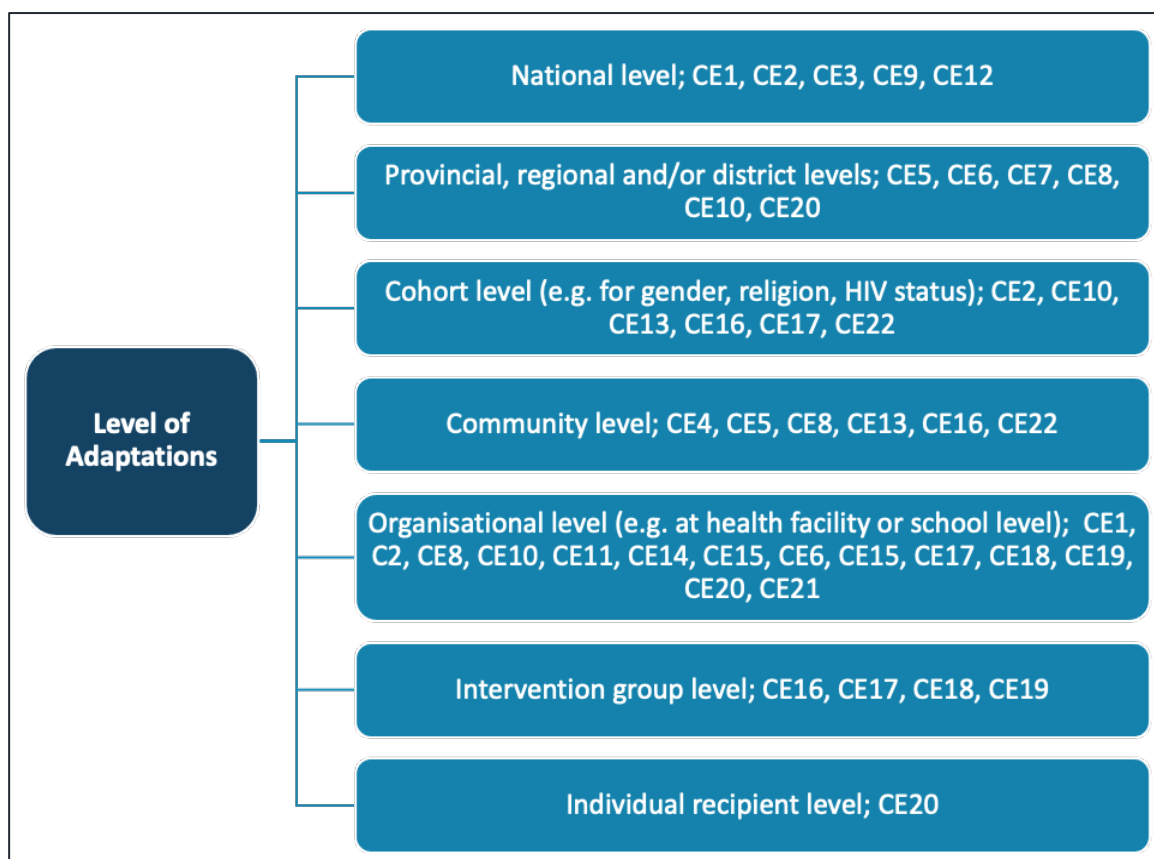


Figure 5.3 Level adaptations reported. Adapted from (1)

A number of adaptations were reported at a national level (CE1, CE2, CE3, CE9, CE12), often carried out by the programme managers/central resource team for scale-up, with or without the assistance of partners or a coalition of stakeholders such as religious leaders (CE1, CE2). Other adaptations were reported at regional, provincial and/or district levels (CE5, CE6, CE7, CE8, CE10, CE20) often with decentralisation of decision making to local management at the respective levels. Adaptations were also reported at an organisational level (e.g., hospital, health facility, school or CBO level) (CE1, CE2, CE8, CE10, CE11, CE14, CE15, CE6, CE15, CE17, CE18, CE19, CE20, CE21). For those case examples where autonomy of decision making was transferred to local levels, this is discussed further under the action of ‘local decision making’ (see Section 5.3.9, Action 3 below). Many case examples reported that adaptations occurred at community level (CE4, CE5, CE8, CE13, CE16, CE22), especially when adapting education or sensitisation messaging to fit local beliefs (CE4, CE5, CE8, CE13, CE22). Community level adaptations often occurred with support from community

members to guide adaptations (CE4, CE8, CE13, CE22), sometimes reported as a formalised community partnership approach (CE4, CE16). Additionally, adaptations were also reported at intervention group level (CE16, CE17, CE18, CE19), with some further reporting the involvement of intervention recipients in decision making (CE16, CE18). Adaptations were also reported at individual recipient level, for example based on levels of literacy in the case of ART adherence education interventions, with pace or content modified to suit an individual's abilities in some sites (CE20). There were also adaptations reported for specific cohort or populations based on: gender (CE2, CE17), religious schools (CE2), for specific community members (CE10, CE13) (e.g. traditional birth attendants (CE10)), for those who experienced specific traumas (e.g. migration trauma) (CE16), based on HIV status (CE17), and for sex workers (CE17, CE22).

5.3.7.4 Results: Who Participated in Decisions for Adaptations

Those involved in making decisions for adaptations, where made explicit, are presented in Table 5.4. In many case examples, however, it was unclear who made the decision for each adaptation. New codes were added to further differentiate who made decisions, as different populations emerged. For example, programme leaders was refined to 'scale-up leaders'. A heading for religious leaders was also added as this group appeared as an important contributor in three case examples (CE1, CE2, CE6). For example, in the case of SRH education in Pakistan (CE2), the involvement of Islamic scholars assisted in adaptations for acceptability within Islamic boarding schools, whereby the SRH curriculum messages were supported with references from religious texts. In contrast, the involvement of religious leaders in the case of family planning interventions in Brazil (CE6), together with enforcement of local religious laws, led to the removal of emergency contraceptives in some municipalities, or in some areas, the prohibition of implementation of the whole intervention.

While wider community members being a part of decision making was frequently reported, recipients of the intervention directly influencing adaptations to the intervention content was less frequent. Of the case examples that discussed the recipients making adaptations, one was an adherence to ART intervention, whereby people living with HIV could make adaptations for their own group (CE18). Here, and while the intervention was developed with set eligibility criteria, group size and guidance on operating the group, the intervention was also flexible to adaptations outside these components. Intervention recipients were also supported in making adaptations in CE16, which employed a community partnership approach to implement a group based mental health intervention in schools where adaptations could be made in consultation with each treatment group at the start of particular modules to ensure cultural acceptability. Overall, the volume of case examples reporting the transfer of autonomy of decision making to local levels either at provincial, regional or district levels, to health facility levels, or to the frontline intervention team or

practitioner was high. Moreover, transfer of autonomy of decision making to local levels was discussed as an approach which allowed for sustainability, time sensitive adaptations, along with the incorporation of local knowledge for fit (CE5). Local decision making is discussed in further detail in Section 5.3.9, Action 3.

Table 5.4 Who Participated in Decisions for Adaptations. Adapted from (1)

Who Participated in Decisions for Adaptations	Case Example Who Referenced
Political leaders (could include MoE or MoH)	CE1, CE2, CE6
Scale-up leadership (i.e. central resource team)	CE1, CE2, CE8, CE9, CE14, CE15, CE19, CE22
Funders	CE17
Researcher	CE16
Intervention developer	CE1, CE14
Regional/provincial/district management	CE2, CE5, CE6, CE7, CE8, CE10, CE11, CE20, CE21
Hospital/health centre/facility manager	CE8, CE10, CE11, CE17, CE20, CE21
Frontline providers	CE1, CE2, CE4, CE11, CE13, CE14, CE16, CE17, CE18, CE19, CE20, CE21, CE22
Community members	CE2, CE4, CE8, CE11, CE12, CE13, CE16, CE18, CE22
Local leaders (at community level)	CE6, CE8, CE12, CE13
Religious leaders	CE1, CE2, CE6
Coalition of stakeholders	CE2, CE3, CE8, CE10, CE12, CE13
Recipients	CE16, CE18

5.3.7.5 Results: Type of Adaptations

The type of content adaptations for each case example is presented in Table 5.5. The most commonly reported content adaptation types were ‘adding elements’ ($n = 13$) and ‘tailoring, tweaking or refining’ ($n = 13$), with over half the case examples reporting one of these adaptation types. An example of ‘adding elements’ was seen in the education intervention *Fives Alive!* Ghana (CE11), which aimed to educate communities on the importance of women giving birth in the presence of a skilled birth attendant. During the scale-up, a local site adapted their education approach by adding a video of birth complications, which they reported was effective in the local area to increase attendance to the health facility for delivery. This addition was later shared and scaled to the wider district. An example of ‘tailoring, tweaking, and refining’ was seen in *CBITS* - a group based mental health intervention in schools (CE16) - where they referenced adapting to include relevant examples from pop culture that the group were more likely to relate to.

Table 5.5 Type of Content Adaptations. Adapted from (1)

Type of Content Adaptations	Description	Case Examples Who Reported
Tailoring, tweaking, refining (n=13)	Minor change reported which leaves major principles in place e.g. changes to language	CE2, CE3, CE4, CE5, CE10, CE11, CE14, CE15, CE16, CE17, CE20, CE21, CE22
Changes in packaging or materials (n=4)	Changes to materials used with recipients e.g. adapted from book to CD, added more pictorial elements	CE2, CE8, CE11, CE17
Adding elements (n=13)	Distinct elements added to intervention e.g. a clinic might add an optional treatment buddy when delivering ART education and treatment)	CE1, CE2, CE8, CE9, CE10, CE11, CE14, CE16, CE17, CE18, CE20, CE21, CE22
Removing/skipping elements (n=8)	Elements are dropped or skipped e.g. those that are culturally not appropriate left out	CE1, CE2, CE6, CE7, CE8, CE16, CE17, CE21
Shortening, condensing (n=4)	Shorter amount of time or reduced number of sessions used	CE1, CE2, CE5, CE17
Lengthening, extending (n=3)	Longer amount of time or increased number of sessions used	CE16, CE17, CE20
Substituting elements (n=1)	Element is replaced with another e.g. condom application demonstration replaced with abstinence talk	CE8
Re-ordering elements (n=0)	Sessions reordered or moved around	n/a
Spreading (n=0)	Spreading of intervention e.g. content of one session delivered over two to adapt for cognitive capacity	n/a
Integrating parts of intervention into another framework (n=1)	Intervention is utilised in full or part within another intervention e.g. selecting elements to incorporate into another intervention	CE17
Integrating another treatment into EBP (n=1)	intervention is used as a starting point, but other techniques and approaches integrated throughout e.g. use of motivational interviewing technique within an intervention that did not specify its use initially	CE17
Repeating elements (n=1)	Elements usually prescribed as once, or already present in intervention are repeated e.g. repeating a dose of vaccine	CE12
Loosening structure (n=7)	Flexibility with programme/process was reported e.g. opening and closing pf sessions changed, layout was different	CE12, CE16, CE17, CE18, CE19, CE20, CE21
Departing from the intervention followed by a return to protocol within encounter (n=1)	Reported leaving intervention protocol and used another, followed by a return to original intervention e.g. started with CBT and moved to supportive therapy, with a return to CBT	CE17

Drift from protocol without returning (n=7)	Left intervention protocol and does not report return e.g. started with CBT, moved to supportive therapy for rest of treatment	CE1, CE6, CE7, CE8, CE12, CE18, CE19

5.3.8 Results: Potential Impact of Adaptations on Fidelity

A specific fidelity assessment was not present in the majority of case examples, with only one case example (CE17) reporting conducting two fidelity assessments. In the first assessment, a qualitative study with providers from 22 CBOs in the Los Angeles area self-reported on fidelity and adaptations to core elements across a range of the HIV prevention interventions scaled (known as DEBIs) (239). A second mixed-methods study was carried nationally in the USA in which 61 CBOs completed a survey, and 5 CBOs completed key informant interviews, self-reporting on fidelity and adaptations specifically to one of these HIV prevention interventions - the VOCE/VOICES intervention² (62). Overall, this study found that the fidelity to core elements was often reported by providers to be maintained (239). However, some adaptations, for example where a key lesson was removed based on negative feedback from recipients, were identified as having changed the core elements, or internal logic, of the intervention and were therefore classified as ‘re-invention’, with the authors suggesting that these revised interventions should be re-evaluated for effectiveness (62, 239). Of note, these fidelity assessments were primarily focused on the *delivery* element of fidelity, (i.e., whether the intervention was delivered as intended (81)), with focusing on only this element of fidelity acknowledged as a limitation within the study (62, 239). Additionally, as self-report measures were used to assess fidelity these may have been subject to social desirability bias. Another consideration is that only one of the DEBI interventions was assessed within the larger national study, resulting in fidelity of the wider intervention package only being explored in the Los Angeles area and the fidelity of the wider package unknown in the broader national context.

In terms of adaptation types (as seen in Table 5.5 above) ‘removing/skipping elements’ ($n = 8$) was also frequently completed within the case examples. Notably, ‘removing/skipping elements’ may have been associated with a loss to fidelity. For example, in the scale-up of family planning interventions in Brazil (CE6), where the contraceptive options of an intrauterine device (IUD) and emergency contraceptives were removed from the intervention package in some areas, based on local laws or opposition from religious leadership.

Two further case examples discussed in their evaluations that adaptations *could have* impacted fidelity to the intervention, though a specific fidelity assessment was not carried out (CE18, CE19).

² VOCE/VOICES intervention is a HIV prevention intervention that was part of the Dissemination of Behavioural Interventions for HIV (DEBI) in the USA.

Three case examples (CE1, CE6, CE7) did not report on a specific fidelity study or evaluation, however did acknowledge that elements removed or adapted, either nationally or in some districts or sites, would have affected key intervention components.

Assessments of fidelity for the remainder of the case examples presented in this review therefore rely on an estimate of whether adaptations appeared consistent or inconsistent to fidelity, based on the information provided in the document. Throughout many of the case examples, there was ambiguity in terms of the actual intervention, and whether there were theory, core function, elements, components or standards to follow (see Table 5.6). Some case examples did note and detail core elements or functions (CE16, CE17), or core topics (CE1, CE2) within an intervention, with flexibility to adapt outside of these elements. Other case examples noted more overarching intervention components such as: internationally recognised essential elements for PAC (CE3, CE4), key components and minimum physical activity and health eating standards (CE14), components and criteria for adherence group formation and operation (CE18, CE19), or a minimal method mix in family planning (CE8). For other case examples however, and in the absence of knowing what the intervention was intended to be, including what would be its constituent parts, it was challenging to discern the impact of adaptations on fidelity. The level of detail of the adaptations themselves was also lacking in the majority of case examples. It therefore follows that given that the interventions and their constituent components and/or the adaptations were not well described, an assessment of fidelity within this review was not possible. Instead, details of what could be discerned of the relationship between adaptations and fidelity for each case examples were considered by the reviewer with judgements made of *appeared consistent*, *appeared inconsistent*, *unclear*, or noting whether fidelity was lost. To note, as multiple adaptations were reported in many documents, some were judged as *appeared consistent and inconsistent* to represent that some adaptations appeared in keeping with intervention components, while others did not. These assessments are presented in Table 5.6 below with a short comment made on the reasoning for this assessment for each CE.

Table 5.6 Consideration of Fidelity for Adaptations Reported in the Case Examples of Scale-Up

Ref	Was the intervention being adapted described?	Intervention theory, core elements, components, functions or minimum standards identified?	Was fidelity assessed?	Did adaptations maintain fidelity?	Comments
CE1	Yes	Yes, core topics	No	No*	Fidelity to core topics lost in both intervention/curriculum design and during delivery by providers
CE2	Yes	Yes, core topics	No	Appeared consistent & inconsistent	No formal fidelity assessment reported. Reports core topics maintained during curriculum redesigns. Appears removal of core topics during delivery may have occurred in some regions
CE3	Overarching essential elements of PAC identified and referenced	Components of essential elements of PAC were available in referenced document (278)	No	Appeared consistent	Language of post-abortion changed to post-haemorrhage to increase acceptability. Did not appear to affect the essential components of PAC (278)
CE4	Overarching essential elements of PAC identified and referenced	Components of essential elements of PAC were available in referenced document (278)	No	Appeared consistent	The adaptation described adding a service provider and youth theatre collaboration, which would appear consistent with the essential elements of participation of community members and education on importance of PAC (278)
CE5	Did not have detailed information on education interventions	Simplified package of interventions given to scale-up sites to allow for flexibility	No	Appeared consistent	Adaptations to address local beliefs and misconceptions on family planning methods (228) which would appear to be consistent to providing informed education on family planning methods (274-277)
CE6	Overarching core interventions reported but not described in detail	Noted core service innovations to be scaled which included availability of contraceptives	No	No*	Removal of contraceptive options that were intended to be delivered of IUDs and emergency contraceptives in some sites due to lack of acceptability by local laws or religious leadership
CE7	Yes	Yes, key components of innovation stated	No	No*	Adaptations reported the introduction of DMPA without the wider quality of care initiatives in some provinces. This affected the fidelity to provision of balanced information and counselling on family planning
CE8	Yes	Three focus areas including a minimum method mix and a common set of strategies given to sites to support implementation and flexibility	No	Appeared consistent	Adaptations reported: whether method mix available on site or through referral mechanisms; community education messages being incorporated into local rites of passage (e.g. menarche); re-packaging of high dose oral contraceptives as emergency contraceptives. These adaptations would appear to have maintained consistency with the minimum method mix and were in keeping with international family planning standards (274-277)

Ref	Was the intervention being adapted described?	Intervention theory, core elements, components, functions or minimum standards identified?	Was fidelity assessed?	Did adaptations maintain fidelity?	Comments
CE9	Not much information given	Not described	No	Appeared consistent	Adaptation during extension stage reported introduction of injectable contraceptives which were made available by community workers 'at the doorstep'. This adaptation would appear to be in keeping with international standards (274-277) of increasing range of contraceptive options available and not to negatively impact fidelity
CE10	Details on key components and theory present. Dose/frequency not given	Overarching key components and theory identified	No	Appeared consistent	Minimal description of adaptations made. Discussed in detail processes for adaptation with autonomy given to regional and district steering committees. For those adaptations that were described it appeared consistent with key components and theory
CE11	Multi-intervention programme, in-depth details for each intervention not given	Not described	No	Appeared consistent	The scale-up approach gave autonomy to local sites through use of QI methods, to inform and guide adaptations for local fit. Adaptations to the education component of importance of skilled birth attendance to address local beliefs (for example perception of bravery for delivery at home) were primarily reported. These adaptations would appear consistent with fidelity to this component
CE12	Yes, however did not report on guidance for spacing of potential repeated vaccine doses	Not described	No	Unclear	Adaptation was reported for feasibility due regular lack of vaccination records for children. An approach was taken if no records to give initial Diphtheria-pertussis-tetanus vaccine again to ensure coverage. For polio and measles vaccines an approach was taken to give regardless of history to provide coverage. In the article it was not mentioned if potential spacing between vaccines was considered for those without medical records, therefore more information is needed
CE13	No, education and sensitisation messages adapted but not much information given	Not described	No	Appeared consistent	The reported adaptation was tailoring of community education and sensitisation messages in order to gain support and increase acceptability and uptake of vaccines. For the HPV and rotavirus vaccines they specifically noted for each vaccine rollout that focus groups with the community to learn of community knowledge, attitudes and beliefs took place. This would appear consistent with fidelity of increasing education and awareness on vaccines
CE14	Yes	Yes, minimum standards for physical activity and healthy eating provided in addition to key components of intervention	No	Unclear	Fidelity was assessed in efficacy and effectiveness trials but not during scale-up. The article gave sufficient detail on the intervention key components and minimum standards, along with supports in place for school for implementation and adaptation. However adaptations occurring locally at school levels with insufficient details reported in wider study. Fidelity to intervention is unclear

Ref	Was the intervention being adapted described?	Intervention theory, core elements, components, functions or minimum standards identified?	Was fidelity assessed?	Did adaptations maintain fidelity?	Comments
CE15	Yes	Yes	No	Appeared consistent	Reported adaptations appeared unavoidable due to resource availability and cost however appeared in keeping with the intervention components
CE16	Yes	Yes	No	Appeared consistent	Adaptations reported primarily illustrated the use of the community partnership approach to ensure cultural relevance
CE17	Yes	Yes theory and core elements identified	Yes	Appeared consistent & inconsistent	While primarily adaptations were reported in keeping with the core elements identified (62, 239). It was also noted that some 're-invention' occurred which may have changed the effectiveness of the intervention and so was inconsistent with fidelity (62, 239). To note fidelity studies not completed in all geographic areas, or on all DEBI's. Self-report used so also may have been open to bias
CE18	Yes	Yes, eligibility criteria, group size and guidance on operation of group present	No**	Appeared consistent & inconsistent	Reported adaptations over time included flexibility of eligibility criteria to wider population which could be considered inconsistent with intervention as it was originally designed for stable persons on ART. Other adaptations such as addition of code of conduct may have been consistent or inconsistent depending on what the code entailed
CE19	Yes	Yes, key components identified including eligibility criteria, group size and guidance on operation of group	No**	Appeared consistent & inconsistent	The reported adaptations over time were primarily due to feasibility with reported increases in group size to 40 participants and flexibility of eligibility criteria. These would appear to be inconsistent with the initial criteria and components of group and unclear what impact on effectiveness they may have had. Other adaptations for example changing location of meetings from health facility to community or home would appear consistent and in keeping within the original intervention design
CE20	Yes	Not specified	No	Appeared consistent	Adaptations included tailoring of education messages on adherence to ARTs based on an individual's level of literacy and understanding. This would appear consistent with providing education on ART. Other additions included use of pill boxes to assist in adherence. It also noted the addition of treatment buddies or group peer support in some sites. While these could be considered an additional intervention in itself, they would appear to support the aim of the original interventions
CE21	No, discussed PMTCT of HIV including provision of ARTs, however did not clearly outline which exact	Unclear what was core components or minimum standards throughout different stages. To note	No	Appeared consistent & unclear	Detailed descriptions on process of adaptations with ownership given to local sites to make adaptations using QI methods. Less information on what local adaptations made. Successful adaptations were shared with other sites through change packages. Tailoring education messaging on infant feeding practices appeared

Ref	Was the intervention being adapted described?	Intervention theory, core elements, components, functions or minimum standards identified?	Was fidelity assessed?	Did adaptations maintain fidelity?	Comments
	education (and other) interventions scaled	evolving international guidance and best practice over lifetime of scale-up (279)			consistent with original intervention aim. Other adaptations unclear such as if treatment buddy if unavailable use of a 'mother's day' HIV clinic day for peer support instead
CE22	No, discussed HIV prevention interventions however details on each not given	Overarching core minimum programme (CMP) identified with standards and activities to include but not much information given on specifics	No	Appeared consistent	For the adaptations reported they appeared to focus on tailoring of education messages and outreach for HIV prevention based on local knowledge from key population members. Other wider programme adaptations included adding of core components to the CMP such as peer educators

* No formal fidelity assessment, however study reported that elements removed or adapted central to intervention.

** No formal fidelity assessment, however evaluation had findings relevant to fidelity

5.3.9 Results: Actions

5.3.9.1 Results: Progression from IPT Framework to Actions Used in Practice

The following section presents the results of data extraction for *what actions* were used to achieve the aforementioned adaptations throughout the scale-up (as opposed to within the piloting phase) for local fit in practice (objective 2.2). Ultimately, the actions headings derived from the initial IPT phase (i.e., phase one) were updated based on the case examples, with one action heading remaining the same, six actions refined, and four actions removed. An overview of the progression of the IPT actions headings identified in phase one, based on findings from the case examples extracted in phase two, can be seen in Figure 5.4. More details on the actions, including what case examples referenced them, and an example of each action in practice can be found in Table 5.7. Each action is also described in more detail under their own heading, below.

An example of the refinement of an IPT action heading was that of the action heading ‘guidance to sites’, which through learning from the case examples was made more specific and useful. Specifically, changes were made to highlight what type(s) of guidance was provided, i.e. provision of guidance on the (i) intervention components, (ii) how to implement and adapt the specific intervention, or (iii) of tried and tested examples of adaptations from other sites. In addition to this, the format of guidance i.e., written, online, technical assistance, peer learning opportunities was also highlighted. This refinement was considered necessary given the varied type of guidance given across the case examples (with some providing guidance on only one area, and others providing guidance on all), often with a range of guidance formats used.

Another example of IPT actions heading refinement was that of ‘creating and using knowledge’ and ‘feedback loops’. These were found to be too broad of headings, being overly sensitive of actions that could be captured under these headings. Consequently, three refined actions emerged from these initial headings: (i) ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations, (ii) the use of data to assess progress and inform or evaluate adaptations, and (iii) use of Quality Improvement (QI) methods. Each heading is discussed and detailed further in their own section below.

Examples of the removal of IPT action headings included the actions of ‘participation’ and ‘communication’, both of which were found to be insufficiently specific to describe actions for the purposes of answering the research question. Therefore, these were removed in favour of more specific actions, such as use of QI methods, which utilises both participation and communication, but is more tangible and specific. The action heading of ‘definition of roles’ also did not emerge as a definitive action for adaptations during scale-up across the case examples and was therefore

removed as a stand-alone heading. Finally, the heading of systems thinking was removed as, upon reflection, it was found to be too difficult to define as a specific action, and is rather more representative of an overarching lens to critically view a complex system such as health.

In addition to this, it was noted there was some unavoidable overlap between the actions headings. For example, the use of data to assess progress and inform or evaluate adaptations (action 7), would also be captured as a key element of QI methods (action 8). However, the QI methods reported in the CEs often encompassed more than just this element, including creating peer learning opportunities (action 5) and sharing of tried and tested ideas (action 2c). Therefore, QI methods was given its own stand-alone action in order to capture the combination of elements used.

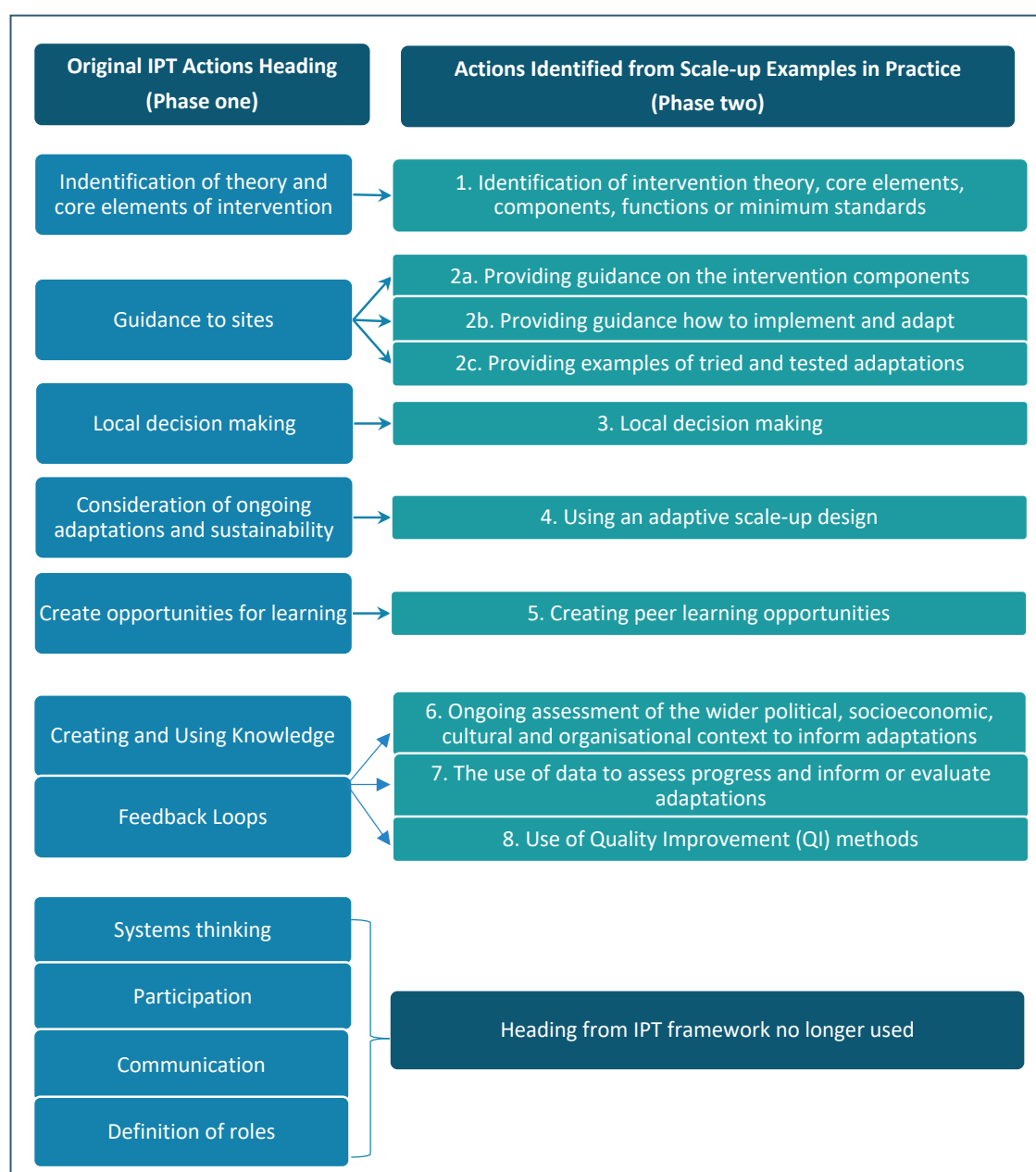


Figure 5.4 Progression of actions headings framework from phase one (IPT headings) to phase two (extraction from case examples)

5.3.9.2 Results: Actions Used for Adaptations during Scale-up

A total of eight actions were ultimately identified across the case examples to support adaptations during scale-up. The final framework of actions used are presented in Table 5.7 and are described and discussed in more detail under their own headings below. The majority of case examples reported using more than one action to support adaptations. The range of actions coded for each case example can be seen in Table 5.8. Together, they provide an overview of what actions were used to support adaptations when scaling-up, in fulfilment of research objective 2.2. These findings, in turn, provide the foundation for phase three (see Chapter 6), which will examine one of these actions in more detail and complexity, in order to develop theory on how this specific action works and in what circumstances when scaling-up.

Action 1. Identification of Intervention Theory, Core Elements, Components, Functions or Minimum Standards

The identification of intervention theory, core elements, components, functions or minimum standards to support implementation and adaptation was reported by a number of case examples, as summarised in Table 5.6. This action however, ranged from whether the theory or internal logic of the intervention was identified with specific elements to follow that embodied this internal logic (54) (e.g. gender empowerment theory to underpin discussion on sexual health; CE17), to the identification of specific components as essential to include (e.g., inclusion of minimum amount of contraceptive types, i.e. a minimum method mix, in a family planning intervention; CE8). This initial identification could happen in the intervention development and testing phase, as was the case in the DEBIs (CE17), *CBITS* (CE16) and *Actions Schools!* (CE15) case examples, where the interventions were developed outlining future adaptations that could occur when scaled-up. This action could also occur at later stages, for example, in the implementation of family planning in five cities in Kenya (CE5), where essential intervention components, as part of the wider complex intervention, were identified and a simplified intervention package with embedded flexibility for local needs was developed during scale-up. The identification of intervention components to follow, with flexibility of what could be adapted outside of these essential components encouraged and assisted local sites in making adaptations for local fit during the course of scale-up.

Table 5.7 Actions for Adaptations during Scale-up Framework, with definition, case examples who reported each action and description of the action in practice

Ref No.	Action	Working Definition	Case Examples who Reported	Description of Action in Practice
1.	Identification of intervention theory, core elements, components, functions or minimum standards	The identification of intervention theory, core elements, components, functions or minimum standards to support adaptation and implementation. These could be identified at intervention development stage and combined with other actions below such as providing guidance to sites on these components for future adaptations, or developed at a later stage during the rollout of scale-up as needs arose (e.g. a minimum contraceptive method mix to address supply chain issues)	CE1, CE2, CE3, CE4, CE5, CE8, CE10, CE14, CE16, CE17, CE18, CE19, CE22	<i>Action Schools!</i> intervention developed with key components to be included e.g. use of a classroom action bin with equipment to encourage physical activity (CE14). Schools could adapt intervention during delivery based on local needs once these key components were maintained
2.	Providing guidance to sites	Guidance provided to sites which could for example be in the format of: written guidance (e.g. manuals), technical assistance (e.g. access to a support team), online guidance (e.g. webinars) or facilitating guidance from peers (e.g. through learning collaboratives)	As per 2a, 2b, & 2c below	See below
	2a. Providing guidance on the intervention components	Guidance on intervention theory, core elements, components, functions or minimum standards provided to sites	CE1, CE2, CE5, CE8, CE10, CE14, CE16, CE17, CE18, CE19, CE22	Core curriculum document given to schools with core topics identified for sexual health education (CE2)
	2b. Providing guidance on the implementation and adaptation process for the specific intervention	Guidance on the implementation and adaptation process for the specific intervention provided to sites. This could include steps to take to adapt or evaluate changes to the intervention	CE5, CE6, CE7, CE8, CE10, CE11, CE12, CE14, CE16, CE17, CE18, CE20, CE21, CE22	Regional, district and institutional steering committees were developed and encouraged to develop and adapt contextually relevant plans for their local area (CE10). Representatives from these attended workshops for training, received guidance materials e.g. workbooks and shared learning between peers in sessions
	2c. Providing examples of tried and tested adaptations	Provision of guidance on tried and tested adaptation examples from past sites as a way to encourage cross-site learning	CE5, CE8, CE11, CE14, CE21	Change packages developed with tried and tested ideas from local sites to share with other areas. Reported less innovation needed in later stages with more use of previously tested ideas (CE21)

Ref No.	Action	Working Definition	Case Examples who Reported	Description of Action in Practice
3.	Local decision making	Autonomy was given to local stakeholders to make decisions on adaptations for local fit within their setting. This could occur at varying levels within the system for example at provincial, regional, district, community, health facility levels, by frontline providers or the recipients themselves	As per 3a, 3b, 3c, 3d below	Local decision making occurred at multiple levels of the system. Please see 3a, 3b, 3c & 3d below for examples
	3a. Regional, Provincial or District Levels	When local decision making for adaptations occurred during scale-up at regional, provincial and/or district levels	CE5, CE6, CE7, CE8, CE10, CE11, CE20, CE21, CE22	Regional and district steering committees were given workshops and guidance materials to support development of contextualised local action plans which could be updated in an ongoing basis at local level (CE10)
	3b. Community or Health Facility Level	When local decision making for adaptations occurred during scale-up at community or health facility level. This could include CBOs and school level. This could also include the use of formalised community partnerships	CE1, CE2, CE8, CE10, CE11, CE14, CE16, CE18, CE19, CE20, CE21, CE22	Adaptations often made at CBO level by those working closely with the community for local fit, this was facilitated by an intervention designed with identified theory with flexibility to adapt outside of this (CE17)
	3c. Frontline Provider Level	When local decision making for adaptations occurred during scale-up by frontline providers delivering the intervention	CE1, CE2, CE11, CE14, CE16, CE17, CE18, CE19, CE20, CE21, CE22	Frontline providers taught how to collect and use data, with simplified indicators to allow for trial and testing of locally generated ideas. Successful ideas were later shared as change packages for other sites (CE21)
	3d. Recipient Level	When local decision making for adaptations occurred during scale-up by the recipients of the intervention	CE16, CE18	Intervention designed for flexibility with individual CAG recipients (i.e. group members) given autonomy to make decisions for best fit. Some groups added a code of conduct for example around secrecy of group (CE18)
4.	Using an adaptive scale-up design	Where an adaptive scale-up design was used to incorporate flexibility allowing for large scale change as learning occurred and contexts change over time	CE11, CE22	Adaptive scale-up design was used with openness to change direction as needs emerged. This led to more focus on the area of interventions to increase attendance at skilled birth along and ensuring these interventions were contextually relevant to address local beliefs (CE11)

Ref No.	Action	Working Definition	Case Examples who Reported	Description of Action in Practice
5.	Creating peer learning opportunities	Where proactive opportunities to learn from peers were created allowing for cross-site learning. This could include sharing lessons learned through implementation and adaptation. This could be through in person opportunities (e.g. learning collaboratives), and/or through dissemination of materials (e.g. change packages). Peer learning is understood to be learning from those at the same or similar levels of the system e.g. between frontline providers at differing sites, as opposed to top down support and guidance	CE2, CE6, CE8, CE10, CE11, CE14, CE16, CE18, CE19, CE20, CE21	Workshop took place in original province where clinical and community partners from other provinces visited and could learn of approach and observe in the field, along with engaging with recipients of the intervention (CE19)
6.	Ongoing Assessment of the Wider Political, Socioeconomic, Cultural and Organisational Context to Inform Adaptations	This could include ongoing assessment of the wider political, socioeconomic and cultural context to inform adaptations. For example to capture dynamic political situations that may affect the intervention e.g. unsupportive policy change. It may also include ongoing assessment of the organisational landscape and resource availability	CE2, CE6, CE9, CE13, CE15, CE22	Ongoing contextual, political and bureaucratic analysis was promoted for each municipality to complete to capture changes relevant to intervention acceptability and feasibility, for example reduced political support, over time (CE6)
7.	The Use of Data to Assess Progress and Inform or Evaluate Adaptations	The use of data, for example through monitoring and evaluation processes, to assess progress of health or implementation outcomes which may inform adaptations throughout the scale-up. It may also include use of data to evaluate chosen adaptations	CE5, CE11, CE21, CE22	Daily mapping of at risk populations which allowed for peer workers to plan their intervention based on needs identified (CE22)
8.	Use of QI methods	Where formalised QI methods were utilised such as: the breakthrough series (BTS) model, learning collaboratives and the model for improvement (MFI) during the course of the scale-up to inform adaptations	CE11, CE16, CE19, CE21	IHI BTS model used which involved formalised learning collaboratives with activity periods between to test ideas. At later stages of scale-up changes packages of tried and tested ideas shared with sites (CE21)

Table 5.8 Each Case Example and Actions Coded

Case Example	Actions Coded*	Case Example	Actions Coded*
CE1	1,2a,3b,3c	CE12	2b
CE2	1,2a,3b, 3c, 5, 6	CE13	6
CE3	1	CE14	1, 2a, 2b, 2c, 3b, 3c, 5
CE4	1	CE15	6
CE5	1, 2a, 2b, 2c, 3a, 7	CE16	1, 2a, 2b, 3b, 3c, 3d, 5, 8
CE6	2b, 3a, 5, 6	CE17	1, 2a, 2b, 3b, 3c
CE7	2b, 3a	CE18	1, 2a, 2b, 3b, 3c, 3d, 5
CE8	1, 2a, 2b, 2c, 3a, 3b, 5	CE19	1, 2a, 3b, 3c, 5, 8
CE9	7	CE20	2b, 3a, 3b, 3c, 5
CE10	1, 2a, 2b, 3a, 3b, 5	CE21	2b, 2c, 3a, 3b, 3c, 5, 7, 8
CE11	2b, 2c, 3a, 3b, 3c, 4, 5, 7, 8	CE22	1, 2a, 2b, 3a, 3b, 3c, 4, 6, 7

* To note only coded from what was reported to assist adaptations, it is acknowledged each case example may have utilised further actions not reported

Action 2. Providing Guidance to Sites

While the scale-up team providing ‘guidance to sites’ was identified in the original IPT heading, results from the case examples further suggested the importance of refining *what* content should be included in this guidance for sites. Accordingly, three key headings for the content of the guidance emerged including: (i) guidance on the intervention components itself; (ii) guidance on how to implement and adapt the specific intervention; and (iii) providing examples of tried and tested examples from other sites. In addition to this, the heading was further refined to include different formats of guidance including (i) written guidance (e.g. manuals, workbooks), (ii) technical assistance (e.g. through mentorship, access to support team), (iii) online guidance (e.g. webinars), and (iv) guidance from peers (e.g. through meetings or learning collaboratives). Finally, further considerations were identified for the timing of guidance as well as the source of guidance (i.e. when it is given and who provides it). Figure 5.5 offers an overview of considerations when providing guidance to sites.

Overall 14 case examples reported on how guidance to sites assisted in adaptations when scaling up. These case examples, along with the type and format of guidance provided, are presented in Table 5.9, below. To note from the case examples referencing use of guidance offered no clear best practice design in terms of content of guidance or in what format guidance should be delivered emerged.

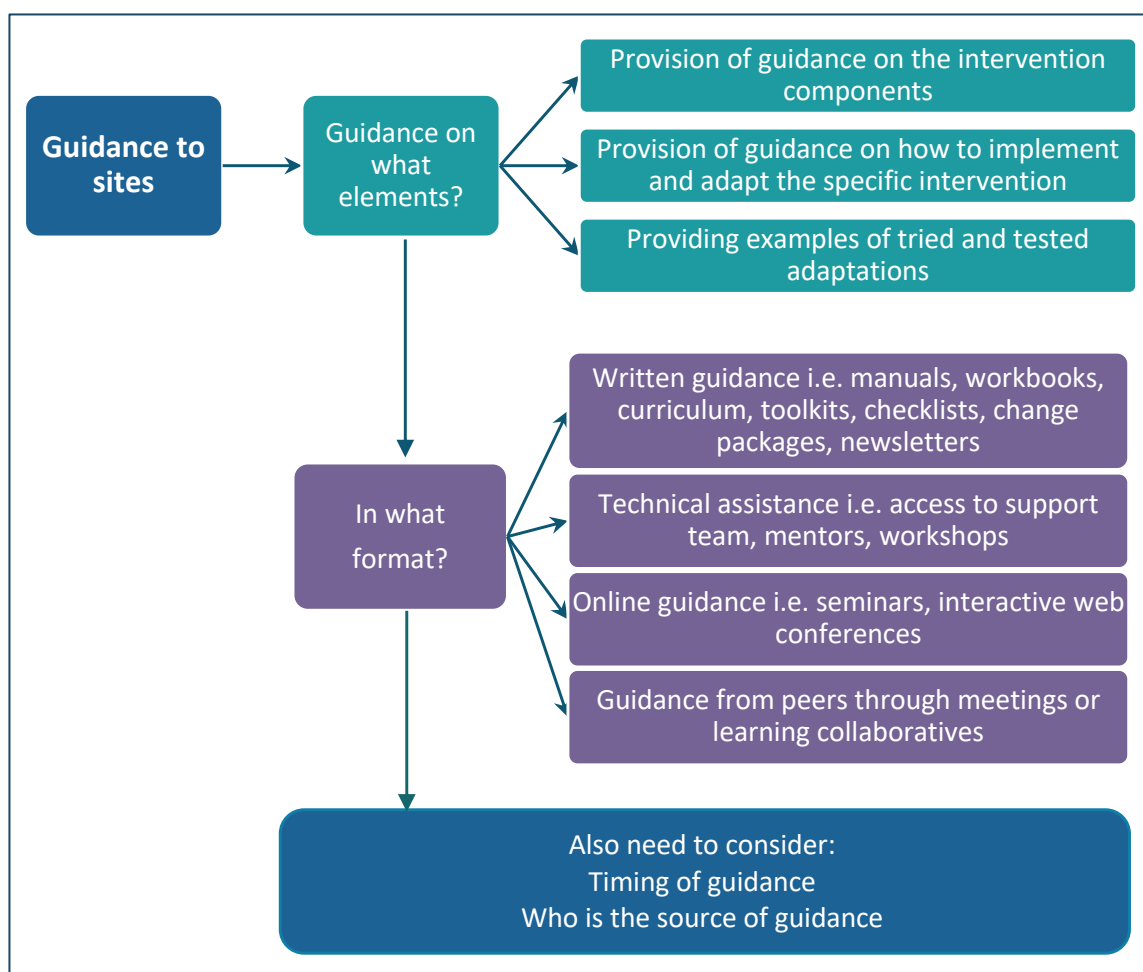


Figure 5.5 Consideration for providing guidance to sites for adaptations when scaling-up

2a. Guidance on the Intervention Components

Eleven case examples specifically reported on providing guidance on the intervention components itself (see Table 5.9). An example of this can be seen in the scale-up of DEBIs in the USA (CE17), where the interventions were theory-driven, with core elements identified from the outset. Guidance in the form of written toolkits, in addition to training and technical support, was also made available. This included guidance on what components within the intervention were open to adaptation, while still maintaining effectiveness, and which elements, if adapted, would be considered ‘reinvention’, and would therefore need to be reassessed for effectiveness. Guidance thus provided sites with the knowledge of what was essential and what was flexible for adaptation in order to make decisions locally. However, in this case, there were issues highlighted with regards to *who* provided the guidance impacting uptake and use for local decision makers, which will be explored in greater detail in phase three (Chapter 6, Section 6.2, PT7).

2b. Guidance on the Implementation and Adaptation Process

Guidance on the implementation process and on how to adapt the specific intervention was reported by eleven of the case examples (see Table 5.9). An example of this is the scale-up of Kangaroo Mother Care (KMC) Ghana (C10) where regional steering committees attended workshops on how to develop their own action plans for local settings, in keeping with components of KMC. Documents and CDs were provided with practice standards, policies and workbooks, outlining practical guidance for contextual adaptation and assignments to assist preparation for local implementation. An emphasis was also placed on local decision making and ownership of the implementation and adaptation process, with this guidance supporting capacity building and awareness of how to implement and adapt KMC at local levels.

2c. Guidance on Examples of Tried and Tested Adaptations

Provision of guidance on tried and tested adaptation examples from past sites, as a way to encourage cross-site learning, was identified in six of the case examples (see Table 5.9). The format of the examples from previous sites ranged from written formats (i.e., in the form of change packages (CE11, CE21) or newsletters (CE5, CE11, CE14)), while others also provided more interactive face-to-face meetings in the form of learning collaboratives (CE11, CE16, CE19, CE21). Case examples reported that with this action less innovation and testing of new ideas was needed in later stages of scale-up, as adaptations which took place in one site could be replicated in other contextually similar facilities (CE11, CE21). Thus, this action allowed for more efficient scale-up with for those sites who faced similar contextual challenges that had already been addressed.

Table 5.9 Providing guidance to sites: content of guidance and what formats used

Guidance on what content	Case Examples who Reported
a. Providing guidance on the intervention components	CE1, CE2, CE5, CE8, C10, CE14, CE16, CE17, CE18, CE19, CE22
b. Providing guidance on the implementation and adaptation process for the specific intervention	CE5, CE6, CE7, CE8, CE10, CE11, CE14, CE16, CE17, CE18, CE20, CE21, CE22
c. Providing examples of tried and tested adaptations	CE5, CE8, CE11, CE14 CE16, C19, CE21
Format of Guidance	Case Examples who Reported
a. Written guidance (e.g. manuals, curriculum, workbook)	CE1, CE2, CE5, CE6, CE7, CE8, CE10, CE11, CE14, CE16, CE17, CE21
b. Technical assistance (e.g. through mentorship, access to support team),	CE7, CE10, CE14, CE17, CE18, CE19, CE21
c. Interactive online guidance (e.g. webinars)	CE6
d. Guidance from peers (e.g. through meetings or learning collaboratives)	CE5, CE8, CE11, CE14, CE16, CE21

Format of Guidance

The format of guidance could be categorised into four main types: (i) written guidance (e.g. manuals, workbooks), (ii) technical assistance (e.g. through mentorship, access to support team), (iii) interactive online guidance (e.g. webinars), and (iv) guidance from peers (e.g. through meetings or learning collaboratives) (see Table 5.10). Written guidance was reported in the form of: manuals (CE14, CE16, CE17), curriculum documents (CE1, CE2), toolkits (CE5, CE7, CE14, CE17), workbooks (CE10, CE14), checklists (CE16), change packages (CE11, CE21), newsletters (CE5, CE8, CE11, CE14), resource directories (CE14) and web resources (CE5, CE6, CE14, CE21). Technical assistance was reported in the form of trainings and workshops (CE7, CE10, CE17, CE18, CE21), access to a centralised technical support team (CE14, CE17) and/or mentors for the intervention (CE19). Interactive online guidance was reported in the form of online participatory seminars and web-based conferences (CE6). Guidance from peers was reported through face-to-face formalised learning collaboratives (CE11, CE16, CE21), such as weekly meetings (CE16). Additionally, guidance was provided through the aforementioned written formats of change packages (CE11, CE21) and newsletters (CE5, CE8, CE11, CE14). Case examples often utilised more than one of these methods. While some of these could be considered more passive forms of guidance (i.e. written materials such as manuals) and others more active (i.e. technical assistance through mentorship), there was a lack of comparison across the approaches used within the case examples which meant that conclusions could not be drawn as to which guidance format(s) were most beneficial, and in which circumstances.

Timing of Guidance

Another factor to consider in relation to guidance is the timing. One case example (CE10) specifically noted the importance of timing of the guidance, where materials developed during the workshop were shared (on CD) directly after the training, resulting in a positive impact on assisting action planning for local steering committees. Specifically, this timely distribution of guidance facilitated the sharing of learning, which participants could share with those not at the workshop once they had returned to their local area, assisting the development of local action plans. Alternatively, CE17 noted some guidance was not available at initial rollout. Consequently, many CBO sites started implementing without accessing the guidance and may have been unaware of its existence, leading to low uptake of guidance. Therefore, other implementers should note that the timing of guidance may directly impact its effectiveness, uptake, and use.

Source of the Guidance

Availability however, does not always guarantee uptake. For example, the large amount of technical support and materials made available by the DEBIs, USA (CE17) were not always utilised at local levels.

The authors suggested this lack of use may have been due to power dynamics as the guidance was provided by an agency linked to funding streams (62, 280, 281). The case examples where peers provided guidance, particularly in the form of face-to-face learning collaboratives, and through written change packages and newsletters, reported a positive impact on decisions being made locally, with less innovation needed in later stages, and greater sharing of already tried and tested adaptations (CE11, CE21).

Many case examples noted insufficient guidance available (CE1, CE17, CE19, CE20), or that sites were unaware of its availability (CE17). For example, the scale-up of CSE in Senegal (CE1) noted that core curriculum documents given potentially did not contain enough information and that curriculum documents were not always followed. Likewise, and while some guidance was given to sites in the scale-up of adherence clubs for ARTs in three provinces in South Africa (CE19), the authors noted that more guidance was often needed. This lack of clear guidance often led to each health facility making ad-hoc decisions, based on their own situation and resources (244). It was therefore suggested that further guidance for this intervention, with a clearer policy statement for criteria (e.g. eligibility, group number and population), may have assisted this.

Therefore when and who provide the guidance, what format it is in, and the content of guidance (i.e. of intervention theory or components, on how to adapt or with examples of adaptations) are all important factors for implementers to consider when providing this to sites. The circumstances that influence the use of guidance for adaptations for local sites will be explored in more detail in phase three (Chapter 6, Section 6.2, PT7).

Action 3. Local Decision Making

Local decision making was reported in the majority of case examples (see Table 5.7) and refers to the autonomy of local stakeholders to make decisions on adaptations for local fit within their setting during scale-up. Local decision making therefore allows for local knowledge to be utilised to provide best fit for acceptability and/or feasibility. Furthermore, local decision making could occur at varying levels within the system including at provincial, regional, district, community, health facility levels, or by frontline providers or the recipients themselves. For many CEs, local decision making occurred at multiple levels, as depicted in Table 5.7. This often allowed for a time sensitive, sustainable approach to adaptations, with adaptations able to take place on an ongoing basis, as needs arose, allowing for local knowledge to be utilised (CE11, CE21). In addition, local decision making, through engagement, could also lead to buy-in for the intervention and adaptations (CE5, CE8, CE11, CE21).

3a. Decision making at Regional, Provincial and/or District Levels

Many case examples reported the transfer of decision making to regional, provincial or district levels (see Table 5.7). Primarily, this transfer of decision making was made to local health authorities or government in the area, with the exception of one case example (CE22) who noted the use of larger NGO partners with autonomy given for local decision making to smaller NGO partners and frontline providers on elements of the intervention. Two CE's specifically noted being influenced by the ExpandNet guidance (167) in their decision to use local decision making (CE5, CE8). Whether a local decision making approach at regional, provincial or district levels was reportedly positive or negative however, differed across the case examples. For example, CE6 and CE10 both reported local decision making with the transferring of autonomy of decisions to regional/district levels, with guidance in the form of training and support for implementation (Action 2b). While, CE6 reported a significant loss to intervention fidelity within different local regions, CE10 reported a positive impact on developing contextualised plans in keeping with intervention components. To note in CE6, the move to local decision making was not by choice of the scale-up team and was a consequence of a federal mandate for decentralisation, along with the sheer scale of the country and providing hands-on support to over 5,000 municipalities unfeasible. They further noted the conservative religious cultural context and lack of political support affected fidelity in some areas. Thus, each context may have different needs and outcomes in the transfer of local decision making to authorities at regional, provincial or district levels and careful consideration is needed on what may best fit within each scale-up, given available resources.

Decentralised decision making was not always reported as initially welcomed by local government authorities. For example, CE5 reported that the transfer of decision making to county level was met with initial reluctance, as previous implementation had taken more of a top-down management approach. However, the authors reported buy-in from local government authorities for the new approach as the scale-up progressed. In particular, noting that participation by local government authorities led to the use of a simplified intervention package and that the development and use of local data fostered a sense of ownership of the intervention by local stakeholders and increased responsiveness to local needs. Therefore, consideration of how this approach may be different to organisational norms and the risk of being met with hesitation need to be considered, with approaches that may support this process differing based on the needs and experiences of different contexts.

3b. Decision making at Community and/or Health Facility Level

A number of case examples reported local decision making at community level (see Table 5.7), including through community partnerships (CE4, CE8, CE16, CE22). In addition, two case examples highlighted local decision making for adaptations was encouraged among community-based organisations (CBOs) working and implementing at this level, specifically for HIV prevention interventions (CE17, CE22). Local decision making at school level (CE14) or health facility level was also reported by a number of case examples (CE10, CE11, CE18, CE19, CE20, CE21). In the scaling of *Action schools!* (CE14), local decision making could occur at school or a classroom level. This allowed for principals and/or teachers to make decisions on what elements of the intervention best fit within their local setting, with this flexibility built into the original intervention design.

There were differing levels of capacity building, guidance given to sites, intervention types and design when using local decision making across the case examples. For example, while some used structured QI methods (see Action 8; CE11, CE21), others provided in-depth training and guidance materials for steering committees (Action 2b; CE10), with another having built the intervention with components for future flexibility at this level (Action 1; CE14). Those that utilised a structured QI approach (Action 8; CE11, CE21) also generated research in support of a positive impact of using this approach (232, 253, 255, 258). However, negative outcomes were also reported for local decision making. For example, CE17 reported loss to intervention fidelity due to local adaptations made.

Overall, three case examples stood out as supporting communities through formalised partnerships in order to directly influence changes to the content of interventions (CE8, CE16, CE22). As previously discussed in Chapter 4 (Section 4.2.1.3.8.3), community engagement and partnership is a complex process, and resources to fully engage and support partnerships are needed at scale. Community partnerships were a central part of the *CBITS* intervention (CE16), which was developed and initially implemented using a Community Based Participatory Research (CBPR) approach. However, increasing demand and the resources needed to have academic partnerships across all sites meant that the type of partnership had to shift to community partnerships (as opposed to CBPR) in later sites. In CE8, local development committees with key community members including local chiefs, spiritual leaders, and community groups was found to influence the content of programmes such that they were more acceptable and feasible in their communities. The authors reported that the formation of community committees aided community buy-in, with some development committees advocating for increased services and highlighting the importance of other related services, such as natural family planning methods being offered as part of the method mix. In CE22, the central team initially actively selected NGOs and CBOs in local areas which had experience and partnerships with the target communities.

As the scale-up progressed however, the value of local knowledge was further prioritised, becoming such a core component of the programme that members from these communities eventually became peer educators. These peer educators were then given autonomy to tailor messaging and outreach approaches based on what they believed to best fit within their setting. This level of engagement led to insights into hard-to-reach community members, including those who identify as transgender, men who have sex with men, and sex workers. Therefore, while formalised partnerships to support community level decision making may be resource intensive, their benefits in terms of informing adaptations for local fit and through engagement lead to buy-in and support for implementation need to be weighed up.

3c. Decision making at Frontline Provider Level

Where local decision making occurred at community, CBO, health facility or school level this often also included autonomy for decision making by frontline providers (see Table 5.7). Decision making by frontline providers was moreover, regularly reported as proactively planned and embedded into the scale-up or intervention design (CE14, CE16, CE17, CE18, CE19, CE20, CE22), for example, through use of QI methods (CE11, CE21).

However, there were also unplanned adaptations that occurred at provider level (CE1, CE2). An example of this was observed in the scale-up of sexual health education in Senegal (CE1). Here, the intervention was developed as a cross-curricular programme (i.e., not a separate subject in itself), giving principals and teachers autonomy to make decisions on content inclusion and integration into other subjects. This local decision making, however, led to some omissions of core topic areas due to discomfort with the content within this conservative context. Thus, consideration of local decision making at provider levels in conservative cultural contexts needs to be considered as to whether it is the optimal approach or whether strategies need to be put in place to mitigate ad-hoc adaptations. This will be explored in greater detail in phase three (Chapter 6, Section 6.2.3, PT2).

3d. Decision making at Recipient Level

Two case examples gave autonomy for decision making to recipients of the intervention (see Table 5.7). The *CBITS* intervention (CE16), for example, reported that cultural adaptation could be decided through a collaboration between provider and recipients. They further discussed an experience where each group was consulted on the cultural appropriateness of content such as speaking the name of the dead, leading to a collaborative decision as to whether adaptation was needed in this setting to ensure the acceptability of the intervention.

The use of local decision making by those who understand the cultural context and nuances is a promising action during adaptation to ensure cultural acceptability, particularly given as this was a frequently cited reason for adaptation (Table 5.3). However, giving recipients the autonomy to make decision for adaptations in the absence of support and guidance may also leave an intervention vulnerable to loss of fidelity. CE18, for example, reported that some adherence groups for ART added a code of conduct. While this code of conduct varied depending on the group, it was often based on privacy, with confidentiality of group members being emphasised. However, other groups also formed codes of conduct emphasising avoidance of certain foods and behaviours that have no evidenced impact on ART adherence. Therefore, and while openness to recipient adaptation has great potential to increase engagement and retention of the intervention by making it more acceptable, care needs to be taken to ensure recipients are supported to make adaptations that are in keeping with the active components of an intervention, avoiding adaptations that may reduce or remove intervention effectiveness, or place an unnecessary burden on individuals by adding elements unrelated to the intervention.

Local decision making is complex with many factors contributing to how it may work, with no one-size-fits-all approach. Local decision making was often completed in the context of other actions such as identification of intervention theory or core components (Action 1; CE14, CE16, CE17), by giving extensive guidance to sites (Action 2; CE10), with peer learning approaches for cross-site learning (Action 5; CE8, CE11, CE21) and /or as part of a structured QI methods approach (Action 8; CE11, CE21). Local decision making was at times not the choice of the scale-up team with mandates for decentralisation or due to volume of scale-up sites. When this occurs within varying socio-political contexts, such as within conservative religious cultural contexts (CE6), this may impact what adaptations were made and lead to a loss of fidelity to the intervention. Local decision making for example at community level is a promising approach for generating culturally acceptable interventions, however care needs to be taken to ensure sufficient guidance and capacity is in place to meaningfully engage and support local communities through this process. Consideration of the context and supporting actions are therefore needed in order to decide how best to support local decision making when scaling-up. This will be explored further in phase three (Chapter 6, Section 6.2.3).

Action 4. Adaptive Scale-up Design

The use of an adaptive design was discussed in CE22, where the lead scale-up team utilised business management principles including a 'dynamic and evolving strategy'. This scale-up therefore reported a purposively flexible approach with overlapping stages of designing, organising, executing, and

sustaining, allowing for learning and ‘jump-outs’ where large changes in planning could occur at central level, based on identified needs throughout the scale-up. Incorporating such flexibility within the scale-up design allows for approaches to change as learning occurs, needs are identified, and contexts change over time. In CE11, an adaptive design allowed for adaptations to address when learning occurred throughout the scale-up. This included the need to focus on certain interventions within the wider package, for example, interventions to increase the presence of a skilled attendant at birth. The authors noted that ongoing formal and informal communication between partners, and in particular funders, resulted in a shared understanding of needs and allowed for use of an adaptive scale-up design, and consequently, changes in planned spending and timelines to reflect actual needs as scale-up progressed.

Action 5. Creating Peer Learning Opportunities

The case examples which reported creating peer learning opportunities to support adaptations can be seen in Table 5.7. For the purpose of this study, creating peer-learning opportunities were defined as proactive opportunities to learn from peers allowing for cross-site learning through sharing examples of adaptations, approaches used or lessons learned through in-person opportunities (e.g. meetings or learning collaboratives), and/or through dissemination of materials (e.g. change packages or newsletters). Peer learning was defined as learning from those at the same or similar levels of the health system (e.g. between frontline providers at differing sites), as opposed to top down support and guidance. A number of potential benefits of learning from peers were noted across the case studies. For example by sharing guidance of successful adaptations made in earlier sites (Action 2c), CE21 noted less innovation was needed in later stages of scale-up, as ideas from other contextually relevant sites were shared. In CE22, they found that creating a learning platform avoided the need for ‘re-inventing the wheel’ (p212, (256)) during later stages of scale-up.

A clear example of peer learning opportunities was in the scale-up of KMC Ghana (CE10), where a representative from regional, district or institutional steering committees could attend workshops. This allowed for designated time and facilitated assistance in developing localised action plans. Following time in the field to enact these plans, the committees met again at follow-up workshops to share practical experiences, discuss challenges, and problem solve. In addition to peer learning at local levels during scale-up, CE10 also noted that prior to scale-up, extensive attention was paid to other low-resource countries that had implemented KMC (e.g., Bangladesh, South Africa and Malawi). Learning what worked within countries facing similar challenges heavily influenced the scale-up design, for example, and following the results from trials in Bangladesh, by choosing to focus on a hospital-based rather than community approaches. While some of this cross-context learning was

prior to scale-up, and therefore beyond the scope of this research, it is important to note the value of learning from other similar settings when planning an intervention scale-up design.

One consideration in creating peer learning opportunities is the level of motivation of local sites to take part. In the scale-up of family planning services in Brazil (CE6) for example, there were over 5,000 municipalities in the country, rendering it unfeasible for the central team to actively support all sites. Municipalities were thus encouraged to provide peer support to neighbouring areas to share learning. This included the visiting of sites to observe lessons learnt in practice. This however, happened to varying degrees, or not at all in some areas, as, though encouraged, it was not mandated, and was therefore dependent on the motivation of local sites to take part. In contrast, in CE8, local sites were incentivised through benefits in-kind or 'credits' earned through assisting neighbouring areas in trainings, acceptance of referrals, etc. This approach was found to facilitate collaboration (i.e. districts could achieve a minimal method mix and cost-sharing through joint buying initiatives) and encourage sharing of learning and skills.

Peer learning could also occur as one-off events and need not be ongoing approaches requiring ongoing facilitation. For example, in the scale-up of CAGS in Mozambique (CE19), the authors noted that workshops took place in an original province where clinical and community partners from other provinces could learn the approach and observe in the field, while also engaging with recipients of the intervention (specifically referenced in (243)). Where resources are limited, this approach allows for peer learning to occur and learning in practice to take place, without requiring additional demands of time and resources within ongoing approaches.

Action 6. Ongoing Assessment of the Wider Political, Socioeconomic, Cultural and Organisational Context to Inform Adaptations

The need for ongoing assessment throughout the lifecycle of scale-up to inform adaptations was highlighted in a number of CEs (see Table 5.7). This included ongoing assessment of the wider political, socioeconomic and cultural context, as these change over time. It could also include ongoing assessment of the organisational context, including resource availability, logistics and supply chains. For example, in CE6, emphasis was placed on how changes in political and bureaucratic contexts over time affected implementation and often led to the removal of elements from the intervention. The authors therefore proposed the need for each municipality to complete contextual, political and bureaucratic analysis on an ongoing basis to allow for the capture of contextual changes over time. CE22 highlighted how such continuous assessment captured changes in population needs, both geographically and demographically, resulting in differing educational needs as population dynamics,

including make-up of sex worker populations, changed over time. Specifically, change in population between home-based versus street-based sex workers led to differing risk reduction approaches for prevention of HIV transmission. The annual population estimates and mapping in CE22 was further reported to influence adaptations, with the adaptive scale-up design used allowing for the integration of changes into wider programming, as needed.

Ongoing stakeholder consultations were reported as central to monitor the wider cultural context and ensure cultural acceptability (CE2). In CE2, sexual health education was scaled-up in a conservative context, where multi-stakeholder involvement in curriculum development and revisions during the scale-up - as opposed to on a one-off basis – including with community, parents, teachers, community leaders, religious leaders, school heads, Islamic scholars, led to both increased acceptability of the intervention and to adaptations in content on an ongoing basis. An example was given where Islamic scholars assisted with adaptations for cultural fit for use within a religious school, whereby lessons within the intervention were supported with references and explanations from religious texts perspective. Through their engagement, religious leaders gave endorsement of the programme which the authors reported as critical for the programme's success.

A further case for ongoing assessment was identified in the need to ensure that any changes would be sustainable given realistic resources. In CE9, pilot testing took place with additional staff and finances. Therefore, and in order to ensure successful implementation, an 'extension area' was created to allow for testing under realistic organisational resources throughout the lifecycle of scale-up. Throughout the scale-up, any new adaptations, for example the provision of doorstep injectable contraceptives, were tested in this area prior to extending to a wider network to ensure its feasibility with usual in-country resources. This provided ongoing justification that changes could be sustainable given the country's resources at the time.

Action 7. The Use of Data to Assess Progress and Inform or Evaluate Adaptations

The use of ongoing data to assess progress to inform adaptations, for example data assessing health or implementation outcomes, was noted in a number of CEs (see Table 5.7). This could be through routine or newly embedded monitoring and evaluation mechanisms as part of the scale-up. The use of data to evaluate adaptations was specifically reported in two CEs (CE11, CE21), and two additional CEs noted the importance of accessibility of data collection and analysis at local levels (CE5, CE11, CE21, CE22). Accessibility of data collection and analysis at local levels could include programme designers simplifying the data collection or analysis for use at local level, sometimes accompanied by capacity building for data collection and analysis (CE11, CE21, CE22). This use of accessible data at

local levels was found to lead to local ownership of data and of the implementation process (CE5, CE11, CE21), allowed for more time sensitive adaptations, as well as for ongoing adaptation throughout scale-up and sustainability (CE11, CE21, CE22). In the scale-up of HIV prevention interventions in CE22, for example, the ongoing use of accessible data, including by peer outreach workers to inform decisions, was highlighted. Here, pictorial tools were utilised to assist in data capturing and planning for those with lower literacy levels. A pragmatic approach was also taken in not waiting for ‘perfect data’, whereby decisions were made even if data were unavailable on time. In the scale-up of PMTCT of HIV in South Africa (CE21), for example, data was simplified for use at local level using key indicators mapped onto a traffic light system and dashboard for ease of interpretation (specifically referenced in article (251)). In addition, capacity was built in QI methods (see Action 8) to allow for local decision making and action planning through learning collaboratives during early stages of scale-up, and through trainings in mid- and later- stages of scale-up. Thus, the development and use of accessible data, which could also be accompanied by capacity building, greatly supported the action of local decision making (Action 3) within these CEs. This will be explored in greater detail in phase three (Chapter 6, Section 6.2.3, PT5). In the scale-up of family planning in Kenya (CE5), the authors describe how data was integrated into the government’s health management information system (HMIS) already in place, rather than creating a separate system. They also encouraged district health management teams to use data directly accessible through their district health information system (DHIS) to report to higher levels of government, as opposed to going through the central scale-up team. This approach to accessing data, they reported, led to ownership and engagement with the intervention and implementation.

Action 8. QI Methods

Four case examples reported the use of QI methodology to support adaptations at local levels during scale-up (see Table 5.7). These case examples specifically referenced the Institute for Health Improvement’s (IHI) QI methods which include: the breakthrough series model (BTS), learning collaboratives and the model for improvement (MFI). One also referenced use of driver diagrams. Table 5.10 describes each of these QI methods in greater detail and in which case examples they were reported.

The same QI approaches were not always used throughout all stages of scale-up or throughout all sites. For example, CE21 reported using the BTS in early and mid-stages, switching to change packages sharing ideas from earlier sites and use of MFI at local sites during later stages. Likewise, in CE16 they noted that formal learning collaboratives took place in the Jersey City Public Schools (JCPS) area, but that clinicians did not attend learning collaboratives after initial training. Nevertheless, the authors

report that higher level district leadership continued to attend the learning collaboratives. Therefore, the QI methods used can be adapted to fit the needs and capacity available within the context of the scale-up.

Table 5.10 QI approaches reported: MFI, BTS, Learning Collaboratives and Driver Diagrams and case examples which reported each method

QI Approach	Case Examples
Model for Improvement (MFI) (282)	CE11, CE21
The MFI has three set questions to assist a systematic approach; to identify the desired change, how to measure if change is achieved, and what to do to try and achieve improvement in an identified area. This is then followed by action cycles where the changes are planned, carried out, studied and actions taken on what is learnt in the form of a Plan-Do-Study-Act (PDSA) cycle.	
Breakthrough Series Improvement Collaborative Model (BTS) (283)	CE11, CE19, CE21
The BTS model is a structured learning system working towards an identified topic/aim with experts (usually 5-15) across relevant disciplines recruited to lead the breakthrough series. Following this key stakeholders in the field are recruited to join the improvement collaborative network (ICN) for a set period of time. Stakeholders take part in learning sessions which are face-to-face, where groups come together to learn from experts, share experiences, collectively problem solve, make action plans etc. Participants learn the MFI (as per above) and are encouraged to use in their local settings to develop and try out action plans. Following this they return to learning sessions and review how it went and share experiences. Learning cycles and action periods are repeated for agreed time periods.	
Learning Collaboratives (283)	CE11, CE16, CE19, CE21
Learning collaboratives form part of the BTS above but can also be used by themselves without the formalised time limited approach.	
Driver Diagrams (284)	CE11
Driver diagrams are a QI tool which visually displays the aim of the project (e.g. reduce preventable deaths in children under five years), along with the primary drivers which influence this aim (e.g. delay in seeking care), followed by secondary drivers which make up components of the primary driver (e.g. low risk awareness of malaria). This can be followed by change ideas for the secondary drivers.	

The use of QI methods such as the BTS, learning collaboratives and the MFI is arguably a hybrid approach. Specifically, these methods use data to inform or evaluate adaptations (Action 7), support local decision making (Action 3), encourage peer learning and collaboration (Action 5), provide guidance on the implementation and adaptation process (Action 2b), and share tried and tested ideas between sites (Action 2c). Case examples reporting their use suggest that QI approaches are promising to support adaptations at local levels given that they are used in a time sensitive way, use local knowledge of the context, and have built-in evaluations to assess if outcomes are being achieved (CE11, CE21). CE11, for example, found that the use of QI approaches supported systems thinking, the generation and testing of local ideas, iterative learning, transparency, and use of local data, further discussing how the learning collaborative served as ‘marketplace’ for the harvesting and sharing of ideas (257). They further noted that as the phases progressed, there was more emphasis on spreading

tried and tested adaptations over innovation of new strategies as similar challenges were faced across sites (257).

CE11 and CE21 reported using QI methods in LMICs, both with external support from the IHI. While it is unclear what level of support was given, the use of QI methods may be difficult to successfully incorporate in contexts that do not have a background in QI methods, or access to additional support and mentorship from organisations such as the IHI. That said, the IHI do provide detailed information and open access to resources on their website (282-284). Therefore, while more challenging, it would not be impossible for future scale-ups to use this approach without direct IHI support provided consideration is given to how to build capacity and to the resources needed to implement this approach. There may also be options for shared learning across low-resourced settings that have utilised IHI approaches.

5.4 Discussion

5.4.1 Adaptations Made in Practice During Scale-up

Results from phase two evidenced that there are numerous and simultaneous adaptations occurring to health interventions in practice during the course of scale-up, with the need to adapt for cultural acceptability and reduced resource availability emerging as the most prominent reasons. Cultural adaptation within the HICs examples of CE16 and CE17 primarily focused on adaptations for specific minority groups within the wider population. This is in keeping with much of the previous adaptation literature in HIC settings (54, 107, 110, 114, 120, 121). However, the importance of adaptation in order to align to the societal/cultural norms of a community or the wider national context was also evident in practice in LMICs. Specifically, implementers in these contexts were often faced with the introduction of interventions within a conservative national or regional context, where the intervention topic could be controversial within the wider population, for example with the introduction of SRH education in Pakistan (CE2) and Senegal (CE1). Similarly, cultural acceptability at the wider community level was often cited as a reason for adapting family planning and MCH interventions, where implementers felt it important to address widely believed misconceptions around contraception methods (CE5) or fear of giving birth within a health facilities (CE11). Likewise, the wider conservative political climate influenced removal of elements of a family planning intervention in Brazil (CE6), where supports were affected by politicians and their motivations for re-election. Together, these findings demonstrate the importance of ongoing assessment of the wider political, socioeconomic and cultural context, which is in keeping with many of the previous scale-up guidance (as discussed in Chapter 4, Section 4.2.1.3.1) (24, 40, 133, 196, 197). This research further demonstrated that instances where the wider population may have issues of acceptability may also

lead to significant changes to the intervention, greatly affecting fidelity, or resulting in lack of implementation (CE6). This highlights the unique challenge for implementers to find a balance between the needs and fit for the recipient, while taking into consideration the wider cultural context in deciding how to approach cultural acceptability, all without affecting the intervention's effectiveness.

The large amount of case examples reporting the need to adapt due to reduced resource availability, particularly in LMICs, was not unexpected, and is consistent with the broader scale-up literature (13, 24, 123, 125-127, 132, 174, 176, 178, 285). This finding recalls Holliday et al., (61) suggestion that adaptations could be classified as acceptable or unacceptable, and avoidable or unavoidable (discussed in more detail in Chapter 2, Section 2.4), in that adaptations noted for resource availability to improve feasibility in LMICs could often be classified as unavoidable. For example, in CE8, drug stock-outs and supply chain logistics, or in CE15 lack of access to equipment and capacity of staff in semi-urban and rural areas, both led to a need for adaptations. In other resource limited settings, approaches were put in place to avoid loss of elements of the intervention. For example, promoting a minimum method mix (i.e., offering a minimum number of contraceptive options for family planning) allowed for improvement of supply chain and pricing for some medication (CE8), or providing incentives for collaboration between districts for joint buying of supplies to ensure access (CE8). Therefore, while access to resources may at times be unavoidable and warrant adaptation, in other cases, it may be avoided through more systems-thinking approaches to service delivery.

5.4.2 Embedding of Processes for Future Adaptations

A promising finding of this research was the large number of case studies which reported proactive adaptations, whereby implementers had embedded processes for future adaptations within the scale-up design. Scale-up is a complex process, occurring over a long time period (51), with the possibility that early decisions are no longer relevant in later stages due to contextual changes. As discussed previously in Chapter 4 (Section 4.2.1.3.10) the scale-up and sustainability literature has commonly identified the need to continually address intervention fit as contexts change, with the need to plan in advance for addressing local fit over time (13, 24, 40, 49, 124, 125, 131, 132, 285, 286). As seen in the introduction of SRH intervention in Brazil (CE6), scale-up to the wider contextual landscape - encompassing political leadership, motivation, and funding - dramatically changed throughout the lifetime of the scale-up, and necessitated ongoing assessment in order to capture this change. Contextual changes may also occur more locally with organisational change, staff turnover, or within the target population group. The importance of planning the scale-up from the outset, with embedded

monitoring and evaluation to give insights on what may need to be changed as the scale-up progresses has also been highlighted in a recent review of the scale-up of public health interventions in LMICs by Bulthuis et al., (14). Guidance in the literature such as the CFIR (287) and more recently, an integrated context coding framework by Rogers et al., (288) may provide implementers with determinants to consider for the ongoing assessment of context affecting scale-up.

While engaging with stakeholders is not a new concept, frequently highlighted in previous scale-up frameworks (124, 126, 132) and was discussed previously in Chapter 4 (Section 4.2.1.3.8), the importance of embedding ongoing consultation, valuing local knowledge, making ongoing changes based on input, and therefore achieving a culturally acceptable intervention and buy-in was a key findings of phase two, for example as seen in CE2. Therefore, while ongoing consultation may be time consuming its importance throughout the scale-up process cannot be understated. It is further important to consider that this and other assessments can be resource intensive and costly, and capacity to continually monitor this in low-resourced or local settings may pose additional challenges. Balancing the importance of understanding contextual changes along with capacity to assess and analyse the impact it may have on an intervention at different levels, e.g. national versus local health facility, is thus required. Other actions identified which allowed for embedding of future adaptations included using an adaptive scale-up design, local decision making, and using a formalised QI approaches, such as learning collaboratives. Each of these come with different challenges and with capacity and resource needs that need to be considered by implementers when deciding on an approach, particularly in less resourced settings.

In terms of unplanned adaptations they were primarily reported to negatively affect fidelity, particularly occurring at frontline provider level. In order to address and reduce unplanned adaptations, implementers may need to take time to anticipate future issues. For example, a mismatch between provider, religious and cultural beliefs could have been foreseen in the instance where core topics were removed from a SRH education intervention by providers due to discomfort (CE1). More time pre-implementation and during implementation to sensitise and build support for the intervention may have mitigated this. Or, alternatively, looking at who delivers the intervention and whether another provider may be better placed to deliver the full intervention, as needed. Stronger anticipation and planning which considers the wider socioeconomic, political, cultural and organisational context in addition to provider capacity and beliefs may, therefore, assist in avoidance of unacceptable adaptations in future scale-up efforts.

5.4.3 Consideration of Fidelity

Both large and small changes to the interventions were reported. Often the smaller changes were for cultural acceptability, for example, by adding relevant cultural references (CE16, CE17) or acceptable language to an intervention (CE3). These may appear simple, and only constitute tailoring or tweaking an intervention, however, cultural competence and understanding of the nuances of local cultures can also be crucial to achieving the right fit (289). Larger changes such as adding or removing distinct elements (sometimes with an associated drift from protocol) may have impacted fidelity to the intervention and potential effectiveness. And while some of the CEs highlighted this potential impact on fidelity (CE1, CE6, CE7, CE18, CE19), others did not discuss considerations for fidelity. Although it may be complex and time consuming, considering the potential impact on fidelity is important, given that deviations from fidelity may undermine an intervention's overall effectiveness.

The field of adaptation and fidelity currently has no clear preferred frameworks, study design, or reporting guidance. The majority of guidance, as discussed in Chapter 4 (Section 4.2.1.1), is from HIC contexts, often focusing on cultural adaptations for a minority group within this population (27). In addition as discussed in Chapter 2 (Section 2.4), there is also a lack of agreement on what constitutes fidelity, further adding to the challenge for implementers in assessing and reporting on adaptations. Only one case example reported on any kind of fidelity assessment for the scale-up (CE17), and even with that, focused on element of fidelity of delivery only (62, 239). Consequently, it was a challenge to assess which adaptation(s) affected the fidelity and effectiveness of an intervention. However, this low level of fidelity assessment and reporting was not unexpected given the dearth of guidance and lack of consensus with what constitutes fidelity. Those case examples which did report on fidelity, either through a fidelity assessment or acknowledgement of a loss of fidelity should be commended. For others, only an estimate on fidelity could be made, working with the available information which was often lacking. Therefore, for many case examples it is unclear whether fidelity was impacted and whether adaptations may have impacted intervention effectiveness.

Those involved in the field of fidelity have tried to address the lack of standardisation and guidance. For example, the National Institute of Health Behavioural Change Consortium (NIH BCC) proposed components of treatment fidelity for behaviour change interventions (i.e. study design, training, delivery, receipt, and enactment) (290). Other frameworks have also highlighted the importance of the fidelity criteria of adherence and dose, with subcategories available for these (101). However, the merits of standardised fidelity categories relevant to all interventions has also been challenged by Pérez et al., (56) who promote that each intervention should have its own specific descriptors of

fidelity unique to the intervention. Likely all of these arguments ring true, with a role for common indicators for elements such as adherence, but also for specific fidelity indicators based on individual interventions and implementation contexts. In all, this remains a debated area within the fidelity literature. Further, it could be argued that it is an unfair expectation for implementers to assess and report on fidelity without a clear consensus on: a definition of fidelity, what elements constitute fidelity, and how to assess and report on it.

Scale-up is a challenging, time consuming, and resource intensive process (14, 285). Adding fidelity studies into this may therefore be unrealistic. For example, even within the *Action schools!* intervention (CE14) conducted in a HIC, the authors report having conducted fidelity assessments in the efficacy and effectiveness studies, but not in the implementation study (236). If fidelity studies are unable to take place due to limited resources or time, a compromise may to ensure the inclusion of fidelity supports for sites. In CE16, for example, they reported that while fidelity was not formally monitored or assessed, they did have support systems for fidelity in place, with clear intervention essential components, clinician self-reported checklists, and regular supervision and meetings, where these essential components were reviewed (207). Fidelity support systems such as these may therefore be preferred over full fidelity assessment studies. While this may not be a perfect approach, clarity of the intervention components and supports to maintain these may lead to greater intervention fidelity throughout scale-up at local sites throughout adaptations.

The lack of fidelity assessments across the case examples further had implications for this research and meant that only crude judgements of the relationship between adaptations and fidelity could be made for the majority of the adaptations, based on what was reported in the case examples. Therefore, unless a definite loss to fidelity was reported in the case example, only judgements of *appeared consistent* or *appeared inconsistent* to fidelity could be made. While there may have been an expectation of a publication bias, whereby authors are reluctant to report negative findings, surprisingly, a considerable number of case examples did employ adaptations which they reported constituted a loss or potential loss to fidelity. However, the wider implications in terms of health outcomes were not clear. As discussed previously, adaptations were often made in relation to cultural acceptability, with the challenges of implementing in a conservative cultural context or due to resource limitations rendering adaptations largely unavoidable. Those that appeared to have high fidelity to the intervention often had clear intervention components identified, with guidance given to sites on this to support adaptations.

5.4.4 Identification and Reporting on the Intervention Content

One area of consensus across the adaptation literature as discussed in Chapter 2 (Section 2.5), is the benefit of clear identification of intervention theory, core elements, components or functions (57, 110, 120, 121, 187, 188). That said, many case examples identified in this study did not report on this (CE9, CE11, CE12, CE13, CE20, CE21). Given the consensus in the adaptation literature on the importance of identification of intervention theory, core elements, components or functions, it is disappointing that the identification of intervention theory, core elements, components or functions is not uniformly occurring or reported on during adaptation within scale-up. It remains unclear however, whether this absence occurred in practice in these case examples, or whether this was down to lack of documenting and reporting within the study reports, as the level of detail reported on what the intervention consisted of varied greatly across studies. In some case examples, such as the *Action Schools!* Intervention (CE14), the authors gave extensive details on each of the component of the intervention (236). However, a number of case examples inadequately described what was scaled-up (see Table 5.6). For example, when scaling family planning interventions the term ‘education’ was often reported without details on what elements of family planning were part of this education, and in what format this was to be delivered (CE5). In particular, the term ‘community education’ was used often with minimal description of what this entailed (CE11). While it is acknowledged that the focus of the majority of the articles was to evaluate or discuss the process of scale-up and not necessarily describe the intervention itself, this lack of description of the intervention leads to ambiguity in what was actually scaled-up.

The content of the intervention itself is a vital piece of information in considering the implementation, particularly when adaptations to this intervention have been made. The poor reporting of intervention details in these scale-up case examples could be considered common across other study designs. For example, it is widely agreed that intervention details are often lacking in RCTs, where the focus is arguably on the intervention (291). To address this, it is recommended that future studies use guidance such as the TIDieR (100) reporting checklist for intervention reporting. Although this was developed for RCTs, this research suggests that the TIDieR guidance (100) could also act as a useful tool for reporting details of interventions in scale-up research.

It is important to note that the identification of intervention theory, core elements, components or functions alone does not guarantee that they will be followed. In the examples of the different adherence groups for ART retention (CE18, CE19), both CE’s identified key eligibility and group operation components. However, both also noted that these were not always followed based on

feasibility, i.e. the group size increasing or those with co-morbidities joining the group based on growing demand and lack of other services (241, 244). Additionally, the identification of core topics for sexual health education in Senegal (CE1) did not always lead to their inclusion in the curriculum, nor to them being delivered based on acceptability within the conservative context. This illustrates the important point that identification and clarity on core components alone does not guarantee fidelity to these, particularly in LMIC contexts where feasibility and strained health systems mean that fewer supports are available. This is also the case for conservative contexts where cultural acceptability at local or national levels may greatly impact the acceptance of an intervention. Therefore, identification of intervention theory, core elements, components or functions could be viewed as a foundational building block, with further importance paid to what type of guidance and in what format these are provided, in addition to embedding further actions to address the intervention components being followed, while also allowing for flexibility and adaptation in challenging contexts.

5.4.5 Suggested Advancement of FRAME

A challenge for this review was that the majority of the studies did not primarily report on adaptations, focusing instead on describing the process of scaling-up or on evaluation of intervention or implementation outcomes. While poor reporting of adaptations was not unexpected given the lack of guidance and agreements of taxonomies, future studies should consider detailing both the process (with the actions used) and the adaptations in order to better inform future learning. Guidance on how to study and report adaptations is an emerging field. And while there is growing recognition of the need to adapt when scaling up (24, 49), there is also a need for further clarity on what constitutes adaptations, the different types of adaptations, and how to assess and report them.

The FRAME for coding of modifications represents an important advancement in the field of adaptation, providing key guidelines and a framework through which to describe adaptations (1, 15). However, the use of the FRAME within this research was not without its limitations, particularly when applied in the context of a review as opposed to primary research. Developed in a HIC setting, and largely based on adapting behaviour change interventions for minority groups within the wider population (54, 110, 114, 120, 121), meant the FRAME (1) was not as applicable for the context of LMICs. This suggests a need for further expansions to FRAME is required for use in these contexts. The original FRAME (1) headings listed improve fit at recipient level i.e. 'improving fit with recipients', with an additional sub-heading of 'addressing cultural factors' at recipient level. However, this was problematic in this research as the heading did not adequately capture improving fit by addressing cultural factors at community or wider socio-political levels. This was particularly the case for SRH

interventions, where a conservative societal context led to challenges in implementing the intervention leading to adaptations (CE1, CE2, CE3, CE6, CE7). Interestingly, in some cases, it was noted that the recipients themselves may not have shared the same beliefs. For example, women wanting access to a broader range of contraceptive choice, but the wider cultural societal context finding it unacceptable (CE6, CE7). This provides a unique challenge for implementers, who need to balance and provide fit to both the recipients and the wider context in cases where their beliefs may differ. Therefore, an additional code of 'improving fit within the wider community or sociocultural context' was added within this research to capture this.

Another suggested expansion of FRAME (1) for resource limited contexts (i.e. LMICs) is to expand the reason heading of 'available resources' at organisational level to capture which resource(s) acted as a limiting factor(s). This heading could benefit from specifying what element of available resources was lacking (e.g. logistics and supply chain, cold chain storage, human resource capacity and/or availability, facilities and equipment, etc). As each resource issue comes with their own unique opportunities and challenges to overcome, identifying the cause for adaptation may lead implementers to engage in more systems-thinking approaches to avoid future unacceptable adaptations.

The overarching purpose for the adaptation (referred to as the goal in the original FRAME guidance) often was not clearly stated within the case examples and therefore had to be inferred from the reason itself. For example, if available resources at organisational level was cited as a reason for adaptation, the purpose (or goal) of improving feasibility was coded. In addition, FRAME (1) purpose headings often overlapped. For example, in the case of 'reducing cost' and 'improving feasibility'. Additionally, there was little differentiation between reasons and the purpose headings for cultural acceptability. The heading of 'increase satisfaction' was not found to be useful, with 'increase reach and engagement' found to capture a similar purpose. The wording of 'improve fit' with recipients could also benefit from further specification. For example, this was used to capture acceptability among recipients, but was also relevant in terms of matching intervention to the literacy of participants. Finally, with acceptability being such a dominant theme within implementation and adaptation literature (41, 129, 133) it may warrant its own heading under the purpose within the FRAME to capture this importance.

FRAME (1) may also benefit from more consolidation with other implementation outcome frameworks to ensure all factors relevant to adaptation are being captured, as well as for ease of use. Specifically, the FRAME purpose headings overlap considerably with the implementation outcomes

suggested by Proctor et al., (179). For example, cost and feasibility. Others, such as sustainability, were not a part of the FRAME (1) coding framework. Further clarification of the purpose headings and their consolidation with the implementation literature may assist with this.

While the most recent update of FRAME (1) includes a 'consideration of fidelity' section, minimal information is given on how to code for fidelity. This is a major weakness of the updated FRAME given the importance of fidelity in adaptation. Consequently, there was a need to search outside the scope of FRAME to develop a method to consider fidelity for the case examples (56, 101). To this end, the current study developed a fit for purpose method to consider fidelity within the case examples, with further sub-questions added to the extraction to aid in coding for fidelity. This included considering whether the intervention was described in detail, whether clear components (elements, functions, theory, minimum standards etc.) of the intervention were identified, whether the adaptation appeared in keeping with these, and whether a fidelity assessment took place. Any coding framework for adaptations including a heading on fidelity should therefore give more guidance and weight to this area. Further iterations of this FRAME (1) would benefit from either exploring and describing how to code fidelity further, or alternatively, if this is beyond the scope of the framework, to refer to a more in-depth fidelity framework to use in tandem with FRAME.

While there are developments in the field of adaptation reporting there remains room for improvement in order to make reporting more comprehensive and user friendly for implementers. Therefore, it is unsurprising that adaptations were found to be poorly reported and assessed in this review. One challenge of this review was that FRAME (1) was developed and tested in primary research to document adaptations on a specific, known intervention. However, when used in a review of secondary data, there were often many details (including an in-depth description of the intervention being adapted) lacking within the documents, making it challenging to identify all elements within the framework. Scale-up studies reporting adaptations should therefore strive to utilise a multi-guidance approach. For example, a combination of the TiDieR guidance (100) for intervention reporting together with the FRAME (1) for adaptation reporting would greatly assist in capturing what occurred as well as support learning for future scale-up and adaptation efforts. Refining the FRAME based on the suggested updates, as discussed above, along with keeping the importance of fidelity in mind, would further help to improve its usefulness, particularly within LMIC settings.

5.4.6 Challenges in Heterogeneity and Quality of Documents Identified

There were vast differences in the design and reporting of the scale-up case examples which made analysing, synthesising and appraising a challenge. This was unsurprising as although there is an abundance of frameworks in this field for addressing scale-up determinants, processes, and evaluation (148), to date there remains no consensus on which is best practice for use. While the ExpandNet guidance was utilised for guidance and reporting in a number of case examples, these primarily came from the flagship ExpandNet book from 2007 (CE6, CE7, CE8, CE9) (16, 268-270), and only two further case examples using it more recently (CE5; CE2) (197, 228). While this may be explained by ExpandNet having been developed with SRH examples, its language and relevance is open to all healthcare innovations (12). Thus, its lack of use in more recent case examples and its current deemed relevance should be explored further. Another option for reporting guidance available is that of Neta and colleagues' (292) framework for reporting of dissemination of implementation research, which uses the headings of planning, delivery, evaluation, results and reporting, long term outcomes, and goals - with suggested elements to consider and report under each of these. It also suggests documentation of crosscutting issues such as multi-level context, societal costs and multi-stakeholder perspectives.

The above outlines just some of the options to support implementation and scale-up study design and reporting. The problem may therefore not be a lack of guidance for implementation and scale-up, but more the overwhelming amount of guidance and frameworks to choose from, with none being suited to meet all needs. As a quickly evolving field, and as these frameworks get utilised, refined and consolidated overtime, more clarity for implementers and researchers may be offered, in order for them to select a framework based on what is best fit for their scale-up study design and emerging best practice for reporting.

While the challenges of scale-up, adaptation, and fidelity design and reporting are acknowledged above, issues in quality were also present in the studies. While some case examples gave detailed descriptions on how the content of the article or report was developed, others gave few details. For example CE22, although peer reviewed and though providing a detailed description of the process of scale-up, lacked any information on how the process information was gathered (e.g. whether through a document review, interviews with stakeholders involved in scale-up etc.) (256). It also did not reference the role of the authors in the scale-up. Therefore, it is unclear whose perspective is being told and whether it is reflective of other stakeholders involved. While it is not necessarily an issue to have the authors' experiences and perspective as the sole take on the process of scale-up, this would need to be clearly acknowledged, and the role of the authors in the scale-up clearly stated, so that the

reader understands which perspective of the process is being presented. This was common in articles which focused on both an evaluation of outcomes and on describing the process of scale-up, whereby the methods were only reported for the former (234). In contrast, other studies reported on both how the data was collected and analysed. For example, Rasschaert et al., (241) described their mixed methods study with qualitative data from in-depth interviews (24) and focus groups (16), analysed using inductive thematic analysis. They also reported a quantitative component with information from routine monitoring data, reported that the findings were triangulated through these sources, and compared the initial planned implementation activities with findings in practice. This clarity in reporting of methods used and analysis could be used as an example of good practice for scale-up reporting.

While all studies do not need to use the same methodological approach, including details on the methods used allows for transparency and trust in the findings. Lack of guidance in scale-up, adaptation, and fidelity study design does not excuse lack of transparency and reporting on what methods were used and how information was analysed. If anything, a lack of guidance should encourage greater openness and acceptability of a range of methods, once they are transparent. With greater reporting there can also be greater sharing of what was done, allowing for consensus to build as to how best to design and report findings in the future.

5.4.7 Actions used During Scale-up for Adaptations

Phase two of this research led to the identification of a common range of actions used to support adaptations during scale-up that can be used to inform future implementers. Despite some commonalities across actions there was no clear single process to follow. Actions were used across various contexts, on different intervention types, with different combinations of actions used together, often resulting in different outcomes of the adaptation. Therefore, the actions identified serve more as a 'menu' than a prescriptive checklist to follow when making adaptations for scaling-up. There may also be a need to consider multiple actions, as in practice these are rarely used in isolation, with the majority of case examples reporting use of numerous and simultaneous actions to assist adaptations during scale-up. For example, local decision making was often supported in the context of peer learning opportunities, or provision of guidance on intervention elements, or guidance on how to implement and adapt to local sites.

The level at which the action was carried out also varied. Some actions were part of the role of the scale-up team, such as providing guidance to sites on intervention components or standards, or by

deciding to use an adaptive scale-up design. Others were carried out at frontline provider or community level, such as use of community partnerships or QI methods to support adaptations. The range of actions at different levels provides opportunity for implementers to choose what best suits their setting. If there are concerns over capacity at local level, or an inability to provide resources to train or support an approach at local levels, the results of this phase of the research demonstrate that there are other actions that can be selected (e.g. at the scale-up team level) to support adaptations for local fit. Thus, lack of capacity at local level does not negate the ability to achieve adaptations, and actions can be selected based on best fit for the context of the scale-up and the resources available in that setting. Also noted was that unplanned ad-hoc adaptations were primarily reported at frontline provider level, so anticipating and considering how to mitigate this and embed thoughtful and reflective adaptations at this level may be of benefit to scale-up programming.

Despite variation in the actions, there are arguably some common elements in how these actions might work. For example, many actions centred around participation, communication or creation and use of knowledge. Participation is central to the scale-up literature (as discussed in Chapter 4, Section 4.2.1.3.8), with involvement of those delivering and receiving the intervention proposed as a way to increase buy-in and support (13, 24, 40, 52, 67, 124, 126, 129, 131, 132, 134, 166, 173, 174, 178, 285). In the case of adaptations, participation also allows for local knowledge to be utilised (173), with those on the frontline or community members having the ability to recognise elements which may not be acceptable or feasible locally, and to subsequently develop solutions. Such participation also allows for ongoing adaptations over time as contexts may change, in support of a more sustainable approach (24). For example, local decision making and use of QI methods, among others, allowed for participation and creation and use of knowledge of frontline providers and/or recipients. Actions, therefore, often demonstrated more than one element and to work in many ways.

Variation was also observed in terms of the amount of planning and resources needed across the range of actions. Some actions, such as developing local decision making through a community partnership, consisted of a structured formalised approach. As discussed in Chapter 4 (Section 4.2.1.3.8.3) community engagement is complex and may take time to build, develop trust, and facilitate meaningfully. Other actions, such as the use of accessible data to inform adaptations, may be reliant on the setting's underlying IT and ICT capacity for reliable capturing and reporting. Further to this, actions such as providing examples of tried and tested adaptations, could be used in a less formal and time consuming way (e.g. by a newsletter disseminated to sites). Each action will have its own benefits and drawbacks which need to be weighed up by the scale-up team when planning which

action(s) to choose. While some approaches may take more time and resources to train and plan for, they may also have the advantage of embedding sustainable practices for ongoing adaptations once the scale-up team withdraws. Therefore, investment of time and resources needs to be weighed-up against future benefits and payoffs when selecting approaches, and in some cases, there may be a need to use a combination of simple, cost-effective, less resource intensive actions alongside investment in more sustainable, long-term approaches.

A number of case examples noted insufficient guidance available. Adaptation is a complex process, with no agreed approach in the literature. As discussed previously, much of the adaptation process literature stems from HIC contexts, and occurred with academic research partners (54, 110, 114, 120, 121). In local settings without academic research partners, adaptation is challenging to achieve without explicit guidance and support on how to achieve this for their setting. Without clarity on what is to be implemented, what is adaptable and how to go about accomplishing this, it can be very burdensome for local sites, particularly in LMICs, where local level implementers may not have the skill-sets or time to complete and evaluate adaptations from scratch. Within the case examples referencing use of guidance, there was no clear design in terms of content of guidance or in what format it was delivered. As discussed in Chapter 4 (Section 4.2.1.3.5) providing guidance to sites had been identified by a number of frameworks as important, however the content of what guidance to share was not clear. The lack of consistency of what was provided in terms of guidance across the case examples further evidences a lack of agreement on how to achieve adaptations during scale-up. As a result, implementers have an influx of frameworks and approaches with no clear preferred approach coming to the fore. More consensus is thus needed on what type of guidance should be provided to sites, and in what format, depending on the intervention type and context. This research contributes to this gap in knowledge by putting forward some considerations for guidance to sites that could be concluded from the case examples, as seen in Figure 5.5. These include consideration of what type of guidance should be provided, in what format, at what timepoints, and who is the source or delivering the guidance. These considerations may differ depending on the intervention type and context of the scale-up.

Since completion of this phase of the study, some new literature has emerged in the field of adaptation providing consolidated adaptation steps that may be useful for implementers to incorporate into the suggested guidance materials above for local sites. Firstly, Movsisyan et al., (29) completed a systematic review in 2019 of adaptation frameworks for population health interventions as part of the NIHR and UK MRC funded ADAPT study (2018-2020) (293, 294). Through identification

of 35 guidance documents adapting the content, context or evaluation for interventions the authors amalgamated steps found resulting in 11 suggested steps which include: 'initial assessment', 'identification of potential mismatches', 'pilot testing', 'intervention revision and implementation, and further 'evaluation'. To note the majority of the guidance documents they developed these steps from were focused on HIC settings (i.e., 34 of 35 documents) and on cultural adaptation for minority groups, with only four exploring the international transfer of interventions to a wider context (17, 113, 183, 186). Additionally, there was no specific process guidance for scale-up and adaptation drawn upon to develop these steps. A further recent scoping study conducted in 2019 by Escoffery et al., (163) also looked at adaptation guidance for public health interventions, and while it was acknowledged this was a scoping study and not systematic review, a difference was seen in that they only identified 13 adaptation frameworks, but then also suggested 11 steps based on an amalgamation of findings. The two sets of 11 steps differ between these reviews, in that Escoffery et al., (163) recommended as separate steps 'consult with experts' and 'consult with stakeholders', and also to 'train staff', while the framework by Movsisyan et al., (27) suggested the three of these as one step the 'establishment of networks, capacity and infrastructure'. Movsisyan et al., (27) also have a specific step for re-design following testing with 'intervention revision and implementation', however for Escoffery et al., (163) this step is embedded under the step of 'test the adapted materials'. Overall, the concepts are similar for example: select an intervention, learn more of the context, involve stakeholders and experts as needed, build capacity, adapt, evaluate, review and implement, however the specific suggested steps did vary. Further to these recent reviews, Kirk et al., (164) developed the Model to Adaptation Design and Impact (MADI) in 2020 consolidating adaptation taxonomies from Wiltsey Stirman et al., (1), Stirman et al., (15) and Moore et al., (59), and the implementation taxonomy from Proctor et al., (295). This gives implementers further domains to consider such as: adaptation characteristics, possible mediating or moderating factors and implementation and intervention outcomes (both intended and unintended).

While these further reviews are welcome in the field of adaptation, the volume and differing steps remains confusing for implementers with no clear consolidated framework coming to the fore even within this more recent work. It is also important to note that these steps are not specific to scale-up. For example, for local sites a step of intervention selection may not apply as the intervention to be scaled has already been selected and is being rolled out. Consequently, only some of the later steps, for example of revision and evaluation of the intervention, may be applicable to scale-up and prove as a useless resource for implementers when giving guidance to local sites. A question could be asked as to whether use of full guidance such as these consolidated adaptation frameworks (27, 163) would

be most appropriate in the context of scale-up or other methods such as those seen in use in some of the case examples (such as QI methods with plan-do-study-act cycles) may be more user friendly and address the needs of local sites. However, it is important to note that other methods, for example QI methods, were not designed for adaptation and scale-up (and more often would have been used for other purposes for example to audit against a clinical standard (296)), and critically, may not include consideration of fidelity to the intervention in their guidance. It is clear the field of adaptation guidance likely needs to evolve, with trials of what exists and feedback with one coming forward as most useful needed in the field of scale-up. What may be beneficial is if these consolidated frameworks with steps specific to adaptation are tested in future within a scale-up setting by local sites, which may assist in determining utility for this context. This review has identified that local sites need specific guidance to be given to them by implementers on how to implement and adapt the specific intervention, with the scale-up team having to select which of the guidance and methods available appear most appropriate for their setting given the needs, time and resources available.

Peer learning emerged as a promising action to support adaptations the current study. As discussed in Chapter 4 (Section 4.2.1.3.7) this was suggested by some of the scale-up guidance and frameworks, where peer learning could take place formally e.g. through learning collaboratives (13, 176), or more informally through site visits (173). The potential for sharing of ideas to dramatically save time, in reducing need for innovation, and learning of successful adaptations therefore appears advantageous in the process of scale-up. This is particularly relevant in low-resource settings where the capacity to evaluate changes, and time to develop and test new ideas, is often limited. However, one must also consider the motivation to share learning between peers, and the level of facilitation and resources that may be needed in order to accomplish this. Motivation and resources being key determinants of whether peer-learning occurs in an ongoing basis, or as a one-off learning experience, if at all. Some sites may have more skills and resources, but are not necessarily incentivised to share with other sites. Particularly in low-resourced setting, where services are under strain, there may be little time to devote to sharing of learning and ideas with other sites. The example in CE8 of incentives is interesting as it appeared to promote collaboration and referral between sites despite initial reluctance. Motivation and incentives for collaboration should thus be considered if one hopes to embed peer learning opportunities into scale-up. There was an emphasis in the case examples on reporting of more formalised approaches to peer-learning. However, it is recognised that informal peer learning may also have occurred, but not routinely documented in articles discussing the overarching scale-up. Therefore, informal peer learning should not be ignored and further research is needed to better understand how and when it is happening, in order to support adaptations when scaling-up.

The development of accessible data for use at local levels was spoken of positively in all case examples who referenced its use in adaptations, whereby the ability to utilise data at local levels is one way of achieving ownership and buy-in (228). Additionally, if the action of local decision making is to be utilised, it follows that this should be accompanied with data accessible for use at the level where decisions are made. The examples given of accessible approaches for data use, such as traffic light systems (CE21) or pictorial tools (CE22), appeared to facilitate data uptake and use within these scale-ups at local level and serve as promising solutions to ensure that data is accessible even within low-resourced settings, where experience with data or literacy levels of health workers or peer educators may limit its use.

A promising, albeit initially resource-heavy approach to set-up in terms of initial capacity building and the need for ongoing supports, was the use of formalised QI methods such as BTS or learning collaboratives. For the case examples that developed capacity in QI methods, it could be argued that those who participated in this approach could now use QI methods for scale-up of further interventions. However, even if the QI approach is familiar, allocating the resources and time to implementing this approach in resource-limited settings should be pragmatically considered under usual resources. The BTS, for example, requires significant facilitation and planning (283). In the scale-up of adherence clubs (CE19) within the Western Cape region, the authors reported the use of a BTS steering committee, which over time and as scale-up sites dramatically increased, experienced reduced time for mentoring and workshops (specifically referenced in article (245)). This illustrates how high resource initiatives can be challenging to scale-up within resource limited settings. Overall, the use of QI methods in scale-up and adaptation appears to be a promising approach, once consideration of the capacity needed to set-up and facilitate this in any given context is considered. There are also options such as the MFI which do not involve formalised time-bound learning networks, that may be more achievable with limited resources.

5.5 Clarifying the Scope of the Review for Phase Three

The most frequently reported action for adaptations during scale-up was the use of local decision making, with over half the case examples reporting its use (see Table 5.7). Moreover, local decision making was reported at varying levels of the system, depending on the scale-up, from provincial to frontline provider and recipient levels, and with many case examples reporting local decision making occurring at multiple levels in the system adding to complexity. Phase two therefore evidences the frequency of use of local decision making for adaptations during scale-up of health interventions. As discussed in Chapter 4 (Section 4.2.1.3.9) several scale-up guidance and frameworks had highlighted

use of local decision making within scale-up (13, 124, 129, 132, 134, 173), however the level at which this occurs, what approach to use, and the capacity required varied between the frameworks, with no clear guidance on how best to achieve local decision making in various contexts. Additionally, within current scale-up literature it appears local decision making has not been previously explored in the context of scale-up and adaptation, representing an important and emergent gap in the scale-up and adaptation literature.

From a positive standpoint, local decision making can allow those who know the local context to inform adaptations for best local fit. Local decision making further provides a way in which adaptations can be completed on an ongoing basis, as needs and resources change over time. It can also continue after the formal scale-up has finished, allowing for sustainability of local fit. The potential of local decision making as a sustainable approach for ongoing adaptation is promising, particularly as the need for ongoing adaptations throughout scale-up has been highlighted within this study and across the literature (24, 49). There are many considerations in *how* local decision making may work, for example, participation of those at local level may lead to increased buy-in and support for the intervention. It is also possible that recipients harbour greater trust for the adaptations made by those known to them.

However, the action of local decision making is complex and, as findings suggest, was rarely used in isolation, with numerous and simultaneous other actions being used in tandem to support it. For example, creating peer learning opportunities (Action 5), which could include sharing of tried and tested examples (Action 2c), allowed for cross-site learning to support local decision making. The use of accessible data to inform and evaluate adaptations (Action 7) and the use of formalised QI methods (Action 8) also allowed for capacity to be built and supported decision making at local levels. The provision of guidance on intervention components (Action 2a) and on how to implement and adapt (Action 2b) created knowledge and encouraged ongoing adaptations at local levels. Thus, the interaction of these actions and their role in how local decision making works across contexts warrants further exploration.

While local decision making as an approach is promising, it does not come without risk. Local beliefs, or a lack of capacity or guidance on how to adapt, may influence changes to intervention that impact fidelity. For example, giving frontline providers autonomy to make decisions on adaptations is arguably empowering those who know the context best in order to provide the best fit for the intervention. However, as seen in the example of the SRH intervention in Senegal (CE1), it also leaves

the intervention open to unwanted adaptations based on personal beliefs or prevailing cultural norms. Therefore, care needs to be taken to ensure that strategies are in place to support adaptations with fidelity, as guidance on core topics alone does not appear sufficient to account for contextual factors that may impact on adherence to core components of an intervention. Accordingly, safety checks and measures may need to be in place to ensure local decision making can occur, while also ensuring the intervention remains as effective as possible. Additionally, capacity at local levels may vary. Setting up and sustaining a local decision making approach may require significant resources and ongoing support. Therefore, unpacking the approaches used in differing contexts and how and why they may (or may not have worked) is of benefit to support future scale-up and adaptation efforts, and to promote local decision making at these levels.

A further gap in knowledge highlighted within the scale-up literature concerns *who* makes decisions and *how* decisions are made for scale-up (63). Taken together, and due to its frequency of use, potential benefits, drawbacks and the complexity of local decision making, its further exploration is warranted. Therefore, it was decided to focus on this specific action for phase three. Specifically, to explore how, why and in what circumstances local decision making works for adaptations when scaling-up health interventions for local fit. Consequently, the research question, aim and remaining objectives were refined to the following for phase three, in fulfilment of objective 2.3 of phase two:

Focused Research Question for Phase Three

- How does *local decision making* work (i.e. by what mechanisms, and in what contexts) as an action to achieve adaptations during scale-up of health interventions?

Focused Research Aim for Phase Three

- To develop theory on how *local decision making* can be used to make adaptations to health interventions for local fit during scale-up across diverse contexts, which has practical application for implementers involved in scaling-up

Focused Research Objectives for Phase Three

Phase three was therefore designed to achieve the remaining two refined research objectives:

- 3.1 Discover *how local decision making* works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit through generation of CMOCs

- 3.2 To develop and refine programme theories and propose a Middle Range Theory (MRT) on how *local decision making* works to achieve adaptations when scaling-up health interventions for local fit, by identifying demi-regularities within the uncovered contexts and mechanisms

5.6 Methodological Considerations for Phase Two

Phase two of the research was primarily descriptive, answering objectives 2.1 and 2.2: identifying adaptations made in practice and actions used during scale-up for adaptations. Consistent with the stages of realist review (Chapter 3, Figure 3.3) phase two incorporated elements from: Stage-I (clarifying scope – by identifying actions used in practice and clarifying scope of research to explore local decision making in phase three); Stage-II (developing the systematic search strategy); Stage-III (selection and appraisal of case examples to use in this and future phases); and Stage-IV (data extraction of actions used which built upon those in the IPT framework). Under the realist search components framework (45) phase two could be considered primarily part of the *background search*, *search to formulate review question* and also *search to identify empirical evidence*. Specific theory building did not primarily occur in this phase. There was, however, a need for this phase in order to move forward in the research. Firstly, and as the actions used and adaptations made in practice for scale-up had not previously been explored, phase two addresses a clear gap in research within the field of scale-up and adaptation. Secondly, phase two served as a further building block for phase three, as it was challenging to focus on one action before gaining a picture of what actions were used in practice and identifying which action warranted further exploration. In addition, and as actions rarely occurred in isolation, focusing on one action before discovering what others were being used would omit valuable contextually relevant information on the circumstances in which local decision making may work for phase three. Therefore, while a lot of time and resources ended up being devoted to phase two, this phase provided an essential knowledge-base for theory building and refinement for local decision making for phase three.

5.7 Phase Two Contributions and Conclusions

At time of completion, and to the best of my knowledge, this was the first review to systematically document what adaptations were being made (objective 2.1) and what actions were being used in practice (objective 2.2) during scale-up, across a range of health interventions in both HICs and LMICs. Findings support the argument that adaptations are occurring in practice during scale-up for local fit, with the majority occurring due to cultural acceptability or resource availability (as seen in Section 5.3.7), and with many being potentially unavoidable, particularly in resource limited settings. While multiple actions were found to be used, commonalities were also identified. Which actions to choose however, may vary based on context, including the capacity and resources available, along with the

level of adaptation needed. One of the key contributions of this phase of the research is therefore the synthesis of a 'menu' of actions that have previously been used in practice when scaling-up, and that can now be selected from to support future adaptations (as seen in Section 5.3.9.1.2, Table 5.7). An action which came to the fore was that of guidance to sites. While there was no one-size fits all approach, this review put forward considerations for implementers on: what type of guidance should be provided (i.e. on intervention theory, core elements, components, functions or minimum standards, implementation and adaptation process for the specific intervention and of tried and tested adaptations), in what format, at what timepoints, and who is the source or delivering the guidance (as seen in Action 2, Figure 5.5). These considerations may differ depending on the intervention type and context of the scale-up. Figure 5.5 offers an important resource for implementers when selecting an approach for provision of this guidance.

This review highlighted weaknesses in the reporting of scale-up and adaptation in practice. Practical suggestions are put forward for how the FRAME guidance (1), though a welcome contribution in this field, could be strengthened. For example by further inclusion of factors relevant to LMICs, and building upon fidelity guidance and consolidation with implementation outcome frameworks (see Section 5.4.5 for recommendations). This review also suggested how the TIDieR guidance (100), already present for RCTs, could be used as a complementary framework to assist better intervention reporting for scale-up case examples. Methodological reporting gaps within the scale-up examples were highlighted, and although there was no preferred study design approach which came to the fore, this review puts forward a call for more transparency of the methodology when reporting on the process of scale-up, with a good practice example of transparent methodological reporting highlighted (241).

Taken together, this review provides both new information to the field of scaling-up health interventions, by identifying actions used and adaptations made in practice, in addition to contributing a framework as to how to approach providing guidance to sites for adaptation during scale-up. Additionally this review has built upon current adaptation taxonomies and has highlighted methodological issues in the literature when reporting on the process of scale-up.

Chapter 6. Phase Three - How Local Decision Making Works for Adaptations During Scale-up of Health Interventions

Phase three of the research focused on discovering how, and in what circumstances, local decision making works for adaptations during scale-up. In order to achieve this, the study generated CMOCs from identified case examples explaining how *local decision making* works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit (objective 3.1). Following this CMOC generation, programme theories were developed and refined, and an MRT was proposed (objective 3.2). The resultant theories (PTs and an MRT) provide an explanation of how *local decision making* can be used to make adaptations to health interventions for local fit during scale-up across diverse contexts, which can have practical application for implementers involved in scaling-up. This chapter will outline the methods used and stages of the realist review that took place in this phase. It will present the results in the form of PTs, referencing the corresponding evidence from the case studies for each theory, and where substantive theory supplemented the findings. Following a discussion of the PTs, the MRT will be presented. A glossary of realist terminology used in this research can be seen in Chapter 3, Table 3.1.

6.1 Methods Phase Three

6.1.1 Stages of the Realist Review

The stages of realist review used in phase three of the study are outlined in Figure 6.1. This phase included elements from all of the six proposed stages (43, 44). In relation to Stage-I, this phase included the development of IPTs specific for local decision making (LDM) (detailed in Section 6.1.2 below). Regarding Stage-II, a further search strategy was developed to identify more documents on selected case examples and to identify substantive theory to assist in PT refinement (detailed in Sections 6.1.3-6.1.5 below). As for Stage-III, selection and appraisal, selection of case examples from the sampling frame from phase two took place, with appraisal for relevance and rigour (detailed in Section 6.1.6 below). In relation to Stage-IV, data extraction of CMOCs from the case examples took place (detailed in Section 6.1.7 below). With respect to Stage-V; CMOC synthesis, IPT refinement with development of PTs and an MRT occurred (detailed in Sections 6.1.8 and 6.1.9 below). In addition to this, a Stage-VI of theory refinement from stakeholders also took place in this phase (detailed in Section 6.1.10 below).

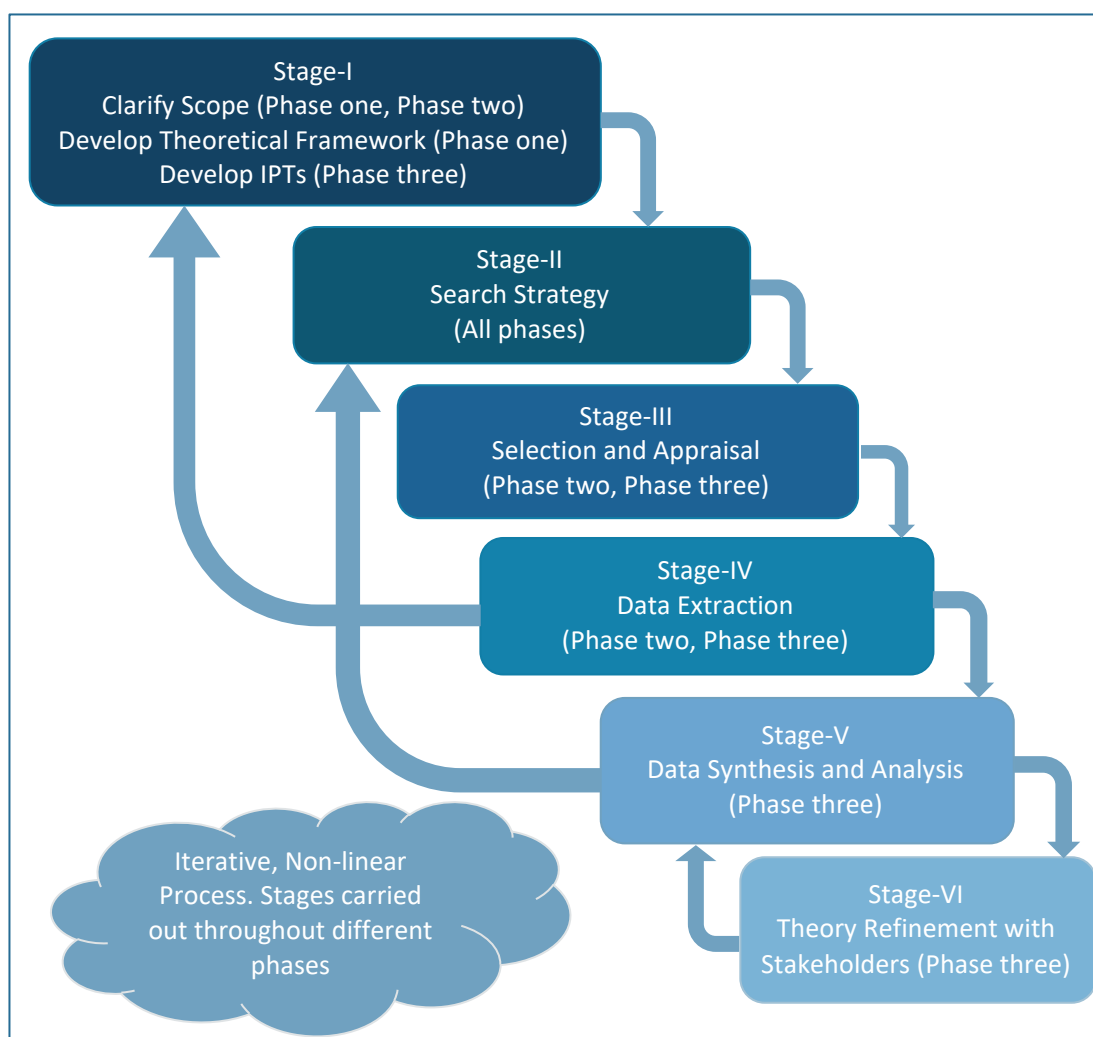


Figure 6.1 Overview of stages of the realist review (43, 44) and when they occurred in this study.
Adapted from (44, 158, 159)

6.1.2 IPTs for Local Decision Making

To guide phase three of the review IPTs specific to how LDM may work for adaptations during scale-up were developed at the beginning of this phase. These were based on outputs from phase one, including the IPT framework (Chapter 4, Figure 4.5), in addition to learning from phase two, with initial familiarisation of the case examples who used LDM through extraction of their actions and adaptations. The initial IPT framework, which explored the wider question of how actions can support adaptations, identified numerous outcomes not specific to LDM. In addition, some distal outcomes were very broad, such as scale-up with local fit and sustainability. While LDM could contribute to these outcomes, multiple other factors would also have contributed. Therefore, and in order to focus on LDM, and on outcomes that could be evidenced by the documents, three primary outcomes featured in the IPTs. These were how LDM could lead to: (i) adaptations for local fit (e.g. acceptability, feasibility), (ii) buy-in and support for the intervention and implementation, and (iii) time sensitive

adaptations. To note that the concept of buy-in and support had been previously identified as a mechanism in the initial IPT framework with ownership as an outcome, however, it was felt that there were pre-cursor mechanisms to be explored such as ‘feeling valued’ that could generate the outcome of buy-in and support. This could in turn lead to a later outcome of ownership. Additionally, and while it would have been optimal to have adaptations with fidelity to the intervention as an additional outcome, given the lack of fidelity assessments (as discussed in Phase two, Chapter 5, Section 5.3.8), it was decided that unfortunately there would not be sufficient evidence for this in the documents. However, the IPTs still allowed for the capturing of adaptations where a definite loss to fidelity occurred. The goal of developing these IPTs was therefore to provide a base for building and refining PTs and allow for some initial coding of CMOCs. In line with realist methods, these were open to further refinement as the review progressed.

As discussed in Chapter 4 (Section 4.1.5) a challenge of IPT development is to decide upon a level of abstraction that allows for recognition of the demi-regularities and variation within the evidence, while also being specific enough to answer the research question. As a result, rather than a large volume of overly detailed IPTs, five IPTs were developed at a level of abstraction that allowed for capturing of demi-regularities while also seeing variation in the evidence. For example, IPT B consisted of a statement “By making changes to the intervention local decision makers may see the compatibility and relative advantage of the intervention for their setting leading to buy-in and support for the intervention and implementation”. This allowed for CMOCs relating to participation, compatibility, and relative advantage to be coded to this IPT and for demi-regularities of contexts and resources to emerge. These IPTs were consequently refined and branches of the programme theory added as more detailed learning occurred. For example, this could include that participation, with the use of a data driven approach to evaluate adaptations, led to local decision makers identifying a relative advantage of the intervention which resulted in buy-in and support. In this case, a new sub-code was added for use of data to inform and evaluate adaptations and perception of relative advantage. The thought process for refinement was documented for each PT under the corresponding supporting evidence table. These are presented for each final PT in the results section of this chapter (Section 6.2.7). A total of five IPTs specific to LDM were developed and can be seen in Figure 6.2 below. However, and consistent with realist methods, CMOCs outside of this could be captured and new codes and PTs added as they emerged.

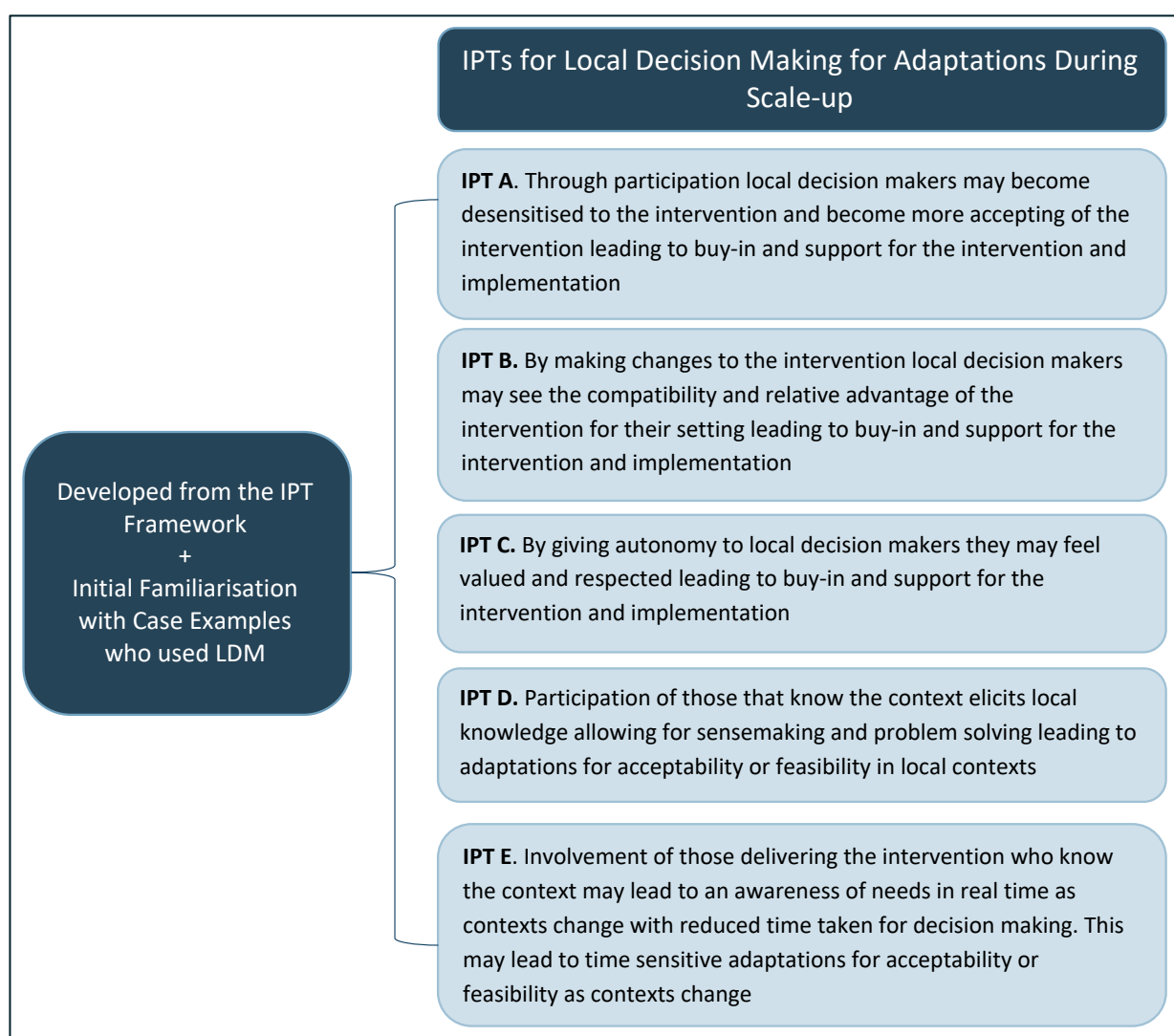


Figure 6.2 IPTs on How LDM may work for adaptations during scale-up

6.1.3 Searching Phase Three

Under the components of the realist search based on Booth et al., (45), this phase completed *searches to identify empirical evidence*, with further searching to identify more documents on the included case examples (Section 6.1.4), and at a later stage, *searches to refine programme theory*, by identifying relevant substantive theory to guide PT refinement (Section 6.1.5). An overview of the components of the realist search and what took place in each phase can be seen in Chapter 3, Figure 3.4.

6.1.4 Searching for Further Documents on Case Examples

The realist review approach supports further rounds of searching to provide more information as needed for CMOC development and programme theory refinement (3). Searching for clusters of documents relating to a study can provide more information and ‘contextual thickness’ (297). Accordingly, the case examples from the systematic search in phase two ($n = 22$) were screened for

those that used LDM for adaptations during scale-up (details of how the original systematic search was completed can be seen in Chapter 5, Sections 5.2.1 & 5.2.2). Those that reported LDM for adaptations during scale-up were considered as relevant and included at this stage. A further search was then carried out for each of these case examples to identify any further relevant documents which could provide more contextual background or richness of information to support CMOC formation. Further searching was guided by cluster searching techniques suggested from Booth et al., (297) and from Bates (298) and included: (i) identification of a key pearl citation for each case example, (ii) forward citation searching for this reference using Google Scholar, (iii) lead author searching (through Google Scholar or their institutional webpage), (iv) lead author search within previous search results in reference management software (Endnote X9) and (v) contacting of lead author for further documents including unpublished and/or grey literature sources. In addition to this, (vi) the database of previously excluded full-text studies was re-visited and notes reviewed for any potentially relevant studies. This searching took place in July and August 2020.

6.1.5 Searching for Substantive Theory

The methods used for the search component of *searching to refine programme theories* (229), which could include searches for substantive theory to guide PT and MRT development, vary within the realist review literature. Some realist reviews rely on the expertise of the review team or stakeholders, or past searches, or, less commonly, may undertake a further systematic search (229). Whatever the approach used, Booth et al., (229) have called for more transparency for this search component. At a later stage, and as the programme theories began to be refined, this review used: (i) returning to the search results from phase one which had captured implementation, scale-up, adaptation and fidelity theory, guidance and frameworks as a bank of knowledge to draw from, (ii) screening the reference lists from included case examples for reference to relevant theory (297), and to further complement this (iii) soliciting stakeholders to suggest relevant theory throughout the theory refinement process. This searching took place in September and October 2020.

6.1.6 Relevance and Rigour

6.1.6.1 Appraising for Relevance

The RAMESES guidance states relevance as “whether it [the document] can contribute to theory building and/or testing” (p34), (3). The further full texts identified on the case examples through the supplementary searching outlined in Section 6.1.4 were therefore screened and included if they could provide more contextual background or information relating to LDM for adaptations during scale-up to support CMOC formation. If a document did not appear relevant at this stage, but related to the

scale-up case example as a whole, it was excluded and a note was taken on its contents in case it needed to be re-visited should it become relevant later on as theories were further refined.

6.1.6.2 Appraisal of Rigour for CMOCS and Programme Theories

The RAMESES guidance define rigour as “whether the methods used to generate the relevant data are credible and trustworthy”(p34), (3). The consideration of rigour in realist reviews is complex and there is no one-size-fits-all approach to assessing it. In the book chapter ‘Data Gathering in Realist Reviews: Looking for Needles in Haystacks’, Wong (155) outlines the challenges in assessing for rigour within a realist review. As he notes, “the norm is that a programme theory is underpinned by multiple arguments (reasons given in support of a theory) based on analyses and interpretations made on ‘nuggets’ of data almost always spread across multiple documents and other sources.” (p8), (155). Within this chapter he further discussed that ideally *trustworthy* data and *coherent* arguments should come together to form a *plausible* theory (155).

Trustworthiness of data relates to the piece of evidence being used to contribute to theory that needs to be considered, and not necessarily the wider methodological considerations of the study (155). Morton (299) highlighted this issue in practice while completing a realist review, where they found that the traditional rigour of a study may relate to elements that are not of interest to the research question at hand. Therefore, it is important to consider what piece of evidence from the study is actually being used for CMOC and theory development and determine considerations related to rigour in light of this (299). In the case of the current review, evaluations of scale-up were often focused on whether the health outcomes were achieved. However, this was not deemed a primary outcome of LDM, with many factors contributing to whether a health outcome was achieved. Therefore, the methods used to assess the wider health outcomes may not relate to the methodological quality of the data piece being used for CMOC formation for how LDM worked.

The RAMESES realist review quality standards suggest that selection and appraisal of documents should “demonstrate sophisticated judgements of relevance and rigour in the domain” (p6) (152). Therefore, the trustworthiness of the specific piece of evidence that was being used for CMOC development was reviewed. Assessment of trustworthiness also varied based on the study or document type the piece of evidence came from. Considerations for trustworthiness included whether the methods used were transparent (300), and whether they were fit for purpose for the piece of evidence generated (300). This could involve whether there were any quality standards that applied to the method used. To provide an example of methodological considerations and

judgements, a piece of evidence for a CMOC in one case example was related to a fidelity related outcome for an adaptation to a behaviour change intervention (239). The methods were transparently reported, however, there is no agreed study type or quality standard for fidelity assessment. Thus, how they assessed fidelity needed to be judged as to whether it was fit for purpose for the finding on LDM. This included exploring what concepts of fidelity they chose to assess (e.g. which of the suggested concepts of design, training, delivery, receipt and enactment were assessed (81)). In addition, considerations, such as the fact that self-report for fidelity was used, was noted, as this may leave the study open to social desirability bias. The thought process in relation to rigour for each CMOC was documented for transparency.

In practice, a significant amount of evidence from the scale-up case examples were qualitative perspectives or reflections within a wider case report. Therefore an important question to consider was when a piece of evidence put forward a perspective, to identify whose perspective is being presented and whether they were consulted in generating this piece of evidence. For example, one case example reported how peer workers were motivated and empowered by planning and making decisions on their own work (256). In this case, an examination of whether peer workers themselves were consulted in generating the piece of evidence (i.e., whether the document reported key informants at peer worker level and/or included direct quotes) or whether this was the impression and perspective of the authors or scale-up team themselves, as the latter may affect the weight put towards this piece of evidence. An additional deliberation was whether there was a third party interest, e.g. a philanthropic donor promoted in the study, that may affect publication bias of more positive findings for the scale-up.

While each document for the case examples was reviewed for whether the methods for development of the evidence were transparently reported (300), as discussed in Chapter 5, and there was overall a lack of transparency in the methodology described across a number of the case examples. If no methods for development of a document was reported, the document was assumed to be a perspective, or reflections of the authors. Adjudication was used as a tool (3, 42) (see Table 6.1) when synthesising CMOCs to make judgements on contribution to theory based on strengths or shortcomings of the pieces of evidence used.

In addition to the trustworthiness of evidence, the concept of *coherence* was also used to assess rigour of an argument used for a theory. Coherence was understood to relate to how consistent and logical an argument was (155). Wong (155) discusses that a coherent theory may provide “inference to the

best explanation” (p10), or that it is able to explain as much of the data as possible, it is simple and does not have ad-hoc assumptions made to explain data, and may fit in with substantive theory or what is currently known. Coherence became an important consideration, as in practice, the majority of studies and documents identified in this review were not focused on adaptations. Many were case reports on the scale-up as a whole, with reference to adaptations or LDM as a small part of this. As a result, specific methods to assess for LDM and adaptations were rarely used and reported and so the trustworthiness of the evidence was often challenging to ascertain. Additionally, LDM often occurs across multiple adaptations and across multiple local sites. Each adaptation would therefore not be specifically reported on or assessed in documents discussing the scale-up as a whole.

Valuable insights into contexts, mechanisms and outcomes often came from case reports with the reflections of the scale-up team. Thus, a lot of the evidence for CMOCs on LDM came from these reflections from the scale-up team, or a case report which captured input from stakeholders at multiple levels. Case reports however, may not have distinguished which stakeholders contributed to which piece of the case report. Pawson (154) had previously discussed that useful information can arise from studies which would not be prioritised on a traditional hierarchy of evidence. To provide an example of how coherence was considered as part of a rigour assessment in this review, in one case example the scale-up team reflected that positive visibility of results of their adaptations motivated and encouraged local decision makers to continue with the implementation (257). This was part of a report from the scale-up team with input from multiple stakeholders at national and regional levels of management, but to note, did not reference input from local decision makers themselves. A separate implementation outcomes study on the scale-up showed buy-in for the LDM approach with multiple change ideas (of adaptations) being generated and tested (through PDSA cycles) (232). The explanation from the report of positive visibility providing motivation is simple, explains uptake and buy-in for the implementation with multiple sites using the approach as demonstrated in the implementation outcomes study (232), and is logical. It would also be in keeping with substantive theory, in this case Rogers’ diffusions of innovations theory (53), in relation to how perceptions of relative advantage and observability of benefit can affect implementation. Thus it could be considered a coherent argument. Demi-regularities from other data sources from other case examples then supplemented this argument to provide further weight to the theory as it developed.

Considerations of rigour and the thought process were documented for each CMOC extracted. As the review progressed, CMOCs were synthesised based on demi-regularities, and programme theories were developed and refined, and the criteria of whether the theory was *plausible* based on

trustworthy evidence and *coherent* arguments (155) was considered and discussed for transparency for each theory in their supporting evidence table.

6.1.7 CMOC Extraction

When developing CMOCs, mechanisms were considered both a resource (R) that gets introduced into a context (C), which can trigger a mechanism in the form of a response (M), which in turn could generate an outcome (O) (2). CMOCs were causal explanations formed using this pattern extracted at case example level. To complete this, each of the case example's documents were reviewed in detail and any CMOCs relevant to LDM for adaptations during scale-up were extracted. Working definitions for C, M, O's can be seen in Appendix H. Multiple rounds of reviewing the same data has been noted in a previous realist review by Papoutsi et al., (301) with depth and understanding growing as the reviewers become more familiar with the literature. This also occurred within this review with the case examples reviewed multiple times following initial extraction, allowing for familiarisation with the literature, and with the process of extraction, thus allowing for any further relevant CMOCs to be identified, or CMOCs to be made more or less detailed to allow for future synthesis of findings as learning progressed. For each case example a document was made in NVivo (NVivo 12.6.0 Mac) which captured a short summary on the case example, what level LDM was made and any CMOCs generated. For each CMOC generated the (i) source document(s) which led to its development were referenced, (ii) the thought process for development of CMOC was documented, (iii) considerations of rigour was discussed, and (iv) any quotes which supported the CMOC were captured. An example of this for CE1 can be seen in Box 6.1. A second reviewer took a random sample of two of the case examples (>10%) and reviewed independently to check for consistency of CMOC extraction (44). A number of 10% was agreed based on its use in previous realist reviews (302-304) and was achievable within the resources of this review. CMOCs were agreed and any discussions between the reviewers were recorded in the research logbook.

Together, these methods aimed to accomplish the objective of discovering how LDM works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit through generation of CMOCs (objective 3.1)

Box 6. 1 Example of Extraction at Case Example Level for CE1

CE1. Scale-up of Sexuality Education in Schools, Senegal

Summary: Sexual health education intervention where teachers and principals had autonomy to choose the extent of what was integrated into carrier subjects. Challenges around acceptability in a conservative cultural context in addition to logistical constraints with lack of time to integrate additional content into subjects. Case report noted some teachers omitting sensitive topics due to

discomfort, and at national level some components not integrated into curriculum due to cultural sensitivity and acceptability.

CE1 CMOC Influence of local beliefs, conservative cultural context

C: Conservative cultural context (wider context) and introduction of SRH intervention

R: LDM with teachers and principals given autonomy on level of integration into subjects

M: Discomfort with some components of intervention considered sensitive or taboo by local decision makers/belief of lack of compatibility with local context

O: Adaptations for local fit with a loss to fidelity with removal of sensitive core topics at provider level in some sites (to note this also occurred at curriculum level)

Source: Chau et al., (230)

Thought process: Within the conservative cultural context when autonomy was given to providers on what to integrate into teachings this led to loss of topic content due to discomfort. The local decision makers own beliefs of lack of intervention compatibility were at play leading to loss of intervention fidelity due to acceptability.

Consideration of rigour: Sources for case report included semi-structured interviews with multiple stakeholders. Data would appear trustworthy for inference made.

Supporting quotes:

- "Teachers' commitment to delivering FLE and reproductive health education was influenced by conservative social norms that limited their ability to address sensitive topics with pupils." (p510), Chau et al., (230)
- "A core curriculum document and several teaching aids were produced. It is important to note that, as a cross-curricular programme, teachers and school principals had autonomy to choose the extent of content integration in carrier subjects." (p506), Chau et al., (230)
- "The quality of the programmes was negatively affected by the factors noted above, namely sociocultural conservatism, lack of space in the curriculum, insufficient teacher training and lack of teaching materials. In fact, both the content and the implementation of the current national curriculum have significant gaps. It focuses primarily on biological and physiological aspects of reproductive health, while omitting important topics including: rights, gender, personal values, interpersonal relationships, gender-based violence, skills-building related to SRH (e.g. negotiating condom use) and critical thinking skills to assess social norms (UNESCO 2011, 2013a). The factors listed above also limit the quality of how FLE and reproductive health education are delivered. Many teachers omit sensitive topics and/or do not apply skills-based pedagogical approaches in classrooms, resulting in partial implementation of the programmes." (p508), Chau et al., (230)

C=Context, R=Mechanism(Resource), M=Mechanism(Response), O=Outcome

6.1.8 CMOC Synthesis – Search for Demi-regularities

Using NVivo (NVivo 12.6.0 Mac), the CMOCs from the case examples were coded to search for demi-regularities, understood as semi-predictable patterns of causation (3). To assist in coding for these demi-regularities, nodes were initially developed for the five IPTs relating to LDM (see Figure 6.2). New nodes (or child nodes) were added or refined as needed, and any nodes that were no longer useful were removed. CMOCs were synthesised based on these demi-regularities seen. This stage of

analysis and synthesis contributed to objective 3.1 of discovering how LDM works by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit, in this case by generation of synthesised CMOCs.

A similar process used by Gilmore B, McAuliffe E, **Power J**, et al., (161) of using NVivo for realist analysis was adopted, with memo links being made to nodes which served as a space to document the commonalities seen and to keep track of the thought processes in development of synthesised CMOCs. In order to synthesise CMOCs further the analysis was then moved from NVivo to Microsoft Word to allow for easier reading of data and tables were used to display findings. Relevant content from the memo notes in NVivo were included in the table for each synthesised CMOC in Microsoft Word (these evidence tables are presented in the results Section 6.2.7). This approach greatly assisted in transparency of the synthesis process. As the CMOCs were synthesised and the PTs refined the conceptual tools of adjudication, juxtaposition, reconciliation, consolidation and situation were available to guide the process (3, 42). Examples of how each of these conceptual tools were useful in guiding the review can be seen in Table 6.1.

6.1.9 Programme Theory Refinement and Developing an MRT

The synthesised CMOCs came together to support, refine or develop new PT's. Each PT was then given its own table (in Microsoft Word) and the synthesised CMOC (or multiple synthesised CMOCs) were placed in the relevant PT table. For each PT that emerged or was refined, each case example was reviewed again to see if it contained any further information that could support, refute or refine the theories. The format for these tables was adapted from the RE completed by Gilmore (305). As the PTs evolved, retroduction could be used to infer deeper causal mechanisms which may have caused a phenomenon to occur (10), with further substantive theory sought to explain findings as needed. As documented in Section 6.1.5 above, searching for substantive theory involved returning to search results from phase one, identifying if any relevant theory was cited in the documents for the case examples, and soliciting further suggested theory from stakeholders. The resultant PT's were reviewed as to whether they could be considered *trustworthy*, *coherent* and *plausible* (155), based on the cumulation of evidence and data sources, and coherency of arguments, which contributed to their development and refinement. This was documented for each PT under the headings of 'thought process' and 'considerations of rigour' for transparency. These tables are presented in the results Section 6.2.7, below, for each PT.

Table 6.1 Conceptual tools for Realist Review with examples in practice. Adapted from (3, 42, 306).

Conceptual Tool	Understanding of conceptual tool for this review	Example of How Conceptual Tool was Utilised During the Review
Adjudicating	To make judgements on contribution to theory based on appraisal of quality of information used	Adjudication was needed for evidence relating to CE22. The mechanism of empowerment of local decision makers with the outcome of buy-in and support was identified. However, in the source document (256) there was no transparency of methodology and there did not appear to be input from local decision makers. In addition this article was openly promoting a philanthropic agency and thus could be vulnerable to bias. Through searching, further articles were identified, which included an ethnographic study (307) with observations and direct quotes from frontline peer workers in the field that demonstrated engagement and sense of belonging through involvement in LDM, which further supported the mechanism and outcomes found in the case (307). While the initial source article (256) did not hold as much weight of evidence, through the combination of sources (256, 307) it was considered that the evidence was of sufficient trustworthiness for the CMOC. This was then combined with further evidence from other CE's to add further weight to this CMOC
Juxtaposing	To use information from one study to help explain a finding in another	In CE11 an implementation outcomes study demonstrated the resource of using a data driven approach to inform and evaluate adaptations (R) in the context of LDM (C). It also demonstrated a proxy outcome of buy-in for the LDM approach with multiple change ideas (of adaptations) being generated and tested (through PDSA cycles) (O) (232). However, the mechanism was missing. A separate document which was a report with reflections on the scale-up approach discussed that positive visibility of seeing the advantage of adaptations made motivated local decision makers, leading to buy-in (257). When the two studies were compared together this helped guide potential explanation of the findings
Situating	To identify differences which may assist in providing a coherent explanation for variations in findings	Situating was used to identify contextual nuances that impacted whether a mechanism was activated. For example in CE17 a context was found that when training and support was given by a central agency linked to funding a power imbalance was present (C). This lead to reduced utilisation and receptivity to training by local decision makers (O) with fear of repercussions or judgement if reaching out for support (M). However, in CE10 training was provided by an agency linked to funding and this was not reported to be the case. Following stakeholder involvement it was highlighted in the second case example, in the LMIC in question, their status quo and normal practice was donor agencies (and others) coming in and providing trainings and interventions. As a result of this being highlighted it was reasoned that the contextual circumstances in the first instance may have been due to the HIC setting with local decision makers not being as used to this approach and fearing repercussions, while in the second instance the power imbalance may have not been the same with the local decision makers as they would have had numerous past experiences of this and so the mechanism of fear of repercussions may not have been activated
Consolidating	To put together findings to build 'multi-faceted explanations of success'	The use of data driven approaches to guide LDM was multi-faceted and required consolidation of multiple explanations in how it can achieve buy-in and support for the intervention and its implementation. In some CEs the use of data was discussed to provide positive visibility of results with local decision makers experiencing pride and motivation in seeing their accomplishments leading to buy-in and support (CE5, CE11). Another important

Conceptual Tool	Understanding of conceptual tool for this review	Example of How Conceptual Tool was Utilised During the Review
		finding was that ownership and autonomy of the data (with local sites reporting directly their achievements to higher levels of management), led to the local decision makers feeling valued, respected and empowered leading to further buy-in and support for the intervention and implementation (CE5). Further to this, the need to consider and select approaches suitable for the capacity level at local sites to allow for inclusion and participation in the process, was also highlighted as important (CE11, CE21, CE22). Thus multi-faceted explanations emerged of how a data driven approach could lead to local decision makers participation, buy-in and support for an intervention and its implementation. These all contributed to building a consolidated explanation and PT
Reconciling	To interpret rival explanations by differences in causal pathways e.g. in context A, mechanism A fires, in context B, mechanism B fires	Reconciling was used to identify changes in causal pathways based on contextual differences. For example in CE17 a context was identified that when trainers were not from the local setting, (Context A), local decision makers may have distrust (Mechanism A) and often not view them as credible for their setting, and therefore were not as receptive to training and support given (Outcome A). However in contexts where trainers were not from the local setting, however they were experienced implementing the intervention in diverse settings and through dialogue in trainings demonstrated their relevant experience (context B), this could lead to perception of credibility (Mechanism B) and increased receptivity and uptake of training (Outcome B)

6.1.10 Stakeholder Involvement

As per the study protocol (44), stakeholders were involved during phase three to assist in refining the PTs. Two groups were identified, (i) implementers leading a scale-up, e.g. members of the scale-up central resource team (41), and (ii) local decision makers i.e. those who had been involved with making decisions for adaptations at local levels. Initially it was hoped a panel for each could be developed and consultation happen in a group format. Unfortunately, due to unforeseen circumstances, this part of the research occurred during the height of the global COVID-19 pandemic (Sept-Nov 2020). This made recruitment of local decision makers and those involved in implementing and scaling-up health interventions extremely challenging. As a result, instead of a group consultation, individual phone/skype calls took place at a time that suited. This occurred throughout the theory refinement stage. Recordings were uploaded to NVivo and any relevant passages transcribed and coded to the applicable PT. Consent was obtained from each participant. As per ethical approval from Trinity College Dublin their involvement was confidential and any identifying information (e.g. location, names) were removed or anonymised (308). When a stakeholder contributed to theory refinement this was documented for transparency in the table of the relevant PT using a code assigned for the stakeholder (e.g. S1, S2). Additionally, stakeholders could highlight any results they thought were particularly relevant to practice to focus in subsequent dissemination of findings.

6.1.11 Middle Range Theory Development

Following the refinement of PTs and search for substantive theory an MRT was developed. An MRT was understood as; “A theory that is specific enough to generate hypotheses (for example in the form of propositions) to be tested in a particular case, or to help explain findings in a particular case, but general enough to apply across a number of cases or a number of domains.” (p15), (3). This MRT was at a level of abstraction that was detailed enough to be testable, but also generalisable enough that it potentially could be applied in other situations (3). Taken together, the above stages assisted in completing the remaining objective of; developing and refining programme theories and proposing an MRT for how LDM works to achieve adaptations when scaling-up health interventions for local fit, in fulfilment of objective 3.2.

6.2 Results Phase Three

6.2.1 Results of Search: Screening and Appraisal

From the $n = 22$ case examples identified in phase two, $n = 16$ of these reported LDM for adaptations during scale-up and were included as relevant. For each of these $n = 16$ case examples a further search was completed for any additional documents (carried out in July-August 2020), which included contacting of authors for unpublished materials, that may have provided useful information for CMOC formation and theory building, refinement or testing. A total of $n = 78$ further full texts were screened. From this an additional $n = 38$ documents were included as relevant to provide more information for these case examples. Combining this with relevant results from phase two resulted in a total of $n = 16$ case examples, across $n = 81$ documents. Figure 6.3 summarises this screening process. The included documents consisted of peer reviewed literature and grey literature, such as project reports. A breakdown of the document types for each case example can be seen in Appendix G.

6.2.2 Demographics of Case Examples Who Used LDM

The demographics of the case examples with who carried out LDM, an overview of the LDM approach taken, topic of the intervention and location for the case examples using LDM can be seen in Table 6.2. Three case examples were from HIC contexts, with the remaining 13 case examples from LMIC. Six case examples were for SRH interventions, six for HIV interventions, two for MCH interventions, one for an obesity prevention intervention, and one for a mental health intervention. The LDM approach varied across the case examples (an overview of each can be seen in Table 6.2) with many reporting LDM during scale-up at multiple levels of the system.

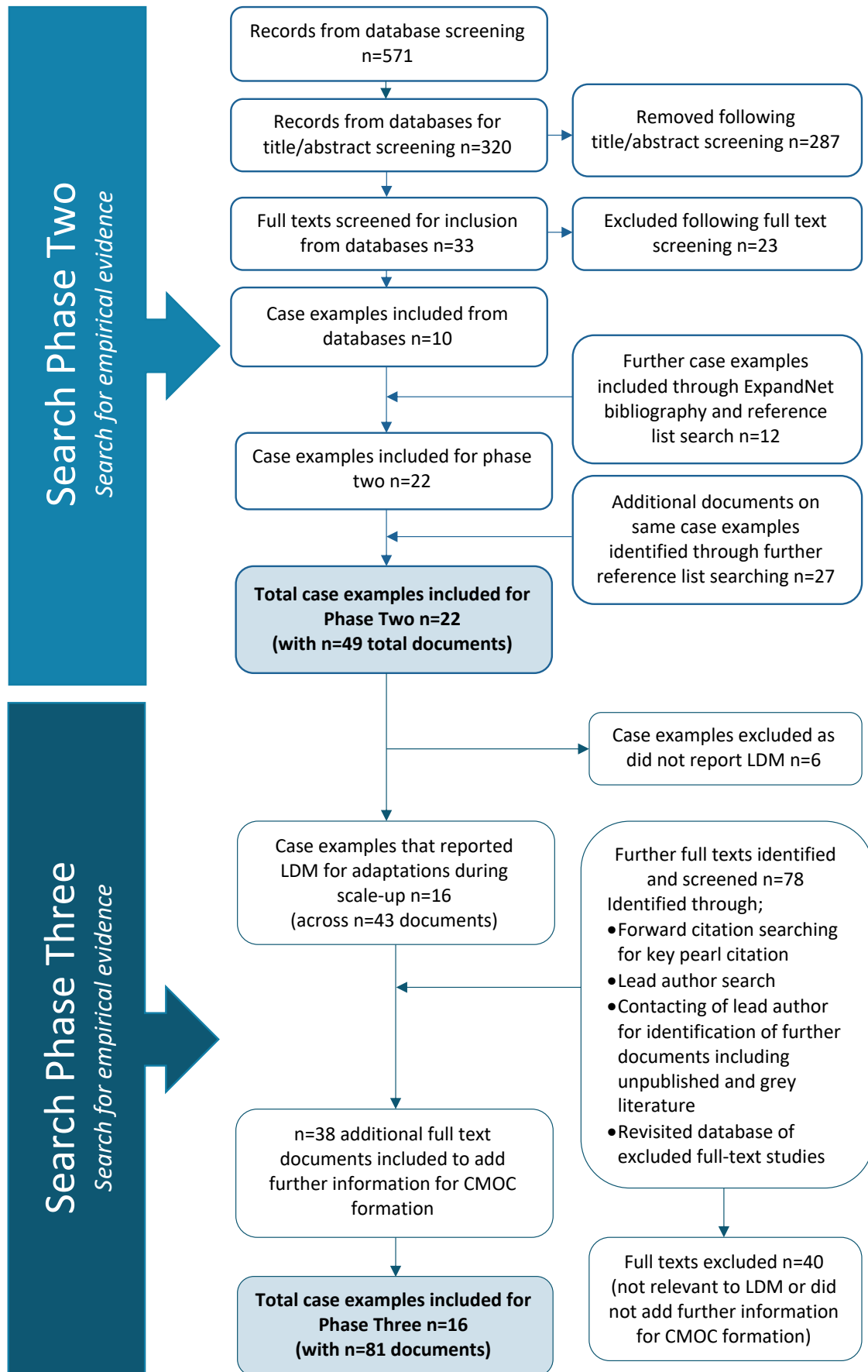


Figure 6.3 Flowchart of screening for further documents on case examples in Phase Three

Table 6.2 Demographics of who carried out LDM, an overview of the LDM approach, topic of the intervention and location for the case examples

Ref	Who carried out LDM	Overview of LDM Approach	Topic	Location	HIC/ LMIC	Citations
CE1	Frontline provider (School)	Cross curricular sexual health education programme where teachers and principals had autonomy to choose the extent of what was integrated into which carrier subjects	SRH	Senegal	LMIC	(230)
CE2	Frontline provider (School)	Sexual health education intervention introduced as an extra-curricular subject. Core curriculum given however teachers and schools could decide what and how to deliver intervention	SRH	Pakistan	LMIC	(197, 309, 310)
CE5	District	Following the scale-up team leading implementation in the first three cities, a sustainable approach taken for scale-up in the following two cities with autonomy given to local government authorities at district level to make decisions for their area with a simplified intervention package	SRH	Kenya	LMIC	(228, 267)
CE6	District	Decentralisation federally mandated at municipality level. Municipal implementing teams responsible for intervention in their area. These teams were supported by local municipal administrations for funding	SRH	Brazil	LMIC	(129, 270, 311)
CE7	Provincial	Decision making at provincial level as part of routine health system structure	SRH	Vietnam	LMIC	(268)
CE8	District, Community	Decision making at district level. District specific plans were generated for three key content areas. Community partnerships also took place which guided some decision making at community level	SRH	Zambia	LMIC	(16, 312)
CE10	Regional, District, Health facility	Steering committees formed at regional and district levels (with some further ones at institutional level). Following workshops, each area developed and implemented their own individualised action plans	MCH	Ghana	LMIC	(226, 231, 313, 314)
CE11	District, Health facility, Frontline provider	LDM was carried out through use of formalised QI methods to support the scale-up (based on IHI approaches; see Ch 5, Section 5.3, Action 8). This took place with QI teams at frontline provider level and also with teams at higher levels of management including district levels	MCH	Ghana	LMIC	(232, 233, 257, 262-266, 315-317)
CE14	Frontline provider (School)	Physical activity and health eating intervention developed for schools and teachers to be able to adapt for their individual school and classroom setting	NCD	Canada	HIC	(236, 318, 319)
CE16	Community, Frontline Provider, Recipients (Group)	Group based mental health intervention in schools. Community partnership approach where intervention was adapted for community and individual group need. Adaptations could also be made at frontline provider level and by recipients in the group as it was delivered in schools	Mental Health	USA	HIC	(207, 238, 320-322)

Ref	Who carried out LDM	Overview of LDM Approach	Topic	Location	HIC/ LMIC	Citations
CE17	CBO, Frontline Provider	Theory based interventions developed which allowed for decision making at CBO and frontline provider level to meet local needs	HIV	USA	HIC	(62, 239, 240, 280, 281, 323-326)
CE18	Frontline Provider, Recipients (Group)	Group based intervention for ART adherence. Recipients in group could make adaptations. Groups were also supported by a new 'regulatory cadre' of a counsellor in later stages	HIV	Mozambique	LMIC	(241-243, 327-329)
CE19	Provincial, Health facility (Club level), Frontline provider	Adherence club intervention for ARTs. Adaptations made at health facility/club levels by frontline providers. Further adaptations, for example around longer term prescribing for holiday periods, occurring at higher levels of system	HIV	South Africa	LMIC	(244-249, 330-335)
CE20	Provincial, Health Facility, Frontline provider	Provincial decision making as part of routine health system. Different approaches taken depending on the province. Varying levels of flexibility given at lower levels of the system, with two provinces reporting further decision making at health facility and frontline provider levels	HIV	South Africa	LMIC	(250, 260, 271)
CE21	District, Health facility, frontline provider	LDM was carried out through use of formalised QI methods to support the scale-up (based on IHI approaches; see Ch 5, Section 5.3, Action 8). This took place with QI teams at frontline provider level and also with teams at higher levels of management including district levels	HIV	South Africa	LMIC	(251-255, 258, 259, 336, 337)
CE22	State, District, Community, Frontline provider	Decision making at multiple levels reported at: state, district, community/NGO level and frontline providers including by peer workers	HIV	India	LMIC	(256, 307, 338-342)

6.2.3 CMOC Synthesis and PT refinement

A total of 61 individual CMOCs were extracted at a case example level. These were then synthesised based on identified demi-regularities, resulting in a total of 19 synthesised CMOCs carried forward for theory refinement. The synthesised CMOCs contributed to supporting, refuting or refining the IPTs, or led to the development of new PT's. During this stage of the synthesis the tools of: adjudication, juxtaposition, consolidation, situation and reconciliation, as highlighted in Table 6.1, were utilised (3, 42). To note, these tools were also used in tandem.

6.2.4 Refinement from IPTs to PTs

A total of 5 IPTs on LDM for adaptations during scale-up were initially developed to guide this phase (Section 6.1.2, Figure 6.2). These assisted in initial extraction of CMOCs and coding in NVivo and were all refined following CMOC synthesis, yielding a resultant PT, or contributing to multiple PTs. A total of eight final PTs emerged. Four PTs resulted from refinements of the IPTs (PT2, PT5, PT6, PT8), and four new PTs emerged as the synthesis progressed (PT1, PT3, PT4, PT7). An overview of the process of refinement from the five IPTs to final eight PTs is presented in Figure 6.4, below. Justification for the refinement of IPTs is documented in the supporting evidence table for each PT, where relevant.

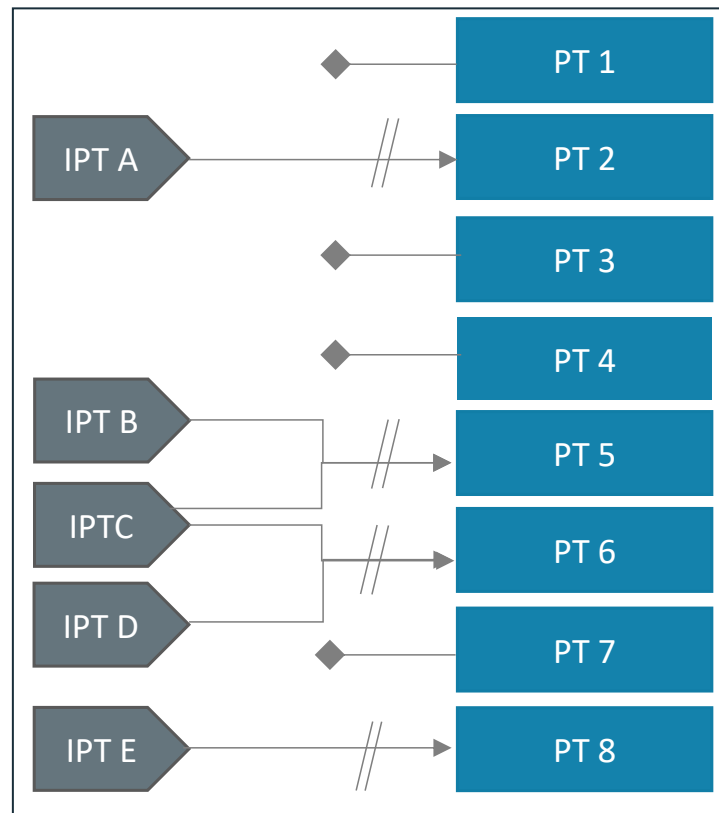


Figure 6.4 IPT refinement to final PTs. Adapted from Gilmore B, McAuliffe E, Power J, et al.(161)
// indicates refinement ♦ indicates new PT emerged

An example of IPT refinement can be seen from IPTA to PT2 (this is also detailed in Section 6.2.7, Table 4 below). IPTA suggested that; “through participation local decision makers may become desensitised to the intervention and become more accepting of the intervention leading to buy-in and support for intervention and implementation”. What was found through CMOC synthesis from the case examples was that when the intervention does not align with the social norms, values and beliefs of the local decision maker, this can trigger the mechanisms of discomfort and belief of lack of compatibility for the intervention. Participation by itself, as suggested in the IPT, did not appear to change these mechanisms, however there was evidence in CMOC 2.2 (which will be detailed in Table 6.4 below) that specific desensitisation strategies such as training, guidance manuals, and peer learning forums could assist in local decision makers becoming more comfortable and believing in compatibility and lead to buy-in and support. IPTA was therefore refined to reflect this, resulting in PT2; *“In the scale-up of interventions which do not align to the local decision makers social norms, values and beliefs, local decision makers may feel discomfort and believe in a lack of compatibility for the intervention (or lack of compatibility of certain components) for their setting. This may lead to adaptation with loss to fidelity of core components of the intervention. When strategies are used to desensitise local decision makers to the intervention, along with adapting intervention to align with social norms, values and beliefs where possible (while keeping core components intact), this can lead to local decision makers becoming more comfortable in the intervention and believing in its compatibility for their settings, leading to buy-in and support.”*

6.2.5 Stakeholder Involvement for Theory Refinement

Stakeholders from the two identified groups (i) those that had been involved in leading scale-up (n=3), and (ii) local decision makers (n=3) were involved in theory refinement. Stakeholders with experience in LMIC (n=3) and HIC (n=3) were captured. Adaptations included for: resource availability; cultural acceptability and to increase intervention effectiveness based on cultural beliefs, norms and values; along with adapting from hospital to community settings to allow for differing resources and populations. Stakeholders assisted in supporting or refinements of PT4, PT6 and PT7. In addition to this, stakeholders who were local decision makers, emphasised the significance of PT6 and PT7 relating to adequate and accessible guidance for local decision makers as a finding of the review that would have important implications for practice.

An example of how stakeholders assisted in theory refinement can be seen in PT6, in particular for CMOC 6.3, where stakeholders who had been involved in LDM assisted in ‘situating’ (3, 42) evidence

by identifying contextual nuances that may have impacted whether a mechanism was triggered. A lack of guidance on how to implement and adapt had been identified by CE19, which took place in a LMIC, where there was resource shortages and additional workload caused by running adherence groups for ARTs. The lack of guidance resulted in staff feeling overloaded and overwhelmed, reducing buy-in and support. Two stakeholders (S2, S4), who were local decision makers, reported insufficient guidance for how to implement and adapt the specific intervention (S2, S4) and on intervention content (S4). However, both reported completing adaptations in HIC settings and that having resources, for example being given non-clinical time to work out how to approach the adaptation (S2), or having capacity and skills embedded within the team (S4), led to the adaptation and implementation feeling manageable. While they reported frustration at the lack of guidance, they did not report feeling overloaded and overwhelmed. Thus, this assisted in emphasising how in the context of under-resourced settings, the lack of guidance may have a greater impact and trigger feelings of being overloaded, that may be less likely when adequate resources and capacity are in place. This finding was thus incorporated into the final PT (PT6, Table 6.8).

6.2.6 Use of Substantive Theory

In addition to synthesising the CMOCS, further substantive theories were identified to support or refine the PTs. This occurred throughout theory refinement. The following theories proved useful: Rogers' diffusions of innovations theory (53) (PT1, PT2, PT5, PT8), role conflict theory (343) (PT1, PT2, PT3) and sensemaking theory (344, 345) (PT6). In addition to these the Theoretical Domains Framework (TDF) (346) (PT1, PT3, PT4, PT7) and Holliday et al., (61) conceptual framework for adaptations (PT4) also provided further insights for some of the PTs. When these theories were applied, they were documented and discussed under the relevant PT supporting evidence table (Section 6.2.7 below) and are discussed in more detail in Sections 6.3 and 6.4.

6.2.7 Results: Programme Theories

The eight resultant PTs are presented below. For each PT, a narrative description and figure outlining the relevant resources, contexts, mechanisms and outcomes are presented in the text. Following this, a table is presented for each PT, with the supporting evidence cited, along with the thought process for the PT, considerations of rigour and details on what theory refinements took place in developing the PT. Following the initial presentation of the PTs, they are then discussed with additional insights from substantive theory, and an MRT ultimately proposed (in Sections 6.3 and 6.4). The PTs and MRT are then presented collectively in Table 6.11 below.

PT1. How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community

When choosing to use an LDM approach in circumstances where the intervention does not align with the social norms, values, and beliefs of the wider community, consideration of perceptions of compatibility of the intervention is needed and the resultant influence on local decision makers needs to be understood as the intervention may be vulnerable to adaptations with loss of fidelity. Discrepancies between the intervention and the social norms, values and beliefs may occur at the wider level, where local decision makers are influenced by those in positions of power around them (PT1). However discrepancies between the intervention and the social norms, values and beliefs of the individual decision maker themselves can also occur and may influence adaptations made (PT2).

The influence of the beliefs of community members and those in positions of power in the community on adaptations was observed (please see Figure 6.5 for an overview of CMOC relating to this). In culturally conservative contexts, for example, where religious leadership did not view the intervention or certain components as compatible for the local area, there was often pressure to remove components. In these settings, where there was a reliance on local support and funding, there was a fear of negative repercussions on local decision makers and implementers if support was given to the intervention, or certain components of the intervention. The fear of repercussions was identified at higher levels of the system, for example with local politicians fearing lack of support from religious leadership if they support the intervention, or funders fearing opposition from community members. This was particularly seen in SRH and HIV prevention interventions. This fear of repercussions was also seen at the level of the frontline provider, for example with fear that funding will be affected if they continue to deliver or support all components of the intervention. In some settings, this led to reduced support for the intervention and implementation, and loss to fidelity of intervention, with core components adapted or removed (see CMOC 1, Table 6.3). This could be viewed as adaptations due to extrinsic influence on the local decision makers, which could occur despite them believing in the advantage and compatibility of the intervention themselves.

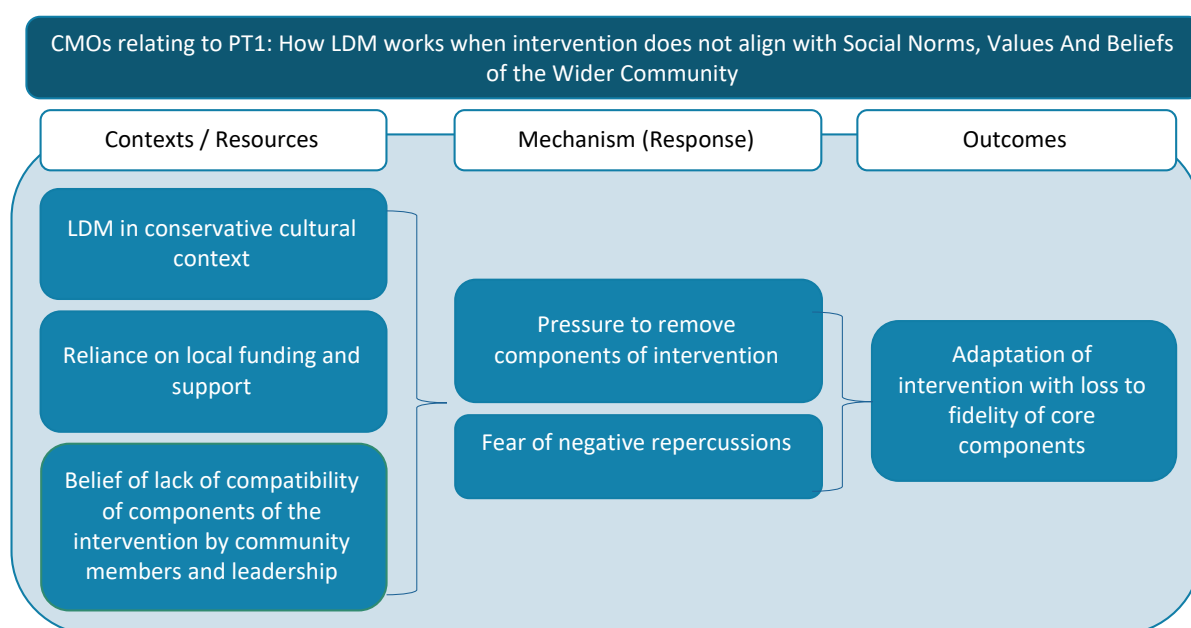


Figure 6.5 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works when intervention does not align with Social Norms, Values And Beliefs of the Wider Community

Together, this resulted in the following understanding of how LDM works when the intervention does not align with the social norms, values and beliefs of the wider community (more details with supporting CMOs and evidence can be seen in Table 6.3);

PT1: *When interventions are scaled-up that do not align with social norms, values and beliefs within a context, community members and/or those in positions of power, such as religious leadership, may not view the intervention, or components of the intervention, as compatible with social norms and values leading to pressure to adapt components of the intervention in line with wider sociocultural beliefs. When there is a reliance on local funding and support, local decision makers may fear negative repercussions if adaptations do not take place, leading to adaptation or removal of components affecting fidelity to the intervention, despite they themselves or recipients of the intervention not holding the same beliefs.*

Table 6.3 Supporting evidence for PT1 - How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community

PT1. How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community			
CMOC 1. Conservative Cultural Context and influence of Social Norms, Values and Beliefs and of the Wider Community			
Contexts / Resources* C1: LDM in culturally conservative context where intervention may not align with social norms, values and beliefs C2: Reliance on local funding and support C3: Belief of lack of compatibility of components of the intervention by community members and leadership	Mechanism (Response) M: Pressure to remove components of intervention M2: Fear of negative repercussions if support intervention (or certain components)	Outcomes O. Adaptation of intervention with loss to fidelity of core components	Resulting CMOC: When there is LDM in a conservative cultural context, and reliance on local funding and support, the beliefs of those in the community and those in positions of power in the wider setting can pressure local decision makers to adapt or remove components of the intervention with fear of repercussions if they do not comply
Thought process for CMOC: When LDM is in place in conservative cultural contexts and the intervention does not align with social norms, value and beliefs, it leaves an intervention vulnerable to those in positions of influence and power in the community. In CE6 the influence of conservative local religious leaders was identified as detrimental to implementation of the intervention in numerous local municipalities. Local politicians fearing recourse and impact on re-election reduced funding and allowed for enactment of local religious laws which prohibit elements of intervention despite these laws being counter to federal laws. In CE17 (280) the funder within a county did not want to risk introducing a website resource for gay men in fear of response from conservative community members. In this intervention publicity was a core component of the intervention that ended up being removed. An additional example was given in CE17 (62) where beliefs and policy within church and prison settings where the intervention was delivered pressured providers to remove the core component of condom distribution. In some cases this was substituted with vouchers for condoms or demonstrations of condoms.			
Source**: CE6, CE17 Supporting quote: <i>"The political sensitivities surrounding contraception are an important explanation for the low priority accorded to family planning. Even though the Church does not officially oppose family planning, many politicians prefer to support other issues, fearing opposition from local priests who continue to be concerned that methods such as the intrauterine device (IUD) and emergency contraception are abortifacients."</i> (p148) (270)			
Considerations of rigour for this CMOC: Key source for CE6 (270) compiled data from numerous relevant sources for this inference. From CE17 direct quote from respondent (62) relating to Mpowerment intervention and removal of core components which directly supported CMOC formation. In CE17 (62) data from survey of providers gave information on how conservative settings influenced loss to fidelity. CMOC from these sources could be considered trustworthy.			
CMOCs support, refute or refine an IPT or build a new PT?:			
New PT			
Further evidence or theory for PT:			
Rogers' diffusions of innovations theory (53), specifically how perceived compatibility with values may affect adoption of an innovation. This supports this finding in how perceived lack of compatibility by those in leadership may lead to pressure on local decision makers to remove components of the intervention that do not align with the wider cultural context.			

PT1. How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community
• Role conflict theory (343), specifically intra-role conflict, where conflicting expectations and requests on how to perform tasks could apply. Local decision makers may be advised to implement intervention by management, however other stakeholders such as funders or religious leadership are advising or pressurising alternatives. • The Theoretical Domains Framework (TDF) (346), specifically the 'beliefs about consequences' domain could support this theory in how fear of negative repercussions may affect behaviour and lead to removal of components of the intervention.
Thought process for PT: This CMOC demonstrates the influence of those in the community and in positions of power in the wider community and how their beliefs over lack of compatibility effects adaptations through pressure to adapt and fear of repercussions if local decision makers support all components of the intervention. The fear of repercussions can be seen at higher levels. For example, with politicians fearing lack of support from religious leadership if they support the intervention, or funders fearing opposition from community members. It can be also seen at the level of the local decision maker for example with fear that funding will be affected if they continue to deliver or support all components of the intervention. The sources that contribute to the CMOCs would appear trustworthy for this inference. This CMOC and resultant PT is further supported by substantive theory of diffusions of innovations theory (53) (specifically on the area of compatibility), role conflict theory (343) (specifically of intra-role conflict) and TDF (346) domain of beliefs about consequences and could be considered coherent and plausible.
PT1: When interventions are scaled-up that do not align with social norms, values and beliefs within a context, community members and/or those in positions of power, such as religious leadership, may not view the intervention, or components of the intervention, as compatible with social norms and values leading to pressure to adapt components of the intervention in line with wider sociocultural beliefs. When there is a reliance on local funding and support, local decision makers may fear negative repercussions if adaptations do not take place, leading to adaptation or removal of components affecting fidelity to the intervention, despite they themselves or recipients of the intervention not holding the same beliefs.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example * As Resources are introduced into a Context they were placed under this heading. An R under this heading depicts when Resources were present in CMOC, a C in this column depicts an identified Context. Note not all CMOCs contained identified Resources

**Depicts how many sources contributed to this CMOC (i.e. one synthesised CMOC came from two case examples CE6 and CE17)

PT2. How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Local Decision Maker

Another consideration of introducing LDM in culturally conservative contexts is when the local decision maker themselves has strong individual cultural beliefs which can lead to an intrinsic influence on adaptations made (please see Figure 6.6 for an overview of CMOC relating to this). When an intervention does not align with their social norms, values and beliefs, this may trigger mechanisms of discomfort with components of the intervention and belief of lack of compatibility of the intervention for their setting. This may in turn lead to a loss to fidelity, with core components removed, to make the intervention more acceptable (see CMOC 2.1, Table 6.4). To address culturally conservative contexts and the issue of compatibility, approaches to desensitise providers to the intervention (e.g. through learning forums) and intervention re-design to ensure alignment with religious/cultural values, where possible, were shown could lead to increased belief in compatibility by providers and generate buy-in and support for the intervention (see CMOC 2.2, Table 6.4). An example of this in practice can be seen in Box 6.2, below.

Box 6. 2 Perception of Compatibility by Local Decision Makers

CE1 described the scale-up of a school based sexual health education intervention in a conservative cultural context in Senegal. In this example, LDM was in place where providers could decide how and what to include with a guide curriculum given. Due to discomfort with some components of the intervention and the perceived lack of compatibility with social norms and beliefs, it was reported that sensitive components were often removed at provider level. To note, this removal occurred at provider level and also at higher levels of the system with some internationally recognised core components of sexual health education not being integrated into curriculum at national level.

In CE2 when scaling-up a sexual health education intervention for schools in Pakistan, the authors reported a similar conservative cultural context with lack of compatibility seen and discomfort in a number of settings and regions. To mitigate this, the intervention was re-designed on an ongoing basis to ensure core components remained in place while making it more compatible with cultural beliefs (e.g. language was used which aligned with religious values for particular settings). In addition, approaches were used such as trainings, guidance manuals and peer learning forums to desensitise providers to the topics areas. Unfortunately, as no formal fidelity assessment was carried out, it is not known as to whether all core components of the intervention were chosen to be delivered following this. However, significant buy-in and support, with high rates of implementation of the intervention were observed. This was attributed within the study to a combination of factors, including desensitisation and ensuring the intervention was designed to be perceived as compatible within this culturally conservative setting.

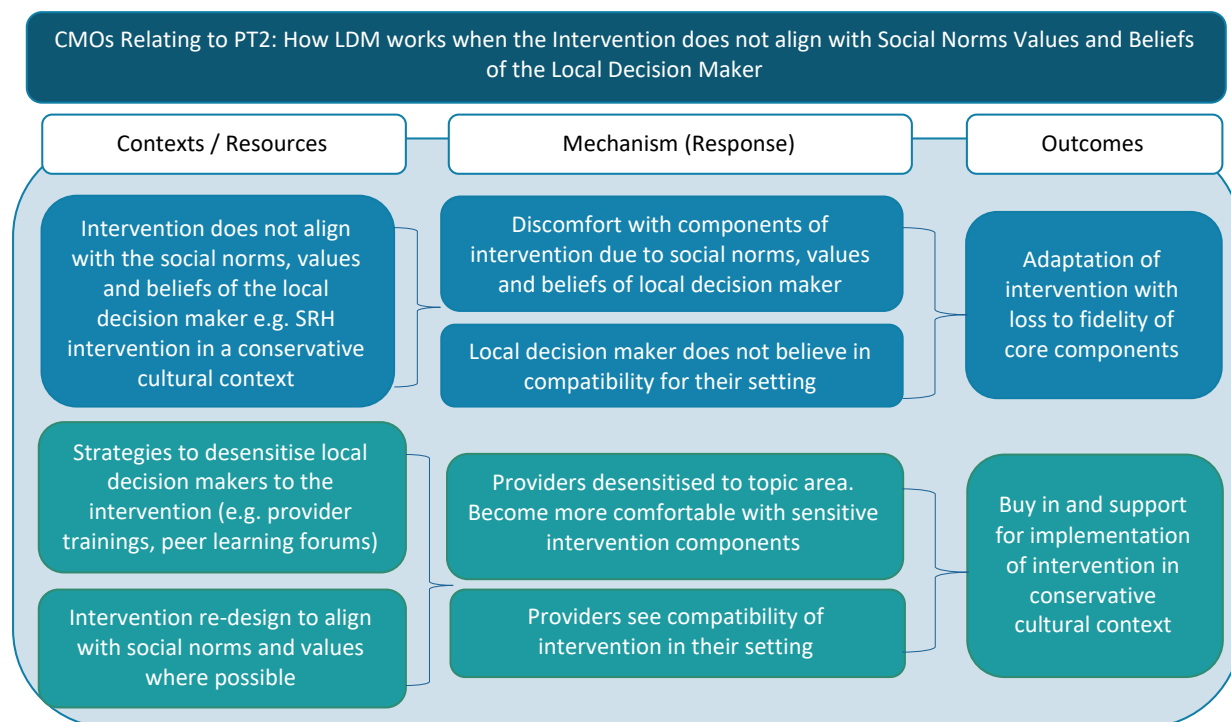


Figure 6.6 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker

This resulted in the following understanding of how LDM works when the intervention does not align with social norms, values and beliefs of the local decision maker (more details with supporting CMOs and evidence can be seen in Table 6.4);

PT2: *In the scale-up of interventions which do not align to the local decision makers social norms, values and beliefs, local decision makers may feel discomfort and believe in a lack of compatibility for the intervention (or lack of compatibility of certain components) for their setting. This may lead to adaptation with loss to fidelity of core components of the intervention. When strategies are used to desensitise local decision makers to the intervention, along with adapting intervention to align with social norms, values and beliefs where possible (while keeping core components intact), this can lead to local decision makers becoming more comfortable in the intervention and believing in its compatibility for their settings, leading to buy-in and support.*

Table 6.4 Supporting evidence for PT2 - How LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker. Adapted from (305)

PT2. How LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker			
CMOC 2.1 Influence of Social Norms, Values and Beliefs of Local Decision Maker			
Contexts / Resources C1: When intervention does not align with social norms, values and beliefs of local decision maker e.g. SRH intervention in conservative cultural context	Mechanisms (Response) M1: Discomfort with components of intervention due to social norms, values and beliefs of local decision maker M2: Local decision maker does not believe in compatibility for their setting	Outcome O: Adaptation of intervention with loss to fidelity of core components	Resulting CMOC: When there is LDM in conservative cultural contexts and introduction of SRH intervention(s) local decision makers may not be comfortable with all intervention components and may not see compatibility with the local setting leading to removal of components of the intervention with loss to fidelity
Thought process for CMOC: The social norms, values and beliefs of both central and local decision makers may influence the adaptations. In CE1 frontline providers and higher management felt discomfort with some topics considered sensitive or taboo within a conservative cultural context. Because of the autonomy given to local decision makers this led to removal of some topics from curriculum.			
Source: CE1 Supporting quote: "However, some individuals within the national Ministry of Education were reticent about content areas considered sensitive or taboo, resulting in an incomplete integration of FLE topics into national curriculum documents. Teachers' commitment to delivering FLE and reproductive health education was influenced by conservative social norms that limited their ability to address sensitive topics with pupils." (p510) (230)			
Considerations of rigour for this CMOC: The key source (230) for this CMOC involved consultation a range of stakeholders for development of article at different levels of the system. Discusses loss to fidelity due to discomfort delivering some topics. Source can be considered as trustworthy for this inference.			
CMOC 2.2 Strategies to Mitigate Influence of Social Norms of the Local Decision Maker			
Contexts / Resources C: LDM in conservative cultural context R1: Strategies to desensitise local decision makers to the intervention (e.g. provider trainings, guidance manuals, peer learning forums) R2: Intervention re-design to align with social norms and values where possible	Mechanisms (Response) M1: Providers desensitised to topic area. Become more comfortable with sensitive intervention components M2: Providers see compatibility of intervention in their setting	Outcome O: Buy in and support for Implementation of intervention in conservative cultural context	Resulting CMOC: When there is LDM in conservative cultural contexts, strategies to desensitise local decision makers to intervention along with intervention re-design to align with social norms and values where possible (while keeping core components intact) can allow providers to become more comfortable with the intervention and see compatibility for their setting. This can contribute to buy in, support and implementation of the intervention in these settings
Thought process for CMOC: In contrast to CMOC 2.1 in CE2 they reported on a number of strategies to mitigate the discomfort and potential removal of elements by frontline providers. This involved both adapting the intervention to make more compatible (while maintaining core components) and sensitising providers to the subject matter through trainings, guidance manuals, peer learning forums etc. Through curriculum redesign and use of language that aligned with religious values this allowed for compatibility to be seen between social norms and values and the intervention. Through information sharing in trainings, guidance manuals, peer learning forums and school showcases the providers became desensitised to the intervention and more comfortable delivering the subject matter.			

PT2. How LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker	
Source: CE2	
Supporting quote: <i>"Compatibility with user organisations' current values and services is a challenge in a context where talking openly about sexuality and bodily development runs counter to social norms and traditions. Rutgers WPF addressed this problem by involving teachers, school administrations, district education departments and Muslim scholars in the development and review of the curriculum. This helped to ensure the use of vocabulary aligned with religious and cultural values."</i> (p257) (197) <i>"I was really moved by the session on gender and sex during the training. It has clarified many misconceptions and I feel confident now while talking about equal rights"</i> (p20) (309) [Direct quote from frontline provider]	
Considerations of rigour for this CMOC: Two key documents supported this CMOC from CE2 (197, 309). To note, while there was no formal fidelity assessment to show that providers delivered all core topics areas, there were direct quotes from providers in (309) expressing more comfort and confidence in topics areas after trainings. Additionally the curriculum was re-designed numerous times with core topics intact. Overall high levels of implementation achieved, and also documented implementation in particularly socio-conservative areas of the country. This CMOC could be considered as trustworthy from these sources.	
CMOCs support, refute or refine an IPT or build new PT?:	
IPT A: <i>"Through participation local decision makers may become desensitised to the intervention and become more accepting of the intervention leading to buy-in and support for intervention and implementation"</i> The CMOCs refine and build upon this IPT. What was found was that a conservative cultural context led to the mechanisms of discomfort and belief of lack of compatibility for the intervention. Participation by itself as suggested in the IPT did not appear to change that, however there was evidence in CMOC 2.2 that specific desensitisation strategies such as training, guidance manuals and peer learning forums could assist in local decision makers believing in compatibility and lead to buy-in and support. PT refined to reflect this.	
Further evidence or theory for PT:	
- Rogers' diffusions of innovations theory (53), specifically how perceived compatibility with values may affect adoption of an innovation. This supports this finding in how perceived lack of compatibility by local decision makers may lead to lack of adoption or removal of components of the intervention that do not align with their beliefs - Role conflict theory (343), specifically the element of person-role conflict could apply to this PT where expected behaviour of delivery of SRH intervention components is in conflict with personal beliefs.	
Thought process for PT:	
While this PT2 is similar to PT1, the latter focuses on beliefs and compatibility by the wider community and the pressure this places on local decision makers in spite of their own beliefs or those of recipients (i.e. extrinsic influence on the local decision maker). In contrast CMOCs 2.1 and 2.2 and PT2 focus on the beliefs of the local decision maker themselves and how their feelings on compatibility and level of discomfort with an intervention may lead to changes to the intervention with loss of fidelity. While the CMOCs identified SRH interventions, on reflection it was interventions which may not align with social values, norms and beliefs that are the issue, which can include SRH, but may also include other interventions such as mental health. Therefore this was taken to a level of abstraction to encompass a wider intervention group. CMOC 2.2 highlights how when strategies to desensitise and ensure the intervention appears in alignment with social norms and values this may assist in beliefs of compatibility. Thus by introducing the resources of these desensitisation strategies it can change the context and reduce triggering of the mechanism of discomfort. It may also change the beliefs to one of compatibility for the local setting leading to buy-in and support. This refines IPTA which put forward that participation alone may lead to desensitisation and belief in compatibility, however this was not specifically reported in the case examples with the need for specific desensitisation strategies highlighted. The sources for these CMOCs could be considered trustworthy for this inference and importance was placed on the impact of LDM in this context in both CE sources. The lack of evidence of fidelity	

PT2. How LDM works when the Intervention does not align with Social Norms Values and Beliefs of Local Decision Maker

assessment in CE2 meant that adaptations with fidelity was not included as an outcome for CMOC 2.2, however it was felt there was sufficient evidence for buy-in and support for the intervention within the sources. These CMOCs and resultant refined PT are also further supported by Rogers' diffusion of innovations theory (53) (relating to compatibility) and role conflict theory (343) (relating to person-role conflict) and so the below PT is considered both coherent and plausible.

PT2: In the scale-up of interventions which do not align to the local decision makers social norms, values and beliefs, local decision makers may feel discomfort and believe in a lack of compatibility for the intervention (or lack of compatibility of certain components) for their setting. This may lead to adaptation with loss to fidelity of core components of the intervention. When strategies are used to desensitise local decision makers to the intervention, along with adapting intervention to align with social norms, values and beliefs where possible (while keeping core components intact), this can lead to local decision makers becoming more comfortable in the intervention and believing in its compatibility for their settings, leading to buy-in and support.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example

PT3. How LDM works in Contexts where there is a Reliance on External Funding

When there is a reliance on external funding a power imbalance can occur between funders and local decision makers (please see Figure 6.7 for an overview of CMOCs relating to this). Examples of this reliance on external funding from the case examples came in different forms, for example smaller CBOs receiving funding from national agencies (CE17) or a national health service and a hospital network receiving funding from a large international philanthropic organisation (CE11). In contexts where funders do not understand the importance of all components of intervention, this reliance on funding can lead to local decision makers being vulnerable to pressures to adapt core components, with fear of negative repercussions if they do not comply. Adaptations may be linked to funders' beliefs or targets and not necessarily based on the local needs of the community. This can lead to adaptations with loss to fidelity of core components, and can occur despite local decision makers being aware of core components and not wanting to adapt them themselves (please see CMOC 3.1, Table 6.5). Counter to this, one case example reported that having ongoing communication with funders, and making them a genuine consultative partner, led to the funders having an ongoing understanding of the intervention, local needs and importance of re-designs (CE11; (257)). They reported that this led to priorities of local communities being acknowledged and valued, with funding agencies facilitating changes in budgets and timelines, allowing for adaptations for local fit to meet identified local needs throughout the scale-up (please see CMOC 3.2, Table 6.5).

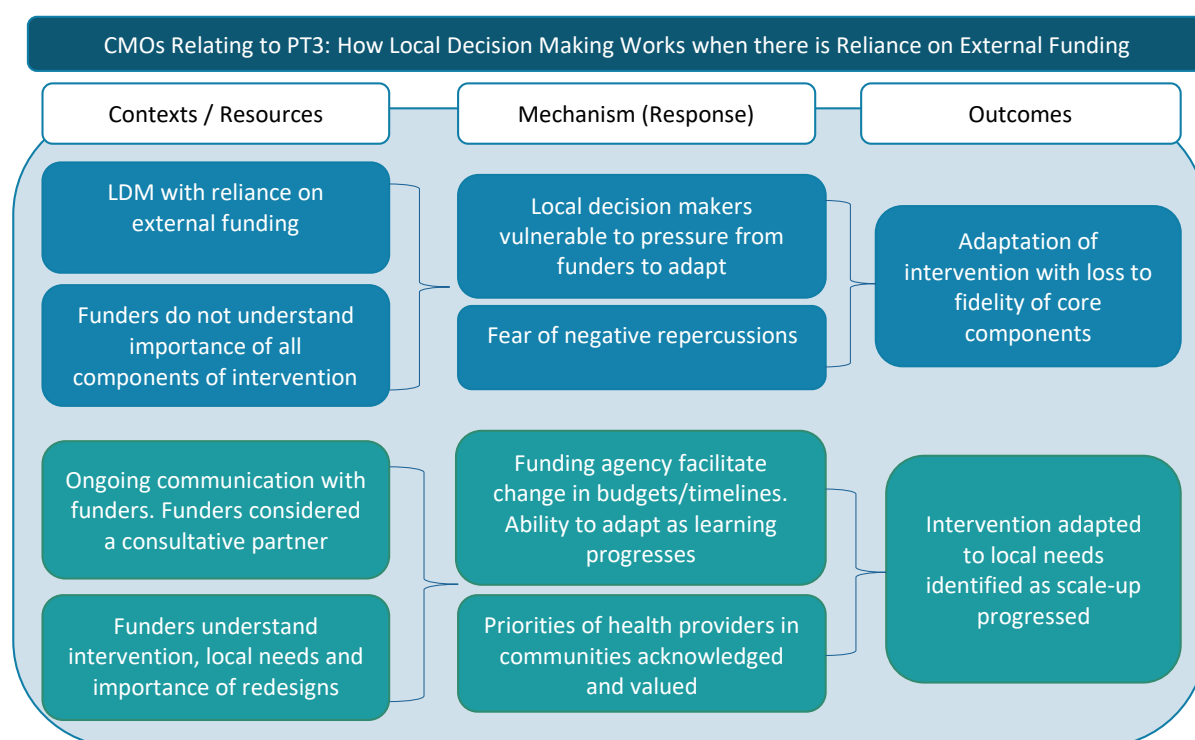


Figure 6.7 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How LDM works when there is a Reliance on External Funding

This led to the following understanding of how LDM works in contexts where there is a reliance on external funding (more details with supporting CMOCs and evidence can be seen in Table 6.5);

PT3: *When local decision makers are reliant on external funding, they can feel under pressure to adapt the intervention based on funders' needs and beliefs, fearing negative repercussions such as loss of funding if they do not comply. In contexts where funders have a lack of understanding of the importance of all essential components of the intervention, this can lead to pressure on local decision makers to adapt elements with loss of fidelity to the intervention. When communication is used to strengthen a funder's understanding of the intervention components and local needs, this can change the underlying context and remove the pressure on local decision makers to make unnecessary adaptations, in support of adaptations in line with local needs, as identified during the scale-up.*

Table 6.5 Supporting Evidence for PT3 – How LDM works in Contexts where there is a Reliance on External Funding. Adapted from (305)

PT 3. How LDM works in Contexts where there is a Reliance on External Funding			
CMOC 3.1 Reliance on funding, pressure from funders			
Contexts / Resources C1: LDM with reliance on external funding C2: Funders do not understand importance of all components of intervention	Mechanisms (Response) M1: Local decision makers vulnerable to pressure from funders to adapt M2: Fear of negative repercussions	Outcome O1: Adaptation of intervention with loss to fidelity of core components	Resulting CMOC: When LDM as reliant on external funding they are vulnerable to pressures from funders to adapt components of the intervention. When funders do not have an understanding of the importance of all core components of the intervention, this can lead to adaptations with loss to fidelity
Thought process for CMOC: Pressure from funders to make changes or remove elements was seen, with the level of understanding of the funder of intervention components being important. For example in CE7 (268) it was suggested that funders may not have appreciated the importance of quality of care elements in the scale-up of contraceptives and supported the introduction of long lasting injectables only in some areas. In CE17 (239) there was also pressure to add components that were counterintuitive to intervention logic, such as peer workers to complete risk assessment information within a peer conversations session. There was also reported pressure from funders in CE17 (239) to deliver to groups not initially intended for intervention (e.g. for HIV positive individuals). Being reliant on external funding leaves LDM vulnerable to pressure as not making these changes may result in loss of funding streams for intervention.			
Source: CE7, CE17 Supporting quote: “Funders, CBO management and staff needed to know about MP [Mpowerment intervention] to implement with success. Funders who lacked an understanding of the program often developed contracts that contained unrelated “deliverables,” objectives that the CBO was required to achieve. The CBOs then had to choose between fulfilling their contractual obligations or implementing the MP with fidelity. For example, weekly core group meetings and regular social events are necessary to implement MP with fidelity, but many contracts did not include core group meetings or social events in them, and instead required an unrealistic number of M-groups resulting in an unsuccessful MP implementation. CBOs that were funded under these circumstances were in a dilemma about how to implement the intervention with fidelity—needing to put a “round” community-level intervention into a “square” group- or individual-level oriented contract. “ (p7) (280)			
Considerations of rigour for this CMOC: For CE17 this CMOC was developed from (239, 280). In (239) this included interviews and surveys with those delivering the intervention with direct quotes on impact of funder pressure on fidelity to the intervention. For CE7 the source (268) was a report developed by the scale-up team implementing the intervention with reflections from their experience and observations. This included the challenges of loss to fidelity in some provinces in part due to pressure to expand rapidly to capitalise on funding. These sources could be considered trustworthy for this CMOC.			
CMOC 3.2 Communication with funders to facilitate understanding of intervention			
Contexts / Resources R1: Ongoing communication with funders. Funders considered a consultative partner C: Funders understand intervention, local needs and importance of redesigns	Mechanisms (Response) M1: Priorities of health providers in communities acknowledged and valued M2: Funding agency facilitate change in budgets/timelines. Ability to adapt as learning progresses	Outcome O: Intervention adapted to local needs identified as scale-up progressed	Resulting CMOC: In contexts where there is a reliance on external funding when there is strong communication with the funders leading to an understanding of the importance of the intervention and local needs, this can lead to facilitation of the funder for adaptations for local fit in keeping with needs of the community

PT 3. How LDM works in Contexts where there is a Reliance on External Funding
Thought process for CMOC: This CMOC is a positive experience of where funders understand the intervention and importance of planned redesign. In CE11 (257) they attributed this in part to the strong communication between the scale-up team and funder and ensuring they were a consultative partner. This led to facilitation of many changes as learning progressed and extensions of budgets and timelines. Core work areas were also adapted in the wider scale-up design, however this was in response to local needs identified and they did not report any negative adaptations with loss to fidelity.
Source: CE11
Supporting quote: <i>“Fortunately, the funder was flexible in accommodating continuous adaptation of the Project design. For example, the funder was receptive to changes in the pace and scope of the work, as well as to extensions in the duration of the Project and corresponding adjustments in the budget. The funder was a genuine consultative partner throughout the Project.”</i> (p15) (257)
Considerations of rigour for this CMOC: The source for this CMOC (257) is reflections from the scale-up team who worked directly with the funders. The outcome of ongoing adaptation can be evidenced by the amount of change ideas and changes to the core work areas over time. This source could be considered trustworthy for this level of inference.
CMOCs support, refute or refine an IPT or build a new PT?:
New PT
Further evidence or theory for PT:
• Role conflict theory (343), specifically intra-role conflict, where conflicting expectations and requests on how to perform a role and tasks could apply to this PT also. Local decision makers may be encouraged to implement whole intervention by organisation or community, however funders are conflicting to this pressuring alternatives by removal of components • The Theoretical Domains Framework (TDF) (346), specifically the ‘beliefs about consequences’ domain could support this theory in how fear of negative repercussions may affect behaviour and lead to removal of components of the intervention to avoid negative consequences
Thought process for PT:
CMOC 3.1 demonstrates where there can be a lack of understanding and appreciation of all components of the intervention from funders this can lead to local decision makers feeling pressure and fearing negative repercussions (such as loss of funding) if adaptations are not made in line with funders beliefs. CMOC 3.2 builds upon this to provide an example of when communication strategies were in place to make funders aware of local needs this led to funders having an understanding of local needs and not placing pressure on local sites to make adaptations with loss to fidelity, thus the context was changed and mechanism not activated. Together they build a picture of the importance of a context where funders understand the importance of essential components of an intervention and local needs. The sources for these CMOCs would appear trustworthy for this inference. Role conflict theory (343), specifically intra-role conflict, further supports this theory. Where the intra-role conflict was in place this led adaptations with loss to fidelity, however when this intra-role conflict was not present by use communication strategies with funders this led to more positive outcomes. In addition to this the TDF (346) domain of ‘beliefs about consequences’ would further support this theory. This PT would appear coherent and plausible based on the above.
PT 3: When local decision makers are reliant on external funding, they can feel under pressure to adapt the intervention based on funders’ needs and beliefs, fearing negative repercussions such as loss of funding if they do not comply. In contexts where funders have a lack of understanding of the importance of all essential components of the intervention, this can lead to pressure on local decision makers to adapt elements with loss of fidelity to the intervention. When communication is used to strengthen a funder’s understanding of the intervention components and local needs, this can change the underlying context and remove the pressure on local decision makers to make unnecessary adaptations, in support of adaptations in line with local needs, as identified during the scale-up.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example

PT4. How LDM Works in Resource Limited Settings

LDM during scale-up can be challenging when introduced in resource limited settings (please see Figure 6.8 for overview of CMOCs relating to this). In contexts where limited resources are available, scaling-up can lead to providers being under pressure to meet local demand and deliver the intervention within realistic resources, which can result in the removal or adaptation of core components of the intervention. This occurred despite intervention components being known and guidance given to sites. This pressure may also contribute to reduced motivation and support for the intervention over time (see CMOC 4.1, Table 6.6). A strategy to mitigate some resource limitations was the use of systems thinking to capitalise on synergies across sites (see CMOC 4.2, Table 6.6).

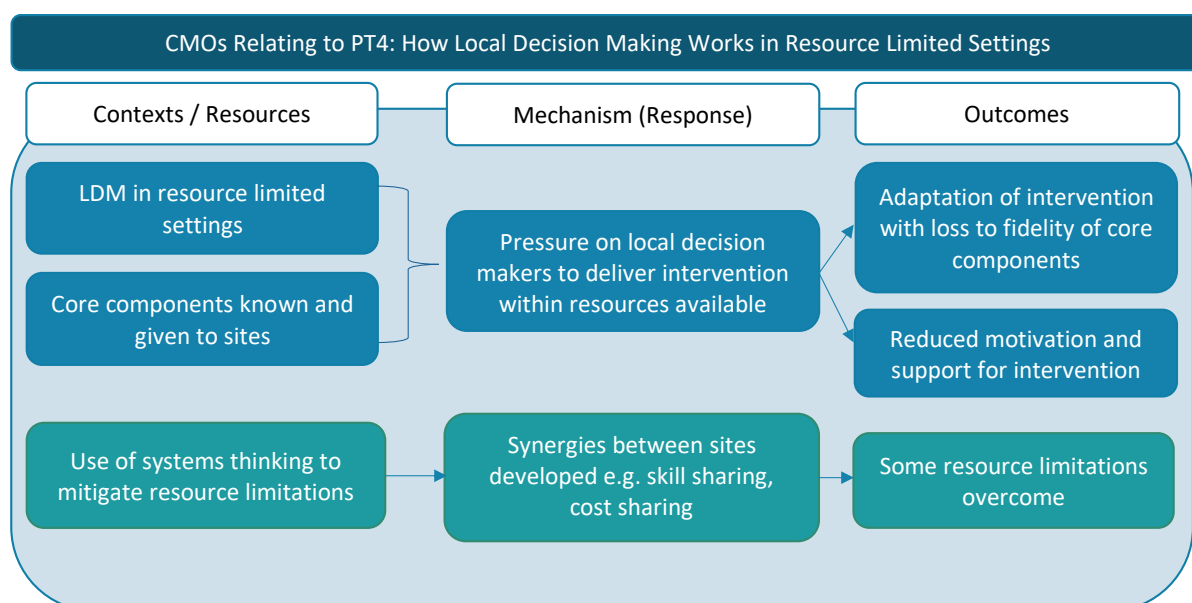


Figure 6.8 Overview of Resources, Contexts, Mechanisms and Outcomes relating to how LDM works in Resource Limited settings.

This led to the following understanding of how LDM works in resource limited settings (more details with supporting CMOCs and evidence can be seen in Table 6.6);

PT4: *When LDM occurs in resource limited settings, there can be pressure on local decision makers to adapt to meet the needs and demands of their local setting. Adaptations with a loss to fidelity can occur, despite core components being known and guidance given to sites, as some adaptations may be deemed unavoidable. Using a systems thinking approach to identify where synergies can be utilised across local sites, e.g. skill and cost sharing, may avoid some adaptations being made due to resource limitations*

Table 6.6 Supporting Evidence for PT4 – How LDM Works in Resource Limited Settings. Adapted from (305)

PT 4. How LDM works in Resource Limited Settings			
CMOC 4.1 Despite Core Components known Resource Limitations affecting Adaptations			
Contexts / Resources C1: LDM with limited resources C2: Core components known and guidance given to sites	Mechanisms (Response) M: Pressure on local decision makers to deliver intervention within resources available	Outcome O1: Adaptations with loss to fidelity O2: Reduced motivation and support for intervention if resources unavailable	Resulting CMOC: Despite core components being known and guidance given sites, in contexts where there is limited resources available local decision makers may have pressure to deliver within available resources leading to adaptations with loss of core components. This may also contribute to reduced motivation and support for intervention over time
Thought process for CMOC: Despite some of the CEs reporting having clear core components which were articulated to sites, with the realities of resource feasibility there was pressure to adapt within available resources. In three of the CEs some adaptations were related to demand (CE17, CE18, CE19) with group sizes were increased or eligibility changed from original criteria to accommodate access within given resources including staffing. In one CE it was referenced regarding cost of equipment (CE14). In CE14 and CE19 they discussed that resource limitations and pressure on staff may have contributed towards reduced motivation and support over-time (245, 318). To note that two of these CEs were from LMICs (CE18, CE19) and two from HICs (CE14, CE17). S2 (stakeholder - local decision maker) also highlighted that lack of resource availability led to an inability to make the intervention fully culturally acceptable with a conflict between the needs of community and resources in their setting.			
Source: CE14, CE17, CE18, CE19, S2 Supporting quote: "We knew exercising in a mixed gender context was not acceptable to them but we didn't have the facilities to do a male and a female class. So there was a conflict there between what they wanted and what we could do." S2 (local decision maker) <i>"CAG members, health staff and MSF implementers confirmed that the established medical eligibility criteria were not always respected. They had some discrepant opinions concerning the required duration on ART, ranging from three to eight months, and the need to be clinically stable before joining a CAG. Some nurses and health authorities strongly defended the need to be adherent prior to joining a CAG, while others opted to target patients at risk for poor adherence such as TB patients, pregnant women and/or children."</i> (p5) (241)			
Considerations of rigour for this CMOC: Sources for CE18 (241) and CE19 (245) documented adaptations to cope with increasing demand within resource shortage. For CE19 key source focused on overloaded health system and stress on HRH. This was developed from data from multiple levels of the system and sources. For CE17 examples of where adaptations with potential loss to fidelity for specifically for the VOCE/VOICES intervention were given in (62) by providers delivering intervention in CBO settings in response to resources being inadequate to meet demand. For CE14 direct quote from teacher in (318) on frustration at delivering intervention component of action bin without being supplied with enough resources. This CMOC was further supported by input from S2. These data sources are trustworthy for this CMOC.			
CMOC 4.2 Use of systems thinking to mitigate resource limitations			
Contexts / Resources C: LDM in resource limited setting R: Use of systems thinking to mitigate resource limitations e.g. incentives for inter-site collaboration and resource sharing, minimum method mix to facilitate logistics and supply chain	Mechanisms (Response) M: Synergies between sites developed – skill sharing, cost sharing	Outcome O: Some resource limitations overcome	Resulting CMOC: When there is LDM in resource limited settings the use of systems thinking to develop strategies to address resource limitations may lead to synergies between sites with skill and cost sharing allowing for some resource limitations being able to be overcome

PT 4. How LDM works in Resource Limited Settings
Thought process for CMOC: This CMOC was developed to demonstrate how systems thinking could lead to use of approaches to address resource limitations. This included approaches to increase collaboration between sites which allowed for skill and cost sharing to occur. This can contribute to some resource limitations being overcome at local levels.
Source: CE8
Supporting quote: <i>“The strengthening of interdistrict linkages also made it possible to maximize economies of scale by encouraging districts to pool assets and exchange material resources such as transport, training facilities, equipment and supplies. By the second year of the initiative, the districts were conducting joint training; they were collectively procuring equipment, supplies and commodities and collaborating on other activities, such as annual planning, that they once pursued on their own. They also introduced a series of exchange programmes, whereby staff from one district served as external observers and examiners in the training programmes of another.”</i> (p85) (16)
Considerations of rigour for this CMOC: This CMOC was developed from one case example with the key source being from the perspective of the scale-up team (16). For this inference this perspective would be valid, with multiple examples given in the text of strategies used to address resource limitations. As a result this CMOC could be considered trustworthy.
CMOCs support, refute or refine an IPT or build a new PT?:
New PT
Further evidence or theory for PT:
• Role conflict theory (343), specifically intra-role conflict may apply here where there are expectations to deliver the intervention with components intact, however pressure from realities on the ground with demand from recipients to be included in intervention despite not meeting eligibility criteria or demands from management to meet targets (in particular seen in examples for ART coverage (16, 241)) may lead to local decision makers experiencing pressure and conflict • Holliday et al., (61) framework of adaptations, specifically of the concept of unavoidable adaptations could apply to some of these settings
Thought process for PT:
CMOC 4.1 demonstrates that despite core components being known there can still be unavoidable adaptations due to resource limitations. Therefore considerations of available resources and future pressures on local decision makers to adapt need to be considered when selecting interventions to be scaled-up. CMOC 4.2 demonstrated how systems thinking with inter-district collaboration for skill and cost sharing reduced some resource limitations. Interestingly not all CEs were from LMICS, with resource limitations also experienced in HICs. For the inferences made the sources for the CMOCs can be considered trustworthy. The arguments and theory developed is coherent and plausible and supported by role conflict theory (343).
PT 4. When LDM occurs in resource limited settings, there can be pressure on local decision makers to adapt to meet the needs and demands of their local setting. Adaptations with a loss to fidelity can occur, despite core components being known and guidance given to sites, as some adaptations may be deemed unavoidable. Using a systems thinking approach to identify where synergies can be utilised across local sites, e.g. skill and cost sharing, may avoid some adaptations being made due to resource limitations.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example

PT5. How Local Decision Making Works in the Context of Using Data to Assess Progress and Inform or Evaluate Adaptations

The use of a data driven approach was reported to support LDM in a number of ways (please see Figure 6.9 for an overview of CMOCs relating to this). The use of approaches which taught methods of idea generation and testing (such as MFI which utilises plan-do-study-act cycles – see Chapter 5, Action 8 for more details) allowed for local decision makers to use data to assess progress and inform and evaluate adaptations, develop an awareness of local needs and whether an adaptation worked, with successful adaptations identified and continued, and in some cases, these adaptations shared with other sites (CMOC 5.1, Table 6.7). In addition to assisting in the identification of successful adaptations, the use of data-driven approaches also helped to develop buy-in and support for the intervention and implementation at local levels. Seeing positive changes in data as a result of successful adaptations and implementation led to increased motivation by local decision makers as well as a sense of pride in these achievements. This then led to buy-in and support for the intervention and implementation at local levels (CMOC 5.2, Table 6.7). A further positive finding of using data-driven approaches for local decision makers was that by giving ownership and autonomy of the data and process, local decision makers were empowered and felt valued and respected, leading to further buy-in and support for the intervention and implementation (CMOC 5.3, Table 6.7). Strategies which supported ownership and autonomy of the process and data included allowing local decision makers to report data directly to higher levels of management through government health system reporting mechanisms, as opposed to through the scale-up team, reducing the presence of the scale-up team by not setting-up site offices in later sites, and encouraging local sites to organise and present their findings at meetings themselves.

One key building block for the use of a data-driven approach was the consideration of capacity at local levels. The CEs that specifically reported a use of a data driven approach were based in LMICs, with differing capacity limitations, and all reported this style of approach as new in their setting (CE5, CE11, CE21, CE22). Capacity limitations related to data generation and analysis (CE21), along with literacy issues of the local decision makers in the case of peer workers (CE22). Selection of data approaches that were suitable for the capacity level of local decision makers (for example use of pictorial tools for capturing and analysing data, CE22), along with capacity building and ongoing support (such as training and support in QI methods, CE11 & CE21) were identified as a key resource. This allowed for empowerment of local decision makers leading to their participation in the adaptation and implementation process (CMOC 5.4, Table 6.7), and could in turn lead to adaptations being made for local fit as well as local buy-in for intervention and implementation.

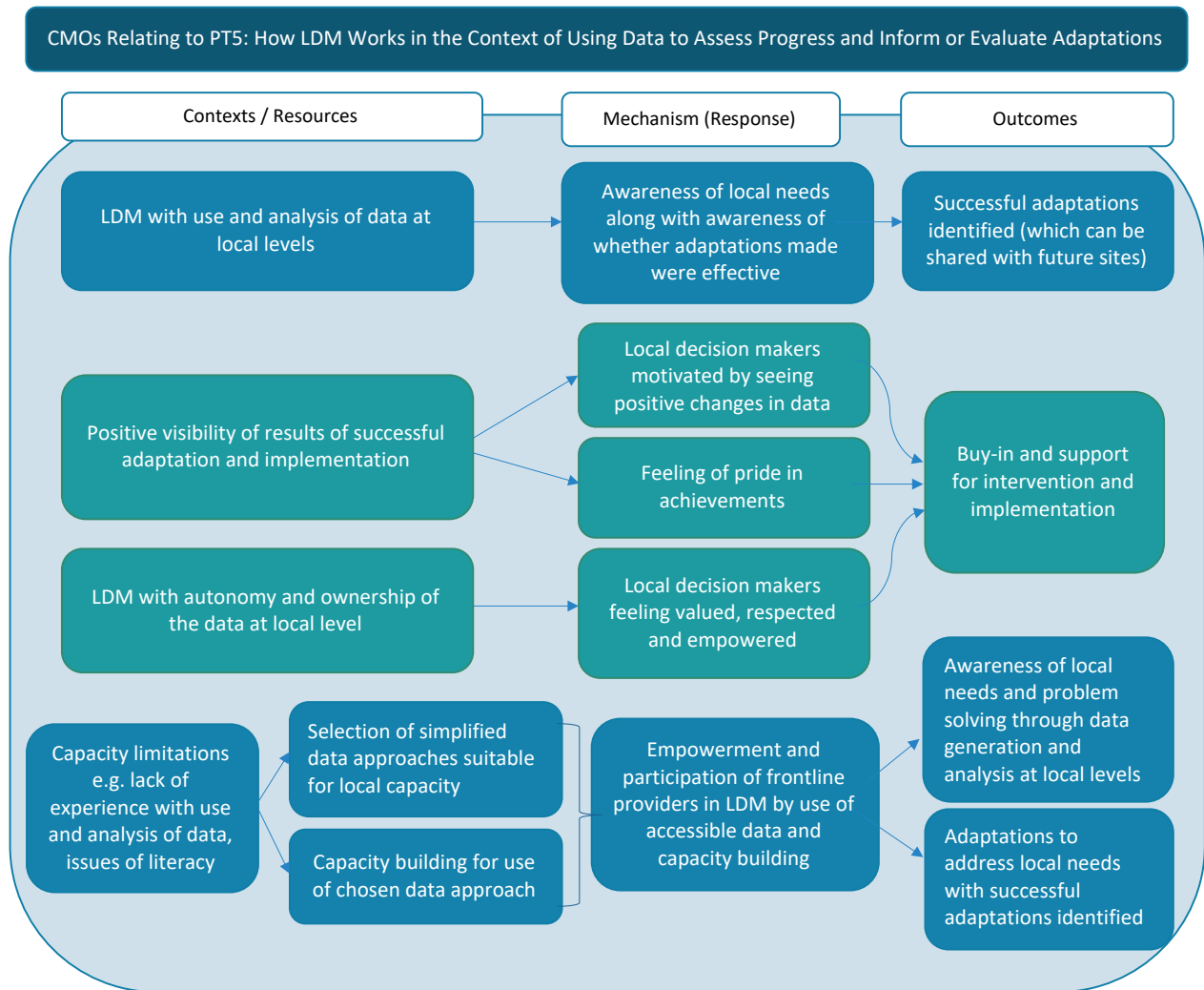


Figure 6.9 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How LDM Works in the Context of Using Data to Assess Progress and Inform or Evaluate Adaptations

The consolidation of these findings led to the programme theory on how LDM works in the context of using data to assess progress and inform or evaluate adaptations (more details with supporting CMOs and evidence can be seen in Table 6.7);

PT5: *The use and analysis of local data by local decision makers to inform adaptations and/or for evaluating adaptations when scaling-up can create an awareness of local needs and an awareness of whether adaptations made were effective. Local decision makers can be motivated by seeing positive changes in data demonstrating a relative advantage of the intervention and adaptation, as well as experience pride in these achievements, leading to buy-in and support for the intervention and implementation. When local decision makers feel autonomy and ownership over the data and process, this can lead to empowerment through feeling valued and respected, resulting in further buy-in and support for the intervention and implementation. In settings where there may be capacity limitations*

and no history of data-driven approaches, consideration needs to be made in the selection of suitable data-driven approaches, based on capacity at local level. Considerations based on existing capacity could include whether capacity building and ongoing support are needed for the empowerment and participation of local decision makers to use a data-driven approach to support LDM.

Table 6.7 Supporting Evidence for PT5 - How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations. Adapted from (305)

PT5. How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations			
CMOC 5.1 Data to Demonstrate Effective Adaptations			
R: LDM with use and analysis of data at local levels	M: Awareness of local needs along with awareness of whether adaptations made were effective	O: Successful adaptations identified (which can be shared with future sites)	Resultant CMOC: The use and analysis of local data to guide adaptations can lead to an awareness of local needs along with whether resultant adaptations made were effective or not. Therefore successful adaptations can be identified, with the potential to share these with other sites
Thought process for CMOC: Two CEs (CE11, CE21) used QI methods which included the MFI (which includes plan-do-study-act cycles) where change ideas were tested at local levels. This allowed for awareness of adaptations that were effective. Following identification of successful ideas these were then put into change packages and/or newsletters for cross site learning. It was noted that in later stages of scale-up less new innovation was needed as previously identified successful ideas were taken up by later sites.			
Sources: CE11, CE21 Supporting quote: “The teams were highly energized, having tested their change ideas in a real setting with some good results and/or learning along the way. Each team was given an opportunity to present its work at the Learning Session, often using the site visit that occurs prior to the Learning Session to prepare the teams for their report-outs.” (p43) (257)			
Considerations of Rigour for this CMOC: Both of these CEs had descriptive outcome data to show use of the QI process e.g. amount of change ideas tested and sites using approach (232, 253, 255, 258). They also both reported and gave examples of successful ideas which were shared with later sites. This sharing took place in learning collaboratives and BTS models (257, 258) and was seen through published newsletters (262-266) or change packages (259). This CMOC appears trustworthy.			
CMOC 5.2 Data and Visibility of Positive Results			
Contexts / Resources R: LDM using a data driven approach. Positive visibility of results of successful adaptation/implementation	Mechanisms (Response) M1: Local decision makers motivated by seeing positive changes in data M2: Feeling of pride in achievements	Outcomes O1: Buy in and support for intervention and implementation at local level	Resulting CMOC: When data driven approaches are used at local levels which show positive visibility of results with successful adaptations identified, local decision makers can be motivated and experience pride in achievements, leading to buy-in and support for intervention and implementation
Thought Process for CMOC: With the positive visibility of results, local decision makers were motivated and felt pride in results leading to buy-in and support for intervention and implementation e.g. as evidenced by further change ideas developed and tested at local levels (CE11, CE21). This was developed from three CEs (CE5, CE11, CE21). The use of formalised processes based on QI methodology (from the IHI) was reported in two case studies (CE11, CE21) where a data driven approach was used to generate and test ideas at local levels. This was described at multiple levels including at district, facility and frontline levels. This led to			

PT5. How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations			
successful adaptations identified and being encouraged by positive results seen which was particularly referenced in CE11. Leading to buy-in for approach as evidenced by ongoing development and testing of these change ideas as the scale-up continued (CE11, CE21). In CE5 the local government authorities took ownership of the data and as a consequence reported feelings of pride and ownership over the achievements seen.			
Sources: CE5, CE11, CE21 Supporting quote: <i>"In PFA! [Project Fives Alive!] there was clear pride of workmanship in people seeing how data they had influenced improved over time."</i> (p49) (257)			
Considerations of Rigour for this CMOC: Two case studies included descriptive outcome data to show buy-in and support for the approach e.g. as evidenced by amount of change ideas tested and sites using QI approach (232, 253, 255, 258). For CE11 a reflections/lessons learnt report (257) written by the scale-up team, with key informants from management, supported the mechanisms of motivation and pride. To note the report did not specifically use informants at frontline level i.e. the mechanisms were put forward by observations of the scale-up team and management. While direct input from those involved with generating and testing ideas on the frontline would have been preferable evidence, given the scale-up team and management involvement with the project and observations in the field, along with the coherence and plausibility of these mechanisms, it warranted inclusion for this CMOC. In CE5 the key source (228) was developed from robust process of reflections from the scale-up team, key informant interviews at multiple levels (including local health authority level), site visits, and routine monitoring data. This article was developed with input from both scale-up team and decision makers at local authority level so for this CMOC it could be considered a trustworthy source of evidence. Due to the cumulation of evidence sources this CMOC can be considered trustworthy and coherent.			
CMOC 5.3 Autonomy and ownership of the data and process			
Contexts / Resources R: LDM with autonomy and ownership of the process and data at local level	Mechanism (Response) M: Local decision makers feeling valued, respected and empowered	Outcomes O: Buy-In and support for intervention and implementation at local level	Resulting CMOC: When autonomy and ownership of the data and process is given to local decision makers this can lead to them feeling valued, respected and empowered. This can lead to buy-in and support for the intervention and implementation
Thought process for CMOC: A specific CMOC was warranted for autonomy and ownership of the data at local level given the importance placed on it in CE5. In this case the scale-up team reduced their input in later sites by not setting up sites offices and reducing planning and presenting at technical meetings to re-enforce local leadership. In addition to this data was integrated into government health systems and local authority leadership could directly report the findings themselves to higher levels of management without the need for the scale-up team. This gave local authority decision makers autonomy and ownership of the process and data, making them feel valued and respected and experiencing a sense of pride and ownership over the achievements. This lead to buy-in and support for the intervention and implementation from local decision makers with ongoing participation and reduced need for central scale-up team input as the programme continued.			
Source: CE5 Supporting quote: <i>"Data concerning key Tupange interventions were integrated into the government's health information system. As a result, the government teams began to own the data and to present the results to higher level health authorities rather than having the Tupange representatives do so. This brought the local government teams respect and appreciation and they now felt that "we own the process and we own the achievements". These changes represented a major</i>			

PT5. How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations			
<i>shift in how Tupange had been working previously in the core cities. The local health management teams were now driving the process and the project was in a supportive role. " (p108) (228)</i>			
Considerations of Rigour for this CMOC: Key document for this case (228) developed from robust process of reflections from the scale-up team, key informant interviews at multiple levels (including local health authority level), site visits, and routine monitoring data. This inference takes the perspective of the scale-up team and decision makers at local authority level and this article was developed with input from both so for this CMOC this source could be considered trustworthy. While this CMOC came from one case study the article was robust and specific importance was weighted on this finding.			
CMOC 5.4 Consideration of capacity and accessibility of data at local levels			
Contexts / Resources C: LDM using a data driven approach. Capacity limitations e.g. lack of experience with use and analysis of data, issues of literacy R1: Selection of simplified data approaches suitable for local capacity to allow for inclusion R2: Capacity building for use of chosen data approach	Mechanisms (Response) M1: Empowerment and participation of frontline providers in LDM by use of accessible data and capacity building	Outcomes O1: Awareness of local needs and problem solving through data generation and analysis at local levels O2: Adaptations to address local needs with successful adaptations identified	Resulting CMOC: The consideration of local capacity in selection of a suitable data driven approach and capacity building where needed to ensure data is accessible for use empowers local decision makers, including frontline providers, allowing for participation in LDM. The use of data at local levels allows for awareness of local needs and problem solving through data generation which can inform adaptations for local fit. These adaptations can be tested at local levels through data driven approaches with identification of successful adaptations
Thought Process for CMOC: Ensuring the accessibility of data (in particular for generation and use by frontline providers) was discussed in CE11, CE21 and CE22. Often there was little experience in data driven approaches and significant training and support was given. In the case of CE11 and CE21 this was in the form of formalised QI methods from the IHI (this included the BTS, learning collaboratives, and MFI using plan-do-study-act cycles, see Chapter 5, Action 8 for more details). The accessibility of a data was discussed in CE11 and CE21 where routine indicators were identified for use and examples of simplified colour coded dashboards given to ease analysis and identify problems. In CE22 they specifically noted literacy as an issue in capacity to use data and developed pictorial tools to aid peer workers in risk mapping and planning their interventions. By ensuring data was suitable for the level of available capacity along with building capacity and providing ongoing supports where needed, this allowed for empowerment of frontline providers with participation in LDM, awareness of local needs and problem solving through the generation of data and analysis of data. This also led to awareness of whether adaptations were working in their setting by analysis of results.			
Sources: CE11, CE21, CE22 Supporting quote: <i>"The conversion of data into useful information to guide programmatic decisions on an ongoing basis, rather than only to evaluate its ultimate impact, was crucial. All members of the Avahan implementation chain, down to peer outreach workers in the field, were empowered with tools to record and analyze data on their contacts with each community member, for performance management and work planning. In the case of peer educators, many of whom had low literacy skills, pictorial tools enabled them to gather useful data about their communities and plan their daily outreach accordingly." (p215) (256)</i>			

PT5. How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations

Considerations of Rigour for this CMOC:

For CE22 the use and accessibility of data was discussed in multiple documents (256, 338-341). Two of these documents were case reports written by those involved in the scale-up (256, 338) however did not specifically mention methods for development of article in particular whether key informants were included. Therefore this was taken to be the perspective of the authors who were part of the central scale-up team. However the same case study completed a Delphi study (339) with inputs from multiple levels of stakeholders where agreement was reached that the pictorial micro-planning tool for peer workers and the active use of data at all levels were important for the success of the programme. Further to this an ethnographic study which completed observations of peer workers in the field reported engagement with risk mapping tools and participation (307). With the combination from these sources this CE could be considered trustworthy for this inference. For CE11 a lessons learned document written with inputs from key informants (primarily from the scale-up team and management) discussed the use of accessible data and QI approaches used along with engagement and participation of those delivering services (257). This was further supported by an outcomes study (232) which had evidence of amount of change ideas tested. For CE21 sources primarily described the process and completed outcome evaluations (253, 255, 258), while this provided evidence of change ideas tested and engagement with the data driven process, the sources lacked more detailed qualitative evidence. To note the testing of adaptations and sharing of successful ideas was only noted in CE11 and CE21. When considering the three case studies together there is sufficient consolidated evidence and rigour to support this CMOC as trustworthy.

CMOCs support, refute or refine an IPT or build a new PT?:

Two IPTs (IPT B and IPT C) related to these CMOCs and were further refined:

- IPT B: *“By making changes to the intervention local decision makers may see the compatibility and relative advantage of the intervention for their setting leading to buy-in and support for the intervention and implementation”*
CMOC 5.1 and 5.2 aids refinement of this IPT. The original IPT discusses how by making changes to the intervention compatibility and relative advantage may be seen by local decision makers. However this was refined further in that making changes to the intervention *and also* using a data driven approach to demonstrate whether these changes were effective led to positive visibility of results, such that relative advantage could be seen by local decision makers. This positive visibility of results led to motivation and pride in achievements and resultant support and buy-in for the intervention.
- IPT C: *“By giving autonomy to local decision makers they may feel valued and respected leading to buy-in and support for the intervention and implementation”*
In the original IPT it was suggested that by giving autonomy, local decision makers may feel valued and respected. This was found to be the case in one CE, however there were further details of specific resources that may contribute to this and so the IPT was refined. In CMOC 5.3 it appeared that ownership of the data and results, with local decision makers directly reporting positive results themselves, assisted feelings of autonomy. In addition to this, further resources such as reducing the presence of the scale-up team at later sites also contributed to this autonomy. Thus when a data driven approach was used with local decision makers being given ownership of the data, this led to a context of autonomy, leading to local decision makers feeling valued, respected and empowered and thus contributing to buy-in and support for the intervention and implementation.

Further evidence or theory for PT:

- Rogers' diffusions of innovation theory (53) specifically the relative advantage of an innovation where what is new is seen as better than what was in place before, can further support this PT. When local decision makers see the positive results in the data through testing of an adaptation the relative advantage is seen leading to motivation and buy-in and support for the intervention and implementation. This theory supports this part of the finding.

PT5. How LDM Works in the Context Using Data to Assess Progress and Inform or Evaluate Adaptations
Thought process for PT:
A consolidated explanation is built on the different aspects of using a data driven approach to support LDM for adaptations during scale-up. A key building block for use of this approach is consideration of capacity to select and train in approaches to support use. This refines two IPTs (IPTB and IPTC) and also builds in new elements of need for capacity considerations when using a data driven approach. This PT appears to have trustworthy evidence sources and be coherent and plausible based on substantive theory.
PT5. The use and analysis of local data by local decision makers to inform adaptations and/or for evaluating adaptations when scaling-up can create an awareness of local needs and an awareness of whether adaptations made were effective. Local decision makers can be motivated by seeing positive changes in data demonstrating a relative advantage of the intervention and adaptation, as well as experience pride in these achievements, leading to buy-in and support for the intervention and implementation. When local decision makers feel autonomy and ownership over the data and process, this can lead to empowerment through feeling valued and respected, resulting in further buy-in and support for the intervention and implementation. In settings where there may be capacity limitations and no history of data-driven approaches, consideration needs to be made in the selection of suitable data-driven approaches, based on capacity at local level. Considerations based on existing capacity could include whether capacity building and ongoing support are needed for the empowerment and participation of local decision makers to use a data-driven approach to support LDM

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example

PT6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM

While local knowledge was important for LDM, this alone may not be enough for implementing and adapting an intervention. This research found local knowledge needed to be supplemented with awareness and knowledge of the intervention components (which could be in the form of intervention theory, core elements, components, functions or minimum standards), in addition to awareness and knowledge on how to implement and adapt the specific intervention (see CMOC 6.1, Table 6.8). Therefore two important resources identified were: (i) clarity of intervention content, with intervention theory, core elements, components, functions or minimum standards identified and accessible guidance given to sites and (ii) accessible guidance on how to implement and adapt the specific intervention given to sites. Together these contributed to the mechanism of local decision makers gaining awareness and knowledge of what was essential and what was flexible within the intervention for adaptation, along with how to implement and adapt accordingly. This awareness and knowledge, combined with local tacit knowledge, led to sensemaking and problem-solving for adaptations for local fit for local contexts. Sensemaking for the purpose of this research was understood as giving meaning to circumstances by forming a plausible explanation based on local understanding, which can lead to a proposed action (344, 347). Problem-solving was understood as finding solutions to difficult or complex issues (348). An overview of CMOCs relating to the importance of guidance on the intervention components and on how to implement and adapt for local decision makers be seen in Figure 6.10.

In addition, providing guidance on intervention content or on implementation and adaptation of the specific intervention reportedly led local decision makers to feel encouraged and empowered, through flexibility to adapt, capacity building, and knowledge to make adaptations (see CMOC 6.2, Table 6.8). This was particularly noted with multiple CEs reporting at frontline provider level, and one CE at community level (see CMOC 6.2, Table 6.8). Feelings of encouragement and empowerment could then lead to buy-in and support, with local decision makers developing their own specific individualised plans for their health facility, district, or region. An overview of this CMOC is included in Figure 6.10 and an example of how guidance supported LDM is summarised in Box 6.3.

The potential consequence of a lack of guidance for implementation and adaptation of the specific intervention, in particular in the context of an under-resourced health system, was also identified. In this context, and despite provision of guidance with clarity of intervention content, an absence of further adequate guidance on the implementation and adaptation process led to staff feeling overloaded. This in turn, reduced buy-in and support, with reactive rather than proactive responses

to challenges by frontline providers (please see CMOC 6.3, Table 6.8). Therefore, in settings where both guidance on intervention components and guidance on how to implement and adapt the specific intervention are provided, particularly in under-resourced settings, guidance can assist in contributing to sensemaking and problem solving with adaptations for local fit, resulting in buy-in and support for the intervention and implementation.

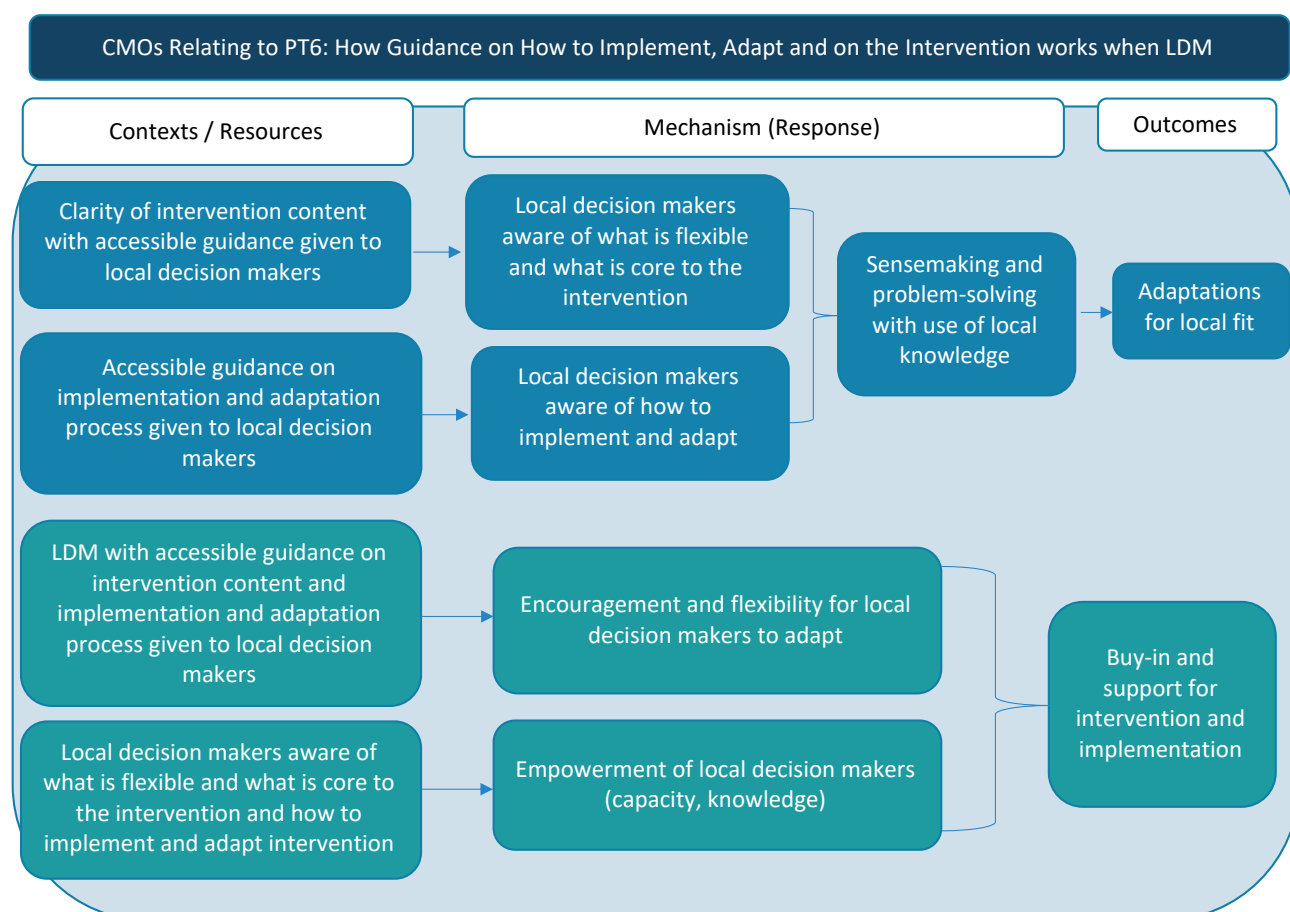


Figure 6.10 Overview of Resources, Contexts, Mechanisms and Outcomes relating to How Guidance on How to Implement, Adapt and on Intervention Components works when LDM

As previously noted within the wider subset of CEs (Chapter 5, Section 5.3.9, Action 2), the range of formats of guidance on the intervention content varied across manuals, workbooks, trainings, workshops, fidelity checklists and revision of intervention components in meetings. The guidance for the implementation and adaptation process was also reported in many forms with: workshops, workbooks, programme rules, and use of standardised IT systems etc. Notably, two CEs specifically referenced implementation and adaptation guidance that was not prescriptive, but which instead gave prompts for reflection to local decision makers on how and what may apply for their setting (CE5, CE8), for example through a workbook with questions for implementers. Both of these CEs reported that local decision makers developed individualised action plans for their setting. Conclusions could not be drawn however, on what format of specific guidance and technical support types may work in

given settings, as despite examples of numerous formats of guidance given, specific evaluations of the different types had not been completed. Consequently, minimal conclusions can be made as to which of the different type(s) of guidance and supports may be best in different settings, and how and why they may specifically work. That said, the need for the guidance to be accessible to the local decision makers was found. Accessibility of guidance is particularly important in contexts where community level providers, with varying backgrounds of educational achievement, may be adapting an intervention and where for example the use of primarily written guidance manuals may limit accessibility (please see CMOC 6.4, Table 6.8).

Box 6. 3 Clarity of Intervention Content and Guidance on the Implementation and Adaptation Process for Local Decision Makers

In CE10, KMC was scaled in four regions in Ghana. Both the intervention and style of LDM was new to this context. A steering committee approach was used with regional, district (and in some cases institutional) committees formed to develop and drive individualised action plans for their setting. A phased approach was also used where training was given through workshops with training on the intervention components of KMC and guidance provided on implementation and development of contextually specific action plans. Through workshops, sites shared learning with each other. An ethos of the approach used was to avoid having a rigid 'bible' of implementation and instead local decision makers were supported to reflect and problem-solve on the needs of their local area. An example of how this was delivered was that workbooks were used that were not prescriptive but instead had questions for local decision makers to ask themselves for their local setting. Through building capacity and knowledge on the intervention and options for implementation and adaptation, local steering committees were encouraged and empowered to develop their own action plans. This allowed for sensemaking and problem-solving with local tacit knowledge. The evaluation for this scale-up was also completed by trained peers who provided a further contact point for support with constructive written feedback given to sites at time of evaluation. This scale-up took place within a one year period, after which implementers had achieved buy-in and support with individualised action plans, mobilisation of resources for KMC at majority of sites, and high rates of implementation observed, with over two-thirds of sites demonstrating evidence of practice of the intervention.

This resulted in the following understanding of how guidance on intervention content and on how to implement and adapt can support LDM (more details with supporting CMOCs and evidence can be seen in Table 6.8);

PT6. *When local decision makers are provided with accessible guidance on intervention content, along with accessible guidance on the implementation and adaptation process for the intervention, this can create awareness on what is flexible and what is core to the intervention and ways in which to implement and adapt the intervention with fidelity. This knowledge can then be combined with local tacit knowledge for sensemaking and problem solving towards adaptations for local fit. Choosing an*

LDM approach with provision of guidance to sites gives encouragement and flexibility to adapt, along with supporting knowledge and capacity building, for local decision makers. This can empower local decision makers, particularly at frontline level, to make adaptations, contributing to buy-in and support for the intervention and implementation. Counter to this, a lack of guidance, particularly in under-resourced health systems, can lead to local decision makers feeling overloaded, causing reduced buy-in and support for the intervention and its implementation.

Table 6.8 Supporting Evidence for PT6 - How Guidance on How to Implement, Adapt and on Intervention Components supports LDM. Adapted from (305)

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM			
CMOC 6.1 Guidance on intervention, implementation and adaptation for adaptations for local fit			
Contexts / Resources R1: LDM with clarity of intervention content with accessible guidance given to local decision makers R2: Accessible guidance on how to implement and adapt given to local decision makers	Mechanisms (Response) M1: Local decision makers aware of what is flexible and what is core to the intervention M2: Local decision makers aware of how to implement and adapt M3: Sensemaking and problem solving (use of local knowledge with knowledge of above)	Outcome O: Adaptations for local fit	Resulting CMOC: When there is LDM, having clarity of intervention content (with intervention theory, core elements, components, functions or minimum standards) and accessible guidance on how to implement and adapt the specific intervention given to local decision makers can lead to awareness of what is flexible and what is core to the intervention and of how to implement and adapt, this can then be combined with local knowledge for sensemaking and problem solving to make adaptations for local fit.
Thought process for CMOC: Clarity of intervention content appeared central to many CEs with intervention theory, core elements, components, functions or minimum standards identified and shared with sites which allowed for local decision makers to be aware of what is flexible and what is core to the intervention. In addition to this, the importance of accessible guidance on how to implement and adapt the specific intervention being shared with sites was highlighted (this was specifically present in CE8, CE10 and CE20). For this CMOC the mechanism of awareness, for example of what was flexible and what was core to the intervention was referenced either directly or indirectly by the case examples e.g. with providers through intervention theory and core components guidance being aware of the 'internal logic' of the intervention (p7) (239). The concept of sensemaking was either directly referenced e.g. "scaled up what made sense to them" (p79) (16) or problem solving alluded to, for example "creativity and initiative among local stakeholders to find local solutions" (p112) (228). For the outcomes of adaptations for local fit examples were given in numerous case studies. For example in CE17 frontline providers based in CBOs who know the context reported numerous adaptations for cultural context, for example substituting video content which was deemed not appropriate for the target group. Unfortunately as no formal fidelity monitoring was carried out in the majority of these case examples (with the exception of CE17 who completed self-reported fidelity assessment (62, 239)), there was not enough evidence for the synthesised CMOC to include adaptations with fidelity to core components as an outcome. Therefore it was kept as adaptations for local fit only.			
Source: CE5, CE8, CE10, CE16, CE17, CE20 Supporting quote: <i>"Staff at all levels of the CBOs who had a deeper understanding of the intervention were substantially more able to implement it with fidelity than were those who did not fully understand it. A lack of knowledge about the intervention affected analysis of the community, subsequent solutions, prioritization of tasks by front line staff and the abandonment of core elements and guiding principles originally designed to support the intervention ."</i> (p5) (280)			
Considerations of rigour for this CMOC: Multiple case examples contributed to this CMOC. The type of evidence from each varied. For CE8 (16) and CE16 (238) the information relating to this CMOC appeared to be primarily reflections from authors/implementers. For CE5 (228) this source included informants from the district level who made decisions on adaptations. For CE16, the key article for development of this CMOC (238) did not provide details on how the article was developed and was written with reflections from technical experts on the intervention. However, a further article (207) which carried out evaluation at two sites with multiple data			

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM			
sources and key informants at different levels provided some further support for this CMOC for this case. For CE17 (62, 239) the key source was from data from surveys and interviews with providers on their experience adapting the intervention and using guidance and support (280). There was cumulation of evidence from multiple sources which were appropriate for the level of the finding. For CE20 (250, 271), this was based from the Western Cape provinces experience of use of standard processes, programme rules and IT systems to assist scale-up with openness for local sites to adapt adherence approaches. These sources (250, 271) used operations research data which had included key informants at health provider level. Considering the cumulation of evidence sources this CMOC could be considered as trustworthy.			
CMOC 6.2 Guidance, Empowerment and Buy-in for Intervention			
Contexts / Resources R: LDM with accessible guidance on intervention content and/or how to implement and adapt given to local decision makers C: Local decision makers aware of what is flexible and what is core to the intervention and of how to implement and adapt intervention	Mechanisms (Response) M1: Encouragement and flexibility for local decision makers to adapt M2: Empowerment of local decision makers (capacity, knowledge)	Outcome O: Buy-in and support for intervention and implementation	Resulting CMOC: When there is LDM with accessible guidance on intervention content and/or how to implement and adapt, this leads to local decision makers feeling encouraged with flexibility to adapt for their setting. Local decision makers are empowered through developing capacity and gaining knowledge on intervention content and how to implement and adapt. When LDM occurred at community level there was also empowerment through community members opinions feeling valued. This contributed to buy-in and support for intervention and implementation with development of adaptations and specific plans for local settings
Thought process for CMOC: A specific CMOC was warranted (in addition to CMOC 6.1 above) on how giving guidance to local decision makers could lead to buy-in and support. For CE5, CE8, CE10 this occurred mainly at district or local authority level, for CE11, CE17, CE20 (Western Cape area), CE21 and CE22 this was specifically referenced for frontline providers, with empowerment to develop local solutions at this level. At CE8 they also specifically referenced empowerment of community members to drive local solutions leading to buy-in and support. While the specific guidance varied between CEs the commonality was one of building knowledge and capacity of local decision makers, along with encouragement to adapt which led to empowerment of local decision makers and contributed to buy-in and support for the intervention and implementation. For example in CE10 they discussed how guidance was developed with questions for local decision makers rather than a rigid implementation plan to follow to allow for reflection and problem solving to develop their own local action plans. In CE8 they noted that local decision makers were given clarity of intervention components along with options of implementation processes e.g. training regimes. Districts were then empowered by being encouraged to select what made sense to their setting in development of district specific plans.			
Source: CE8, CE10, CE11, CE18, CE20 (Western Cape), CE21, CE22 Supporting quote: <i>"..through these processes, programme rules evolved, such as the standardisation of the information system for the province. However, individual sites were also encouraged to experiment with different approaches: "Local managers and clinical coordinators have proven to be well-informed regarding the most appropriate choices to be made and it has been possible to capitalise on this local knowledge". In contrast to the Free State, the Western Cape sites evaluated in the models of</i>			

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM			
<i>care study not only expressed a variety of individual delivery methods and routines, they were also more likely to modify or try out new approaches as problems were confronted and services evolved.” (p8) (250)</i>			
Considerations of rigour for this CMOC: Numerous CEs contributed to this CMOC with varying considerations. To note for CE8 the article (16) was written from perspective of those leading the scale-up with some overall health outcome data from MoH and thus did not appear to have direct contribution from local decision makers. A proxy outcome of buy-in and support could be taken from reporting of districts developing their individualised action plans following period of reflection and analysis. For CE5 (228) this was based on qualitative data from key informants at local authority level in combination with reflections from the scale-up team. For CE10 (231) the mechanisms of empowerment through capacity building (including workshops, workbooks) was inferred from an article written by implementation team (231). Overall this CE10 had relatively high rates of implementation seen in its evaluation to show the outcome of buy-in and support (231). For CE17 the key sources for this CMOC (62, 239) involved survey and interviews directly with frontline providers on their experiences adapting the intervention. CE18 also emphasised the importance of guidance and the key source had qualitative inputs from multiple levels of informants (241, 242). For CE20 (250, 271) this was based from the Western Capes experience of use of standard processes, programme rules and IT systems to assist scale-up with openness for local sites to adapt adherence approaches, these sources used operations research data which had included key informants at health provider level. For CE22 multiple data sources (256, 307, 338, 339) contributed to this CMOC, with the two key papers for this CMOC (256, 338) being a case study/reflections paper by lead implementers. However this finding was also further supported by a Delphi study who gained consensus from multiple levels of stakeholders (339). Further to this an ethnographic study had observations of community engagement and sense of belonging through involvement which further supported the outcome found in the case example (307). The majority of CEs had input from local decision makers in source documents to support mechanisms, and proxy indicators of buy-in and support. This CMOC with accumulation of evidence could be considered trustworthy.			
CMOC 6.3 Lack of Implementation and Adaptation Guidance in Under-resourced Health System			
Contexts / Resources C1: LDM in under-resourced health system C2: Absence of adequate implementation/adaptation guidance	Mechanisms (Response) M1: Lack of knowledge of organisational processes for implementation or adaptation M2: Staff feeling overloaded	Outcome O1: Reduced buy-in and support for intervention and implementation O2: Reactive instead of proactive response to challenges	Resulting CMOC: In under-resourced settings where health systems are under strain prior to implementation of the intervention, when there is an absence of adequate implementation or adaptation guidance this can leave frontline providers feeling overloaded and reduce motivation and support for the intervention. It may also contribute to reactive instead of proactive approaches to problem solving for the intervention.
Thought process for CMOC: In CE19 (245, 330) they discussed that the guidance on adherence club components was clear and outlined for sites, but what was missing was organisational guidance allowing for the complexity of the health system. In addition to this, there was a lack of shared learning between sites and what was happening on the ground in realities of the health system. This lack of guidance in a system where frontline staff were overloaded contributed to a negative tipping point with reduced buy-in and support from some staff for the intervention and reactive instead of proactive approaches to challenges faced. This may also have led to successful innovations at local sites for these health system challenges not being spread. Counter to this, within another under-resourced health system CE8 highlights the benefits of having both guidance on clarity of intervention content and on the process for organisational change to contributing to success of districts making their own plans. Two stakeholders who were involved in LDM helped to situate this CMOC further Both reported insufficient guidance on how to			

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM			
adapt (S2, S4) and on intervention components (S4). However both were based in contexts where they reported that resources such as designation of non-clinical time to work out how to approach the adaptation, adequate staffing and capacity and skills embedded within the team assisted this lack of guidance. While some frustration was reported with lack of guidance, the resources in place in these HIC settings meant that they did not report feeling overloaded or overwhelmed, the adaptation just took longer to complete. Therefore this context of under-resourced settings was identified as key to triggering of the mechanism.			
Source: CE19, CE8, S2, S4 Supporting quote: <i>"The SOPs for the club model outlined the functioning of clubs very proficiently, adequately informing a roll-out phase for starting clubs afresh in a facility, and detailing the methodology for supporting mutual learning across new facilities in waves of adoption. However, organisational protocols did not explicitly account for adaptations to consider the smooth functioning of the model at a significant scale, as more clubs were added per facility. Documentation had not evolved to produce an output informed significantly by what was happening 'on the ground' and to distinguish the distinctive requirements of 'roll-out' and 'scale up'. The extent of creativity, solution-finding, and emergent spin-off innovations appeared impressive, but a systematic sharing of such learning across the service platform had also waned. A senior WCDoH policy-maker indicated that requests for information about clubs were coming in from other provinces, but the documentation required updating: "We need to reflect on the challenges as well". This kind of synthesis of learning is vital to inform diffusion of the club model, both geographically, but also to other chronic disease groups."</i> (p14) (245)			
Considerations of rigour for this CMOC: Key source (245) discussed in detail challenges of implementing within an overloaded health system and lack of guidance for organisational complexity and sharing of learning. Reduced buy-in and motivation for intervention as seen by proxy indicator of reduced motivation for recruitment to the adherence groups and implementation by staff (245, 330). The key source for this (245) appeared reliable with a mixed methods study of 12 facilities in Cape town area. Used observations, interviews (n=45) with recipients, frontline staff, local managers and senior policy-makers and managers, document review from AC club documents and policies, in addition to use of routine monitoring data. Data triangulated through multiple sources as described. Counter to this CE8 supports this CMOC by providing example of how guidance on implementation process supported implementation in another under-resourced health system, to note this source was perspective from the scale-up team (16). CMOC can be considered trustworthy. This was also further supported by S2 and S4 who identified a lack of guidance led to no clear process to follow however due to adequate resources the mechanism of feeling overwhelmed was not activated.			
CMOC 6.4 Accessibility of Guidance Limiting Use			
Contexts / Resources C: LDM by frontline providers or at community level. Varying education levels R1: Guidance on intervention components primarily in manuals in written format	Mechanisms (Response) M: Use of guidance materials limited by accessibility of education levels and learning styles	Outcome O: Limited use of written guidance by some providers	Resulting CMOC: When LDM is made at frontline provider or community level there may be varying levels of educational achievement. When guidance primarily is in written format its use may be limited by accessibility and learning styles
Thought process for CMOC: The accessibility of guidance may limit their use, particularly in contexts where those implementing intervention may have lower levels of education. There may also be preference of other learning styles to written formats. While there was an outcome of loss to fidelity reported in assessments (323) in some sites this could not directly be linked to accessibility of guidance and so was not added as outcome here.			

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM

Source: CE17, S5

Supporting quote: *“Written materials and limited training and TA are insufficient for effective translation of evidence-based interventions into practice ... Some CBO staff members dislike reading written materials, and staff who have relatively little education will often not use written materials extensively.”* (p185) (280)

TA=Technical Assistance

Considerations of rigour for this CMOC: This CMOC came from two sources specifically for the Mpowerment intervention. The key source (280) reported on specific issues faced during implementation which were put together through collaboration with intervention developers and CBOs implementing the intervention. They reported accessibility of guidance as one of these issues and reasons for limited use in some settings. Further to this, a baseline assessment of fidelity for Mpowerment intervention was used as source (323), with the methodological consideration of self-reported fidelity. S5 also supplemented this CMOC as they reflected the intervention content within their scale-up that was shared with sites was overly detailed and complex and could be overwhelming for providers. Overall evidence appears trustworthy for this CMOC.

CMOCs support, refute or refine an IPT or build a new PT?:

These CMOCs relate to two IPTs (IPT C and IPT D):

- IPT C: *“By giving autonomy to local decision makers they may feel valued and respected leading to buy-in and support for the intervention and implementation”*
Buy-in and support for the intervention and implementation was seen through provision of guidance to sites which encouraged and empowered local decision makers to adapt. In CMOC 6.2 above, feeling valued and respected was not necessarily highlighted, more so that through encouragement, developing capacity and knowledge this contributed to empowerment with buy-in and support. Thus CMOC 6.2 would refine this theory.
- IPT D: *“Participation of those that know the context elicits local knowledge allowing for sensemaking and problem solving leading to adaptations for acceptability or feasibility in local contexts”*
While suggested mechanisms in the IPT did seem to occur in some of the CEs, what was identified was the resources of guidance on intervention content and on the implementation and adaptation process for the intervention were important in creating a context which facilitated sensemaking and problem solving. This guidance led to awareness of what was flexible and what was core to the intervention along with knowledge on how to implement and adapt which *in combination* with local tacit knowledge led to sensemaking and problem-solving with adaptations for local fit. Thus CMOC 6.1 above refines this IPT.

Further evidence or theory for PT:

- Sensemaking theory (344, 347) which could be outlined as efforts to give meaning to circumstances by making plausible explanations based on retrospective framing and the development of actions based on presumptive assumptions of future patterns (344, 345). This could apply to the framing of the intervention within local tacit knowledge and development of plausible explanation of how it may work, or not work, in their setting, with further problem-solving to identify constructive solutions for local fit.

PT 6. How Guidance on How to Implement, Adapt and on Intervention Components supports LDM

Thought Process for PT:

The mechanisms of sensemaking and problem solving by those who know the context appeared central to the action of LDM (CMOC 6.1). While some CEs specifically used the wording of sensemaking i.e. “each district only scaled up what made sense to them” p79 (16), others inferred it through describing how local knowledge was applied to situations in order to problem-solve for constructive solutions (p8; (250)). While there is no agreed definition of sensemaking (347), for the purpose of this research it was understood as applying meaning to circumstances by forming a plausible explanation based on local understanding which can lead to a proposed action (344, 347). Problem-solving was understood to be finding solutions to complex problems (348). These mechanisms appeared to occur in the CEs cited above, with the important underlying resource of clarity of intervention components and guidance on how to implement and adapt leading to local decision makers having awareness of what is flexible and what is core to the intervention and how to go about adaptations, in order to further sense-make and problem solve with local knowledge for adaptations for local fit.

The provision of guidance, which led to encouragement and flexibility to adapt, in addition to the development of capacity and knowledge for adaptations, appeared to empower local decision makers, leading to buy-in and support. This empowerment was particularly noted at frontline provider level. The consequence of inadequate guidance was highlighted with it leading to staff feeling overloaded and reduced buy-in and support. This was particularly apparent in contexts of under-resourced health systems, as in contrast two stakeholders (S2, S4) from HIC settings reporting that due to available resources (such as non-clinical time given) and capacity (with skills embedded in their team) within their setting this did not lead to the mechanism of being overloaded or overwhelmed being triggered. In addition to this the importance of guidance being accessible, particularly when used at frontline provider and community levels was identified. The evidence sources for these CMOCs appear trustworthy. The arguments for sensemaking and problem solving with local knowledge are also coherent and in keeping with substantive theory (sensemaking theory (348)). The below PT could be considered coherent and plausible based on these findings.

PT6. When local decision makers are provided with accessible guidance on intervention content, along with accessible guidance on the implementation and adaptation process for the intervention, this can create awareness on what is flexible and what is core to the intervention and ways in which to implement and adapt the intervention with fidelity. This knowledge can then be combined with local tacit knowledge for sensemaking and problem solving towards adaptations for local fit. Choosing an LDM approach with provision of guidance to sites gives encouragement and flexibility to adapt, along with supporting knowledge and capacity building, for local decision makers. This can empower local decision makers, particularly at frontline level, to make adaptations, contributing to buy-in and support for the intervention and implementation. Counter to this, a lack of guidance, particularly in under-resourced health systems, can lead to local decision makers feeling overloaded, causing reduced buy-in and support for the intervention and its implementation

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example, S=Stakeholder

PT7. Impact of Who Provides the Guidance on LDM for Adaptations

There were some key findings in terms of *who* provides the guidance and how this may influence uptake and receptivity to it. This was particularly noted when there was a power imbalance between those who provided the training and local decision makers. Such a power imbalance could occur where trainers were from an agency linked to funding, with fear of negative repercussions if local decision makers were to reach out for support. Power imbalance could also occur when those providing the training were from higher levels of MoH management, in particular if they were not used to a LDM approach (please see CMOC 7.1, Table 6.9). Another finding of training and potential power imbalance was in the instance where training was coming from a top-down agency from outside the local decision makers' setting. In this case, local decision makers may not perceive the trainers as credible or having the relevant experience, affecting receptivity to learning sessions. This reportedly could be addressed through the selection of trainers with diverse experience in implementing the intervention and through dialogue demonstrating familiarity with issues seen in the local context, in order to build credibility with local decision makers and thus increase receptivity to learning in sessions (please see CMOC 7.3, Table 6.9). For others sites which were not funded by this agency, local decision makers reported a lack of awareness that these training supports were available to them, leading to a lack of use of supports, and adaptations occurring often on an ad-hoc basis, without documentation or evaluation (please see CMOC 7.2, Table 6.9). An overview of these CMOCs can be seen in Figure 6.11.

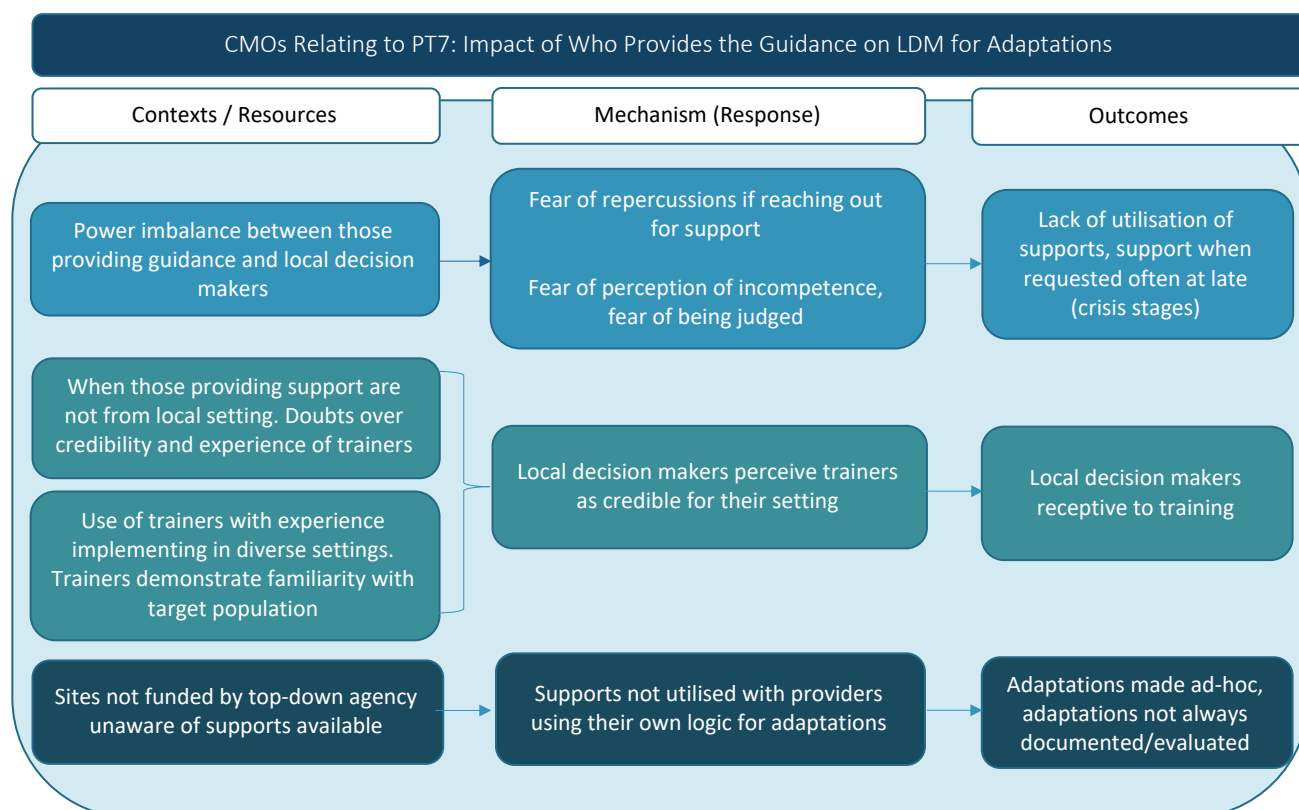


Figure 6.11 Overview of Resources, Contexts, Mechanisms and Outcomes relating to Impact of Who Provides the Guidance on LDM for Adaptations

This led to the following understanding of how who provides the guidance for LDM can influence its use (more details with supporting CMOCs and evidence can be seen in Table 6.9);

PT7. *Guidance on intervention content and on how to implement and adapt can assist in adaptations for local fit and promote buy-in and support for the intervention and implementation. However, who provides this guidance may influence its uptake and use. Where there is a power imbalance between those who provide the guidance and local decision makers, this power imbalance may result in fear of negative repercussions or fear of being perceived as incompetent by those in the position of power, leading to less uptake of guidance and support, or guidance being requested at late (crisis) stages. In addition, in the instance where an external agency provides guidance, there may also be a lack of awareness of available supports, leading to lack of their use. If guidance and support are provided by those not from the local setting, perceptions of credibility and lack of trust from local decision makers may influence receptivity. This can be mitigated by those providing guidance and support by demonstrating their experience relevant to the local setting, in order to build credibility and increase receptivity and uptake of guidance and support.*

Table 6.9 Supporting Evidence for PT7 - Impact of Who Provides the Guidance for LDM. Adapted from (305)

PT7. Impact of Who Provides the Guidance on LDM for Adaptations			
CMOC 7.1 Utilisation of Implementation Supports affected by Power Imbalance			
Contexts / Resources C1: LDM with power imbalance between those providing guidance and local decision makers	Mechanisms (Response) M1: Fear of negative repercussions if reaching out for support M2: Fear of perception of incompetence, fear of being judged	Outcome O1: Lack of utilisation of supports O2: Support often requested at late (crisis) stages	Resulting CMOC: When technical assistance is provided by a central agency who also provides funding there may be a power imbalance in place leading to fears of judgement and stigma of incompetence if reaching out for support, this can lead to reluctance to request and engage with technical assistance at all, or to request it at later (crisis) stages
Thought process for CMOC: Implementation supports were provided through a central agency (CDC) which affected uptake in CE17. This case reported on the scale-up of a range of HIV prevention interventions which were primarily implemented by CBOs. Training and technical support was provided by the CDC. There was low uptake of technical support reported. This was related to CBOs often being reluctant to reach out for fear of being perceived as incompetent by the CDC if having challenges implementing the intervention. CDC also noted that often when requests were received, it was at very late or at crisis stages. Overtime, CDC increased the supports available and in some cases provided proactive scheduled technical supports to reduce stigma of use. This was not particularly highlighted in LMIC contexts where funding agencies were linked to guidance and supports. Through stakeholder input (S1) the difference in context was highlighted with often this being the status quo in LMIC, with funding agencies delivering interventions and trainings, thus previous experience may have led to the mechanisms of fear of repercussions and being seen as incompetent not being triggered. However S3 further built upon this and identified when there is a power imbalance present in LMIC this may often not be external funding but from within MoH itself where a LDM is new. Thus when higher management from MoH is providing the guidance and training this may affect dynamics within the training for local decision makers.			
Source: CE17, S1, S3 Supporting quote: <i>“Organizations often delay in requesting TA. CBOs often delay seeking assistance with a problem until it has become a crisis... Sometimes organizations simply fail to identify a problem early on. On other occasions, they are reluctant to request assistance for some specific reason, such as a fear that their funder will learn of their difficulties. Thus, providing TA proactively is important.”</i> (p187) (280) TA=Technical Assistance			
Considerations of rigour for this CMOC: This was discussed in three documents for this case. For two of the documents it appeared to be reflections from the authors who were involved in the implementation and it was not clear if CBO staff contributed to this inference (62, 281). However in the article exploring issues relating to implementation of the Mpowerment intervention specifically, they reported the involvement of CBO staff in development of the findings for this inference along with intervention developers in a collaborative process of lessons learned (280). CMOC considered trustworthy.			
CMOC 7.2 Awareness of Supports Available			
Contexts / Resources C: Sites who are not funded by top-down agency unaware of supports available	Mechanisms (Response) M: Supports not utilised with providers using their own logic for adaptations	Outcome O1: Adaptations often made ad-hoc O2: Adaptations not always documented or evaluated	Resulting CMOC: When there is guidance and technical support on core elements available, however agencies are not directly linked to a central team, there can be a lack of awareness by local frontline staff of this guidance. This can lead to lack

PT7. Impact of Who Provides the Guidance on LDM for Adaptations			
		(unknown if positive or negative adaptations)	of use and frontline staff making adaptations based on their own logic in an ad-hoc basis with lack of documentation or evaluation of adaptations. The outcome of these adaptations is unknown
Thought process for CMOC: Overall a context of lack of awareness of technical support leading to lack of utilisation, often even when large changes made to intervention which were considered by intervention developers to be reinvention and would need re-evaluation. Core components known by some sites through the guidance materials but potentially not at all sites, often adaptations not evaluated or documented.			
Source: CE17 Supporting quote: <i>"At the time that this study was conducted, few of the agencies that were directly or indirectly funded in Los Angeles, California were aware of such available resources" (p3) (239)</i> <i>"None of the staff making these changes referenced contacting a technical assistance provider about the reinventions during implementation. " (p7) (239)</i>			
Considerations of rigour for this CMOC: Key source (239) was a qualitative study self-reporting on fidelity. Perspective of frontline providers directly reported. While self-report bias was considered, as negative findings were reported data most likely trustworthy for this CMOC.			
CMOC 7.3 Guidance and Support – Perception of Who is Delivering Guidance			
Contexts / Resources C: When those providing support are not from local setting. Doubts over credibility and experience of trainers R: Use of trainers with experience implementing in diverse settings. Trainers demonstrate familiarity with target population	Mechanisms (Response) M: Local decision makers perceive trainers as credible for their setting	Outcome O: Local decision makers receptive to training	Resulting CMOC: When training is provided by central agencies there may be some hesitations over credibility of the trainers in local community settings. However through use of trainers with experience implementing in diverse settings who can demonstrate their experience in training sessions this may lead to frontline providers trusting and viewing them as credible and being more receptive for learning in sessions
Thought process: In CE17 the perceived credibility of trainers was discussed to affect receptivity to learning in sessions by frontline providers. This was mitigated through use of trainers with experience implementing intervention in diverse settings. Through dialogue in sessions of their experiences this led to frontline providers feeling trainers as credible and were more receptive to training.			
Source: CE17 Supporting quote: <i>"In the MPTES, all the trainers were program staff who had coordinated the MPs during the trials and had implemented the program at CBOs subsequently, or the researchers who developed and supervised the original intervention. Hence the trainers had substantial experience with the program and could easily discuss implementation challenges and solutions. This is particularly important with an intervention that is not very scripted. But it may also have been important with respect to affecting the perceived credibility of the program by implementers. Indeed, there often was some suspicion at the start of trainings about the extent to which the trainers "really knew" about the intervention and the target population. As those concerns were allayed, it seemed that trainees were more receptive to learning from the trainers, particularly as adaptation issues are discussed and familiarity with issues facing young ethnic/ racial minority men who have sex with men is displayed." (p196) (280)</i>			

PT7. Impact of Who Provides the Guidance on LDM for Adaptations
Considerations of rigour for this CMOC: This appeared to be perspectives of implementing team/authors (some of which were trainers) in discussion. To note this section did not have direct quotes from CBO staff on their perceptions, however CBO staff were interviewed for this study (280). Given this CMOC can also be supported by substantive theory in Rogers' diffusions of innovation theory (53) if the concept of credibility is applied to those providing information on the intervention affecting adoption, while the data source could be strengthened in terms of trustworthiness, the argument could be considered as coherent.
CMOCs support, refute or refine an IPT or build a new PT?:
New PT
Further evidence or theory for PT:
• The Theoretical Domains Framework (TDF) (346), specifically the 'beliefs about consequences' domain could support this theory in how fear of negative repercussions may affect behaviour and lead to lack of uptake of guidance and support • Rogers' diffusions of innovation theory (53), if the concept of credibility is applied to those providing the information on the intervention this may affect receptivity and adoption.
Though process for PT:
While PT6 emphasised the importance of guidance, there were further findings in how <i>who</i> provided the guidance could impact its use which warranted further theory development. In CMOC 7.1 a power imbalance in terms of who provides the guidance was identified as an issue, with fear of negative repercussions if reaching out for support. The TDF (346) domain of 'beliefs about consequences' would further support this CMOC finding. For this example they noted that the power imbalance was due to agency being linked to funding. Interestingly this was not particularly found in LMIC examples, with stakeholder input assisting in potential explanation for this with LMICs having ongoing external funding agencies coming in to deliver supports and training and thus previous numerous experiences with this may have mitigated any fear of negative repercussions if using supports (S1). However within LMIC a power imbalance may be present if guidance provided by higher levels of management within MoH itself who are not used to a LDM approach and may be dismissive of local decision makers taking ownership and generating ideas (S3). The mechanism of belief of credibility of those providing the guidance was seen to be important with potential issues mitigated through use of dialogue in training sessions where trainers demonstrated their experience of implementation in similar diverse settings, thus building credibility with the local decision makers and receptivity to learning. This finding could be further supported by substantive theory, specifically Rogers' diffusions of innovation theory (53) in relation to credibility thus the argument could be considered as coherent. This PT could be considered coherent and plausible.
PT7. Guidance on intervention content and on how to implement and adapt can assist in adaptations for local fit and promote buy-in and support for the intervention and implementation. However, who provides this guidance may influence its uptake and use. Where there is a power imbalance between those who provide the guidance and local decision makers, this power imbalance may result in fear of negative repercussions or fear of being perceived as incompetent by those in the position of power, leading to less uptake of guidance and support, or guidance being requested at late (crisis) stages. In addition, in the instance where an external agency provides guidance, there may also be a lack of awareness of available supports, leading to lack of their use. If guidance and support are provided by those not from the local setting, perceptions of credibility and lack of trust from local decision makers may influence receptivity. This can be mitigated by those providing guidance and support by demonstrating their experience relevant to the local setting, in order to build credibility and increase receptivity and uptake of guidance and support.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example, S=Stakeholder

PT8. How Peer Learning can Support LDM when Scaling-up

The potential of cross-site learning between peers to rapidly spread successfully tried and tested adaptations between sites was identified (see CMOC 8.1, Table 6.10). Two primary approaches which supported this cross-site learning were: the use of formalised meetings for in-person learning, and development and dissemination of resource packages. Formalised meetings, for example in the form of learning collaboratives, allowed sites to meet after testing their own ideas to share learning with each other. These meetings were reported to provide a 'marketplace' (p43) (257) which allowed for best practices to be shared and utilised by other sites facing similar challenges (CMOC 8.1, Table 6.10). In addition to this, and particularly referenced in mid and later stages of scale-up (252), was the development and dissemination of resource packages which identified successful ideas and created how-to guides for later sites to utilise, as needed. This led to local decision makers gaining an awareness of what worked in other sites and an ability to utilise and select approaches from this bank of knowledge. It was reported that the uptake of previously tested ideas led to reduced resources and time needed in later stages to develop new ideas (see CMOC 8.1). An overview of this CMOC can be seen in Figure 6.12.

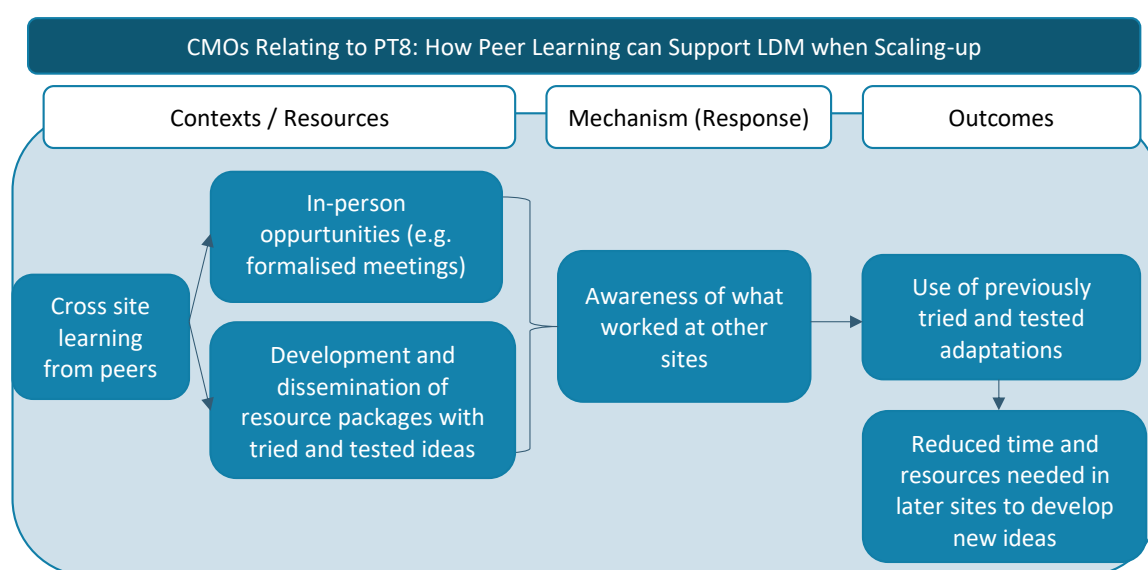


Figure 6.12 Overview of Resources, Contexts, Mechanisms and Outcomes of How Peer Learning can Support LDM when Scaling-Up

This led to the following understanding of how peer learning can support LDM during scale-up (more details with supporting CMOCs and evidence can be seen in Table 6.10);

PT8. *When strategies are used to facilitate cross-site learning to share tried and tested successful adaptations, such as formalised meetings between sites and development and dissemination of resources e.g. change packages demonstrating successful ideas, this can lead to local decision makers*

in future sites having awareness of what previously worked and using compatible ideas for similar challenges within their own sites. This can lead to reduced time and resources needed in later stages of scale-up, as shared learning of what worked occurs.

Table 6.10 Supporting Evidence for PT8 - How Peer Learning can Support LDM when Scaling-Up. Adapted from (305)

PT8. How Peer Learning can Support LDM when Scaling-up			
CMOC 8.1 Peer Learning of Tried and Tested Ideas			
Contexts / Resources Cross-site learning from peers through: R1: In-person opportunities such as formalised meetings (e.g. BTS, learning collaboratives) to share tried and tested ideas R2: Development and dissemination of resource packages with tried and tested ideas	Mechanism (Response) M: Awareness of what worked in other sites	Outcomes O1: Use of previously tried and tested adaptations O2: Reduced resources and time needed to generate new adaptations in later stages	Resulting CMOC: When cross-site learning occurs through formalised meetings (e.g. in the format of learning collaboratives) and through development of resources of tried and tested adaptations (e.g. resource packages, newsletters) which are spread to future sites, this can lead to an awareness of what worked in other sites with spread of these successful adaptations in future sites, leading to reduced resources and time needed to develop and test new ideas.
Thought process for CMOC: Two CEs (CE11, CE21) gave details on how tried and tested successful adaptations were shared with other sites leading to an awareness of what worked, where future sites facing similar challenges could utilise the same approaches. In CE21 they referenced less need for resources and innovation in later stages with a focus on sharing these solutions as part of a change package called the national accelerated plan (A-Plan)(259) instead of continuing with Breakthrough Series Model (BTS) (see Ch 5, Action 8 for more details) at all sites (252). In CE11 they also utilised change packages in later stages (232). In CE11 they particularly referenced how the formalised QI process of learning collaborative with meetings to share learning created a 'marketplace' (p43) (257) which allowed for best practices to be shared.			
Source: CE11, CE21 Supporting quote: <i>"Sharing learning across sites was key to identifying high-impact changes, which were then scaled up across multiple settings. Even then, adaptation and innovation continued as new teams were encouraged to adapt changes from the Change Package to fit their local context."</i> (p44) (257)			
Considerations of Rigour for this CMOC: For CE11 change packages can be seen that were developed and updated after each phase (232), this included those for community and hospital based care so sites could use what applied to them. The outcome of reduced input over time was demonstrated by reduced need for site visits in later phases in the implementation outcome study by Twum-Danso et al., (232). For CE11 while not specific to peer learning they did also show positive wider outcomes of engagement of QI processes as seen in implementation study (232), and wider health outcomes (e.g. reduction under 5 mortality) achieved in an outcome study with use of routine data (317). In CE21 the A-plan was developed in later stages as a how-to guide which supported later sites (252). A key source (252) describes how this A-plan was utilised in future sites along with data driven tested to see if effective locally. CMOC trustworthy for this inference.			
CMOCs support, refute or refine an IPT or build a new PT?:			
CMOC relates to IPT E: IPT E: <i>"Involvement of those on the ground who know the context may lead to an awareness of needs in real time as contexts change with reduced time taken for decision making. This may lead to time sensitive adaptations for acceptability or feasibility as contexts change"</i>			

PT8. How Peer Learning can Support LDM when Scaling-up
This IPT focused on how LDM can reduce time for decision making and lead to awareness of needs in real time. For CMOC 8.1 it did not provide evidence of how LDM assisted awareness of needs in real time, however there was evidence for when cross-site learning was facilitated it can lead to reduced time needed and less resources in later sites, as previously tested ideas are spread to sites facing similar challenges. Thus this CMOC would refine this PT.
Further evidence or theory for PT:
Rogers' diffusions of innovations theory (53), specifically of how observability, relative advantage and compatibility with needs could be seen. These elements were not specifically noted in these studies and so are hypothesised.
Thought process for PT:
For both CEs a qualitative perspective from local decision makers as to what elements led them to using these tried and tested ideas would have strengthened this PT. Rogers' diffusions of innovations theory (53), can hypothetically provide some explanation and build a coherent argument with successful ideas showing relative advantage and observability of benefit to local decision makers, with potential compatibility of the ideas seen with similar challenges faced in their local sites. However these were not specifically stated in the sources for the CE's. However, what was reported was the sharing of tried and tested ideas which was successful leading to reduced time and resources needed in later stages, thus providing a time-sensitive approach to support LDM which aided refinement of IPTe.
PT 8. When strategies are used to facilitate cross-site learning to share tried and tested successful adaptations, such as formalised meetings between sites and development and dissemination of resources e.g. change packages demonstrating successful ideas, this can lead to local decision makers in future sites having awareness of what previously worked and using compatible ideas for similar challenges within their own sites. This can lead to reduced time and resources needed in later stages of scale-up, as shared learning of what worked occurs.

R=Resource, C=Context, M=Mechanism Response, O=Outcome, CE=Case Example

6.3 Discussion Phase Three

LDM for adaptations during scale-up occurs in complex systems, within a wider cultural and socioeconomic context, with varying levels of capacity, and often in tandem with numerous other approaches. The CMOCs (objective 3.1) and PTs (objective 3.2) identified through this study demonstrate the complexity at play when utilising LDM as an approach for adaptations during scale-up. Implementers may select to use an LDM approach during scale-up of health interventions or may be compelled to do so through existing health system structure or given resource constraints. In both situations there are numerous considerations for LDM for adaptations during scale-up, which were highlighted in resultant PTs and are discussed below with reference to relevant substantive theory. This discussion also provides practical considerations for implementers when using a LDM approach for adaptations during scale-up. Following this discussion, an MRT is proposed (in fulfilment of objective 3.2).

6.3.1 Weighting of Evidence for CMOCs

While some CMOCs and PTs drew from multiple sources (e.g. PT6), others came from one or two sources (e.g. PT1). Consideration of rigour and the weight of evidence for each PT was made, with adjudication (3, 42) used as a conceptual tool to assist this. As this review primarily identified case reports of scale-up - with the evidence of interest generated primarily by qualitative input or reflections of implementers and any quantitative evidence (i.e., health outcomes) not of direct relevance to LDM and the CMOC - this led to a primarily qualitative evidence synthesis. Thus, a count of frequency of times a context or mechanism was mentioned did not necessitate importance. Instead, in addition to regularity of a finding consideration was given to whether the finding came across as important to how LDM works (i.e., did major impact occur because LDM was utilised?). For example, in the case of PT1, where the wider beliefs of the community led to adaptations with a loss to fidelity. Here, the context of where the an intervention did not align with the social norms, values and beliefs of the wider community and resultant mechanism was weighted as important irrespective of the number of sources that reported on this given the impact of loss to fidelity to the intervention being identified (PT1, Table 6.3). For other PT's, multiple sources may have reported a similar context and mechanism configuration, thus showing demi-regularity, however this alone did not quantify importance. For example, in PT6, numerous sources cited how guidance on intervention components and guidance on how to implement and adapt supported LDM. However it was not necessarily this frequency alone that was considered when developing and refining PTs, but also if there were important impact which may have occurred as a result. For example many also emphasised this guidance as critical to success, or how absence of guidance led to poor outcomes (PT6, Table 6.8).

Thus, not only was demi-regularity observed, there was also importance placed on the findings from the sources. For each PT transparency was provided through documentation and inclusion of the thought process and considerations of rigour as summarised in each PTs supporting evidence table.

6.3.2 LDM Occurs within a Wider Context

Despite autonomy being given locally, it is important to consider that decisions are made within a wider political, cultural and socioeconomic context. Where perceived intervention incompatibility, or a lack of understanding of the intervention and the importance of all components is present among those in positions of power, such as funders and religious leadership, these can exert pressures on local decision makers to deliver an intervention with certain components removed. These findings are consistent with role conflict theory (343), which offers a useful explanation of these findings. Specifically, where there is a reliance on local funding and support local decision makers often had to balance intra-role conflict (343) between the demands and expectations of the wider community, including local leadership and funders, with that of intervention delivery with fidelity, with potential consequences of not following requests or demands from those in positions of power. Similarly, the theoretical domains framework (TDF) (346) identified that ‘beliefs about consequences’ can affect implementation, as was the case where fear of negative repercussions, such as loss of funding, led some local decision makers to remove core components of interventions. This finding is also in line with the Consolidated Framework for Implementation Research (CFIR) (175, 195), where factors relating to the outer setting of the wider context can affect implementation, along with the broader scale-up literature which identifies the importance of consideration of the wider context (12, 13, 24, 40, 41, 52, 123-127, 129, 133, 134, 147, 176, 194-196). Therefore, if LDM is to be chosen as an approach in culturally conservative contexts, or when there is a reliance on external funding, an important consideration is whether this intra-role conflict and beliefs of negative consequences can be mitigated. In order to ensure that the intervention is viewed as compatible within this wider context (for example by religious leadership), desensitisation approaches (197) and ensuring that the intervention aligns with cultural beliefs, where possible, through adapting language used (while keeping core components intact) (197), for example, have been suggested during scale-up. To increase a funders understanding of the intervention, ensuring open communication with funders (257) has also been suggested. However, where strategies such as these are not possible, or are not effective in their setting, the scale-up team may want to question whether LDM is appropriate within their context.

6.3.3 Consideration of Who is the Local Decision Maker

Another consideration of selection of a LDM approach within culturally conservative contexts is the social norms, values and beliefs of the local decision maker themselves and how this may affect how they perform their role. This was particularly found to be the case for the introduction of SRH interventions. This finding is consistent with Rogers' diffusions of innovations theory (53), which discusses how perception of compatibility of an intervention will affect intervention implementation. Findings from this research suggest that when a belief of incompatibility was present components were often removed. In these settings, it could be argued that by introducing LDM a person-role conflict (343) may be created whereby the local decision maker feels conflicted by the expectations of delivery of an intervention that stand in contrast to their own personal beliefs and values, leading to adaptations with components removed. This had previously been identified in the scale-up literature, for example with Spicer et al., (196) identifying that decision makers' values and ideologies will influence adoption or rejection of programmes. It has also been identified in the adaptation literature, with Moore et al., (59) suggesting philosophical fit, or whether the intervention fits the belief system or view of the problem, as important to consider. In conservative cultural contexts it could be argued that this conflict could be foreseen and planning should take place to mitigate this. Indeed, the findings from phase two (Chapter 5, Section 5.3.7.1) highlight one of the primary reasons for adaptation in practice during scale-up is due to lack of cultural fit. Some suggested strategies to mitigate this conflict include desensitisation through activities such as peer learning forums and re-designing the intervention to align with cultural beliefs, including incorporating religious language and text (197). In addition to this the 'Guide to Fostering Change to Scale up Effective Health Services' (131) provides advice for strategies to achieve buy-in where there is resistance felt to the intervention in local contexts. For example, allowing opportunities to express anxieties and concerns and respecting feelings may result in people more likely to engage with efforts and change. However, it should also be considered as to whether the local decision maker is the best fit for making decisions on the adaptation or delivery of the intervention in these settings. For some contexts, where LDM is federally mandated or practical resource constraints limit a scale-up teams ability to lead all sites, LDM may not be a choice. In other settings where LDM is an option, the scale-up team should consider the risks associated with potential loss to fidelity, which strategies could be put in place to mitigate this, and whether LDM is the best action for adaptations in this setting.

6.3.4 LDM and Unavoidable Adaptations

LDM in the context of resource limited settings leads to challenges in balancing the expectations of intervention delivery and the pragmatic challenges on the ground. Across the cohort of scale-up case

examples identified in phase two, resource availability was also highlighted as one of the primary reasons for adaptations in practice during scale-up (Chapter 5, Section 5.3.7.1) demonstrating the importance of considering this in scale-up and adaptation planning. An area of agreement across the literature is the influence of factors relating to the implementing organisation in implementation and scale-up. For example, the CFIR (287) identifies the inner setting, which represents the organisation, as a key construct that actively interacts *with* implementation rather than simply acting as a backdrop to implementation (175). Consistent with the CFIR, the current research identified the organisational factors of resource availability and capacity limitations as two of the key organisational areas affecting LDM when making adaptations during scale-up. Specifically, increasing demand for the intervention despite HRH shortage (245) and limited access to equipment (318) were both highlighted as some of the challenges faced. Interestingly, challenges with adaptations due to resource limitations when using LDM were not solely reported in LMIC, with two HIC (62, 318) also reporting adaptations with potential loss to fidelity as a result. Additionally, a finding of this review was that often unavoidable adaptations occurred despite intervention core components being known and guidance given to sites, demonstrating that these alone will not ensure that an intervention is delivered with fidelity and that further consideration of how the intervention can be delivered on the ground, under realistic resources during scale-up is needed. Again an intra-role conflict (343) may be created for the local decision maker with pressures to adapt based on resources despite knowing this may affect intervention fidelity. Consistent with Holliday et al., (61) concept of acceptable to unacceptable, and avoidable to unavoidable adaptations (discussed in more detail in Chapter 2, Section 2.2), resource limitations appear to fall under the unavoidable heading within some settings. Consequently, implementers may need to consider if additional resources are required at future sites, and if so, whether there is funding and capacity to achieve this. If the intervention is not suitable for all sites given the resources available, the intervention may need further adaptation prior to scale-up to render it less resource intensive, or a decision taken not to scale due to future, potentially unacceptable adaptations. Findings are also consistent with a systems thinking approach, which applies to an in-depth consideration of the complex links, relationships, inter-dependencies within a system and which has also been put forward as an approach to facilitate the complexities of scale-up by previous guidance and literature (11, 12, 41, 52). A systems thinking lens could therefore also be used by implementers as a way to view the complex system in which the intervention is intended to be scaled in, to see if there are any potential synergies that could be created between sites and some resource limitations overcome.

6.3.5 Consideration of Capacity when using Data Driven Approaches to Support LDM

The use of data driven approaches to support LDM during the scale-up of interventions was found to be promising for informing and evaluating adaptations, in addition to leading to buy-in and support for the intervention. The importance of renewing and regenerating data, which included the use of evaluations, was also highlighted in a previous review of scale-up by Willis et al., (7) which led to the mechanism of awareness of needs and, through positive visibility of results, led to trust and confidence in the intervention. While their study was not specific to evaluation of adaptations during scale-up, the use of data to inform and evaluate adaptations was seen to similarly increase awareness and contribute to buy-in and support in this review. Similarly, Rogers' diffusions of innovations theory (53) discusses how if relative advantage and observability of benefit are seen of an intervention in comparison to normal practice, this will facilitate adoption. Consistent with this theory, findings for the current study suggest that positive visibility of results of adaptations led to motivation, buy-in and support for the intervention and implementation. Another potential benefit is that some of the data-driven approaches such as use of QI methods (including plan-do-study-act cycles) encourage ongoing evaluation of changes made over time. This could address the need for ongoing adaptations which was emphasised in the scale-up and sustainability literature such as in the DSF (24).

A key building block identified was the consideration of capacity at local levels for use of a data driven approach. When introduced in LMICs, the use of data to guide and test adaptation and implementation was often reported as new to the setting, with identified capacity limitations in place. This lack of capacity varied from a lack of experience of analysing data, to a lack of literacy, particularly when peer workers were engaged in the LDM process (CE22). Capacity limitations is not a new concept and has been identified as a key barrier in the scale-up literature with the need to both assess (12, 24, 49, 123-125, 127, 176, 178, 195) and build capacity of the adopting organisation (13, 51, 52, 129, 133, 134, 194). The importance of capacity was particularly highlighted in the literature in the context of LDM within the SEED-Scale (173), whereby building capacity can empower communities to gather and use data for evidence-based decision making as well as address power imbalances and promoting local independence. As previously identified in phase two of the study (Chapter 5, Section 5.3.7.2), ad-hoc unplanned changes were reported to have occurred at frontline provider level, however a potential mitigator for this could be the embedding of a data-driven approach that encourages ongoing evaluation at local levels to ensure the intervention remains effective in their setting over time. A key consideration for implementers however is the time, resources and funding needed to assess and build this capacity for data-driven approaches, particularly in resource limited settings. This can include pragmatics challenges such as lack of IT hardware and software in scale-up sites, in addition

to competence and capacity to use these systems and level of training and ongoing facilitation required. In two of the case examples (CE11, CE21) the QI approach appeared to be supported by an international agency (the IHI) for training and facilitation. In another case example (CE19), the authors noted that after early use of a QI approach, over time and as scale-up sites dramatically increased, the scale-up team experienced reduced time and ability to support sites (specifically referenced in article (245)). This example illustrates how high resource initiatives can be challenging to scale-up within resource limited settings, with resources needing to be set aside not just at the beginning but also for throughout the scale-up process. The issue of resources has previously been raised in the literature (349), with the challenges of bringing QI methods in community settings in LMICs to scale given the intensive resources and ongoing support required. Implementers should also consider however, the future investment of using a data driven approach. Specifically, and once it has been adopted in a region, there may be capacity in place for future scale-ups that do not require as intensive capacity building and support in the future.

6.3.6 Importance of Guidance for LDM

Another key building block for LDM appeared to be clarity and guidance on the intervention content (i.e. intervention theory, components, elements, functions or minimum standards) and accessible guidance for local sites on how to implement and adapt the specific intervention. Where clarity and guidance is available, local decision makers could then combine their awareness of the intervention (i.e., what is flexible and what is core to the intervention), along with knowledge of how to implement and adapt, with their local tacit knowledge in order to allow for sensemaking and problem-solving for adaptations to ensure best fit for their setting. The benefit of clear identification of intervention content emerging from this research is consistent with the adaptation and fidelity literature (54, 110, 114, 120, 121) (as discussed in Section 4.2.1.1.1), and has also been highlighted as a key component in the implementation literature (24, 49, 57, 132, 147, 195). Suggestions for how this guidance could be presented to local sites could be taken from Tomioka and Braun (184), Rolleri et al., (97) and Holliday et al., (61). For example, through the use of a clear prescriptive approach of components such as a traffic light system of acceptable adaptations, with green being acceptable to remove or adapt a component, to red being unacceptable. Alternatively, guidance could take a more theoretical approach, such as that suggested by Anyon et al., (74) in providing a set of key principles to follow. Recent work by Perez Jolles et al., (94) also support this by suggesting theory based explanations of how an intervention functions and being less rigid and prescriptive could be more useful for implementers. However, the literature would suggest that often the intervention theory, core components, functions, elements or mechanisms are unknown or poorly articulated (17). Thus, when

LDM is utilised, this may lead to challenges in deciding on what changes to make to the intervention (115).

In addition to supporting adaptations, the provision of guidance on how to implement and adapt the specific intervention also gave local decision makers encouragement and flexibility, and empowered them, through building knowledge and capacity on the process, to make adaptations. Therefore, the outcome of this guidance not only provided an awareness of what to do in terms of implementation and adaptation, but also served to promote buy-in and support for the intervention and implementation process at local level through this empowerment. The importance of providing guidance in under-resourced health systems was also identified (CMOC 6.3). In these settings, providers may often already be overworked and adding additional expectations to their workload may be unfeasible without significant support. For example, it was found that an absence of implementation and adaptation guidance led to staff feeling overloaded, leading to reduced motivation and buy-in for the intervention (330). Therefore, lack of implementation and adaptation guidance may disproportionately affect LMICs with under-resourced health systems. The need to consider the capacity of who is implementing the intervention when scaling-up has been previously highlighted in the literature (12, 13, 24, 52, 123-126, 194, 195). Therefore, implementers need to consider the resources and capacity at local sites and how they can provide guidance to support adaptations and reduce the risk of them becoming overloaded or overwhelmed. Phase two of the study provided considerations for provision of guidance based on the findings in practice during scale-up (see Chapter 5, Action 2, Figure 5.5) which includes consideration of: the content of the guidance, in what format, the timing and the source of guidance, that could be used as a resource for implementers using a LDM approach going forward.

The power dynamics existing between those who provide the guidance and local decision makers responsible for the adaptations also needs to be considered by implementers. When guidance is provided by those linked to a funding agency, the local decision makers can be influenced by 'beliefs about consequences' as identified in the TDF (346), leading to fear of negative repercussions if local decision makers are seen as incompetent through a need to use this guidance. To mitigate this, a study conducted as part of CE17 (324) reported that some sites were provided with support in the form of regularly scheduled calls to reduce the need for sites to actively reach out for support. However, this received mixed feedback with some sites being receptive to this approach, and others less so with providers not returning calls (324). Therefore, while proactive embedding of support may in some sites increase its use, it may not address the underlying contextual factor of the power imbalance

between local decision makers and those providing the guidance, which should be considered. Another identified issue was when those who delivered the guidance were not from the local setting, local decision makers may not trust or view them as credible.

The complexities of local social values, norms and beliefs along with feasibility and resource issues may be challenging for those external to the setting to understand. The concept of trust, or more specifically distrust of outsiders bringing in an intervention has previously been discussed in the implementation literature (222). The CEs reporting using those from outside the context chose to use trainers who also had diverse experience across many implementation settings, who could throughout training sessions demonstrate this experience, building credibility in the process (280). Thus future implementers may want to consider the following: Is the trainer is from outside the local setting and if so, do they have the relevant experience to give guidance to the selected site? How can this experience be demonstrated to the local decision makers in order to build credibility? Or, where the trainers do not have the relevant experience for this setting, is there another person or agency that could be better suited, or could a combination of trainers with relevant skills and experience be used (i.e., one with experience in the intervention itself complemented with another with experience implementing within the diverse local setting)? Where these considerations are made prior to scale-up, this may facilitate receptivity and uptake to guidance and trainings by local decision makers during the scale-up.

6.3.7 Sensemaking and Problem Solving as Central Mechanisms to How LDM Works

In addition to awareness of the intervention components and how to implement and adapt in place, the concepts of sensemaking and problem-solving appeared as central mechanisms to how LDM works and formed an integral part of PT6 (see CMOC 6.1, Table 6.8). Whereas problem-solving involves the finding of solutions to complex problems (348), there is no clear definition (347) of sensemaking. Sensemaking has however been described as a “largely invisible, taken-for-granted social process” (p417) (344), and as one that involves efforts to give meaning to circumstances by making plausible explanations based on retrospective framing, and the development of actions based on presumptions of future patterns (344, 345). Sensemaking is thus an ongoing process (347) that focuses on plausibility of explanation over accuracy (344), involves articulation and communication of ideas (344), and can be influenced by the wider social, historical and institutional context (350). Weick et al., (344) in the field of organisational sensemaking theory discuss that; “sensemaking involves turning circumstances into a situation that is comprehended explicitly in words and that serves as a

springboard into action” (p409). Based on the above, sensemaking could be outlined as forming a plausible explanation based on local understanding, which can lead to a proposed action.

The concepts of sensemaking and problem-solving were both seen as consistent with and important to the LDM process in the field of scale-up and adaptation, in that an intervention was viewed and interpreted by local decision makers as to whether they believed it was the right fit for their setting. Specifically, through sensemaking, one may consider the intervention, the logistics of implementation and its expected effects using retrospection and their tacit experience of the local context to make judgments on whether they believe the intervention would work in their setting. If continuing the intervention in its current form made sense to them, the intervention may be chosen to be delivered in its original state. However, if this was not the case, or not seen as possible or optimal, sensemaking may have led to problem-solving to identify substitute actions and solutions based on plausible explanations of why changes may need to be made for their setting. However, in a setting where the guidance given on the clarity of intervention content led to an awareness of what was flexible and what was core to an intervention, in addition to guidance leading to awareness of how to implement and adapt the specific intervention, this created a supportive context for these mechanisms of sensemaking and problem solving to occur for changes to the intervention (CMOC 6.1, Table 6.8).

6.3.8 Peer-Learning as a Complementary Action for LDM

How cross-site learning from peers can support LDM was identified, with two key approaches: the facilitation of in-person learning (e.g., through formalised meetings) and the development and dissemination of resource packages sharing tried and tested examples (CMOC 8.1). Both of the CEs (CE11, CE21) who referenced these used cross-site learning in the context of formalised QI methods based on the IHI approaches (282-284) (detailed in Chapter 5, Action 8). Edwards and Barker (351) whose work included learning from South Africa’s scale-up of HIV prevention interventions (i.e. CE21) discuss that when multiple adaptations have occurred across multiple heterogeneous sites that the intervention is likely to scale further with minimal adaptations due to similar contextual challenges faced across sites. The concept of context specificity and how it relates to decision making for implementation was also discussed in recent work by Ornstein et al., (193), in relation to public health interventions. They proposed context specificity as one parameter for consideration by decision makers with problems on a spectrum ranging from universal, where solutions from one area will work in other areas, to problems that are fully context specific, where little can be learned across sites (193). From this thinking, problems that fall under the universal or close to universal on this spectrum may benefit most from cross-site learning from peers during scale-up. Therefore, implementers could

consider whether similar (i.e., universal) contextual challenges are faced between sites (e.g., around resource availability or cultural acceptability), and if it is believed to be of benefit, implementers could choose to invest time and resources in cross-site learning from peers during the scale-up process. If however, implementers believed there was little or no overlap in problems between areas (i.e. high context specificity) then investing resources in another adaptation approach may be of more benefit.

Unfortunately the CEs which identified cross-site learning from peers did not go into sufficient detail to elucidate the causal mechanisms and notable differences for in-person learning versus use of resource packages to support adaptations and shared learning. As a result, the mechanism identified was that of ‘awareness of what worked in other sites’, with the outcome being that of uptake of these ideas by later sites. This led to less hands on support provided at each site in later stages of scale-up as the need for development and testing of new ideas was reduced (232). In this case, theory such as Rogers’ diffusions of innovations theory (53) assisted in retroductive thinking (10), providing a potential deeper understanding of the causal mechanisms that may have led to use of these tried and tested ideas, including their compatibility being seen with similar challenges faced in later sites, in addition to the relative advantage and observability of benefit seen where they had been previously tested and shown to be effective. However, these deeper mechanisms were not specifically discussed within the CEs themselves and are therefore largely conjecture. Within the wider literature the need to support opportunities for learning was noted in a number of scale-up frameworks (13, 41, 129, 173, 176). For example, the SEED-scale noted that learning about what was working, for example from visiting other sites, could also be benefit to support LDM (173). The meta-narrative review of diffusions of innovation in service organisations by Greenhalgh et al., (203) also discussed the use of formal network initiatives, citing QI initiatives as an example (as used in CE11 and CE21). However, Greenhalgh et al., (203) also noted that these are not guaranteed success and that motivation, capacity and receptivity to change, along with quality of facilitation can also play a role in intervention effectiveness. This was also found in CEs (CE11, CE21), for example with prioritisation of management affecting whether local sites bought into the QI process (232). A deeper exploration of how specifically QI methods which use this cross-site learning approach work in the context in scale-up was not present in the CEs found, and is beyond the scope of this research, however, it does warrant further exploration given the potential benefit of using this approach to support LDM.

6.3.9 LDM at Different Levels of the System

LDM was reported at different levels of the system across the case examples, from regional to frontline provider and peer worker levels, with many reporting its use at multiple levels (see Table

6.2). While there were some small distinctions seen across the different levels, for example the particular impact of available capacity (CMOC 5.4, Table 6.7) and empowerment through building capacity and knowledge (see CMOC 6.2, Table 6.8) came across strongly at frontline provider, including peer worker levels. Interestingly however, for the majority of CMOCs when synthesised, the mechanisms at different levels for LDM appeared to be the same (e.g. awareness, sensemaking and problem solving, feeling valued, motivated by positive visibility of results). Thus, the majority of findings could be applied to those at all levels of LDM for adaptations during scale-up, with specific consideration for available capacity at frontline provider, including peer worker, levels.

6.4 Developing an MRT - How LDM works for Adaptations During Scale-up of Health Interventions

How LDM works for adaptations for scale-up can be seen in the resulting eight PTs (detailed in Section 6.2.7 above) and are presented in Table 6.11 below. These demonstrate how LDM occurred for adaptations during scale-up a variety of contexts, with multiple mechanisms at play. These findings will now be considered, along with the substantive theory identified through PT refinement, to develop an MRT, in fulfilment of objective 3.2.

6.4.1 Who LDM Works for when making Adaptations during Scale-up

LDM can work for those who have: guidance on the intervention components and guidance on how to implement and adapt (PT6); access to cross-site learning, where similar contextual issues are faced (PT8); and for those who have the capacity to use a data-driven approach to inform and evaluate adaptations (PT5). LDM may be more challenging for those in settings where the intervention does not align with the social norms, values and beliefs of the wider community (PT1) or the local decision maker (PT2); where there is reliance on external funding and poor understanding of the intervention components from funders (PT3); and in resource limited settings where unavoidable adaptations may need to occur (PT4). There was no one level of the system where LDM was identified as more or less effective, however, at frontline provider and peer worker levels both resources and capacity to carry out adaptations was seen as more likely to be a challenge.

6.4.2 Mechanisms that Contribute to how LDM Works for Adaptations during Scale-up

There were multiple mechanisms that contributed to how LDM worked. The mechanism of *awareness* was seen as important. This involved local decision makers gaining awareness of different elements including: of the intervention components (what is flexible and what is core to the intervention), of how to implement and adapt, of local needs, of whether an adaptation was effective and of what worked in other sites. Awareness was achieved by a variety of resources introduced into the context

to produce the settings identified above including: guidance on intervention components, guidance on how to implement and adapt, capacity building on how to implement and adapt, supporting an accessible data driven approach, and learning from peers of tried and tested adaptations. However, most importantly, what LDM adds is the further mechanisms of sensemaking and problem solving which allow for local decision makers to combine awareness of these different elements with their local tacit knowledge to generate solutions for local fit. Power imbalances such as who provides the guidance, and resource constraints such as funding limitations and capacity to implement, adapt and evaluate adaptations, affected whether this worked.

LDM can have a positive impact on intervention implementation and scale-up by contributing to buy-in and support. This was achieved by a number of mechanisms. For example, with local decision makers: being motivated by seeing positive changes in data and feeling pride in their own achievements, feeling valued and respected, and through participation and empowerment. These mechanisms were achieved by introduction of different resources such as: use of an accessible data driven approach, giving autonomy and ownership of the process to the local decision maker, by developing capacity in how to implement and adapt that provided encouragement and flexibility for local sites, and selecting and using approaches which were accessible for capacity at local levels.

However, it is important to consider that LDM occurs in the wider political, cultural and socioeconomic context. In culturally conservative contexts, and settings where there is a reliance on external funding power imbalances can impact a local decisions maker's ability for adaptations. In these settings, beliefs of compatibility was found to be both a contextual factor and mechanism which affected how LDM worked. At the wider societal level in culturally conservative contexts, a lack of belief of compatibility by those in position of power in the community, or at an organisational level by those providing the funding, can negatively impact LDM with an intra-role conflict created and fears of negative consequences where requests to adapt certain components are not followed. Additionally, beliefs of the local decision maker themselves, particularly in culturally conservative contexts, can place local decision makers in a position of person-role conflict, whereby they experience discomfort and lean towards adaptations based on personal beliefs and values. Often these adaptations were reported to result in a loss to fidelity to the intervention.

6.4.3 Substantive Theory to Further Explain and Support Theory

Theories which assisted in explanation of these findings included; Rogers' diffusions of innovations theory (53), sensemaking theory (344, 345) and role conflict theory (343). Rogers' diffusions of

innovations theory (53) gave insights for when relative advantage and observability of benefit of an intervention is seen this may assist implementation by engagement of staff with intervention or through increased engagement of recipients with intervention. This could be applied to the use of data-driven approaches where adaptations were evaluated and also in the instances of cross-site learning from peers of tried and tested successful adaptations. With relative advantage and observability of benefit seen this could potentially have contributed to uptake of adaptations and buy-in for implementation and intervention. Rogers' diffusions of innovations theory (53) also guided explanation of how beliefs of compatibility may influence implementation within culturally conservative contexts and where there was a reliance on local funding and support. This was combined with organisational role conflict theory (343), in this case the concept of intra-role conflict, where a local decision maker may feel pressure to make adaptations based on the beliefs of those in positions of power in the wider community and of funders. The TDF (346) also assisted in explanation where the 'beliefs about consequences' domain guided explanation of how a fear of negative consequences may lead to actions of local decision makers, in particular to remove components of the intervention with a loss to fidelity, based on the pressures felt. In addition to this, role theory guided explanation of when, such as the case of culturally conservative contexts, local decision makers may experience a person-role conflict (343) whereby their own beliefs differ from what is expected in their organisational role. These role conflicts may also leave an intervention adapted with loss to fidelity. Finally, sensemaking theory (344, 345), which discusses how we can give meaning to circumstances based on retrospective experiences and make decisions on actions based on presumptions of what may happen in future, appeared to guide explanation for how local decision makers can apply their local knowledge and past experiences to a situation to guide decision making and problem-solving. Findings from this study however, further suggest that this sensemaking needs to be complemented by awareness of different elements (e.g. of intervention components and awareness and capacity of how to implement and adapt).

6.4.4 Developing the MRT

The core elements from the PTs were identified and synthesised across the theories to identify any patterns of how LDM works across the variety of contexts identified. Substantive theory that had been identified throughout the theory refinement process was utilised to support and triangulate findings. The findings from this study led to the development of the following MRT;

MRT: *LDM works by allowing local decision makers to combine awareness of intervention components (i.e. what is flexible and what is core), of how to implement and adapt, and of what worked in other*

sites, with local tacit knowledge to sensemake and problem-solve for adaptations for local fit. Strategies such as: providing guidance to sites on intervention components and guidance on how to implement and adapt, supporting the use of data-driven approaches, and sharing of tried and tested adaptations can all work to support this awareness. Resource constraints such as funding limitations and lack of capacity to implement, adapt, and evaluate can have a negative effect on how this works. LDM can also contribute to buy-in and support for an intervention and implementation. Buy-in and support for an intervention and implementation can occur through local decision makers experiencing: motivation by the positive visibility of results, pride in achievements, and by feeling valued and respected. Through capacity building and selection of accessible approaches this can allow for participation and empowerment of local decision makers. An important consideration for LDM is the wider political, cultural and socioeconomic context in which it occurs. Interventions that do not align with social values, norms, and beliefs, or instances where there is a reliance on external funding, may leave the local decision maker experiencing an intra-role conflict, increasing their vulnerability to adapt the intervention based on lack of belief of compatibility of the intervention by funders or pressure from those in positions of power in the community. Additionally, the values and beliefs of the local decision maker themselves may result in a person-role conflict, leading to adaptation of components.

6.5 Phase Three Contributions and Conclusions

Ultimately, phase three of the research contributed to knowledge advancement by developing eight programme theories and an MRT on how LDM works for adaptations to health interventions during scale-up. These are presented in Table 6.11 below. This represents a unique contribution to knowledge, in the field of adaptation and scale-up and to my knowledge is the first study to put forward theory for LDM works in this context.

Table 6.11 Resulting PTs and MRT on How Local Decision Making (LDM) Works for Adaptations of Health Interventions during Scale-up

How LDM works when the Intervention does not align with Social Norms, Values and Beliefs of the Wider Community or Local Decision Maker	
PT 1	When interventions are scaled-up that do not align with social norms, values and beliefs within a context, community members and/or those in positions of power, such as religious leadership, may not view the intervention, or components of the intervention, as compatible with social norms and values leading to pressure to adapt components of the intervention in line with wider sociocultural beliefs. When there is a reliance on local funding and support, local decision makers may fear negative repercussions if adaptations do not take place, leading to adaptation or removal of components affecting fidelity to the intervention, despite they themselves or recipients of the intervention not holding the same beliefs.
PT 2	In the scale-up of interventions which do not align to the local decision makers social norms, values and beliefs, local decision makers may feel discomfort and believe in a lack of compatibility for the intervention (or lack of compatibility of certain components) for their setting. This may lead to adaptation with loss to fidelity of core components of the intervention. When strategies are used to desensitise local decision makers to the intervention, along with adapting intervention to align with social norms, values and beliefs where possible (while keeping core components intact), this can lead to local decision makers becoming more comfortable in the intervention and believing in its compatibility for their settings, leading to buy-in and support.
How LDM works in Contexts where there is a Reliance on External Funding	
PT 3.	When local decision makers are reliant on external funding, they can feel under pressure to adapt the intervention based on funders' needs and beliefs, fearing negative repercussions such as loss of funding if they do not comply. In contexts where funders have a lack of understanding of the importance of all essential components of the intervention, this can lead to pressure on local decision makers to adapt elements with loss of fidelity to the intervention. When communication is used to strengthen a funder's understanding of the intervention components and local needs, this can change the underlying context and remove the pressure on local decision makers to make unnecessary adaptations, in support of adaptations in line with local needs, as identified during the scale-up.
How LDM works in Resource Limited Settings	
PT 4.	When LDM occurs in resource limited settings, there can be pressure on local decision makers to adapt to meet the needs and demands of their local setting. Adaptations with a loss to fidelity can occur, despite core components being known and guidance given to sites, as some adaptations may be deemed unavoidable. Using a systems thinking approach to identify where synergies can be utilised across local sites, e.g. skill and cost sharing, may avoid some adaptations being made due to resource limitations.
How LDM works in the Context of Using a Data Driven Approach	
PT 5.	The use and analysis of local data by local decision makers to inform adaptations and/or for evaluating adaptations when scaling-up can create an awareness of local needs and an awareness of whether adaptations made were effective. Local decision makers can be motivated by seeing positive changes in data demonstrating a relative advantage of the intervention and adaptation, as well as experience pride in these achievements, leading to buy-in and support for the intervention and implementation. When local decision makers feel autonomy and ownership over the data and process, this can lead to empowerment through feeling valued and respected, resulting in further buy-in and support for the intervention and implementation. In settings where there may be capacity limitations and no history of data-driven approaches, consideration needs to be made in the selection of suitable data-driven approaches, based on capacity at local level. Considerations based on existing capacity could include whether capacity building and ongoing support are needed for the empowerment and participation of local decision makers to use a data-driven approach to support LDM.

How Guidance on Implementation, Adaptation and the Intervention Components supports LDM	
PT 6.	When local decision makers are provided with accessible guidance on intervention content, along with accessible guidance on the implementation and adaptation process for the intervention, this can create awareness on what is flexible and what is core to the intervention and ways in which to implement and adapt the intervention with fidelity. This knowledge can then be combined with local tacit knowledge for sensemaking and problem solving towards adaptations for local fit. Choosing an LDM approach with provision of guidance to sites gives encouragement and flexibility to adapt, along with supporting knowledge and capacity building, for local decision makers. This can empower local decision makers, particularly at frontline level, to make adaptations, contributing to buy-in and support for the intervention and implementation. Counter to this, a lack of guidance, particularly in under-resourced health systems, can lead to local decision makers feeling overloaded, causing reduced buy-in and support for the intervention and its implementation.
PT 7.	Guidance on intervention content and on how to implement and adapt can assist in adaptations for local fit and promote buy-in and support for the intervention and implementation. However, who provides this guidance may influence its uptake and use. Where there is a power imbalance between those who provide the guidance and local decision makers, this power imbalance may result in fear of negative repercussions or fear of being perceived as incompetent by those in the position of power, leading to less uptake of guidance and support, or guidance being requested at late (crisis) stages. In addition, in the instance where an external agency provides guidance, there may also be a lack of awareness of available supports, leading to lack of their use. If guidance and support are provided by those not from the local setting, perceptions of credibility and lack of trust from local decision makers may influence receptivity. This can be mitigated by those providing guidance and support by demonstrating their experience relevant to the local setting, in order to build credibility and increase receptivity and uptake of guidance and support.
How Peer Learning support LDM when Scaling-up	
PT 8.	When strategies are used to facilitate cross-site learning to share tried and tested successful adaptations, such as formalised meetings between sites and development and dissemination of resources e.g. change packages demonstrating successful ideas, this can lead to local decision makers in future sites having awareness of what previously worked and using compatible ideas for similar challenges within their own sites. This can lead to reduced time and resources needed in later stages of scale-up, as shared learning of what worked occurs.
MRT: How LDM Works for Adaptations when Scaling-Up Healthcare Interventions	
MRT: LDM works by allowing local decision makers to combine awareness of intervention components (i.e. what is flexible and what is core), of how to implement and adapt, and of what worked in other sites, with local tacit knowledge to sensemake and problem-solve for adaptations for local fit. Strategies such as: providing guidance to sites on intervention components and guidance on how to implement and adapt, supporting the use of data-driven approaches, and sharing of tried and tested adaptations can all work to support this awareness. Resource constraints such as funding limitations and lack of capacity to implement, adapt, and evaluate can have a negative effect on how this works. LDM can also contribute to buy-in and support for an intervention and implementation. Buy-in and support for an intervention and implementation can occur through local decision makers experiencing: motivation by the positive visibility of results, pride in achievements, and by feeling valued and respected. Through capacity building and selection of accessible approaches this can allow for participation and empowerment of local decision makers. An important consideration for LDM is the wider political, cultural and socioeconomic context in which it occurs. Interventions that do not align with social values, norms, and beliefs, or instances where there is a reliance on external funding, may leave the local decision maker experiencing an intra-role conflict, increasing their vulnerability to adapt the intervention based on lack of belief of compatibility of the intervention by funders or pressure from those in positions of power in the community. Additionally, the values and beliefs of the local decision maker themselves may result in a person-role conflict, leading to adaptation of components.	

Chapter 7. Implications, Recommendations, Limitations, Methodological Reflections and Conclusions

This chapter will provide an overview of the key contributions of the study to the field of adaptation and scale-up following completion of all three phases of the review. The findings of each phase were previously discussed in detail their respective chapters (Chapter 5, Section 5.4; Chapter 6, Section 6.3 & 6.4), consequently this chapter will provide a number of implications of the research for theory, policy, practice, and research, and resulting recommendations will be suggested. Additionally, the limitations of the research and methodological reflections on the use of realist review methodology are discussed, before the final conclusions for the study are given.

7.1 Contributions of the Study to the Field of Adaptation and Scale-Up

7.1.1 Reasons for Adaptations in the Context of Scale-Up

Despite the recognised need to adapt health interventions during scale-up, how and why these adaptations were occurring when scaling-up in practice was poorly reported understood within the extant literature (17, 352). A consequence of this was a lack of clarity for implementers as to why adaptations may be needed across their sites when scaling-up, which may have led to ad-hoc or reactive approaches to adaptations with potential impact on intervention fidelity and effectiveness (1). To address this gap in the literature, this research firstly aimed to discover what adaptations were occurring in practice, and why, when scaling-up across diverse contexts. To this end, this study has captured learning from adaptations occurring during scale-up across both LMIC and HIC settings, including cultural adaptations occurring at wider population levels, and not just for minority groups (detailed in Phase 2, Chapter 5). This research has shared detailed learning from reasons for adaptations such as resource availability, for example lack of access to equipment at local sites or lack of vaccination records, which is of particular relevance to implementers involved in scale-up within LMICs. The finding from this study of frequent adaptations for resource availability and cultural fit is in keeping with two of the primary adaptation taxonomies, that of Moore et al., (59) who highlights the importance of philosophical fit and logistical fit, and the FRAME taxonomy in which Wiltsey Stirman et al., (1) recognises resource availability and cultural fit at multiple levels of the system as potential reasons for adaptation. What this study has contributed is emphasising the importance of adapting for cultural acceptability of the intervention within the wider cultural context when scaling-up, as opposed to primarily for minority population cohorts. Furthermore this study has supported the importance of resource availability when scaling-up in practice, and in particular in LMIC settings, as a primary reason for adaptations. Consequently, this research has suggested further expansion of the FRAME (1) under the resource availability heading at organisational level to differentiate reasons for adaptations (e.g. supply chain logistics, HR capacity) which could further aid implementers when planning for future unavoidable

adaptations in their setting (discussed in more detail in Chapter 5, Section 5.4.5). By this study identifying the reasons for adaptations made in practice during scale-up across diverse settings (objective 2.1), this contribution may support implementers working in HIC and LMICs in identifying where similar needs may lie in their own contexts, for example adaptations may be needed for equipment availability at local sites, thus informing why adaptations may be needed and to proactively embed actions for adaptations within scale-up planning.

7.1.2 Actions for Adaptations in the Context of Scale-Up

As the call for adaptations to meet local needs continues, for example in the fields of maternal and child health (18), HIV (20-22), and mental health (23), there remained a lack of specific guidance on how to adapt (i.e. what actions could be used) when scaling-up. As was seen in the literature identified through the background search (Chapter 4, Section 4.2.1.2) the lack of guidance for implementers was not for the absence of scale-up guidance and frameworks, of which there were many, however none were specific to the process of scale-up and adaptation. For busy implementers, this led to ambiguity without best practice to follow on how to approach adaptations in their setting when scaling-up. In terms of current adaptation guidance, as previously examined in Chapter 4 (Section 4.2.1.1), it was mainly centred from HIC settings (27-34, 54, 57, 110, 114, 118-121), with a majority focusing on cultural adaptations for minority groups (27-34, 112, 118, 119). Even within recent consolidated adaptation guidance such as that by Movsisyan et al., (29) and Escoffery et al., (163), (as discussed in Chapter 5, Section 5.4.7) there is no clear agreement of the steps to take, and importantly, this more recent guidance is not focused on adaptations in the context of scale-up. Thus the suggested approaches in current adaptation guidance may not be feasible for multiple diverse sites with varying capacity encountered during scale-up, for example involving complex re-evaluations, or when cultural fit needs to be addressed at wider population levels. As a result there was no clear path to follow for implementers for adaptation across multiple sites and diverse contexts with limited resources available during scale-up.

To this end, this study aimed to identify what actions could be used to achieve adaptations when scaling-up across diverse contexts to provide some practical guidance for implementers. Consequently, this study captured learning from health interventions that were adapted during scale-up across both HIC and LMIC contexts, involving a range of intervention types in the fields of SRH, MCH, obesity prevention, HIV and mental health, with a resulting eight practical actions identified for adaptations when scaling-up in practice across these diverse settings (objective 2.2). These were presented and discussed in detail in Chapter 5 (Sections 5.3.9.2 and 5.4). While previous adaptation guidance had been centred from HIC contexts and primarily for cultural adaptations for minority groups, this study has added to this knowledge by identifying actions that can be used

across both HIC and LMICs, and across multiple diverse scale-up sites (e.g. using QI methods such as PDSA cycles at local sites to evaluate adaptations or creating peer learning opportunities through project newsletters showcasing adaptations). This study has built upon previous adaptation guidance by highlighting that when scaling-up in practice often adaptations are made due to the wider political, cultural and socioeconomic context, in addition to for minority groups. Furthermore, and in keeping with sustainability literature such as the DSF (24), this study has recognised that this context may change over time and has identified actions such as ‘ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations’ which implementers can choose to support adaptations in relation to the wider context and as changes occur throughout the course of scale-up. In keeping with the complexity of scale-up there was no one single process to follow, with the identified actions used across various contexts, on different intervention types, at varying levels of the system, with different combinations of actions used together. Therefore, the actions identified serve more as a ‘menu’ than a prescriptive checklist when making adaptations during scale-up. Importantly, this contribution does not negate the use of a wider framework for scale-up. On the contrary, this research acknowledges the complexity and multiple steps needed in scale-up, whereby adaptation is only one aspect of this. Thus, actions for adaptations identified from this study act as a complement rather than a replacement of the wider scale-up frameworks (such as those identified in Chapter 4, Section 4.2.1.2). Thus, relevant actions identified in this study can be proactively embedded into the wider scale-up plans in practice.

7.1.3 Importance of Knowing the Intervention Theory, Core Elements, Components, Functions or Minimum Standards when Adapting in the Context of Scale-Up

An area of great importance within the adaptation literature, that was also supported from the findings of this study, is that of having knowledge of the intervention theory, core elements, components, functions or minimum standards to allow for clarity on what was core to the intervention and what was flexible and may be adapted. The findings from this study emphasise the importance of local sites receiving guidance on these intervention theory, core elements, components, functions or minimum standards when scaling-up, as without this knowledge it is challenging for local sites to know what is important to keep to ensure intervention effectiveness and what is amenable to changes for local fit. In the context of scale-up, the intervention is previously selected by policy makers, funders and/or the scale-up team and so in deciding what intervention to use consideration of whether the above is known and can be shared with sites needs to be made. However, in practice often the intervention theory or components are not known or poorly articulated (17, 115, 192). Given the importance found within the adaptation literature (54-57, 61, 71, 75, 81, 98, 100, 101, 110, 114, 120, 121, 165, 169), which was further supported by this

study, of knowing the intervention theory or components to facilitate adaptation, it is crucial to look towards the funding, design and reporting of RCTs when developing and testing an intervention to ensure that knowledge of these intervention theory, core elements, components, functions or minimum standards and future scale-up and potential adaptation is considered. The responsibility for this belongs with both the intervention developers and triallists, in designing the intervention and testing with the knowledge of the intervention theory, core elements, components, functions or minimum standards prioritised to allow for future implementation and adaptation, as well as with the funders, to ensure funds and timelines for the RCTs can allow for this. While it is acknowledged this can be a timely and costly approach, the call for knowledge of intervention theory, core elements, components, functions or minimum standards is compelling. Intervention testing and development could take the format as suggested in the RCT by Holliday et al., (61) by developing a clear prescriptive approach of a traffic light system for components of the intervention with acceptable and unacceptable adaptations, or alternatively interventions could be developed and tested as a set of key principles (74) or core functions (94) on the intervention to follow with flexibility once these principles or functions are in place. There are merits of both of these approaches, for example a prescriptive traffic light approach may be helpful for those with less time to plan adaptations providing a clear framework of when a loss to fidelity might occur, while a theory based approach with core functions or principles to follow may allow for more flexibility and autonomy. What is important to consider when deciding on which approach to take would be considering what best suits the intervention type along with the future capacity and experience of those who will be delivering the intervention. In addition to the above findings and to further support future implementation, the use of the TIDieR (100) guidance has been promoted by this study (Chapter 5, Section 5.4.4) which gives suggested details for reporting of intervention components which then can be helpful for future implementation and adaptation. Thus, this would further support implementers having detailed information on the intervention that can be shared in guidance materials for local sites to support decision making on what to include and what to adapt, given the needs and resources in their local setting.

7.1.4 Fidelity Considerations

The overall lack of consideration, evaluation and reporting of fidelity with the scale-up case examples was a concerning finding of this study. As discussed previously in Chapter 2 (Section 2.4), there is a lack of standardisation and agreement in the literature of what is fidelity, along with lack of consensus and guidance on how to incorporate and evaluate it in practice, therefore it could be argued as an unfair burden placed on busy implementers to expect fidelity consideration, evaluation and reporting to be achieved in conjunction with the other challenges of scale-up. As discussed in Chapter 5 (Section 5.4.3) those involved in the field of fidelity have attempted to

address these gaps in fidelity guidance and a number of these fidelity frameworks were identified through phase one of these study (Chapter 4, Section 4.2.1.1) which could be used by implementers when considering fidelity in the context of their scale-up plans. For example, a flexible framework that may be useful for implementers is that suggested by Pérez et al., (56) with their modified Carroll et al.'s conceptual framework for implementation fidelity, which proposes rather than generic fidelity criteria, each intervention should have its own specific descriptors of fidelity unique to the intervention. In order to achieve this, and in keeping with the wider adaptation literature and findings from this study, they advise the intervention theory and functions would need to be clearly understood first. Thus the importance of knowing the intervention theory, core elements, components, functions or minimum standards is further highlighted. With these known, Pérez et al., (56) suggest how implementers could develop fidelity criteria unique to the intervention being scaled-up and develop specific questions for sites when deciding on what adaptations to make. While this is one example, it is important to acknowledge that no one fidelity framework comes to the forefront as best to use in the context of scale-up and so implementers could choose what to use based on capacity, intervention type and needs of the scale-up in question. Potentially as these fidelity frameworks get used in practice in scale-up, a preferred frontrunner or consolidation of existing fidelity frameworks for use in scale-up and adaptation may come to the fore. While it is acknowledged that considering fidelity is challenging and resource intensive (89, 90), its importance is highlighted in the findings of this study as adaptations are routinely made in practice during scale-up with unknown impact in fidelity and consequently unknown impact on intervention effectiveness and health outcomes. Thus, in conjunction with use of a scale-up framework, use of a fidelity framework could complement planning when future adaptations to the intervention are expected.

7.1.5 Local Decision Making for Adaptations when Scaling-Up

Through phase two of the study it was identified that adaptations are often needed to meet the needs of multiple diverse sites when scaling-up, and often happened at multiple levels of the system i.e. at district and provincial levels, organisational level, frontline provider, and recipient levels. The action of LDM was identified as a promising option as it allows those who are familiar with the context to drive adaptations and was frequently used in practice within the scale-up case examples. As an action introduced into complex systems however, a better understanding of the circumstances under which LDM may be used was warranted and lacking in existing literature. Therefore this research aimed to provide theory on how LDM works that would have practical application for implementers involved in scaling-up across diverse contexts. To achieve this the final phase of the study focused on development and refinement of theory on how LDM works, in what circumstances, for adaptation of health interventions when scaling-up (objective 3.2). To my

knowledge this was the first study to develop theory on how LDM works for adaptations during scale-up, with eight PTs and an MRT developed from this review representing a unique contribution to knowledge in the field of adaptation and scale-up (these theories were presented and discussed in detail in Chapter 6, Sections 6.2 - 6.4).

As discussed in Chapter 4 (Section 4.2.1.3.9), LDM had previously been suggested by a number of scale-up frameworks (13, 124, 129, 132, 134, 173), with value placed on those who know the context. Within this previous scale-up literature it suggested that use of contextual knowledge can assist in achieving local fit (131, 132) and support for the intervention through greater local participation and buy-in (131). Results from this study identified that LDM was occurring in practice both formally and informally during scale-up for adaptations, and stand in agreement with previous scale-up literature, that this contextual knowledge can assist in achieving local fit by allowing for local sensemaking and problem solving. This research has built upon this literature by highlighting practical steps that can be taken to create a supportive context for LDM to take place, for example when guidance is given on the clarity of intervention content providing an awareness of what was flexible and what was core to an intervention, in addition to guidance on how to implement and adapt the specific intervention. With this foundational knowledge of the intervention and steps to adapt it, local decision makers can then apply tacit experience of the local context to make decisions for adaptations (discussed in more detail in Chapter 6, PT6, Section 6.3.6). Thus, the importance of knowing the intervention theory, core elements, components, functions or minimum standards is further emphasised as a pivotal step for LDM. This study has additionally built upon existing literature by identifying specific mechanisms such as feeling valued, feeling respected, and positive visibility of adaptations that contribute to local buy-in and support when LDM for adaptations during scale-up. This was further supported by data driven approaches for evaluation and giving autonomy of this process to local decision makers (discussed in Chapter 6, PT5, Section 6.3.5). However, this study acknowledges and identifies that adaptations occur within a wider political, cultural and socioeconomic context and numerous circumstances were identified that will have an impact on how LDM works. This in keeping with previous scale-up literature where factors relating to the wider context have been widely accepted to influence implementation (12, 13, 24, 40, 41, 52, 123-127, 129, 133, 134, 147, 176, 194-196). However this study builds upon this, by identifying specific contextual circumstances, for example where the intervention does not align with the social norms, values and beliefs of the wider community or the local decision maker; where there is reliance on external funding and poor understanding of the intervention components from funders; and in resource limited settings where unavoidable adaptations may occur. Additionally this study provides theory on what mechanisms and outcomes may arise and impact when LDM for adaptations and scale-up in these settings. For example how beliefs of compatibility and fear of

negative repercussions can influence decisions on adaptations to the intervention which may lead to a loss of fidelity.

An important finding to consider from this review was the influence of power dynamics that resulted from the above circumstances and the resulting role conflict for the local decision maker. For example when the funder does not understand intervention essential components, or if these components are counter to a funders values and beliefs, it can lead to pressure on the local decision maker and potential removal of elements with a loss to fidelity and intervention effectiveness. Whose responsibility it is to address a funders understanding or their perception of elements of the intervention can be debated between it resting with the funders themselves to fully consider the intervention and its fit within their setting prior to funding, alternatively whether local sites have a responsibility to openly communicate with funders in relation to importance of certain intervention components and their implications if removed or lost in their setting. Likely both have a role, however the complex power dynamics may make it challenging for local sites to express differing views to funders on intervention components in some situations. In previous scale-up literature the potential impact of power dynamics had been discussed in the SEED-SCALE (173) and Learning Process Approach (LPA) guidance (126), although this was primarily in relation to power dynamics affecting a community's ability to engage in decision making more generally, and therefore was not specific for LDM and intervention adaptation, and it was not specific to frontline providers or district levels of management and their engagement with those who fund them. However, the impact of power dynamics specifically in LDM and scale-up has been highlighted in a recent study by Bulthuis et al., (353) that emerged since the completion of this research in 2020, which explored LDM at district level when management interventions were scaled-up across three LMIC countries. They identified that dispositional power dynamics, for example because of hierarchy and funding, affected a district health team's decision making ability during scale-up. Thus, consideration of power dynamics and the potential for role conflict for local decision makers is in keeping with the emerging literature in this field. Who the local decision maker is needs to be considered in this context, and as to whether using LDM is the best approach in a given setting where there is complex power dynamics, given the pressure this may place on local decision makers, and the potential for intervention adaptation with a loss to fidelity. This may be particularly relevant in LMICs where local decision makers may already be overburdened within fragile health systems and thus ensuring that additional pressures are not added to staff unnecessarily. In some settings, LDM is federally mandated or practical resource constraints limit a scale-up teams ability to lead all sites, LDM may not be a choice. In other contexts, where LDM is an option, the scale-up team should consider the risks associated with potential loss to fidelity, which strategies could be put in place to mitigate this, and whether LDM is the best approach for adaptations in this setting. These practical considerations

need to be made by implementers when planning for adaptation during scale-up within their own diverse contexts.

7.2 Implications and Recommendations of this Research

The implications of the above findings of this research are discussed under the headings for theory, policy and practice and for future research, below. Following this, the limitations of the study and reflections on use of realist review methodology are provided.

7.2.6 Implications for Theory, Policy and Practice

This research has demonstrated that there are adaptations occurring in practice when scaling-up health interventions. In many scale-ups, multiple adaptations occur at various levels of the system. A number of adaptations were proactively planned with embedded actions to complete them, others were reactive to dynamic changes that occur throughout the scale-up, and others were unplanned occurring on an ad-hoc basis, the latter primarily occurring at frontline provider level. Given this evidence of adaptations occurring in practice, policy makers and implementers should acknowledge and embed proactive actions to address adaptations throughout the course of the scale-up. This could involve selecting and embedding one or more of the eight specific actions, as identified in this study: (i) identification of intervention theory, core elements, components, functions or minimum standards; (ii) providing guidance to sites; (iii) LDM; (iv) using an adaptive scale-up design; (v) creating peer learning opportunities; (vi) ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations; (vii) the use of data to assess progress and inform or evaluate adaptations and (viii) the use of QI methods (detailed further in Chapter 5, Section 5.3.9.2). These can be selected based on which best suit the capacity and resources of the context in which the intervention will be scaled and can be used in tandem. These actions for adaptations can be incorporated into the wider scale-up planning.

This study further identified the reasons for adaptations during scale-up as primarily to address resource availability and cultural acceptability. Adaptations for cultural acceptability are often needed in response to social norms, values and beliefs at the wider socio-political level, particularly for SRH interventions, but also can be needed at organisational, provider or recipient levels. An implication for policy makers and implementers is to consider in advance what challenges may occur in their setting (e.g. resource shortages or cultural conservatism) that may lead to a need for future adaptations. This may assist in selecting what actions to embed into the scale-up plan. Some of these challenges, for example resource limitations, may lead to unavoidable adaptations where the policy makers and implementers may need to consider whether these are acceptable (i.e. the intervention may still maintain a level of effectiveness) or whether they are unacceptable and

resources could be better spent on another intervention (61). However others may be avoidable, where policy makers, implementers and other stakeholders could reflect on whether strategies could be put in place to mitigate unacceptable adaptations such as building capacity to use data to inform and evaluate adaptations, and use of systems thinking to resource and skill-share between local sites. Policy makers and implementers should carefully consider the potential impact on fidelity and intervention effectiveness of any adaptations that are made.

In relation to the evidence from this research that unplanned, ad-hoc adaptations are also occurring in practice, often with a loss or unknown impact on fidelity, there is a need to forward plan for strategies to mitigate this. As discussed in phase three (Chapter 6, Section 6.3.3), if a provider's own beliefs are counter to an intervention, they may view it as incompatible in their setting, leading to negative adaptations. Considerations of whether strategies such as desensitisation of providers could be put in place, or alternatively consideration of whether that provider may be the best fit for delivery of the intervention could be needed.

This research demonstrated that providing guidance to sites is an action that can support adaptations for local fit in practice. This included guidance on: the intervention content, (i.e. what was core to the intervention and what was flexible), guidance on how to implement and adapt the specific intervention, along with sharing of tried and tested examples. An importance was seen in ensuring this guidance was accessible to those who would be using it, particularly if for use at frontline provider and peer worker levels. A resource provided through this research that may be useful for practice is this study's Figure 5.5 (Chapter 5, Action 2), which outlines guidance considerations for adaptations during scale-up; i.e. what type of guidance to provide, in what format, with further consideration of who provides and the timing of the guidance. As the needs, capacity and resources of scale-ups will differ, this figure could be used as a resource for selection of what may meet the needs of a given context. However, a limitation of this research was the lack of ability to distinguish what guidance format may work best, in what circumstances, due to a lack of evaluation in the studies of the approaches used. With that said, phase three did explore how who provides the guidance (Chapter 6, Section 6.2.7, PT7), in particular how in circumstances where there is a power imbalance, or if guidance is provided by those outside of the context, may affect receptivity and uptake, all of which need to be considered in practice.

This research generated and refined theory on how LDM works for adaptations of health interventions during scale-up. Specifically, through the generation of eight programme theories and the development of a MRT. These theories were discussed in detail in Chapter 6 (Sections 6.2.7, 6.3 & 6.4) and can be seen collectively in Table 6.11. This exploratory research thus provides

implementers with knowledge which can be practically applied of how LDM may work (or not work) in different circumstances. This can allow implementers to decide whether LDM is an approach which may fit their setting given the contextual circumstances and resources available and/or whether strategies may need to be put in place to address potential challenges that may affect how LDM for adaptations during scale-up works. Thus representing an important contribution to knowledge in the field of adaptation and scale-up. Through this theory generation this study has demonstrated LDM has positive potential for adaptations for local fit, but also comes with complexity and potential pitfalls. In practice, circumstances where: an intervention may not align with the wider cultural social norms, values and beliefs or that of the provider; there are resource availability issues; there is a reliance on external funding and a lack of understanding of importance of intervention components by funders; may impact on how LDM works, leading to intra- and person-role conflict (343) for the local decision maker. These contextual circumstances need to be considered in practice in terms of their potential negative impact of adaptations with a loss to fidelity, or whether strategies can be put in place to mitigate this. This may lead to decisions as to whether LDM is the right fit for a given context. There was no one level of the system where LDM was identified as more or less effective, however, at frontline provider and peer worker levels capacity was identified as more likely to be an issue.

The potential positive effects of LDM with those who know the context having the autonomy to for sensemaking (344) and problem solving with local tacit knowledge for adaptations for local fit warrants consideration of use of this approach in practice. However, this research highlighted the importance of building awareness of the intervention content, and of how to implement and adapt the specific intervention, in order to then use this knowledge in conjunction with local tacit knowledge for sensemaking and problem solving. An example for this could be development by the scale-up team of an intervention manual with a traffic light system (61) for acceptable and unacceptable adaptations for local sites to use. Thus, the complementary action of providing guidance to sites on these elements was central to supporting LDM. The evidence generated from this research suggests that in practice, it is important that guidance and supports are in place when choosing a LDM approach. Another positive benefit of LDM for adaptations during scale-up was the potential to contribute to buy-in and support for the intervention. This was facilitated by complementary actions, for example use of data to inform and evaluate adaptations, thus showing positive visibility of local adaptations contributing to buy in. Likewise, local sites retaining autonomy over the data led local decision makers to feel valued and respected, which further contributed to buy-in and support. Other complementary actions included sharing of tried and tested examples, which in later stages of the scale-up allowed local decision makers to utilise approaches already tested in similar contexts reducing resources and time needed to develop and test new adaptations.

In practice, these complementary actions should be considered as to how they may facilitate a LDM approach in a given context.

7.2.7 Implications for Research

This review builds upon current knowledge of how to adapt when scaling-up health interventions, with a particular focus on exploring what was occurring in practice. As an exploratory study, the findings from this work lay a strong foundation for future research. Specifically, the findings from the current study have created an opportunity for researchers to further test and refine the theories proposed for how LDM works for adaptations of health interventions during scale-up. Future research could take the findings of this study to a wider stakeholder group, with a particular emphasis on those who were local decision makers for adaptations during scale-up. Testing the theories across different stakeholder groups, will assist in further validation and refinement of the theories, ultimately leading to a greater understanding of how LDM works for adaptations to health interventions during scale-up across different contextual circumstances. One particular area that may warrant further exploration is how peer learning can support LDM for adaptations when scaling-up. While shared learning of tried and tested examples of adaptations across sites appeared to facilitate LDM for adaptations, there was a lack of evaluation and exploration of qualitative perspectives of local decision makers on how and why this approach works in the documents identified, therefore suggests this could be an important area for future research to consider. The importance of guidance to sites was also highlighted within this research, further research could explore which guidance format works best, in what circumstances, when making adaptations during scale-up.

This review has further implications and recommendations for the future use of FRAME (1) for adaptations reporting and research. The challenges in using this framework as a taxonomy for adaptations are discussed in detail in Chapter 5, Section 5.4.5. This section further detailed recommendations of improvements for use including: provision of more details and guidance on consideration of fidelity, further differentiation between the goal/purpose and the reasons headings (which may include consolidation with existing implementation outcome frameworks such as Proctor et al., (179)), and addition of a heading to capture improving fit for the wider cultural context. What may be of particular assistance to LMIC settings for use of FRAME (1) would be further differentiation of the heading of resource availability (e.g. HRH, supply chain and logistics) to provide more details for implementers. These recommendations may increase the utility of this adaptation framework and improve transparency of reporting and assist in research of adaptations.

Another implication for future research was the issue of poor transparency of reporting for the scale-up case examples, including often a lack of transparency of the methods used to develop case reports, a lack of detail on the intervention components, and lack of details on potential impact on fidelity of adaptations. The absence of transparency of reporting on the methods to generate studies on scale-up can make analysing, synthesising and appraising the findings challenging and may lead to reduced weight and importance placed on findings. As discussed in detail in Chapter 5, Section 5.4.6, there is no clear preferred design or framework for scale-up research, thus many methods can be considered so long as they are transparently reported. Therefore, this research calls for more transparency in the methods used for scale-up reporting. One area of lack of reporting was of the intervention components, whereby for many studies it was unknown exactly what intervention was scaled and how adaptations may have affected its fidelity and effectiveness. Accordingly, findings from this research suggest that the use of existing guidance, such as TIDieR (100), may assist in more detailed documentation of intervention reporting (discussed in Chapter 5, Section 5.4.4). Finally, findings from this research highlight a lack of consideration of fidelity within the adaptation and scale-up literature. Thus the potential impact of adaptation on fidelity and effectiveness of the intervention for the majority of case examples is unknown. As discussed in detail in Chapter 5 (Section 5.4.3), consideration of fidelity is challenging for implementers without clear guidance on what elements constitute fidelity and how to assess for it. Therefore, this research calls for more clarity for implementers on what is fidelity and how it can be assessed across contexts when scaling-up.

As discussed in Section 7.1.3 above, the importance of knowing the intervention theory, core elements, components, functions or minimum standards came across strongly both within this research and within the adaptation literature. Given the evidence of adaptations occurring in practice during scale-up provided by research, an implication for intervention developers, trialists and funders is to prioritise development, testing and reporting of interventions with this explicitly known to avoid future adaptations with loss to fidelity or intervention effectiveness once scale-up.

7.3 Recommendations

In line with the above, this research makes the following recommendations:

- Implementers and policy makers should acknowledge the need for adaptations to health interventions for local fit throughout the course of the scale-up and embed actions within the wider scale-up plans to proactively address this.
- The following actions to support adaptations should be considered by implementers when scaling-up in light of what best suits their context given the needs, capacity and resources available: (i) identification of intervention theory, core elements, components, functions or

minimum standards; (ii) providing guidance to sites; (iii) LDM; (iv) using an adaptive scale-up design; (v) creating peer learning opportunities; (vi) ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations; (vii) the use of data to assess progress and inform or evaluate adaptations and (viii) the use of QI methods. These can often be used simultaneously and can be embedded within the wider scale-up plans.

- Implementers need to consider the potential impact on fidelity and intervention effectiveness of any adaptations that are made. Use of a fidelity framework in scale-up and adaptation planning may assist with this. Fidelity supports can be given to sites for adaptations such as guidance on intervention theory, core elements, components, functions or minimum standards and guidance on how to implement and adapt the specific intervention.
- LDM can be used as an action to support adaptations during scale-up, however, its complexity needs to be considered by implementers when choosing this approach. Contextual circumstances will affect how LDM will work, for example: where the intervention does not align with the social norms, values and beliefs of the wider community or the local decision maker; where there is reliance on external funding and poor understanding of the intervention components from funders; and in resource limited settings where unavoidable adaptations may need to occur. Thus, in these circumstances, consideration of whether LDM is the most suitable approach and whether strategies may need to be put in place to mitigate adaptations that may affect fidelity in these contexts.
- If choosing a LDM approach, implementers should also consider complementary actions such as: providing guidance to sites on intervention theory, core elements, components, functions or minimum standards; guidance on how to implement and adapt the specific intervention and examples of tried and tested approaches from other sites; in addition to other complementary actions such as supporting use of data to inform and evaluate adaptations. Together, these complementary actions can contribute to a local decision maker having the knowledge for sensemaking and problem solving in their setting and contribute towards local buy-in and support.
- Intervention developers, triallists and funders should prioritise development, testing and reporting of interventions with intervention theory, core elements, components, functions or minimum standards explicitly known and disseminated to allow for future adaptation with fidelity to the intervention when scaled-up.
- Researchers should provide more transparency when reporting on methods for development of scale-up studies and reports. Specifically, care should be taken to report on details of the intervention components, for example through use of the TIDieR framework (100), on the adaptations made, and their corresponding potential impact on fidelity, where appropriate.

- The FRAME (1) taxonomy for reporting adaptations should be expanded for example with further detail for reporting on fidelity and some additions for use in resource limited contexts (i.e. LMICs) by providing more specificity under reporting for adaptations based on resource availability (e.g. logistics and supply chain, cold chain storage, human resource capacity and/or availability, facilities and equipment, etc).

7.4 Limitations

This study was not without limitations which are discussed in Sections 7.4.1 - 7.4.4 below. Further to this, specific challenges relating to the timeline of the review and challenges of using a realist review methodology for this research are discussed in Sections 7.5 and 7.6 respectively.

7.4.1 Limitations in Search Strategies and Definitions Used

There were some limitations identified with the search strategy for this study. In phase one, an initial wide background search was undertaken in the field of adaptation and scale-up to allow for a clarification of the direction of the review. Through learning from this initial search, this phase sought to learn from frameworks and guidance in the field of adaptation, fidelity and scale-up. A limitation of this approach is that the guidance and frameworks were identified from this initial search result as opposed to completing new specific exhaustive systematic searches in each topic area (i.e. separate exhaustive systematic searches for fidelity, adaptation and scale-up guidance and frameworks). Instead, it was decided that the results from the wider search could be complemented with reference lists from previously identified reviews in the field, along with linking in with researchers in the field of fidelity and implementation to identify further resources. While the realist review process allows for this flexibility and prioritisation of resources and time for subsequent searches and phases, it remains that certain literature may have been omitted from the search as a result.

A systematic search for case examples of scale-up in practice however, did take place in phase two. Although it is acknowledged that the case examples identified may not represent all scale-up examples where adaptations to the health intervention occurred. There might be further case examples where reporting has not taken place, and these were therefore undetectable through the systematic search. Further to this, it is acknowledged that grey literature is of importance to implementation and scale-up, and that reports and other documentation may not come up through academic database searching. Attempts to mitigate this however, were made through the use of grey literature databases, including the ExpandNet scale-up database which returned some case examples that were ultimately included. Nonetheless, the search strategy used for this phase returned a large volume of case examples ($n = 22$) that allowed for the identification of numerous

actions used and adaptations made. That said, there may be further grey literature which reported adaptations when scaling-up not identified through this search. Further searching for this phase in addition to these approaches were beyond the resources of a PhD. Future research may therefore want to consider further hand searching as a means to build upon this review.

Publication bias, whereby negative results are less likely to be reported, is widely recognised within the health literature (354). The scale-up team themselves may therefore have been less likely to report negative findings or adaptations that would reflect poorly on their role and which may impact future funding. In addition, some studies relied on frontline provider self-reporting and a potential power imbalance between community-level providers and researchers may have led to an underreporting of negative adaptations, as a potential form of social desirability bias (239, 240). Thus all adaptations with loss to fidelity may not have been captured in this study. In saying this however, a number of the case examples did report on potentially negative adaptations with a definite or potential loss to fidelity (CE1, CE6, CE7, CE17, CE18, CE19). These studies should be commended for putting forward their reflections on how and why this occurred, as learning from what went wrong is also a very useful source of information for implementers going forward.

7.4.1.1 Lack of Conceptual Clarity for Scale-up, Adaptation and Local Decision Making

As discussed in sections 2.1 and 2.2 there is a lack of consensus in the literature for definitions and conceptual clarity for scale-up and adaptation, which on reflection, would have impacted this review. A concept analysis for scale-up and for adaptation was beyond the scope of this study. However for the purpose of this review, a working definition for scale-up of *“the purposeful active expansion in coverage of a health intervention to serve a wider population group. This could involve expanding geographically, or to a wider population within the same setting”* was used, which was informed from previous suggested definitions of scale-up by Mangham and Hanson (11) and Simmons et al (12). For adaptation, a working definition of *“any changes made to the health intervention content which could be planned or occur reactively as needs emerge when scaling-up”* was used informed by Stirman et al’s (15) taxonomy. As part of this study’s inclusion criteria it also further focused the adaptation criteria to explore adaptations which occurred past piloting stage and during the roll-out of scale-up. Alongside this, conceptual clarity on LDM was also lacking, and as seen in section 5.3.9 (action 3), there was a lot of variation in what this entailed across different scale-up projects. Again, a working definition was developed for this study of when *“autonomy was given to local stakeholders to make decisions on adaptations for local fit within their setting”*, however it is acknowledged that this was a very broad definition. As a result of this, when screening took place between reviewers, this lack of conceptual clarity for scale-up, adaptation and LDM, and broad definitions used, required further deliberation to identify whether some studies should be

included or not. This decision making was recorded in the research logbook for transparency. On reflection, had there been more conceptual clarity of scale-up, adaptation and LDM and a resulting clearer definition for each used in this study, this may have been avoided. It is also acknowledged that the search terms used “scale-up” as opposed to more general terms of “implementation”, and therefore studies not using this term but may have fit this studies criteria of scale-up may have been missed. Further research completing a concept analysis of scale-up, adaptation and for LDM would be helpful for future studies in this area. In the absence of this, more specific working definitions and inclusion criteria would be helpful for future studies in this field.

7.4.2 Stakeholder Engagement

Stakeholders in the field of scale-up were involved in phase three of this research as a sixth, ‘reality check’ (156) stage to the review, in order to explore whether findings were in keeping with stakeholders’ experiences in practice and to provide further explanations or refinements. Unfortunately, by the time the stakeholder input was planned, it occurred in the landscape of the global health pandemic of 2020 which made recruitment of those involved in health intervention implementation and scale-up challenging. Consequently, individual interviews took place with a number of stakeholders who were able and willing to engage at this point in time, as opposed to the joint panel originally planned. Therefore less stakeholder input occurred in reality than what had been hoped for, which is a limitation of the review and may have influenced the theories developed in this review. A possible direction this review could have taken from the outset would have been one of a co-production approach with stakeholders embedded as part of the research design and analysis throughout the study. This would have influenced the lens through which this review occurred, potentially providing a more nuanced and practice informed interpretation of the literature for this review. The impact of a lack of co-production approach used, in particular when completing implementation research within global health settings, is further reflected upon in more detail in section 7.6.5. As mentioned previously (Section 7.2.3) future research should take the theories developed in this study to a wider stakeholder group, with a particular emphasis on those who were local decision makers for adaptations during scale-up, for further rounds of theory refinement and validation. Further to this challenge, the long timelines for the scale-up of a project also may have affected the ability of stakeholders to recall their scale-up experience which needs to be acknowledged as a potential limitation. This is also a limitation of scale-up research generally, whereby many years may have passed by the time the project is assessed and published. Ongoing assessment and regular data capturing across scale-up projects may assist this, with publishing occurring throughout, as learning progressed, as opposed to at the end of the project. Some of the stakeholders interviewed however were currently engaged with scale-up projects which may have assisted in recall.

7.4.3 Lack of a Review Team

A limitation of this review is that it was carried out for a PhD, and therefore completed by myself as the reviewer, with input from others in terms of second reviewer screening and coding, as resources allowed. For example, a second reviewer was able to assist in screening of articles for phase two and for CMOC coding check in phase three. Thesis supervisors were also available to check and discuss the coding and differentiation of actions headings for phase two. The use of resources and involvement of others occurred in response to the need for safety and quality checks, however, further engagement of reviewers with the material for broader discussion and collaboration may have enriched the review at various stages and may also have resulted in quicker procedural decisions through discussion and feedback. The use of a review team would have been particularly helpful to make judgements on fidelity and to synthesise the different study types. Therefore, the review being primarily completed by one reviewer is identified as a limitation of this study.

7.4.4 Determining Outcomes

There were numerous challenges in determining outcomes within this study. For example, there was lack of fidelity assessment and reporting which affected whether an outcome of impact on fidelity to the intervention could be identified. When studies specifically noted adaptations with a loss to fidelity, this could be included as an outcome. However, adaptations in keeping with intervention fidelity was not routinely assessed for. Therefore, for the majority of case examples, adaptations in keeping with fidelity to the intervention was unable to be included as an outcome for CMOC development. As an alternative, the outcome of adaptations for local fit, such as the intervention being feasible and acceptable in local settings, was often used as a primary outcome. This was also challenging to discern, with no clear metric or assessment on adaptations in most case examples. A lack of local fit (e.g. lack of cultural acceptability) was primarily reported, with a resulting adaptation (e.g. language of intervention aligned with religious texts (197)) described to demonstrate local fit being achieved. Often this was descriptive without an outcome assessment and therefore a judgement needed to be made as to whether local fit appeared to have been achieved through what was reported. For some case examples, proxy indicators such as rates of implementation and uptake were provided following adaptations. However, it is acknowledged that rates of implementation and uptake would have multiple factors contributing to them, and may not just be the result of an adaptation. The challenges in determining these outcomes and the lack of ability to capture if an approach led to adaptations with fidelity is therefore acknowledged as a major limitation of this review. However, this was unavoidable given studies' poor reporting of

adaptations and assessment of fidelity. Hence why this research calls for more fidelity assessments when reporting on adaptations during scale-up.

Another challenge in determining outcomes occurred when developing the IPTs for phase three. The IPT framework in phase one had identified multiple outcomes of interest, however when it came to focusing on LDM and CMOC extraction, some outcomes were deemed too broad (e.g. sustainability). While studies may have included implementation outcomes, or more often wider health outcomes, these broad outcomes may have had LDM contributed in part to, but multiple other factors would have contributed as well, and so it was decided to focus on more direct outcomes to LDM as appropriate. However, a further challenge was a lack of evaluation for these more direct outcomes of LDM (e.g. buy-in and support, ownership etc). For some, proxy indicators could be used, for example, in the case of buy-in when using a QI/data-driven approach to evaluate adaptations, whereby one study documented how many change ideas were generated and tested as evidence of engagement and buy-in with the process (232, 253, 255, 258). However, for many other cases it was the documents reporting that buy-in and support or ownership was seen, either as a reflection from the scale-up team, or at times with a qualitative input from the local decision maker with a direct quote. For each synthesised CMOC the thought process for rigour was documented and provided in the supporting evidence table for the PTs (Chapter 6, Section 6.2.7) for transparency of this process. As the studies included were primarily case reports with outcome data relating to wider outcomes (not specific to LDM in most cases), it was decided that weight should be applied to reflections and qualitative evidence, once they appeared *coherent* and *plausible* (155) and that the perspective of who was providing the piece of evidence should also be considered. To note, often multiple sources contributed to a synthesised CMOC, which allowed for weight of evidence to be built through demi-regularities in many cases, such that the PTs presented in this study were thought to have sufficient evidence to put forward as findings. While other synthesised CMOCs were not included in these final PTs as they were deemed to have insufficient rigour and supporting evidence.

7.5 Challenges in the Timeline of the Review

The timeline for this PhD was a challenge. For example, the review was placed on hold when maternity leave was taken in 2018-2019. In 2020, the review was placed on hold again during the COVID-19 pandemic due to lack of childcare. Additionally, another maternity leave was taken at the end of 2020 once the study was completed, but prior to submission. This led to a few issues. Firstly, as scale-up and adaptation is an evolving field much research has been developed during these time periods. For example, the NIHR and UK MRC funded ADAPT study (2018-2020) to develop guidance for adapting complex population health interventions for new settings (293, 294) is relevant to this

review. As the initial literature review and IPT framework was developed in 2016, the IPT did not reflect this material. Secondly, numerous practical realist resources for example the book 'Doing Realist Research' (162) were published after the commencement of this study and so, while these resources were able to be utilised in later stages, they were not present in the early stages to assist in developing the protocol. Thirdly, it led to a stop-start approach to the review with re-engagement needed on multiple occasions. As mentioned in Chapter 3, the use of a realist review logbook was indispensable in terms of recalling decision making. However, extra resources and time was needed to review new literature and re-engage with the review at multiple timepoints which led to a delay in examination and publication of the findings.

7.6 Methodological Reflections and Challenges of the Realist Review Process

There were also challenges and reflections specific to the use of the realist review process encountered during this study. These challenges included: finding a level of abstraction for IPTs and CMOs to allow for refinement and synthesis, challenges due to the heterogeneity of studies, use of NVivo for extraction and synthesis, the challenges of completing a realist review in the context of a PhD, and challenges due to the flexibility of the realist review process. Each of these are described below.

7.6.1 IPT Development and Refinement to PT's

There were challenges in developing an IPT framework, and IPT statements, in terms of deciding on the level of detail and abstraction. This research began in phase one with an IPT framework for adaptations during scale-up (see Chapter 4, Figure 4.5). The methods for development of this included input from theory, frameworks and guidance in the fields of fidelity, adaptation and scale-up as described in Chapter 4 and in the published study protocol (44). A challenge of developing this framework was deciding on a level which would allow for recognition of demi-regularities and variation, while also still being specific enough to guide the research question. There were a number of iterations of this framework, which included presenting it to members of the Irish Realist Researcher Group for feedback as a sounding board to support learning through the IPT development process. For phase two of this study the 'actions' heading of this IPT framework was refined based from learning of what actions were used in practice from the wider subset of case examples. This refinement can be seen in Chapter 5, Figure 5.4. As the scope was clarified to focus on how LDM works for adaptations of health interventions during scale-up, this IPT framework was refined further, following familiarisation with the case examples in phase two, to develop five rough IPTs (Chapter 6, Section 6.1.2). These five IPT statements were focused on how LDM may work for adaptations during scale-up and were used to guide initial coding and extraction for phase three. Again a challenge in developing these was to allow them to be at a level of abstraction to recognise

both demi-regularities and variation, while still being specific enough to be useful to answering the research question.

As learning progressed all of the IPTs were further refined in phase three through synthesis of CMOCs from the case examples. When these IPTs specific to LDM were developed in phase three, as lead reviewer, I was already familiar with the case examples, and the (inaccurate) assumption was made that these would be close to the final PTs with some minor refinements made. However as more documents were found, including unpublished and grey literature from the scale-ups, and CMOCs were extracted and synthesised from the case studies, a much greater in-depth learning took place that led to significant refinements of the IPTs and development of four new PTs (an overview of this can be seen in Chapter 6, Figure 6.4). Each case example was returned to multiple times in phase three, as each PT was refined or a new one developed, to ascertain whether there was any further evidence to support, refute or refine theories. This led to the articles and documents being re-read for multiple layers and through the lens of different PTs with a more in-depth understanding and explanations forming throughout this process. Taking the time to complete this was well spent and meant that the depth and complexity of this topic was appreciated and captured in the resulting findings. Future realist reviews should allow for sufficient time to allow for layers of extraction and familiarisation as part of the project's timeline.

7.6.2 CMOC Extraction and Synthesis – Level of Abstraction

CMOCs were initially extracted at case example level, which were then synthesised based on observed demi-regularities. The initial extraction I made at case example level was quite detailed, which made synthesis quite challenging. When synthesising the CMOCs the findings needed to be further abstracted to a level to allow for similarities to be seen. The level of detail for the initially extracted CMOCs at case example level may be a reflection of the fact that I was new to the field of realist review, and a lot of learning took place as the review and synthesis progressed. In future reviews considering the level of abstraction needed at an earlier stage may have facilitated and shortened the synthesis process.

7.6.3 Heterogeneity of Studies

The RAMESES realist review quality standards suggest that selection and appraisal of documents should “demonstrate sophisticated judgements of relevance and rigour in the domain” (p6) (152). As discussed in Chapter 3 (Section 3.3), there is no clear preferred design or reporting guidance for IR and scale-up research. As a result, there was large variation in the study types used and level of reporting. A lack of a clear benchmark of quality within the scale-up domain renders appraisal of rigour more challenging. Moreover, often studies did not fall under a category of a primary

qualitative study, or primary implementation outcome, or health outcome study. Instead, case reports of scale-up were developed from multiple data sources leading to a description of what occurred, with some reporting on reflections or lessons learnt, and in some cases also reporting on outcomes (either implementation outcomes, health outcomes or both). As a result, and as per RAMESES training materials for realist review (3) and guidance from Wong (155), a focus was placed on what specifically was the piece of evidence being used from an article or document, and whether this piece of evidence could be considered *trustworthy*, or an argument *coherent* for CMOC and PT development, refinement or testing. RAMESES realist review quality standards state that “during the appraisal process limitations of the method used to generate data are identified and taken into consideration during analysis and synthesis” (p6), (152). This was attempted based on what the piece of evidence being used was. For example, if an article was focused on quantitative implementation outcomes, for example uptake in number of sites, or change ideas developed or tested, the data they used to generate these outcomes was explored. If the evidence was a qualitative perspective, an effort was made to examine whose perspective was being told i.e., if the local decision makers were included as informants as part of the data collection process, or whether this was the perspective of the author themselves. In practice, relevant quantitative evidence was not routinely present (with quantitative evidence regularly referring to the wider health or implementation outcomes and not directly linked to a CMOC for LDM), resulting in qualitative evidence, including reflections from implementers, making up the majority of the sources. Consideration of what weight to give different evidence was also challenging. For example how much weight does one assign to a case example where a single participant quote noted buy-in versus a study where multiple sites demonstrated buy-in through ongoing development of adaptations (i.e. developing change packages at multiple sites). However, for the majority of CMOCs the demi-regularity seen between cases added weight to findings, with multiple sources reporting similar findings contributing to the strength of the evidence, in addition to coherence of the findings with wider substantive theory. For some CMOCs demi-regularity from the sources were less frequent, however, if the study or report placed great importance on a finding as integral to an outcome occurring in their settings, this was also considered in developing the synthesised CMOCs and PT refinement. To address these elements, the thought process for each CMOC was documented in the PT tables to promote transparency.

Wong (155) notes “In an ideal world, any realist programme theory is underpinned by arguments that are based on the most trustworthy data. However, this is often not achievable and data of varying trustworthiness are all that we can find for use in a realist review. In such a situation, even data of limited trustworthiness can make some contribution to building arguments underpinning a realist programme theory which are plausible.” (p10). Trustworthiness was also found to be an

issue within this review, where it was sometimes a challenge to discern which input or data source in the article or document contributed to each finding in order to assess the methodological limitations for the piece of evidence. For other studies, transparency was an issue, with a lack of reporting of how the information for a scale-up case report was gathered and reported. Additionally valuable insights often came from reflections of the scale-up team, or within case reports with inputs from multiple stakeholders, however it was unclear whose opinion contributed to which aspects of the reports. Thus, the use of the concept of *coherence* assisted in assessments of rigour. With these challenges noted, a primary goal within this review for the rigour assessment was to ensure its transparency. As a result, considerations of rigour for the evidence sources were documented in tables for each CMOC and PT. While this made the tables for each PT quite lengthy, it served to demonstrate what considerations were made for rigour to aid transparency in this challenging appraisal process.

7.6.4 Use of NVivo for Extraction and Synthesis

NVivo was used in the extraction and synthesis of this review. While there were benefits to using this software, it also had limitations. A process similar to Gilmore et al., (161) was taken where initial codes were based on the IPTs, however these were added to and refined as the synthesis progressed. A document was created for each case example for the CMOCs at this level. Coding for these CMOCs then took place based on the IPTs and further demi-regularities seen. Memo notes were used to keep track of the thought process throughout, which were helpful to return to for reminders. However, when it came to CMOC synthesis and PT refinement the layout and ability to capture data was limited to the linear form of the memo note within NVivo (NVivo 12.6.0 Mac). At this point the decision was made to move the data to Microsoft Word tables and give each PT a table, within which: the relevant synthesised CMOCs, thought processes, considerations of rigour, details of which IPT it related to, and whether wider substantive theory could contribute to the findings were reported in a more legible format. The use of Microsoft Word tables further allowed the data to be interpreted more clearly. Therefore, NVivo did prove useful for initial coding and capturing of the initial thought process in memo notes, however once a more detailed level of synthesis and theory refinement and development occurred its utility was reduced for this review, and the more user friendly interface of Microsoft Word tables was found to be more useful.

7.6.5 Researcher Reflexivity

A realist review methodology is iterative and lends itself to many ways to approach a research topic and question. Thus, there is a need to reflect on my own background and how this may have influenced the direction of the review. I have worked as a frontline provider in allied health as a physiotherapist for over ten years, which included in acute, primary care and disability settings

across a number of countries. Therefore, I came into this research from the perspective of a frontline provider, who has engaged directly with recipients of interventions, and has experienced different health services and approaches to implementation. I went on to study an MSc Global Health and following this completed research in the global health field. This included research projects based at community level, such as community based approaches to disability services, along with projects taking a macro view of health systems, for example examining health policy, or use of systems-thinking for global access to assistive technologies. Thus, I believe this latter experience has helped to incorporate a macro health systems lens from which to view research as a complement to my frontline provider lens.

Scale-up and adaptation is a complex topic with many elements of the system to consider. I have contemplated as to whether my background on the frontline may have somewhat influenced the focus on LDM in the final phase of this research. However, I also believe there was sufficient justification of choosing LDM including its frequency of use, the complexity, lack of research in the area and the potential positive benefits of using this approach. A potential benefit of exploring the area of LDM with my background as a frontline provider is it may have added to potential understanding of nuanced experiences by those on the frontline, such as power dynamics felt by funders, and contributed to an understanding of the complexity of LDM reported by the case examples.

As discussed in section 7.4.2 a limitation of this research was the lack of a co-production approach chosen for this project. It is acknowledged that as a western researcher I will have viewed the PTs through my own lens. Henrich et al (370) has previously discussed that often theory developed from Western, Educated, Industrialised, Rich and Democratic (WEIRD) societies can be viewed as universal, when in reality these theories were developed in settings that do not represent the majority of the world. Numerous implementation theories informed the IPT framework which primarily were developed in HIC contexts, and further organisational theory which influenced theory refinement at later stages, such as role conflict and sensemaking theory, also come from these HIC settings. A potential mitigator for this western lens, would have been embedding a co-production approach to this implementation research with more in-depth stakeholder input throughout. However, as noted in section 7.4.2 this was, in part, limited due to circumstances surrounding the global pandemic. For future utility of the findings of this research, it would greatly benefit from in-depth stakeholder engagement to work towards further theory refinement, with a focus on embedding knowledge and lived experience from scale-up and adaptation in LMIC settings. This co-production approach with stakeholder engagement throughout may allow for more nuanced refined theories to emerge and greatly add to this work.

7.6.6 Challenges of Realist Methods as part of a PhD

One of the greatest challenges of using a realist methodological approach was it being used for a PhD where the work can feel largely carried out in isolation. Given the iterative, non-linear approach with many ways the research can be focused and analysed, not having a designated realist review team to bounce ideas off was challenging. This was mitigated where possible with peer support from colleagues who were also engaging with realist methods. In addition, thesis supervisors provided a sounding board for approaches selected and used throughout the project, however, a challenge of this was that due to staffing throughout the lifecycle of the PhD there were multiple supervisor changes which at times impacted their familiarity with the review and realist methodological process.

With any research, in particular that of a PhD, there is the challenge of resource availability. In the context of a realist review, which does not have a defined endpoint and potential for further searches that can be continually undertaken, it can be hard to decide when to draw the line. This took balancing resource availability, timelines and reflection on whether sufficient evidence was generated for the theories in deciding when to stop. In particular, a challenge of this mentioned in Chapter 6 was the difficulty recruiting stakeholders in the current timeline. Pragmatism had to be considered in that prolonging the research until more favourable recruitment circumstances were available was not within a realistic timeframe for this review. As part of the learning from this, in future realist reviews I would involve stakeholders at an earlier stage to generate a panel which could be used as a resource throughout the review. The use of a panel may also assist in guiding where best to spend resources exploring further searches (i.e. what theories may be of most benefit for future policy and practice).

7.6.7 Flexibility of the Realist Review Process

The realist guidance (3) and quality standards (152) were created not to be prescriptive but to allow for flexibility and use of the methods across domains. With the flexibility of the review process many lessons were learnt along the way that can be brought to future realist review projects. One such lesson was the when to focus the question and develop initial programme theory. Wong (155) discusses the value of identifying a programme theory early on to aid in the focusing of searching. As actions for adapting health interventions at scale had not previously been explored, it was challenging to choose one and move towards a programme theory without first laying the groundwork of identifying what actions were used in practice. Particularly, and as evidenced by this research, given that many actions were used simultaneously and impacted on each other (e.g. providing guidance on tried and tested examples supported LDM). This resulted in an IPT framework being developed at an early stage, before the question had been truly focused. In

hindsight, what may have saved resources and time, was identifying potential actions to bring forward to phase two (instead of the wider IPT framework at this stage). Following phase two, and when the question was focused to LDM, the resources could have been used at this stage to return the literature to develop the IPT framework to identify potential contexts and mechanisms specifically for LDM. While I do not believe the research suffered as a result of the early IPT framework, given that it assisted in informing the IPTs for LDM in phase three, a lot of resources and time were taken up during phase one that could have been spent elsewhere.

A challenge of the flexibility of a realist review for a novice researcher is that there are many ways the research can be approached. It took time to build confidence in my understanding of the methods and in the approaches selected for use throughout the review. However, what was a challenge can also be seen as a strength, as in the end the approach which made most sense to the data and resources of the review was also able to be used for this study. An overview of the iterative nature of the review with elements of different stages informing each other across the stages of the realist review and steps taken during each phase can be seen in Figure 7.1. Further to this, the realist review quality standards were used (152) to guide and support decisions. An overview of the quality standards and how they were met by the review is presented in Table 7.1 below.

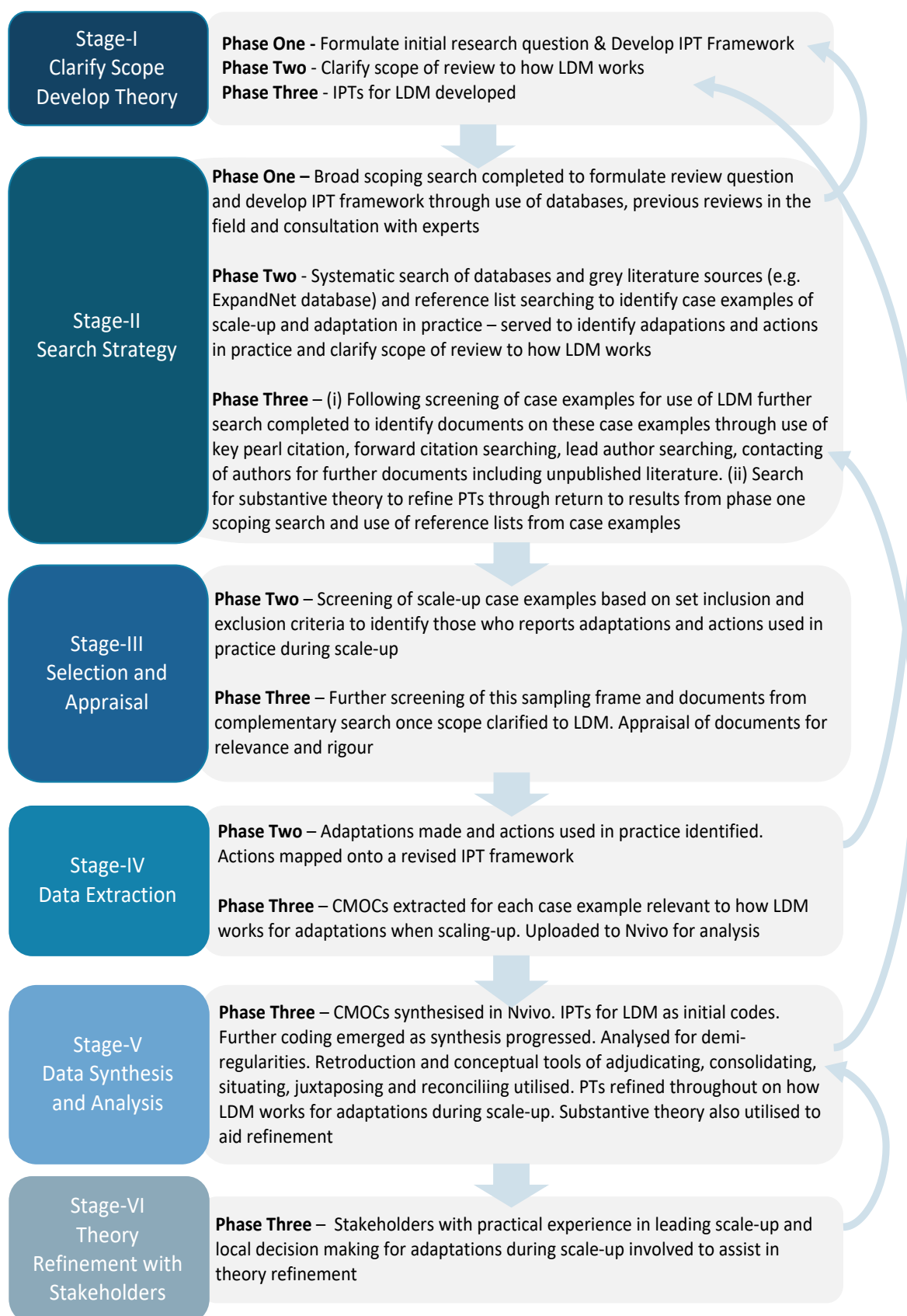


Figure 7.1 Stages of the realist review with overview of steps taken in each phase. Adapted from (43, 44)

7.6.8 Dissemination of Realist Review Methodological Approach and Reflections

A strength of this study is that it provides a transparent account of the process and reflections on the use of realist review methodology which may support future researchers when engaging in this challenging process. Methodological learnings have so far been disseminated through the published study protocol (44) and through presentation on the utility of use of a research logbook in a realist review at the Realist Research, Evaluation and Synthesis Conference in Dublin (February 2021).

Table 7.1 Quality Standards and How the Criteria were Fulfilled in the Review. Adapted from (152, 301)

Quality Criteria	How the Criteria were Fulfilled
1a. The research topic is appropriate for a realist approach	The review focused on how LDM works for adaptations when scaling-up health interventions which is a complex topic occurring across diverse contexts at multiple levels of the health system with multiple actions at play
1b. The research question is constructed in such a way as to be suitable for a realist synthesis	The research question underwent iterations throughout the phases of the review. For phase three the research question was focused as to how does LDM work, by what mechanisms, and in what contexts for adaptations during scale-up of health interventions
2. The review demonstrates understanding and application of realist philosophy and realist logic that underpins a realist analysis	In phase three the data was collected and analysed using a realist logic of analysis using CMOC explanations
3. The review question is sufficiently and appropriately focused	The review question was focused from learning in phase one and two from looking at how actions worked for adaptations when scaling-up, to specifically a question of how LDM works for adaptations of health interventions when scaling-up to allow for greater exploration of complexity of this one action
4. An initial realist programme theory is identified and developed	An IPT framework was developed in phase one of the research, this was refined (specifically the actions headings) following learning in phase two. At the beginning of phase three IPTs specific to LDM were developed based on this IPT framework and familiarisation with the case examples
5. The search process is such that it would identify data to enable the review team to develop, refine and test programme theory or theories	Searches were carried out iteratively throughout all three phases of the research. It included a background search (phase one), systematic search (phase two) and further complementary search (phase three) to identify evidence on identified case examples to provide more richness of information for PT development and refinement. Substantive theory was also sought in phase three of the research to refine theory
6. The selection and appraisal process ensures that sources relevant to the review containing material of sufficient rigour to be included are identified. In particular, the sources identified allow the reviewers to make sense of the topic area; to develop, refine and test theories; and to support inferences about mechanisms	Sources were screened for relevance and rigour. The complexity of rigour assessments in the scale-up domain was considered and discussed in detail in Chapter 6. For transparency consideration of rigour for each synthesised CMOC and PT were presented in tables for each PT in Chapter 6

Quality Criteria	How the Criteria were Fulfilled
7. The data extraction process captures the necessary data to enable a realist review	Data was extracted relating to CMOCs for LDM for adaptations during scale-up. These were coded against the IPTs for LDM, however new codes could emerge and be refined as learning progressed. With each synthesised CMOC and PT developed and refined the case examples were reviewed again to look for evidence to support, refute or refine theory
8. The realist synthesis is reported using the items listed in the RAMESES reporting standard for realist syntheses (151)	Reporting standards and where to find components in the thesis is detailed in Appendix I. The reporting guidelines for realist synthesis will also be used for any subsequent publications. In addition to this, the reporting of search components by Booth et al., (45) was followed during this review

7.7 Conclusions

This study has highlighted that scaling-up is a complex process, occurring within complex systems. When adding the additional component of making adaptations, scale-up becomes an even more challenging task. This research has demonstrated that adaptations to health interventions are occurring in practice throughout the course of scale-up. Adaptations were primarily occurring due to resource availability and to improve cultural acceptability, including to increase cultural acceptability for the wider population and context and not just for specific minority groups. Implementers need to examine in advance what contextual challenges may occur in their setting (for example resource shortages, cultural conservatism etc.) that may lead to future adaptations and their potential impact on fidelity. This may assist implementers in considering whether adaptations are unavoidable, and in selecting what actions to embed into the scale-up plan. Multiple actions that can be used for adaptations during scale-up were identified in this study including: (i) identification of intervention theory, core elements, components, functions or minimum standards; (ii) providing guidance to sites; (iii) LDM; (iv) using an adaptive scale-up design; (v) creating peer learning opportunities; (vi) ongoing assessment of the wider political, socioeconomic, cultural and organisational context to inform adaptations; (vii) the use of data to assess progress and inform or evaluate adaptations and (viii) the use of QI methods. These actions can often be used in tandem, supporting each other and can be embedded into the wider scale-up plans. LDM in particular is a promising action which allows for those who know the context to problem solve for their setting. LDM may also contribute to local buy-in and support for the intervention. However, it is not without complexity. LDM for adaptations during scale-up occurs in complex systems, within a wider cultural and socioeconomic context, with varying levels of capacity, and often in tandem with numerous other approaches. Implementers may select to use an LDM approach during scale-up of health interventions or may be compelled to do so through existing health system structure or given resource constraints. In both situations there are numerous considerations for LDM for adaptations during scale-up. For example, the use of complementary actions such as provision of accessible guidance and support, on intervention

components and how to implement and adapt the specific intervention, is required for local sites. Other complementary actions such as sharing tried and tested examples from other sites, and supporting a data-driven approach to inform and evaluate adaptations may also support LDM by reducing the time needed for adaptations in later phases and by contributing to improved buy-in from implementers. However, the capacity and resources needed for LDM must be considered by the scale-up team in deciding to use this approach. Additionally LDM has potential pitfalls that need to be considered such as in circumstances where the intervention does not align with the social norms, values and beliefs of the wider community or the local decision maker; there is reliance on external funding and poor understanding of the intervention components from funders; and in resource limited settings where unavoidable adaptations. These will all have impacts on how LDM works, potentially leading to such issues as intra- and person-role conflict (343) for the local decision maker. Thus, LDM is a promising approach for adaptations during scale-up, however implementers need to consider of the complexity of how LDM works when choosing this approach across the diverse contexts they encounter during scale-up to ensure adaptations that address local needs are achieved while also maintaining intervention fidelity and effectiveness.

BMJ Open Adapting health interventions for local fit when scaling-up: a realist review protocol

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To cite: Power J, Gilmore B, Vallières F, *et al.* Adapting health interventions for local fit when scaling-up: a realist review protocol. *BMJ Open* 2019;9:e022084. doi:10.1136/bmjopen-2018-022084

► Prepublication history and additional material for this paper are available online. To view these files, please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2018-022084>).

Received 31 January 2018
Revised 21 June 2018
Accepted 23 October 2018



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ABSTRACT

Introduction Scaling-up is essential to ensure universal access of effective health interventions. Scaling-up is a complex process, which occurs across diverse systems and contexts with no one-size-fits-all approach. To date, little attention has been paid to the process of scaling-up in how to make adaptations for local fit. The aim of this research is to develop theory on what actions can be used to make adaptations to health interventions for local fit when scaling-up across diverse contexts that will have practical application for implementers involved in scaling-up.

Methods and analysis Given the complexity of this subject, a realist review methodology was selected. Specifically, realist review emphasises an iterative, non-linear process, whereby the review is refined as it progresses. The identification of how the context may activate mechanisms to achieve outcomes is used to generate theories on what works for whom in what circumstances. This protocol will describe the first completed stage of development of an initial programme theory framework, which identified potential actions, contexts, mechanisms and outcomes that could be used to make adaptations when scaling-up. It will then outline the methods for future stages of the review which will focus on identifying case examples of scale-up and adaptation in practice. This realist review consists of six stages: (i) clarifying scope and development of a theoretical framework, (ii) developing a search strategy, (iii) selection and appraisal, (iv) data extraction, (v) data synthesis and analysis and (vi) further theory refinement with stakeholders.

Ethics and dissemination This review will develop theory on how adaptations can be made when scaling-up. Findings will be disseminated in a peer-reviewed journal and through stakeholder engagement as part of the research process. Ethical approval has been received through Health Policy and Management/Centre for Global Health Research Ethics Committee of Trinity College Dublin.

INTRODUCTION

The process of scaling-up an effective health intervention is complex and occurs across diverse systems and contexts.^{1 2} It is estimated that only 14% of healthcare research makes it into real-world settings.^{3 4} Therefore, many

Strengths and limitations of this study

- The use of a realist review approach will allow for the exploration of the complexity of scale-up and adaptation in practice.
- We present an initial programme theory framework which identifies potential actions, contexts, mechanisms and outcomes that may influence scale-up and adaptation which is based on peer-reviewed literature and frameworks in the fields of fidelity, adaptation and scale-up.
- This protocol provides a detailed account of proposed methods for a realist review, including the supplemental files of a research logbook, coding and synthesis procedures, which may assist future researchers in options for approaches that can be taken and for addressing the issue of decision making and transparency for realist reviews.
- This study will use the inclusion of stakeholders for theory refinement in the later stages of the review, ensuring practicality of findings and dissemination through the review process.
- The scope of this review is ambitious within the time-frame, however in keeping with realist reviews this may be further refined throughout the stages in light of findings from the literature or by stakeholder consultation.

existing health problems could be addressed through scaling-up of interventions already known to be effective. For example, it is estimated that 85% of childhood deaths could be avoided in low-income and middle-income countries through scale-up of existing health interventions like zinc and oral rehydration therapy treatment.⁵ Currently, scale-up has been estimated to take 15 years from pilot to national scale.⁶ Scale-up is time consuming and challenging due to the complexity of implementing across diverse contexts where the population,⁷ finances, resources and capacity⁸ may differ. The result is a growing discussion on the need to provide more evidence for how to address this important research-to-practice gap.

Scale-up, adaptation and fidelity

Scale-up can be defined as a purposeful expansion of a health intervention to a wider population.¹⁹ This could involve expanding geographically, or to a wider population within the same setting. Adaptations can be defined as deliberate and/or unintended changes to the intervention content, context or training and delivery.¹⁰ As per the international classification of health interventions,¹¹ a health intervention can be defined as ‘an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions’ (paragraph 1). When scaling-up it can be necessary to adapt for local contexts as needs and resources may differ between scale-up sites.^{7 12} Adaptation has been seen as an essential process to match community needs, organisation resources and to gain trust and ownership by community.¹³ By addressing and adapting for local fit, it can assist in successful implementation and sustainability of an intervention.¹² However, with adaptations there is also a need to ensure fidelity to the intervention theory and essential components to ensure the effectiveness of an intervention is not reduced or lost.⁷

Fidelity has been described by Castro *et al*¹⁴ as delivering the programme as intended and tested, however they also noted there may often be a need to adapt to the target population.¹⁴ Fidelity can often be seen as a top-down (researcher, intervention developer) driven approach and adaptation has been viewed as more of a community-driven bottom-up approach (frontline service providers, communities, individuals).¹⁵ However, when looking at fidelity it is impossible to ignore potential necessary adaptations for local needs, and when looking at adaptation to ignore how to maintain fidelity to the original intervention. With both proposed as necessary when scaling-up across diverse populations and delivery systems.⁷ In considering fidelity it is suggested that any adaptations retain the underlying intervention theory and that the essential components or active ingredients remain intact, with any changes made to match the unique features of the setting.^{13 15 16} This opinion was shared by Aarons *et al*⁷ in relation to scale-up, and Chambers *et al*¹² in relation to sustainability, where identification of theory and essential elements of the intervention can facilitate adaptation outside of these, and assist in avoiding a ‘voltage drop’,¹² or the tendency for effectiveness to taper with ongoing implementation.

The need for adaptation when scaling-up

Within complex systems, such as healthcare, applying a single approach in all settings is unlikely to be effective, as it does not take into account the complex contextual environment within which the intervention takes place.¹⁷ Therefore, adaptations are important in terms of ensuring that the intervention content, context and/or delivery strategy fits with local needs across scale-up sites.¹⁰ A trade-off may need to occur between increasing scale and adapting to maintain local values, local relevance, quality and sustainability.¹⁸ Additionally, and given that contexts

are continually changing over time, allowing for adaptations with contextual changes is needed to ensure sustainability of interventions.¹² Specifically, adaptation has the potential to enable implementers to match the needs of a more heterogeneous population; to simplify a complex intervention; to focus on a specific problem or to expand to address multiple problems; to increase ownership of an intervention; to adjust to a lack of available resources or requirements made by agencies or funders; allow for additional applications of an intervention and/or address a lack of knowledge of the intervention.¹³ It is important to note that adaptations may be intended or unintended,^{10 19} and may be positive or negative.²⁰ With positive adaptations supporting implementation and achieving desired clinical outcomes, negative adaptations could potentially hinder or reduce these. Holliday *et al*²⁰ put forward in the design and testing of an educational intervention, that adaptations can be on a spectrum from acceptable to unacceptable, and avoidable to unavoidable. Thus, some adaptations may be unavoidable for local fit, however are acceptable as they maintain the intervention theory and essential components. While others may be unacceptable as they change the underlying theory and essential components, or avoidable in that they may not necessarily need to be adapted within that setting.

Although adaptation has been highlighted as a key contributing factor in addressing feasibility and/or acceptability for local settings when scaling-up,^{7 12} adaptation is rarely documented as part of the scale-up process.^{1 21 22} Often efforts to achieve scale-up can focus on the replication of the originally tested pilot or feasibility study. Replication however, does not account for the diverse social, political and cultural contexts across scale-up sites. This results in a need for more tailored approaches.²³ There is a need to understand how an intervention may work in a given context to allow for selection of approaches that are most likely to be effective in that setting, thus avoiding interventions being deemed potentially ineffective and not achieving scale-up.²⁴ The need to adapt interventions for local settings has been put forward across the health spectrum from maternal and child health,²⁵ malaria prevention,²⁶ HIV,^{27–29} to mental health.³⁰ While some recent frameworks have supported the local development of adaptations when scaling-up, and suggested actions such as use of quality improvement methodology.^{2 12} Unfortunately, there still remains minimal guidance on how to complete local adaptation, adding to the difficulty in achieving and reporting of scale-up of health interventions with local fit.^{1 31}

Adaptations in practice

Despite its absence of documentation, adaptation has been discovered as naturally and commonly occurring in the practice of scaling-up.³² For example, within 44 preventive interventions in a Substance Abuse and Mental Health Services (SAMHSA) national database in the USA, over half of these had been adapted, suggesting that adaptation is more common than not.¹⁴ A study by

Moore *et al*³² looked at the adaptation of evidence-based programmes in Pennsylvania for reducing delinquency and violence. Out of 10 evidence-based programmes with over 200 replications across the state, 44% reported making adaptations. It has also been recognised that informal on-the-job adaptations are often made by professionals working in, and deeply embedded in the context and who therefore may understand the nuances.³³ However, this informal on-the-job approach to adaptation is rarely discussed, documented or evaluated, resulting in a dearth of information on how adaptation may impact the intervention in the long term.

Guidance for adaptation and scale-up

Within the implementation and scale-up literature there are many models and frameworks mentioning the need for adaptations, for example, the AIDED and ExpandNet process frameworks.^{1 34} Despite growing recognition of the importance of adapting across diverse local settings, along with evidence that adaptations are occurring in practice,^{14 32 33} there is minimal guidance on what and how specific actions (eg, transferring decision making to local level, generation and use of local data or engagement of the community) can be used to achieve adaptations when scaling-up, and even less guidance on *how, why* and *when* to choose one method over another across different contexts. Moreover, while there is some guidance available for implementers on adaptations, these guidelines are not specific to scale-up, and most existing guidance on adaptation are based in the field of substance abuse prevention and HIV behaviour change interventions.^{13 19 35–38} These were largely designed for high-income country contexts and some of this guidance requires highly skilled, and resource heavy processes. Additionally, some guidance suggests involving the original intervention developers, and at times promoting redesign and testing of the intervention,³⁷ which may not be feasible at multiple diverse sites when scaling-up. Previous scale-up and sustainability frameworks have promoted adaptation for local fit,^{7 12} however, there is a need for more guidance on how to achieve this. A previous review explored the process of scale-up of complex interventions,³⁹ however did not specifically address adaptations for local fit when scaling-up. Therefore, while acknowledging the importance of adaptation for local fit there is minimal guidance for implementers on what actions can be used to achieve adaptations when scaling-up, by what mechanisms these may work and how the context may influence this. Therefore, there is a need to build on current knowledge of scale-up.

Research questions

What are the actions that can be used to guide adaptations when scaling-up healthcare interventions?

How do these actions work (ie, by what mechanisms, and in what contexts)?

Aims and objectives

The aim of this research is to develop theory on what actions can be used to make adaptations to health

interventions for local fit when scaling-up across diverse contexts that will have practical application for implementers involved in scaling-up.

Objectives:

- Identify what adaptations are being made in practice when scaling-up health interventions for local fit.
- Identify what actions are used to achieve adaptations when scaling-up health interventions for local fit.
- Discover how these actions work by uncovering what mechanisms are triggered, in what contexts, to achieve adaptations when scaling-up health interventions for local fit.
- To put forward theories on what actions can be used, and how these actions may work to achieve adaptations when scaling-up health interventions for local fit, by identifying demi-regularities within the uncovered contexts and mechanisms.

METHODS AND ANALYSIS

Realist review methodology

Realist review is a methodology for evidence synthesis that uses a theory-driven interpretive approach to explain findings.^{40 41} It aims to provide an explanation of what works, for whom and why, in what circumstances.⁴² It allows for exploration of the complexity of a topic with a focus on theory generation that may be applicable in the setting under study, and applicable in wider settings through development of theory of ‘middle-range’.^{40 43} Realist review methodology allows for inclusion of a wide body of evidence including grey literature sources.⁴⁴ It supports stakeholder involvement throughout the stages of the review to inform the scope of the review, to develop and refine theory⁴¹ and/or assist in dissemination⁴⁵ of findings.

Realist review focuses on causation, with identification of where an intervention or action under certain contextual conditions (C), may trigger a mechanism (M), to achieve a given outcome (O).^{40 46} It completes this through development of context-mechanism-outcome configurations (CMOCs),⁴² which are central to the analysis and theory building process with mechanisms often seen as the integral link between the context and the outcome.⁴³ They can uncover the ‘why’ a given outcome may have occurred. Dalkin *et al*⁴⁶ conceptualised mechanisms as either resources or reasoning. They put forward that a mechanism can be a resource which can be introduced in a context, which can trigger a mechanism in the form of response or reasoning, resulting in an outcome. However, mechanisms may only activate in specific contextual conditions with the context as acting like a dimmer switch.⁴⁶ Within optimal contextual conditions mechanisms are triggered or ‘fire’, and with suboptimal conditions mechanisms may fire to a lesser degree or not at all.⁴⁶ It is also acknowledged that actions may influence and change the context, which in turn may influence whether and how a mechanism fires.

In the current research, we view actions that were carried out to achieve adaptations when scaling-up (eg,

generation of evidence or participation of stakeholders), as a mechanism in the form of a resource. These actions, under the optimal contextual conditions, may trigger a mechanism in the form of reasoning or response (eg, awareness or commitment), which in turn may generate outcomes. For this research outcomes can be proximal or distal. With distal outcomes relating to the overall aim, for example, adaptations with local fit or sustainability as reported by the evidence, and proximal outcomes relating to those that may occur prior to this, for example, local ownership of the intervention or consensus for adaptations.

Demi-regularities (semi-predictable patterns occurring in the CMOCs) can further assist in explanation of the findings. Abductive reasoning can be used, which Jagosh *et al.*⁴⁷ described as the ‘*iterative process of examining evidence and developing hunches or ideas about the causal factors linked to that evidence*’ (p. 5). Abductive reasoning could be discussed as explaining a finding from both the seen and unseen, and drawing from theoretical perspectives to provide possible explanations for an outcome.^{48 49} This can involve recontextualising or redescribing explanations based on interpretations.⁴⁸ Retrodution can also then be used to situate the findings and put forward what causal pathways and conditions may need to be present for the phenomenon of interest to occur.⁴⁸

A realist review methodology was chosen as appropriate to address the study objectives for four reasons. First, within scale-up research, realist review methodology allows for in-depth consideration of how actions can be influenced by contextual factors (eg, resource availability, level of perceived need for intervention in a local setting, etc) to trigger mechanisms (eg, trust, commitment,

awareness) to generate desired outcomes (eg, local ownership, feasible and acceptable adaptations of a health intervention) leading to successful scale-up and local fit. Second, realist review methodology was chosen as it recognises the use of multiple evidence sources, which was considered particularly important for scaling-up. While not prioritised on a traditional hierarchy of evidence, grey literature reports may contain valuable information on the scale-up process. Third, stakeholder involvement can also assist in validation and refinement of theory⁵⁰ and it has been put forward by Brennan *et al.*⁴¹ that involvement of stakeholders can provide a ‘reality check’ as to whether the findings are consistent with experience and knowledge from practice. Involvement of stakeholders with experience in adaptation and scale-up through research and practice, may assist in ensuring the findings are practical and of utility to implementers in the field. Finally, realist review methodology has been previously successfully used to explore the process of scaling-up complex healthcare interventions.³⁹ This allowed for an in-depth analysis of how complex health interventions were scaled-up across three case studies, identifying active mechanisms that were needed to achieve scale-up, and suggesting how the context may have influenced the scale-up across these cases.

Stages of the realist review

This protocol is based on the five stages of realist review by Pawson *et al.*⁴⁰ with the addition of a further stage of stakeholder involvement for theory refinement, which has been put forward by previous reviews^{41 51} (see figure 1, adapted from Molnar *et al.*⁵² and Groot *et al.*⁵³). These stages are not necessarily carried out in a linear process as the stages are iterative and may overlap and inform

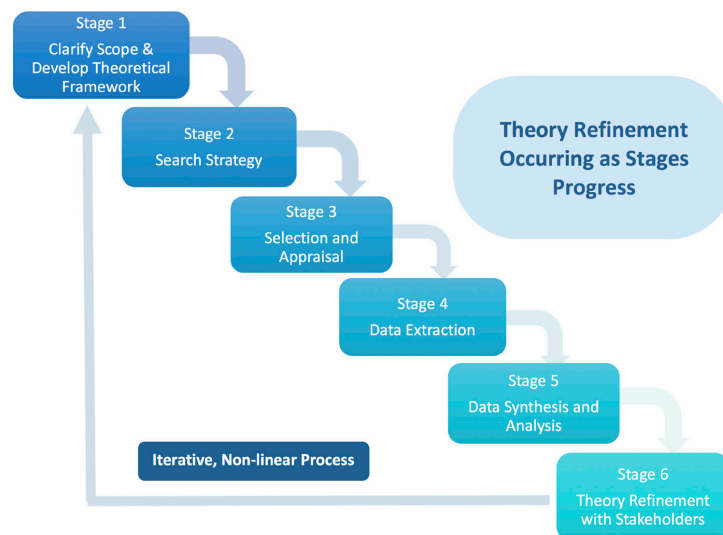


Figure 1 Overview of stages of the realist review. Based on Pawson *et al.*⁴⁰ Adapted from Molnar *et al.*⁵² and Groot *et al.*⁵³ These stages are non-linear and will be carried out in an iterative fashion with theory refinement occurring throughout.

each other as learning on the topic progresses and theory refinement takes place.

Stage one of this review has been completed to clarify the scope of the review and develop the initial theoretical framework. This protocol paper will briefly describe this first stage process and how findings were used to develop the protocol for the following stages 2–6, which are to be carried out from June 2018 to March 2019.

Stage 1: clarifying the scope of the review and developing a theoretical framework

According to Pawson *et al.*,⁴⁰ a realist review begins with clarifying the scope of the review and the elicitation of initial rough theories in the form of an initial programme theory (IPT). The IPT can provide a map of the areas to be investigated and gives a structure for data synthesis.³⁹ These can be further refined, tested and added to as the synthesis progresses.⁴³

Developing the IPT framework

For this research, an IPT framework was developed which was a theoretical framework to guide the review. This will be refined as the review progresses in future stages. The methodology and format of the IPT framework to guide this review was informed by the Willis *et al.*³⁹ realist review, which focused on the process of scale-up of complex interventions, identifying in their initial IPT framework actions, contexts and outcomes. After analysis and synthesis of three case studies, they further identified what mechanisms were triggered to achieve scale-up of complex interventions and what contexts influenced this. Therefore, the realist review by Willis *et al.*³⁹ provided an appropriate guide to inform the methodology for the IPT development for this review. In light of this method, this study developed an IPT framework focusing on what potential actions, contexts, mechanisms, distal outcomes and proximal outcomes may be of relevance to scale-up and adaptation. A particular focus of this IPT framework was the identification of potential actions (eg, definition of roles, use of feedback loops, etc), and how these can achieve the outcome of adaptation for local fit. This IPT framework will provide a theoretical map for further exploration in the following stages of the review.

Purposeful and iterative searching was undertaken for this first stage of the realist review to inform the content of this IPT framework.³⁹ An initial scoping search was undertaken for scale-up and adaptation in healthcare to get an overview of the available literature in the field. There was a large volume returned with many articles discussing the need to adapt for local fit, however without giving guidance for how, why or when to complete this when scaling-up. As a result, a decision was made to particularly focus on guidance and frameworks relating to scale-up, adaptation and fidelity to prioritise identification of what actions could be taken (eg, create opportunities for learning, giving guidance to sites, etc) to make adaptations when scaling-up. Guidance and frameworks were identified from the initial scoping search results, in addition to use of reference lists, in particular of recent reviews in the field of implementation and scale-up by Milat *et al.*,⁵⁴ Subramanian *et al.*,⁵⁵ Nilsen⁵⁶ and also use of the ExpandNet bibliography. This was complimented by input from the review team (with backgrounds in global health and health systems), and two further experts (in the fields of fidelity and of implementation research) to highlight and direct to any further relevant literature (figure 2). The frameworks included can be seen in online supplementary file 1.

A challenge of developing an IPT framework in a realist review is finding a level of abstraction that allows the recognition of demi-regularities among the detail and variation in the evidence, while being specific enough to answer the review question.³⁹ The IPT framework went through revisions aiming to keep the actions, contexts, mechanisms and outcomes that were deemed most relevant to adaptation and scale-up, rather than those relating to scale-up in general. Decision making was recorded in the research logbook (see online supplementary file 2 for an example from the research logbook). Causation between the potential actions, contexts, mechanisms and outcomes were not made at this stage and will be added iteratively as the review progresses and scope is refined. The contexts were placed under headings adapted from the socioecological model⁵⁷ to aid organisation. The IPT framework can be seen in figure 3 (see

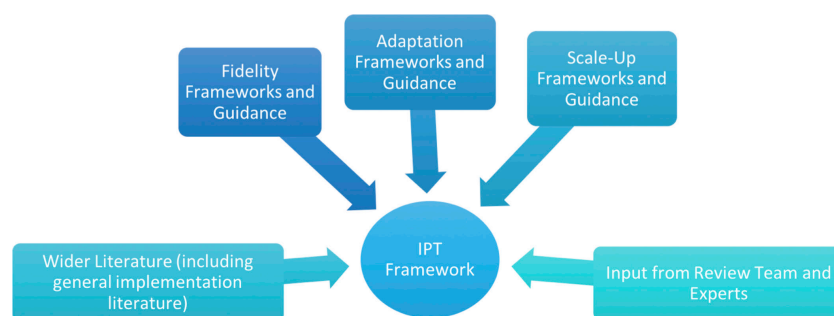


Figure 2 Development of the initial programme theory (IPT) framework.

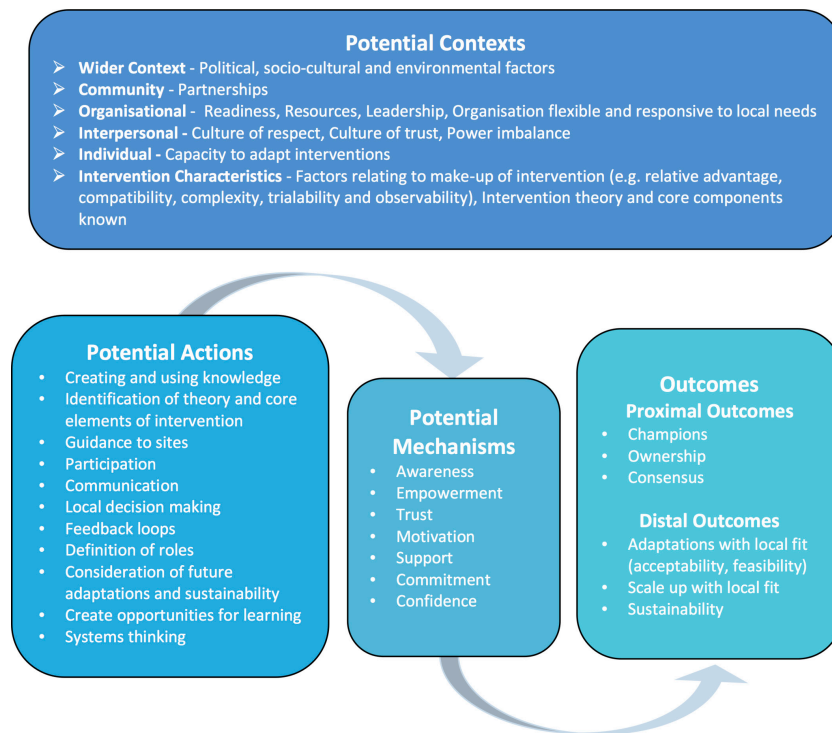


Figure 3 Initial programme theory (IPT) framework. Potential actions, contexts, mechanisms and outcomes identified from stage 1 for further exploration in future phases.

online supplementary file 1 for the guidance and frameworks identified which informed this).

The IPT framework will assist in (i) initial coding of actions, contexts, mechanisms and outcomes for data extraction in stage 4, and will inform a codebook for reviewers (while also allowing for new actions, contexts, mechanisms and outcomes to emerge), (ii) providing an initial framework for the synthesis to assist in organisation of the CMOs and demi-regularities in stage 5 (figure 1). As mentioned, coding and synthesis of findings will be guided by this IPT framework; however, new actions, contexts, mechanisms and outcomes will be identified from the data and added to this as they emerge. Thus, this review will add to and refine the framework as the stages progress.

Clarifying the scope of the review

As learning progressed it was noted that much guidance and frameworks in the implementation and scale-up literature in healthcare may be untested and largely theoretical in nature. Therefore, the scope of the review was refined to include specific examples of scale-up and adaptation in practice. Decision making while clarifying the scope of the review was documented in the research logbook (see example in online supplementary file 2). The scope of this review may be further refined in an iterative process

as the review progresses, as per realist guidance,⁴³ and will be documented in the research logbook for transparency. This iterative focusing of the review may be carried out based on findings from the examples of scale-up in practice and in consultation with stakeholders.

The remaining section presents the protocol for stages 2–6 detailing the methods that will be used throughout the remainder of the realist review which will be carried out from June 2018 to March 2019. An overview of the stages and details can also be seen in figure 4.

Stage 2: search strategy

Stage 2 will involve a search of scale-up and adaptation in practice. Scoping and pilot searches were completed throughout stage 1 and a librarian was consulted to help inform the selection of databases and concept headings for use in stage 2. A systematic search will be completed using the concept headings of scale-up, context (contextualise, adapt, tailor, redesign, etc) and healthcare. Search terms will be adapted for each database. Search databases will include: PubMed, CINAHL, Global Indicus Medicus (WHO library including both academic and grey literature), SCOPUS, EMBASE and PsychINFO. For further grey literature searching, Social Care Institute for excellence (SCIE), Open Grey and GreyLit will be used. Searching of reference lists from identified papers will be

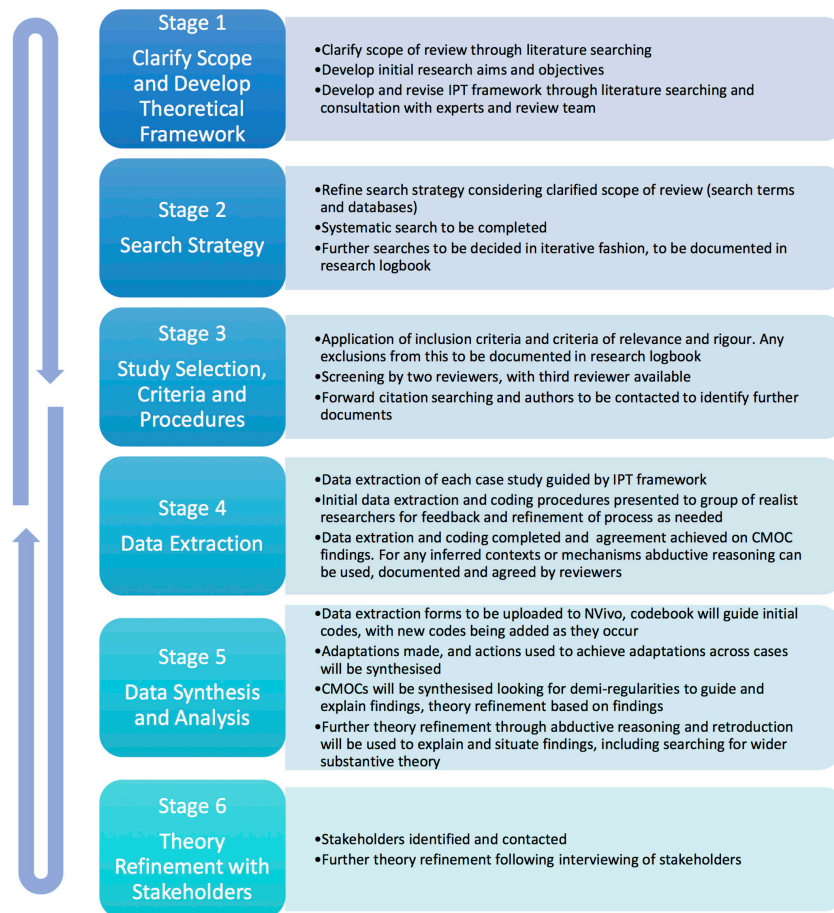


Figure 4 Summary of stages and proposed actions for the realist review. CMOC, context-mechanism-outcome configuration; IPT, initial programme theory.

carried out along with forward citation searching using Google Scholar. Additionally, the corresponding author from the articles selected will be contacted to identify other articles on their scale-up example that could be relevant to answering the research question.

Further rounds of searches may be completed in later stages of the review in keeping with the iterative nature of realist reviews.⁵⁰ This may be to search for further evidence or wider theories that may explain findings and assist in theory refinement. The need for searches, search terms and strategies will be identified as the review progresses. These will be documented in the research logbook, as they occur.

Stage 3: study selection, criteria and procedures

Inclusion criteria

All articles and sources obtained from stage 2 will subsequently undergo further review for inclusion based on three criteria. To be retained for further review sources

must describe (i) an example of scale-up of a healthcare intervention(s) in practice, (ii) adaptations that were made for health intervention(s) to fit local settings and (iii) discuss in detail actions for adapting health intervention(s) at scale. Both scale-up at national and subnational levels will be included once the intervention was being purposefully expanded to a new wider population group in practice. For inclusion in this study, adaptations will need to have occurred during scale-up to adapt for local contexts, and actions used (eg, local decision making) have been documented in detail. Articles discussing the adaptations without describing what actions were used to adapt the intervention will also be excluded. Studies where the adaptations occurred during the randomised controlled trial or pilot stage, and the same intervention was rolled out nationally (or subnationally) without further adaptations to the content, context or delivery, will be excluded. Both positive and negative adaptations

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may be included (see online supplementary file 3 for more details).

As scale-up occurs over a long-time period, with an estimated 15 years to reach national scale, no time limit will be placed on evidence.⁶ Keeping the time period open allows for documents published at the beginning of scale-up projects to also be captured in the search. Searches will be carried out in English. Languages will be limited to those spoken by the review team: English, Spanish, Portuguese and French.

Study appraisal: relevance and rigour

As realist philosophy does not exclude evidence based on type of study, Realist And Meta-narrative Evidence Syntheses: Evolving Standards (RAMESES) guidelines will be applied to assess the relevance and rigour of the studies.⁴³ As discussed by Pawson,⁴⁴ useful information can arise from studies which may not be prioritised on a traditional hierarchy of evidence. Each retained evidence or document will be assessed in terms of its relevance to the research question and whether it is rigorous enough to hold value to theory building, testing or refinement. Any exclusions based on these criteria will be documented in the research logbook.

Procedures

Title and abstract screening will be completed. Following this two reviewers will complete full-text screening independently, with a third reviewer available to resolve any conflicts should they arise. Depending on the number of documents with examples of scale-up returned, further refinement of the scope of the review may be decided by the review team. This will be documented in the research logbook. For further searches as they arise in an iterative fashion, selection criteria will be decided by the review team and will be based on the ability of studies to further refine theory.

Stage 4: data extraction

The following data will be extracted from the scale-up examples identified in stage 3: (i) what adaptations were made, (ii) what actions were used to make these adaptations and (iii) the contexts, mechanisms and outcomes that relate to these actions (in the form of CMOCs). A data extraction form and codebook will be developed from the IPT framework to guide data extraction for each scale-up example (see online supplementary file 4 and 5 for draft versions, noting that these will be refined as the review progresses). Where multiple documents relate to the same example of scale-up, these will be combined into one data extraction form for that case example, and the supporting quotes referenced as to which document it originated from.

Adaptations

It has previously been identified that adaptations are often poorly reported in research.^{10 33 58 59} While some adaptations may reflect small, surface-level changes, others may reflect large deep structural adaptations.

To systematically capture the type of adaptations made, Stirman *et al*⁴⁰ taxonomy of modifications will be used to assist categorisation of adaptations, including what type of adaptations were made, who made them and at what level.

Actions

A description of what action(s) was/were carried out to achieve the adaptation(s) will be extracted from the examples to the data extraction form. These may relate to the potential actions identified in the IPT framework and resultant codebook, or may reflect new actions emerging from the data. Any new actions will be categorised and added to the codebook as they emerge.

CMOCs relating to the actions

CMOCs relating to the actions and adaptations will be extracted from each case example. Note that a case example may contain multiple sources (ie, a peer-reviewed article and a national report on the same scale-up) or just one source. While some CMOCs may relate to the potential actions, contexts, mechanisms and outcomes identified in the IPT framework and resultant codebook, others may reflect new CMOCs emerging from the data. Quotes and descriptions will be taken from the text to support these CMOCs. Abductive reasoning will also be applied for any inferred contexts or mechanisms and the reasoning stated on the data extraction form.^{39 47}

Once the above steps are completed for each case example, an example will be presented to members of the Irish Realist Researcher Group for feedback on the coding procedures to inform refinements of the methods and codebook as needed (online supplementary file 4 and 5). This is a group of 8–10 researchers with experience in realist methods. Following this, the completed data extraction forms for each case will be reviewed again by the first reviewer using the updated coding procedures. A second reviewer will then take a random sample of 10% of the scale-up case examples for extraction following the same coding procedures using a data extraction form for these case examples. The reviewers will then discuss and compare the CMOCs extracted and reach agreement, if differences occur. Following this, the remaining data extraction forms for all case examples will be reviewed by the second reviewer and agreement reached between reviewers on the CMOCs, including any inferred contexts or mechanisms and reasoning for the same. A third reviewer will be available for input or to resolve any discrepancies between the first and second reviewer.

Stage 5: data synthesis

The findings from each example of scale-up will then be synthesised across cases. The data extraction forms from each case example will be uploaded and coded in NVivo, using the IPT framework and resultant codebook to guide initial codes. New codes will be added or refined as they emerge, thus adding to the theoretical framework as the synthesis progresses.

The type of adaptations made will be synthesised across cases to give a picture of what adaptations are happening in practice. Then the actions used to achieve adaptations will be synthesised. To explore how these actions achieved adaptations, the CMOCs identified from each case example will be coded in NVivo to look for demi-regularities occurring across the different case examples. Therefore some, but not all, of the CMOCs from each case example may be identified based on whether demi-regularities were seen and if they add value to theory building and refinement at this stage. These results will be synthesised to make further sense of the findings and refine the theory. The following conceptual tools may be used as needed to assist in this theory refinement^{43 60}: (i) juxtaposing, where evidence from one setting may aid explanation of outcomes from another, (ii) reconciliation, where differences are identified to explain findings which may contradict each other, (iii) adjudication between studies, (iv) consolidation, for example, by building multiple explanations, and (iv) situating by identifying what may happen in one setting compared with another. Reasoning will be documented in a research logbook.

Numerous theories may emerge from the literature. Therefore, further focusing of the review in an iterative fashion may be required. Focusing on particular theories may be guided by demi-regularities occurring across examples. However, it is acknowledged that frequency of occurrence may not necessarily correlate to importance in practice. Therefore, if certain areas are highlighted as particularly critical for successful adaptation by the literature this may also assist focusing of the review. This will be further guided by stakeholder involvement to give a 'reality check',⁴¹ aiming to ensure the review will focus on what is of relevance and importance to those in practice. Decision making for this process will be recorded in the research logbook for transparency.

Abductive reasoning⁴⁷ and retroduction⁴⁸ will be used to guide the review to interpret and explain the findings and put forward contextual conditions that may need to be present for the outcomes to occur. As part of this process, wider substantive theory will be searched for to assist in explanation of the findings and for further theory refinement.⁴³ This will lead to the development of theory relating to how adaptations can be made when scaling-up.

Stage 6: stakeholder involvement

Finally, stakeholders with experience of adaptation and scale-up in both research and practice internationally will be sought and contacted to assist in theory refinement. Initial stakeholders will be identified and contacted by the research team. Stakeholders will also be asked to identify further persons in their field of expertise. Initial review findings will be presented to stakeholders and their opinions sought, based on their practical knowledge and expertise.⁴¹ The resultant theories may be further refined and the review focused based on learning from this process.⁶¹ This involvement of stakeholders with experience in adaptation and scale-up through research and

practice, will assist in focusing the review and its findings, and thus may ensure the findings are useful in practice for implementers in the field. The involvement of stakeholders will allow for initial dissemination of the research findings. This stage may inform further searches through focusing of the review as needed in an iterative fashion.

A summary of the stages and proposed actions for this realist review can be found in figure 4. The above stages will be carried out as per realist review methodology in an iterative fashion, allowing for refinement of theory and the scope of the review and subsequent searches as learning progresses. Any iterations to the above protocol will be captured in the research logbook and reported in the final dissemination of the research. The above stages set out to achieve the study's objectives of discovering what actions can be used to achieve adaptations when scaling-up health interventions for local fit, by what mechanisms do these actions work and what contextual factors may influence this. It is hoped this approach will provide practical and useful findings for implementers in the field of scale-up.

Patient and public involvement

Members of the public and patients were not involved in the development of this protocol.

ETHICS AND DISSEMINATION

The dissemination of the findings of this review will follow the RAMESES reporting guidelines.⁶² The results of this review will be used to put forward theory to explain what and how actions can be used to influence and achieve adaptations when scaling-up for local fit. Use of a realist review methodology, with the stages outlined above, allows for an exploration of the complexity of the process of scale-up across diverse contexts, and the identification of the contextual factors that may influence actions, and by what mechanisms these may work. By including stakeholders with experience in the field of adaptation and scale-up, it is hoped this will add to theory development and refinement, and will help ensure that findings have practical utility for implementers. The findings of this study will be published in a peer-reviewed journal, through conference presentations and dissemination through stakeholder involvement in theory refinement. The review will also be published as a PhD thesis, available through Trinity College Dublin library.

Acknowledgements The authors would like to thank Dr Ayat Abu-Agla from the Centre for Global Health, Trinity College Dublin for lending her expertise to stage one of this review.

Contributors JP is lead reviewer completing this study as part of a PhD. JP developed the general study concept and outline. JP completed the literature review and development of the IPT framework and led the iterations. JP developed the search strategy, and methods for selection, appraisal, extraction, synthesis and stakeholder involvement. BG contributed to IPT framework refinement, the methods for data extraction and coding processes using NVivo and the methods for synthesising across cases. FV contributed to the general study concept and design, clarifying the scope of the review and refinement of the IPT framework. ET contributed as an expert in fidelity in stage one and assisted in refinement

of the IPT framework. ET contributed to the methods of the search strategy and methods of the data extraction and synthesis stages, including the role of second reviewer. HM contributed to conceptual study design, and clarifying the scope of the review by refinement of research question and IPT framework. EM contributed to conceptual study design, refinement of research question and IPT framework, the search strategy, refinement of the data extraction form and contributed to the method of involvement of stakeholders for theory refinement. JP wrote the first draft of the paper, which was reviewed and contributed by all other authors. All authors approved the final version.

Funding This research is supported by the Health Research Board Trials Methodology Research Network (HRB TMRN) of Ireland and Trinity College Dublin through support of a PhD studentship and training.

Competing interests None declared.

Patient consent for publication Not required.

Ethics approval Ethical approval for this study was received from the Health Policy and Management and Centre for Global Health Research Ethics Committee of Trinity College Dublin, Ireland in March 2017.

Provenance and peer review Not commissioned; externally peer reviewed.

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1 March 2017

Re: Scaling-up Health Interventions: How to Contextualise for Local Settings.

Application 05/2017/01

Dear Jessica,

Thank you for your submission of the above proposal to the HPM/CGH REC.

The REC has given ethical approval to the proposed study.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Charles Normand'.

Prof Charles Normand
Chair of the HPM/CGH REC

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7 September 2020

Re: Scaling-up Health Interventions. How to Contextualise for Local Settings.

Application 05/2017/01

Dear Jessica,

Thank you for your submission of amendments to the above study.

They have now been reviewed and approved.

Yours sincerely,

Prof Charles Normand
Chair of the HPM/CGH REC

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APPENDIX C. Phase One Background Scoping Search Details of Databases and Consultation With Experts

Table C 1 Search Terms and Databases for Initial Background Scoping Search Phase One. Search carried March 2016.

Database	Search Terms
PubMed	(context[Title/Abstract] OR contextualization[Title/abstract] OR contextualization[Title/abstract] OR contextualise[Title/Abstract] OR contextualize[Title/Abstract] OR Culture[Mesh] OR Adapt[Title/Abstract] OR redesign[Title/Abstract] OR re-design[Title/Abstract] OR tailor[title/abstract] OR tailoring[title/abstract] OR "Community Health Planning"[Mesh]) AND ("scaling up"[Title/Abstract] OR "scale up"[Title/Abstract] OR "scale-up"[Title/Abstract] OR "scaling-up"[Title/Abstract])
Cinahl	("scale up" OR "scaling up" OR "scale-up" OR "scaling-up") AND (Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Culture (MM) OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored)
Global Indicus Medicus	"scale-up" OR "scaling-up" OR "scale up" OR "scaling up" excluding Medline (as already searched); WHOLIS 76, IMSEAR (SEARO) 73, LILACS 72, WPRIM 47, IMEMR 11, AIM 9
SCOPUS	((TITLE-ABS-KEY ("scale up") OR TITLE-ABS-KEY ("scaling up") OR TITLE-ABS-KEY ("scale-up") OR TITLE-ABS-KEY ("scaling-up")) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci)) AND ((TITLE (context) OR TITLE-ABS-KEY (contextualise) OR TITLE-ABS-KEY (contextualize) OR TITLE-ABS-KEY (contextualisation) OR TITLE-ABS-KEY (contextualization) OR TITLE-ABS-KEY (adapt) OR TITLE (design) OR TITLE-ABS-KEY (redesign) OR TITLE-ABS-KEY (re-design) OR TITLE-ABS-KEY (tailor) OR TITLE-ABS-KEY (tailored) OR TITLE-ABS-KEY (tailoring)) AND SUBJAREA (mult OR medi OR nurs OR vete OR dent OR heal OR mult OR arts OR busi OR deci OR econ OR psyc OR soci))
Web Of Science	("scale up" OR "scaling up" OR "scale-up" OR "scaling-up"). Refined by: TOPIC: (*context* OR adapt OR re\$design OR *tailor*) Social sciences arts and humanities (no science technology).
EMBASE	'scale up' OR 'scaling up' OR 'scale-up' OR 'scaling-up' AND (context OR contextualise OR contextualize OR contextualisation OR contextualization OR adapt OR redesign OR 're design' OR tailor OR tailoring) AND [embase]/lim
Psycinfo	((Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored OR AND (Context OR contextualise OR contextualize OR contextualisation OR contextualization OR Culture (MM) OR Adapt OR Design OR redesign OR re-design OR Tailor OR tailoring OR tailored OR MJ Culture)) AND ("scale up" OR "scaling up" OR "scale-up" OR "scaling-up"))
Grey Lit	"Scale up" OR "scaling up" OR "scale-up" OR "scaling-up"
SCIE	"Scale up" OR "scaling up" OR "scale-up" OR "scaling-up"
Open Grey	("Scale up" OR "scaling up" OR "scale-up" OR "scaling-up" OR "scale-up") AND health

Table C 2 Consultation with Experts to Highlight Further Literature Phase One

Consultation to Highlight Further Literature	Outcome of consultation
Expert 1. Fidelity Researcher, Health Behaviour Change Research Group, NUIG (December 2017)	Literature highlighted: • Hassan modified Carroll's framework (169), this is pre-Pérez et al., (56) modified Carroll's framework • Holliday and colleagues (61) paper from the education literature on acceptability / avoidable adaptation, and a traffic light system to adaptation • Lara and colleagues (71), identifies spectrum of fidelity of implementation, structure process, outcomes • Gearing framework (165), fidelity focused • Importance of NIH BCC framework, highlight further in this section • Importance of Moore (logistical fit, philosophical fit) and Stirman (taxonomy of modifications), • Proctor framework (179) of implementation outcomes • Gagliardi framework (190), more focused on guidelines but may be of relevance Other: • Highlighted importance of identification of intervention theory and core components • Highlighted that often assessment of delivery more common than other fidelity components • May need to consider adaptation at different stages. Think about how this may be affected over time spectrum e.g., earlier or later adaptations
Expert 2. Implementation Researcher, Centre for Global Health, TCD (January 2018)	Literature Highlighted: • TDR IR Toolkit developed by WHO (147), some practical guidance for LMIC present in toolkit
International Doctorate in Global Health (INDIGO) Research Seminar (8 participants), Centre for Global Health, Trinity College Dublin (December 2017)	Literature highlighted: • Inclusion of TiDieR Guidance • ExpandNet guidance emphasized along with bibliography resource

APPENDIX D. Decision Making For IPT Framework

Table D 1 Decision Making from Fidelity and Adaptation Guidance and Frameworks for Inclusion in IPT framework

Source: Fidelity and Adaptation Guidance and Frameworks	Thought process, decision making	Inclusion in IPT framework
Fidelity is often seen as a top-down (researcher, intervention developer) driven approach and adapting more of a community driven bottom-up approach (frontline service providers, community, individuals) (56)	Fidelity and adaptation discussed as top down and bottom-up in their approach. With community and service level providers more engaged with adaptation, and top down intervention developers or researchers driving fidelity. This suggests a power imbalance may exist among the two. The issue of power imbalance came up in the context of the scale-up literature also.	As a result, “power imbalance” was included in the IPT under contexts.
Knowledge of intervention theory, core components, elements or mechanisms (28, 33, 35, 54-57, 61, 71, 75, 81, 90, 98, 100, 101, 110, 114, 120, 121, 165, 169, 182-184).	This came across clearly and was of high importance in the fidelity and adaptation guidance was included in the IPT as both a potential action and a context.	“Identification of theory and core components of intervention” included under potential actions. Given its importance, “theory and core components known and available to sites” was also included under potential contexts.
- Gaining knowledge of the local context, including population group, to make decisions on best fit (54, 57, 110, 114, 120, 121) - Selection of intervention based on the local context and population needs (54, 110, 114, 120, 121) - Identifying implementation considerations within the context, and factors that may have a causal effect on the intervention (55, 56, 71, 75, 98, 101, 169, 171) - Plan adaptations based on these local needs (54, 57, 110, 114, 120, 121).	Learning more of the context and local needs came across in both the adaptation and scale-up literature. With use of this knowledge to select intervention(s) based on local context and needs and consider contextual factors that may have a casual effect on the intervention. It was thought the overarching heading of create and use knowledge would capture this learning and could be further refined at later stages with more details.	“Creating and using knowledge” is included under potential actions.
Identification and evaluation of potential adaptations that may occur (55, 56, 61, 98, 100, 171, 172)	The fidelity and intervention development and testing literature often promoted identification and evaluation of any adaptation that may occur. The planning and evaluation of adaptations was	“Feedback mechanisms” was included as a potential action.

Source: Fidelity and Adaptation Guidance and Frameworks	Thought process, decision making	Inclusion in IPT framework
Evaluating and documenting the process including the adaptations (including building in feedback loops) (54, 110, 120, 121)	identified in several adaptation frameworks. The need for ongoing assessment and feedback mechanisms also came up in the scale-up literature. It was thought the heading of feedback mechanisms may capture this. In addition, a heading of consideration of future adaptations and sustainability could also capture where plans were embedded to identify and evaluate adaptations.	“Consideration of future adaptations and sustainability” included as a potential action which was thought could capture planning for identification and evaluation as adaptations arise.
Involvement of the community/end users in development or review of adaptation and implementation plans (54, 57, 114, 121)	Participation and involvement of community and end users came across strongly in both adaptation and scale-up literature.	“Participation” was included as a potential action.
Use of technical assistance as needed (e.g., getting intervention developers to review adaptation plans) (57, 114)	Two of the adaptation guidance noted technical assistance as needed. This may be further support from intervention developers. It could also be manuals and guidance for sites. This also came up in the scale-up literature. An action of guidance to sites would be able to capture this.	“Guidance to sites” was included as a potential action.

Table D 2 Decision making from scale-up guidance and frameworks for inclusion in IPT framework

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
Lots of commonalities in terms of barriers and facilitators to scaling-up in general. However often they were not specific to barriers and facilitators for adapting when scaling-up.	There are many identified barriers and facilitators to scale-up in general, inclusion of all commonalities would make the IPT framework too detailed to be of use. Decision to aim to identify specific factors that may influence adapting when scaling up, rather than summarizing general barriers and facilitators to scale-up in the IPT framework.	n/a
Process frameworks contained actions for general scale-up, however minimal reference to those that could be used specifically for adapting for scale-up.	Identify those that are specifically identified for adapting when scaling up. Further actions can be identified and added to framework through the next stage of the review.	n/a
No consensus on actions used for adapting when scaling-up.	Need to keep scope of review and IPT framework broad enough to capture all actions that may support adaptations when scaling-up that may arise at this stage. Scope to further focus the review after actions used to adapt have been identified across case examples. Causation for any actions, contexts, mechanisms identified were not sought at this stage for inclusion in the IPT due to the broad scope.	Aim to capture the potential actions used in practice first and then build theories around causation in the next stage.
Learn more about the context - The need to identify contextual factors within the setting that may influence scale-up was identified for example: the wider contextual environment including political, socio-cultural and environmental factors (12, 13, 24, 40, 52, 123-127, 129, 133, 134, 147, 174, 176, 194), the organisational context (12, 24, 49, 123, 126, 131, 132, 134, 147, 174, 178, 194, 195), local beliefs, values and practices that may influence the intervention (41, 129, 133) and community needs (40) - Assessments to fill gaps in knowledge (51, 132). Some examples of suggested methods: situational analysis (194) and stakeholder mapping (194), operations research (132), formative research to learn more of local	Learning more about the context in which the intervention will be implemented came across strongly. This spanned from learning of: community needs, socio-cultural factors, wider political and environmental factors and the organisational context. The heading of “create and use knowledge” was added as an action to the IPT framework. This broad heading was thought could capture any actions used to create knowledge of the local context (and of the intervention itself) which could include formal evaluation, local knowledge etc. It could also capture use of existing knowledge e.g. if local data available. This was initially under separate headings of create knowledge and use knowledge with suggested actions under each. However, this was thought to be too detailed at this stage and a broader this heading	The heading of “create and use knowledge” was added as an action to the IPT framework.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
beliefs (133) and they could span multi-level; from local to global (40)	capturing all was used. Further addition and refinement will take place in the next stages from what was completed in the examples of scale-up in practice.	
Learn more about the intervention - Assess under real world resources (129), test in multiple contexts where it will be scaled (13, 41). - Effectiveness, feasibility and acceptability (194) - Guidance on when to complete new assessments of intervention (49), fidelity assessment as needed (49) - Test local ideas (13) - Knowledge of intervention theory and core components (24, 49, 147, 174)	Learning more of the intervention was identified. For example, learning of the effectiveness of the intervention within the setting or testing in the contexts (and within resources) in which it would be scaled. Whether the intervention was effective and feasible under real world resources will influence choices on whether the intervention may need to be adapted and would be sustainable in these local sites. A heading of creating and using knowledge could capture this. A heading of consideration of future adaptations and sustainability was also thought could capture testing in multiple contexts in which it will be scaled. With the knowledge of intervention theory and components central to its effectiveness coming across so strongly in the fidelity and adaptation literature, it was surprising that relatively few scale-up frameworks mentioned or focused on this. A potential factor influencing this may be that often the intervention theory and core components are not known, and so when scaling-up in practice these may not be available to implementers, or they may be unfeasible to discover without returning to RCT or full-scale evaluation studies. Due to the frequency and importance of identification of theory and core elements of intervention in the fidelity and adaptation literature this was included under actions. In addition, under contexts whether the theory and core components known and available to sites, was included as this may greatly affect ability to adapt.	The heading of “create and use knowledge” was used to capture creating and using knowledge of the intervention and how it may work in the local setting. The heading of “consideration of future adaptations and sustainability” was included under potential actions. “Identification of theory and core elements of intervention” included under potential actions. “Theory and core components known and available to sites” included under contexts.
Make-up of intervention	Elements which were of central importance in the fidelity and adaptation literature such as knowing the intervention theory and	Identified under contexts included “factors relating to make up of the

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
Intervention fit within the setting (12, 24, 49, 52, 53, 125, 127, 132, 134, 147, 174, 176, 178, 194) e.g. compatibility, trialability, relative advantage, complexity and observability of the intervention within the setting.	components central to its effectiveness and those that are flexible to adaptation were notably not present in many of the scale-up frameworks. However, addressing the intervention fit for the local setting was mentioned in most frameworks, many of which were informed by Rogers' diffusions of innovation theory (53) and the compatibility, trialability, relative advantage, complexity and observability of the intervention within the setting. The make-up of the intervention was thought to influence adaptation and scale-up.	intervention" which could include: compatibility, trialability, relative advantage, complexity and observability. This could also include whether it was a simple or complex intervention.
Community and service user - The importance of consideration of attributes relating to the community, or population to which the intervention will be scaled (40, 49, 123-126, 131, 132, 134, 173, 176) - Needs of the community (40, 126) and ability to express their needs (126) - Values and beliefs within the community (176) - Capacity of the community or the individual to implement the intervention (125, 173, 176). - Placing value on those who know the context (124, 126, 132) - Participation of those who know the context (40, 67, 124) - Engagement of community (124) - Support community success (173)	The importance of the community was captured by many frameworks. Learning of the community was felt could be captured under the heading of "creating and using knowledge" e.g. of community needs, values and beliefs. Involvement of the community and potential service users was highlighted with an engaged and active community being a success factor for scale-up. Community involvement also came across strongly in the adaptation frameworks. As a result, numerous headings relating to the local community were included. Placing value on those that know the context was highlighted. A heading of culture of respect which could include an appreciation of the value of those who know the context was specifically identified as a factor that may influence the successful participation and engagement of community members and service users. Capacity came up across community and organisational considerations and so its importance was highlighted and included in the IPT.	"Create and use knowledge" had already been identified and included as an action. The heading of "participation" was made under actions, which could include service user and community active participation in adaptations and scale-up. Additionally, under contexts the headings of "partnerships" was identified as potentially having an influence on community participation and engagement. "Culture of respect" was included under contexts A heading of "capacity to adapt" was added under contexts.
Power imbalance	Power imbalance between partners and specifically in relation to the community being able to express needs was noted. This was identified	"Power imbalance" included under contexts.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
- Power dynamics between stakeholders (173), power and authority of an individual or team (176) - Partnerships (173) - Community having ability to express needs to organisation (126)	as a contextual factor that may have a negative affect adaptation and scale-up. This also came across in the fidelity and the wider literature.	“Partnerships” included under contexts. The nature of partnerships could be further refined at later stages.
Wider context Political, economic and sociocultural factors (12, 13, 24, 40, 41, 52, 123-127, 129, 133, 134, 147, 174, 176, 194)	The influence of the wider context which could include political, socio-cultural and environmental factors was highlighted frequently. While this is a very broad heading, it was not clear at this stage what specific factors would affect adaptation and scale-up. Therefore, it was decided to use the overarching heading of political, socio-cultural and environmental factors at this stage and refine as the review progresses.	“Political, socio-cultural and environmental factors” was included under the context heading.
Participation - Participation (12, 13, 24, 40, 41, 52, 67, 124, 126, 129, 131, 132, 134, 173, 174, 178) for example: local decision making (13, 124, 129, 132, 134, 173), involving the community and user groups in innovating and making adaptations (40), partnerships (173), or through consultations (194) - Participation was identified as potentially assisting in commitment and shared understanding (132)	Participation came across strongly in both the adaptation and scale-up frameworks. This could be for local staff, community members and service users. This was thought to be potentially of high importance to local adaptation. The potential for participation to create both commitment and shared understanding was identified.	“Participation” included under potential actions. “Commitment” was included as a potential mechanism, along with “awareness” which was thought could capture the mechanism of shared understanding.
Champions The benefits of local champions (13, 129, 131, 174) and building of support (40, 41, 51, 129, 194)	The use and benefit of local champions was highlighted. This could be in an organisational or community context. Champions was put forward as a potential proximal outcome (for example participation and engagement may lead to local champions forming, which in turn may assist in local adaptation and scale-up). However, it was acknowledged that also a context where champions are present this may assist in adaptation and scale-up, so it is likely to be added to other sections throughout the refinement process. Support was also included as a mechanism. This could be through champions supporting the process, local organisational or community support, or political support.	“Champions” was put forward as a potential proximal outcome. “Support” was included as a potential mechanism.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
Embed adaptations Embed and plan for adaptations for local fit into the scale-up design (12, 13, 24, 40, 49, 124, 125, 131-133)	The planning in advance for future adaptations was thought to be of great importance.	“Consideration of future adaptations and sustainability” was included as a potential action.
The need to focus on sustainability - Need to embed sustainability into the design of scale-up (12, 24, 131, 134, 194) - Sustainability is linked to intervention fit, and the intervention should not be optimised prior to implementation or sustainability phases to allow for ongoing change and adaption (24) - Participation may lead to increased sustainability with issues being highlighted in real time as they emerge (24)	The need to embed sustainability into the design of the scale-up process was highlighted. The benefits of participation of stakeholders was highlighted, as it may assist in identifying needs in real time and so leading to greater intervention fit and sustainability. The importance of sustainability was also noted in the wider scale-up and implementation literature.	“Consideration of future adaptations and sustainability” was included as an action. “Sustainability” was also included as a distal outcome. “Participation” included under potential actions.
Feedback loops - Embedding of feedback loops (24, 131-133, 194, 199) for example: monitoring and evaluation to inform the process (131, 133), or QI methods such as PDSA cycles (13, 24) - Feedback needing to be both practical and relevant (24), with plans to use the data to inform the scale-up process (129) - Implementation should be local and adaptive with feedback systems for learning at all levels (132)	Feedback loops were thought to be of high importance to adaptation and scale-up. Specific types of feedback loops were not specified at this stage to allow this heading to capture multiple types (e.g. PDSA cycle, monitoring and evaluation plans). This heading can be refined and added to as the review progresses.	“Feedback loops” was included as an action in the IPT framework.
Being responsive to changes in real-time - Needs changing over time (24, 133), ability to respond to needs overtime embedded (24, 125, 132) - The intervention should not optimised prior to implementation (24) - Build capacity to sustain and adapt over time (134)	The need to allow for changes over time for both scale-up and sustainability was identified. This was put forward as key in the DSF. Several headings in the IPT relate to this as it was felt this will have great impact on adaptation and scale-up. The action of consideration of future adaptations and sustainability was thought could capture when there was recognition that needs will change over time and consideration or plans in place to address this. In addition, the use of feedback loops as an action came up in the scale-up and adaptation literature.	The potential action of “consideration of future adaptations and sustainability” were included in the IPT framework. “Feedback loops” had previously been included in the IPT. This was also of relevance to recognition of needs changing over time.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
	The context of an organisation that is flexible and responsive to local needs was also included, as it was thought this could capture when organisations are responsive to changing needs overtime.	“Flexible and responsive to local needs” was included as a potential context.
The adopting organisation - Characteristics relating to the adopting organisation (12, 24, 49, 123, 126, 131, 132, 134, 147, 174, 194, 195) - Specific characteristics that were frequently highlighted included: capacity of the organisation (12, 13, 24, 52, 123-126, 174, 194); leadership (12, 13, 123-127, 174, 176, 178); supervision (24, 123, 133); infrastructure and resource availability (12, 13, 24, 123, 125-127, 132, 174, 176, 178); delivery systems (24, 49, 123, 127, 132); logistical issues such as transport and cold chain storage, presence of health facilities etc. (123, 127) - The perception of the need or value of the intervention by the adopting implementers was also frequently noted (12, 40, 125, 126, 174) - The potential need to mobilise and realign resources in your setting (51, 128, 129, 133, 194)	Multiple different factors came forward in the scale-up frameworks in terms of organisational context. Inclusion of all made the IPT too detailed and may relate to scale-up in general but not necessarily scale-up and adaptation. Whether resources are available was thought to be of particular relevance to scaling-up and adaption. This could relate to human resource availability, or to resources of time of funding to make adaptations. It could also relate to capacity to adapt which could relate to individuals at organisational or community level. Leadership was also highlighted to be of importance, this could relate to whether leadership were supportive and perceived a need for adaptations, or if they were unsupportive.	“Resources” was included as a heading under contexts, with specific reference to “human resources availability”. “Readiness” was included under context which could relate to organisational capacity to scale-up and adapt. “Leadership” was included under contexts. “Capacity to adapt” was included under contexts.
Capacity - The need to assess capacity (12, 24, 49, 123-125, 127, 174, 176, 178) - Build capacity of the adopting organisation (13, 51, 52, 129, 133, 134, 194) - Community capacity (126), the building of societal capital (134, 173)	Capacity in place in the terms of readiness, the ability to adapt and capacity at organisational, community and individual level was all highlighted as important.	“Capacity to adapt” was included under contexts. “Readiness” was also included under context which could relate to organisational capacity to scale-up and adapt.
Opportunities for learning - The need to support opportunities for learning (13, 24, 41, 129, 173, 176) - Use of formalised learning systems to share ideas and knowledge, such as learning networks (13, 176) or change packages (13)	The support and creation of opportunities for learning was identified. This could be in the form of formalised learning networks, site visits or using phased approaches to implementation to learn from past sites. Create opportunities for learning was identified as a potential action. It was considered also as a context, for example in contexts where	“Create opportunities for learning” was included as a potential action.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
- Visiting other sites could be of benefit (173) - Using a phased or cascaded approach to scale-up which allows for learning and refinement (124)	there are opportunities for learning this may facilitate adaptation and scale-up, however this could be added in future as the framework is refined.	
Definition of Roles - Defining of roles (131-133, 194), accountability and agreement on roles (132, 194) - Clarify who are the adopting organisations (52) - Define the “scalable unit” which could be one health facility or a sub-district or district which is implementing the intervention. This “scalable unit” is one part of the wider scale-up (13)	Clarity of who is carrying out different elements of the implementation came across in the scale-up frameworks. This included clarifying who were the organisations and individuals involved, and taking a transparent approach to who was responsible and accountable for elements of the scale-up. This could also be of relevance to definition of roles for adaptation when scaling-up.	“ Definition of roles ” was put forward as a potential action.
Communication - Communication (12, 13, 24, 40, 123, 126, 127, 173, 174) - Identify communication within the delivery system for example the level of communication and infrastructure links (127) - Communication for dissemination (129, 131, 147), communicating results in later phases to gain support of the majority (13) - Importance of clear messaging and personal contact (12), communication and spread through networks (40) - Communication between the beneficiary and the adopting organisation (126)	Community was discussed in different contexts from organisational communication and infrastructure, to social network spread and importance of personal clear communication.	The overall heading of “ communication ” was included under potential actions to capture these. More details can be added as they emerge in future stages of refinement.
Consensus on an agreed vision - Consensus on the expectations of scaling-up (41, 132), define a programme strategy and clear outline of what is to be scaled (13, 133) - Clarification and agreement of what is the intervention to be scaled (51, 52) - Clarity of purpose, benefits and results (131), need for agreement on the problem and suggested solutions (67, 132)	The development of consensus or an agreed vision for what is the problem, intervention and strategy for scaling-up was highlighted. Partners all agreeing on a shared vision was thought to be of importance when thinking of local adaptations and local fit, where the national, district and local level may all be working towards a common goal and support each other.	“ Consensus ” was included as a proximal outcome of interest. However, it may also come up as a context which supports adaptation and scale-up.

Source: Scale-up Guidance and Frameworks	Thought process, decision making	Inclusion in IPT Framework
Decentralisation - The decentralization to local levels (13, 124, 129, 132, 134, 173) - Build social capital locally to sustain and adapt interventions, this can be through HR training, infrastructure, data capturing systems, promotion of local enterprise (134)	The transfer of decision making to local levels was discussed in many scale-up frameworks. This could include transfer of decision making to local district level, frontline professionals or to communities and service users. The heading of local decision making was included as a potential action. This was thought could capture when autonomy was given to local level to make decisions about best fit.	The heading of “local decision making” was included as a potential action.
Guidance to sites - Weak technical guidance (123) - Identifying key features for success to share with future sites (129), for example the use of change packages to share learning from past sites (13) - The need for clarity of the intervention, which could include provision of guidance and materials (40)	The provision of guidance to future sites was identified by a few of the scale-up frameworks. This could be to provide clarity on the intervention and key features, or to describe what earlier sites completed and found successful. While this was present in the frameworks it did not come across as strongly as it did in the adaptation guidance which strongly supported providing guidance on intervention theory and core elements. Guidance to sites had already been included as a potential action from the adaptation literature. However, in this context it could also include more specific guidance on how to embed adaptations into the scale-up process, and learning from past sites.	“Guidance to sites” included as potential action.

Table D 3 Decision making from wider literature (including general implementation literature) for inclusion in IPT framework

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
Intervention • Relative advantage, compatibility, complexity, trialability, and observability (53) • Flexible interventions were highlighted as beneficial and can be relevant to wider user groups (56, 180) • Community driven interventions can be more successfully implemented addressing local need and buy in (180) • Resource heavy interventions a barrier to scale (50, 196) • Make up of intervention simple/complex will affect implementation (50, 196, 200) • Knowledge of core components allow for local adaptation aided buy in from community (180) • However the issue with this is an assumption that this theory, causal mechanisms and essential components are known, which often is not the case (17)	Multiple factors relating to the make-up of the intervention came up in the general implementation literature. Of note is Rogers' diffusions of innovations theory (53) which highlights the <i>relative advantage, compatibility, complexity, trialability, and observability</i>. This was incorporated into multiple frameworks also. The simplicity or complex nature of interventions, along with level of resources needed and flexibility was also highlighted.	A heading of "factors relating to make-up of intervention" was included in the IPT to allow for variation within this heading to capture the above. Both "identification of theory and core components of intervention" included under potential actions and "theory and core components known and available to sites" included under contexts as it came up across all fields of literature.
Community • Community involvement and active engagement (46, 54, 196, 210) • Lack of engagement of local decision makers and of communities a barrier (50) • Community involvement may lead to ownership, buy-in (17, 54, 56, 62, 210) • A barrier to scale-up identified was a lack of buy in from communities (180) • Community driven interventions can be more successfully implemented addressing local need and buy in (180) • History of community engagement, committing to long term partnership, building trust (211) • Partnerships with multiple stakeholders (39) • Participatory action research (PAR) (208)	The involvement of community came across heavily in the literature. Specific contextual factors that may affect the community and their involvement in the scale-up and adaptation of an intervention was a history of involvement which may lead to trust, or ownership and buy in. Additionally, the level of engagement for example through partnerships, and level of relationships present. PAR was also mentioned, however this is a high resource process and potential applicability of completing at scale across multiple sites low. This was decided to not be included in the IPT framework, however if it emerged through the case examples could be added through refinement. It could also potentially be captured under the more general "participation" heading.	A heading of "participation" under potential actions was included. Under the community heading, "partnerships" were included. Specifically, in the codebook nature of partnerships which could capture history of community involvement and relationships was identified. A heading of "ownership" was included under the proximal outcomes in the IPT. This was thought could capture ownership both at community, service user, health facility and local district levels. A heading of "commitment" has been included in the mechanisms. This captures

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
		the concept of buy in which came-up frequently across the literature, including here in relation to community buy in.
Organisational - Human resources (50, 180, 196, 221, 355) - Leadership (46, 203), leadership change (180) (197), lack of leadership (50) - Lack of capacity (50, 355), capacity in community settings (128) - Funding (73), funding availability (47, 203), funding mechanisms (180, 202) - Lack of resources in scale-up settings (46, 180) - Testing in real-world settings with resources that will be available (180), resources at testing not available at scale-up sites e.g. in-depth community dialogue (220) - Rushing to scale (202), lack of readiness (50, 203) - Local champions (46, 53, 180, 203)	Resources came up across the literature. Use of this as a broader heading was thought could capture variation and could be further refined at later stages. It could capture both resource availability or lack of availability. Under this heading specifically human resource availability was highlighted in the codebook. Supportive leadership, along with changing leadership and or lack of leadership was highlighted. This was also highlighted in the scale-up frameworks. Testing in real-world settings with resources that would be available was not specifically included. However, a heading of “consideration of future adaptations and sustainability” was included under potential actions. It was felt that this would be captured under considering future sustainability by trialling under conditions that would mimic future sites resources. Lack of readiness and rushing to scale was noted in the literature. With often this coming from top-down pressure to scale. The context of “readiness” was added as a heading. This could capture the level of readiness of the context.	“Resources” was included under contexts. “Leadership” was included under contexts. “Capacity to adapt” was also included as a heading under context. “Consideration of future adaptations and sustainability” was included under potential actions. “Readiness” was included under contexts. “Champions” who support or drive the intervention was seen across the literature. This was included as a proximal outcome of interest.
Wider context Political interest and will to scale up (47, 50), enabling policy environment (180)	The wider context, in particular the political context came up in this literature. It was decided to keep this heading broad at this stage to keep the IPT framework as simple and useful as possible. This also allows for variation in what may emerge and for this heading to be refined.	An overarching heading of “political, socio-cultural and environmental factors” was added as potential contexts.
Power imbalance	Power dynamics came up in the general implementation literature in addition to the scale-up frameworks. This was	As a result, “power imbalance” was included under contexts.

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
- Funding and power imbalance, only given funding for specific interventions (54), choosing intervention based on funding (356) - Power dynamics influencing whether people could meaningfully participate (e.g. male dominance) (357) - Scale free networks, power imbalance and influence (48)	discussed in relation to funders and a top down power imbalance leading to selection of certain interventions based on available funding. It also came up in relation to being able to meaningfully participate being limited by power dynamics within a community. Complex adaptive systems theory also speaks of scale free networks which could relate to certain people within networks being particularly influential or powerful.	
Evidence, knowledge - Evidence availability (46, 196, 198), insufficient evidence (47, 50, 198, 358) - Nature and strength of evidence (46, 196), range of evidence types needed (47, 196) - Influence of locally generated evidence (359) Create knowledge of the context - Discovering determinants affecting health and behaviours within the setting (55, 58, 120, 132) - Create knowledge of context. Suggested methods included: formative research (210), situational analysis (World Health Organization. Regional Office for the Western Pacific, 2002)(World Health Organization, 2004), rapid assessments (360), qualitative evidence (40), ethnographic research (361), geo-mapping (362), use of local epidemiological data (363-365), use of QI methods (55.) - Feedback loops, monitoring and evaluating (46, 180, 366)	The creation and use of evidence came across in all fields of literature. The type of evidence, including the influence of local data was highlighted. The availability or lack of availability of evidence was also highlighted. Creating knowledge of the context came across in all fields of literature also. This could be by exploring determinants affecting health behaviours in the setting. Suggested methods for creating knowledge of the context such as qualitative research, rapid assessments and use of local epidemiological data were put forward. An overarching heading of creating and using knowledge was included as a potential action. This could allow for variation within and if specific methods were used in the case examples these could be added as the framework is refined in future. Capacity to adapt was included under contexts which could capture ability of implementers and/or service providers to generate and use evidence.	“Creating and using knowledge” was included as a potential action. “Capacity to adapt” was included under contexts which could capture ability of implementers and/or service providers to generate and use evidence. “Feedback loops” was included under potential actions.

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
	The presence and embedding of feedback loops came across strongly across the fields of literature and so this was included as a heading under potential actions in the IPT.	
Planning for scale-up, adaptations and sustainability - Consideration of the future need to adapt for local fit being embedded in design (75, 107) - Planning for scale-up needs to be considered in intervention design, trialling and piloting (12, 41, 75, 202, 215, 216) - Importance of sustainability (73, 204, 367)	This came across in the general literature in addition the scale-up frameworks. The importance of sustainability was highlighted in this literature. It also has many similarities to scale-up in terms of long time-frame and need to embed and plan for future continued use.	“Consideration of future adaptations and sustainability” was included under the heading of potential actions. “Sustainability” was added as a distal outcome of interest.
Systems thinking Use of systems thinking (11, 12, 41, 52, 219)	The use of systems thinking to address the complexity was highlighted.	“Systems thinking” was added as a potential action.
Local decision making Local government, local decision making (12, 196)	The decentralisation of decision making to local level, either at district, health facility or service provider level was discussed in in the wider literature in addition to the scale-up frameworks.	“Local decision making” included as a potential action.
Communication Communication, who is communicating with trust between homogenous groups (53)	Who is communicating and whether there is trust between them was noted. The diffusion of innovations theory noted that communication between homogenous groups may be effective due to levels of trust. Trust and culture of trust were included as headings as a mechanism and context. This was thought could capture when there was a culture of trust within relationship or homogenous groups and more details could be added to the framework as they occurred in the case examples.	“Communication” was included as a heading under potential actions. “Trust” was included as a mechanism. “Culture of trust” was included as a context.
Consensus Lack of consensus on intervention (50)	Consensus, or lack of consensus, came up in the wider literature, in addition to the scale-up frameworks.	“Consensus” was included as a potential proximal outcome.
Roles Roles, who makes decisions (63)	Clarity and definition of roles was present in many of the scale-up frameworks. It was also present in the wider scale-up literature.	This was included under the heading of “definition of roles” as a potential action.
Flexibility Flexibility to allow for unpredictability (48)	Complex adaptive systems theory spoke of the need for flexibly for allow for unpredictability. It was also highlighted that an organisation being adaptive and flexible may enhance	The heading of “flexible and responsive to local needs” was included as a heading under context.

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
A flexible and adaptive organisational structure that is open to devolvement of decision making may facilitate successful implementation (203)	successful implementation. Flexibility also came up in other areas of literature. The idea of flexibility is in keeping with adaptation in the sense of being open to change based on need.	
Guidance - Guidance to sites (180) - Too much guidance, over-manualised or prescriptive a barrier to use (368) - Insufficient guidance to sites on how to understand interventions (192)	Guidance to sites came up in the literature in the context of providing guidance to sites to support them, but also in how over-manualised or prescriptive advice may be a hindrance. This was incorporated as a potential action. This can allow for variation in what the guidance was in (e.g. intervention theory, or delivery elements etc.) and inclusion of the level of guidance given and whether it was a barrier or facilitator.	"Guidance to sites" included as a potential action.
Dynamic Contexts Changing contexts over time (24, 218) e.g. political environment (24)	The need to allow for changing contexts overtime came across in the wider implementation and scale-up literature along with being central to the DSF framework. A heading of consideration of future adaptations and sustainability was thought could help capture this, with recognition of dynamic contexts mentioned as an example under this heading in the codebook.	"Consideration of future adaptations and sustainability" was included under potential actions.
Mechanisms (influencing scale-up or large systems change in healthcare): - Commitment (7, 181) - Awareness(7), understanding (181) - Confidence (7) - Participation (181) - Trust (7, 181), trust between homogenous groups (53), distrust of outsiders bringing in intervention (222)	Some specific mechanisms were highlighted in realist reviews of scaling up complex healthcare interventions and in large scale health system transformation. This included the triggering of commitment, awareness and understanding, confidence, trust and participation. Although these mechanisms were not specific to adaptation and scale-up they were thought to be of relevance and included as potential mechanisms. A heading of participation under actions was included to capture engagement and participation of the community and local stakeholders.	"Participation" was included under potential actions. "Commitment" was included as a mechanism. "Confidence" was included as a mechanism. "Empowerment" was included as a mechanism. "Trust" was included under mechanisms.

Source: Wider literature (including general implementation and scale-up literature)	Thought process, decision making	Inclusion in IPT Framework
	A heading of commitment was included in the mechanisms. This captures the concept of buy in which came-up frequently across the literature. A heading of confidence was included as a mechanism. Willis and colleagues differentiated between commitment and confidence with confidence relating more to a belief of self-belief in an ability to do something. This may also capture feeling empowered. This was seen as different to empowerment which is the action or process of becoming confident or empowered. A heading of “empowerment” was included as this related to the process of becoming empowered or confident. This may be gradual or take time to achieve. This may be a purposeful process or happen by chance through actions. A heading of trust was included as a mechanism. Trust was mentioned in many aspects of the literature. This included trust by the community, service users, or service providers to trust in the intervention or process. It also came up in the context of trust within relationships. Under contexts a heading of “culture of trust” was included which was thought could capture the trust (or lack of trust) within relationships and between groups. A heading of awareness was included as a mechanism. This was thought to capture knowledge or understanding which could relate to the local context, the need to adapt and of the intervention itself for example.	Under contexts a heading of “culture of trust” was included. “Awareness” was included as a mechanism.

Table D 4 Working definitions for headings in IPT Framework

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
Potential Actions	Creating and using knowledge	The creation of knowledge e.g. through evaluation, local knowledge, continual assessment mechanisms and/or the use of existing knowledge e.g. local data, real time data, routine data, evidence for intervention
	Identification of theory and core elements of intervention	The identification of theory or core elements/components of the intervention. This could involve purposeful selection of an intervention where these are known or seeking out this information for the selected intervention
	Guidance to sites	Providing guidance to local sites on intervention theory or core elements, or on how to adapt intervention
	Participation	Participation / engagement of: service users, providers, community, local organisational or government HR. This could be through various activities for example: consultations, partnerships, CBPR, local decision making
	Communication	Communication between individuals or at organisational levels
	Local decision making	Involvement of: local service users, providers, community, local organisational or government HR for decision making for adaptations. Autonomy given to local level for adaptations
	Feedback loops	Feedback loops or mechanisms in place to guide decision making for adaptations this could involve monitoring and evaluation at time points, planned consultations etc.
	Definition of roles	The transparent clarification and definition of roles and responsibilities for adaptation during scale-up
	Consideration of future adaptations and sustainability	Consideration of future adaptations and sustainability and actions planned to allow for this. This includes recognition of contexts changing overtime and actions planned to allow for this
	Create opportunities for learning	Creating opportunities for learning is purposeful activities that could assist in learning for implementers, organisational staff, the community or service users. It could relate to building capacity to complete adaptations, or learning of the context, adaptations or strategies used to address local fit. This could be formal e.g. through learning networks, or informal e.g. arranged through social networks
	Systems thinking	Systems thinking applies to an in–depth consideration of the complex links, relationships, inter-dependencies within a system. This may be difficult to capture however if an example reports use of systems thinking or describes this process it can be included as this

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
Potential Contexts	Wider context	
	Political, socio-cultural and environmental factors	This is a broad heading that can capture elements of the wider system e.g. political, economic, environment that influence whether a mechanism fires. This heading will be added to and refined and learning progresses
	Community	
	Partnerships	This could be between community and an organisation. This could include the nature of the partnerships in terms of history and trust for example
	Organisational	
	Readiness	Where the organisation (or community) are ready for intervention and implementation, for example with resources, capacity in place, community sensitized to intervention, buy in for intervention exists etc. This could also capture a lack of readiness or rushing to scale
	Resources	Resources or lack of resources such as: financial, logistical or human resource availability
	Leadership	This could relate to strong leadership, or a lack of leadership which may influence adaptation and scale-up
	Organisation flexible and responsiveness to local needs	Organisation flexible and responsiveness to local needs. This could relate to where the organisation is open to receiving and acting on feedback
	Interpersonal Relationships	
	Culture of respect	Culture of respect between individuals, or within an organisation. This could include placing value on the knowledge and opinions of those in the local setting
	Culture of trust	Culture of trust between individuals, or within an organisation. This could also relate to a history or relationship of trust built over time
	Power imbalance	Power imbalance between individuals or organisations. This could relate to a power imbalance within a community setting limiting individual's participation, or could relate to top-down/bottom-up power imbalance between funders and an organisation, or between different levels of the health system
	Individual	
	Capacity to adapt interventions	Capacity to carry out actions needed to adapt and/or implement interventions
	Intervention characteristics	
	Factors relating to make up of the intervention	For example: relative advantage, compatibility, complexity, trialability and observability. This could also include whether the intervention was simple or complex

Potential Actions, Contexts, Mechanism and Outcomes identified from the IPT framework below		
	Intervention theory and core components known	Theory and core components of intervention known and available to sites
Potential Mechanisms	Awareness	"Knowledge or perception of a situation or fact"(348). This could relate to the local context, the need to adapt, the intervention itself or the scale-up or adaptation process
	Empowerment	The process of becoming more powerful or confident in the ability to do something(348). This can include authority or power given to someone to do something
	Trust	"Firm belief in the reliability, truth, or ability of someone or something"(348). Trust could relate to the intervention itself, the scale-up or adaptation process or trust between actors e.g. service users, organisation, implementers etc.
	Motivation	Intrinsic or extrinsic motivation towards the intervention, its adaptation or scale-up. Motivation is an internal process that may cause a desire or willingness (348) towards something this is not seen, however relating actions could be visible
	Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in
	Commitment	"The state or quality of being dedicated to a cause, activity, etc."(348). This could relate to a commitment to the problem (e.g. addressing the health problem), the intervention, adaptation or scale-up process. This differs from support as it relates to dedication or engagement and so it is more active than support alone
	Confidence	"The feeling or belief that one can have faith in or rely on someone or something."(348). Confidence relates more to self-assurance(7) or certainty in an ability of oneself or others. This could be confidence in the ability to adapt or implement the intervention, in the intervention itself or of other people's ability to complete actions or goals for scale-up
Outcomes (Proximal)	Champions	Champions who support, encourage, commit to or drive the intervention and/or scale-up or adaptation process
	Ownership	A feeling or sense of ownership of the intervention and/or scale-up or adaptation process by an individual, community or organisation
	Consensus	Shared agreement or vision on the intervention, adaptation or elements of scale-up process
Outcomes (Distal)	Adaptations with local fit (acceptability, feasibility)	Adaptations made which are acceptable and/or feasible in local settings. This could be demonstrated where Interventions match local needs and resources or demand for intervention by service users
	Scale up with local fit	Intervention is scaled-up across sites with local fit where intervention is acceptable and/or feasible
	Sustainability	Intervention is continued to be delivered at sites or the outcome of the intervention is sustained at sites over a time. This intervention may be continually adapted and does not need to remain the same

APPENDIX E. Databases and Search Terms Used Phase Two

Table E 1 Databases, Search terms and Dates for Systematic Search Phase Two

Database	SEARCH TERMS	Results	Date
Pubmed	((Health services[Mesh]) AND (("scale up"[Title] OR "SCALING UP"[Title] OR "scale-up"[Title] OR "scaling-up"[Title]))) AND ((Context[Title/Abstract] OR contextualisation[Title/Abstract] OR contextualise[Title/Abstract] OR contextualize[Title/Abstract] OR contextualization[Title/Abstract] OR tailor[Title/Abstract] OR tailoring[Title/Abstract] OR redesign[Title/Abstract] OR re-design[Title/Abstract]))	61	6th June 2019
Cinahl	(TI "scale up" OR TI "scaling up" OR TI "scale-up" OR TI "scaling-up") AND (Context OR contextualise OR contextualize OR contextualisation OR contextualization)ABSTRACT OR (Culture MM) OR (Tailor OR tailoring OR tailored)ABSTRACT AND SUBJECT HEALTH	45	6th June 2019
Scopus	(TITLE-ABS-KEY (*tailor) OR TITLE-ABS-KEY (*context)) AND (TITLE ("scale up" OR "scaling up" OR "scale-up" OR "scaling-up")) AND (LIMIT-TO (SUBJAREA , "MEDI"))	132	6th June 2019
Global Indicus Medicus	(tw:("scale-up" OR "scaling-up" OR "scale up" OR "scaling up")) AND (tw:(context OR contextualise OR contextualize OR contextualisation OR contextualization OR tailor OR tailoring OR redesign OR design)) AND (tw:("health service" OR "health services" OR health)) Note: Excluding Medline as already searched	36	6th June 2019
Web of Science	TITLE ("scale up"* OR "scaling up"* OR "scale-up"* OR "scaling-up"*) AND TOPIC (context* OR tailor* OR design*) Limit to Categories: HEALTH CARE SCIENCES SERVICES OR HEALTH POLICY SERVICES	67	6th June 2019
EMBASE	("scale up" or "scaling up" or "scale-up" or "scaling-up").m_titl.AND (\$context or \$tailor or \$adapt) [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword, floating subheading word, candidate term word] AND \$health	153	6th June 2019
Psycinfo	("scale up" or "SCALING UP" or "scale-up" or "scaling-up")TITLE AND (\$context OR \$tailor OR \$adapt) AND (\$health)	35	6th June 2019
OTHER DATABASES / GREY LITERATURE			
Grey Lit	("health service" OR "health services") AND ("scale up" OR "scaling up" OR scale-up OR scaling-up)	10	1st Feb 2020*
SCIE	("health service" OR "health services") AND ("scale up" OR "scaling up" OR scale-up" OR "scaling-up")	17	15th July 2019
Open Grey	("Scale up" OR "scaling up" OR "scale-up" OR "scaling-up" OR "scale-up") AND ("health services" OR "health service")	15	15th July 2019

*Site previously down when carried out search in July 2019, returned to complete search when site back-up in Feb 2020

APPENDIX F. Codebook Phase Two

Table F 1 Phase Two Codebook - Extraction of Adaptations and Actions. Adapted from (1, 15, 44, 369)

To note: codebook updated as review progressed. With each new version of codebook each case example revisited for coding

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
Notes: • Primary focus is on adaptations to content of health intervention itself. If relevant can document further adaptations outside of this, however example must have a content adaptation to a health intervention as a primary focus. • For inclusion the adaptations must occur during the scale-up (or sustainment phases) i.e. if adaptations happened during the pilot and the same intervention scaled without further adaptation this would not be included. • Codebook adapted from: IPT framework, Stirman and colleague's taxonomy of modification, expanded FRAME guidance and codebook supplied by FRAME developers (1, 15, 369)	
Health Intervention	A health intervention was defined as “an act performed for, with or on behalf of a person or population to assess, improve, maintain, promote or modify health, functioning or health conditions”(4). For this study, it was limited it to interventions where the direct target was the individual. An example of this would be provision of nutritional supplements, vaccines or medication (e.g. vitamin A, polio vaccine etc.) and/or educational or behaviour change interventions directly delivered to the individual or individuals (e.g. breastfeeding education, safe sex promotion etc.). If the primary intervention was capacity building of HRH which may have future impacts on health this was considered indirect and not included. As scale up often occurs as a package of interventions, case examples of this were included if a specific direct health intervention was identified as a primary part of this package.
Adaptations	Changes to the health intervention content. These could be planned or occur reactively as needs emerge.
Adaptations to Content of Health Intervention	Changes to content itself or that impact how aspects of the treatment are delivered. These can occur from the level of the recipient to across entire networks or systems. • Firstly, note a short description of the adaptation. • In the following column please apply one (or more) of the codes below: 1. Tailoring, tweaking, refining – use this code if a minor change reported which leaves major principles in place e.g. changes to language 2. Changes in packaging or materials – use this code for changes to materials used with recipients e.g. adapted from book to CD, added more pictorial elements 3. Adding elements – use this code if distinct elements added to intervention (e.g. a clinic might add an optional treatment buddy when delivering antiretroviral treatment). NOTE in original FRAME coding it discussed this code as added elements were in keeping with fundamentals of intervention, however this was less useful in global health examples i.e. what was the theory core/components often not known so unsure if added elements were in keeping with fundamentals of intervention. Instead use this code if distinct elements added and further details can be discussed/added to the fidelity column for the adaptation as to whether core elements or functions known and whether addition was in keeping.

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
	4. Removing/skipping elements – use this code if elements are dropped or skipped e.g. those that are culturally not appropriate left out 5. Shortening, condensing (pacing/timing) – use this code if a shorter amount of time or reduced number of sessions used. If elements are removed or skipped as a result of reduced time or sessions, also use code “removing/skipping” 6. Lengthening, extending (pacing/timing) - use this code if a longer amount of time or increased number of sessions used. If elements are added in this extra time or sessions also use code of “adding elements” 7. Substituting elements – use this code if an element is replaced with another (e.g. condom application replaced with abstinence talk) 8. Re-ordering elements – use this code if sessions reordered or moved around. Note if this involved lengthening or shortening also code as this 9. Spreading (breaking up session content over multiple sessions) – use this code if for example content of one session delivered over two (e.g. to adapt for cognitive capacity) 10. Integrating parts of intervention into another framework – use this code if intervention is utilised in full or part within another intervention (e.g. selecting elements to incorporate into another intervention) 11. Integrating another treatment into EBP – use this code if the intervention is used as a starting point, but other techniques and approaches integrated throughout e.g. use of motivational interviewing technique within an intervention that did not specify its use initially 12. Repeating elements – use this code if elements usually prescribed as once, or already present in EBP are repeated. This is distinct from code of “adding elements” which refers to new elements being added. E.g. for simple interventions this could be giving an extra dose of vaccination, or for complex interventions it could be repeating a an education session again as needed 13. Loosening structure – use this code if flexibility with programme/process was reported e.g. opening and closing, layout was different. Note if elements were specifically removed or added also use these codes 14. Departing from the intervention (drift) followed by a return to protocol within encounter – use this code if reported leaving EBP protocol and used another, followed by a return to original EBP e.g. started with CBT and moved to supportive therapy, with a return to CBT 15. Drift from protocol without returning – use this code if left EBP protocol and does not report return e.g. started with CBT, moved to supportive therapy for rest of session 16. Other/new codes can be added to codebook as needed 17. Not enough information to code – Note if not enough information to discern code, this should then be discussed between reviewers
Adaptations to Context	• Definition of context adaptations is the delivery of same programme/intervention content, with changes to the way it is delivered e.g. format, setting, or personnel or changes to the population it is delivered to. Note this research is focused on

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
	adaptations to content of health interventions. Therefore if the same content is delivered through different formats/settings/personnel or a different population this would not be included for this study. • An example of what would not be included for this study is the wider concept of task shifting, where the same content is provided by a mid or lower level provider. This would be beyond the scope of this particular study. • However if by use of a different personnel this in turn changes in content of the intervention this would be included. For example in order to provide emergency care for incomplete abortion, manual vacuum aspiration (MVA) was the primary intervention scaled. However in order to ensure emergency services for remote communities, in smaller health facilities with mid-level providers, it may be adapted to Dilation and curettage (D&C) procedure or a choice of referral to larger site. This could be coded as content, substituting elements (MVA with D&C), and also as context, personnel. • NOTE: Overall the distinction between content and context adaptation is blurred with this framework as content adaptation also references delivery. If primary focus is content adaptation code as this, if secondary context adaptation can also code as such. However if a context adaptation was made without changes to the content of the health intervention then not it is not included for this study. • If meets inclusion criteria discussed above please note short description of a context adaptation and whether to format, setting, personnel, population.
Adaptations to Training/Evaluation	• Adaptations to the way the staff are trained or intervention evaluated. Note this research is focused on adaptations to content of health interventions. Therefore if the same content is delivered with adaptations to training and evaluation this would not be included for this study. However if the training and evaluation had an impact on content adaptations, this could be included and coded for both.
Adaptations to implementation and scale-up activities	• Adaptations to the strategies used to implement or spread intervention. Note this research is focused on adaptations to content of health interventions (please see definition of health intervention for this study above). Therefore if the same content was delivered with differing implementation strategies this would not be included for this study. Note if community education is part of the primary health intervention package and was adapted, this was noted as a health intervention content adaptation as the intervention is delivered to the recipients directly. • Implementation actions that assisted in guiding the health intervention content adaptations will be captured (e.g. use of quality improvement methodology, transferring autonomy to local decision makers). These are coded under "actions" that guide adaptations with more details below.
At what level was the adaptation made	• Please note as many as apply on data extraction form: 1. Individual recipient – changed for a person's needs e.g. literacy, hearing, physicality 2. Target intervention group – changed for all individuals within a target group e.g. risk reduction education elements adapted to be relevant for sex worker populations 3. Cohort/individuals that share a particular characteristic For example adapted for those with dual diagnosis e.g. HIV AND Diabetes, as opposed to those with a single diagnosis of HIV. 4. Individual practitioner – adapted for all recipients working with a particular practitioner

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
	5. Clinic/unit level – all practitioners within the same clinic, unit or department make the same adaptation a. Classroom– adaptations made within a particular classroom (may not occur across the whole school) 6. Organisation – adaptations across the entire organisation e.g. whole health facility or hospital a. School– specific code for adaptation across a whole school 7. Network system/community – adaptations across entire network or system e.g. a hospital group, school district. a. Community – if adaptation occurred for an entire community b. Provincial, region and/or district - if adaptation occurred across entire province, district or region 8. National – if adaptation occurred at country level e.g. syllabus of sex education adapted at national level during scale-up as a result of policy changes during roll out. 9. Other/unclear
Who made decision to adapt	➤ Please indicate where present. Note this often may not be reported if so indicate “unclear”. Please note as many as apply on data extraction form: 1. Political leadership e.g. Ministry of Health, Ministry of Education officials 2. Scale-up leadership e.g. central resource team 3. Funders 4. Administrator – leadership within an organisation e.g. Hospital management Hospital/Health centre/Facility management Regional/provincial/district management 5. Intervention developer – developed original intervention or subject expert 6. Researcher – does not necessarily have to have been involved in developing original intervention but involved in research of the interventions outcome, implementation or scale-up or could be part of community based participatory research 7. Frontline providers – including health professionals and teachers 8. Community members – these do not necessarily have to be recipients of intervention 9. Recipients 10. Coalition of stakeholders – multiple stakeholders from different areas involved in decision making 11. Religious leaders 12. Local leaders – for example at community level 13. Other/unclear
Reasons why need to adapt (Note not as much information needed for this stage)	• Please give short description of reason why adaptation was made (if stated) • In following column please code reason as to one of the following (or add new code if needed): ➤ Socio-political Level (as part of wider context) 1. Existing Laws, Mandates, Policies, and Regulations 2. Align with new Laws, Mandates, Policies, and Regulations as scale-up progressed

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
	3. Political climate—e.g. adapted for addressing controversial elements in current political climate, or refocusing if particular political attention being paid to an area e.g. suicide prevention 4. Funding Policies—adapting based on requirements to receive or spend funding, certain elements not reimbursed so adapted to those that are 5. Historical context 6. Societal/Cultural Norms 7. Funding and Resource Allocation/Availability – lack of availability of funding or resources ➤ Organisational Level 1. Available resources 2. Competing demands or mandates 3. Time constraints 4. Service structure - e.g., health facility only provides group-based interventions 5. Location/accessibility 6. Regulatory/compliance - e.g., concerns over legal regulations could lead to elements being removed such as physical activities 7. Billing constraints - e.g., if providers can only charge for certain intervention 8. Social context (culture, climate, leadership support) – relating to organizational climate as opposed to the wider cultural norms (below) 9. Mission - e.g. aim of the organisation 10. Cultural or religious norms – as they relate to the organisational setting/policies e.g. family members remain present for sessions, or treatment only provided by female providers for female patients. For wider sociocultural norms code at socio-political level (above), those specific to provider (below) or specific at recipient level (below) ➤ Provider level 1. Race/ethnicity/sexual orientation or gender identity – if adaptations made to address providers differences in race/ethnicity/sexual or gender identity and their fit with the intervention or recipient i.e. adding elements to acknowledge differences in experiences (could be coded at recipient or individual level or both) 2. First/spoken languages 3. Previous Training and Skills i.e. their familiarity with the intervention 4. Preferences — relating to their level of interest and comfort in delivering intervention 5. Clinical Judgement – relating to their beliefs about the needs of the recipients 6. Cultural norms and competency (can include utilising peers as educators for example due to their competency/understanding of the cultural context) 7. Perception of intervention— relating to their beliefs about the intervention fit and effectiveness ➤ Recipient factors

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
	1. Race/ethnicity/sexual orientation or gender identity 2. Cognitive capacity 3. Physical capacity 4. Literacy and education level 5. First/spoken languages 6. Access to resources – for example if transport or funds to attend are limited intervention may be shortened or reduced 7. Cultural or religious norms 8. Comorbidity/Multimorbidity 9. Legal status 10. Immigration Status 11. Crisis or emergent circumstances – including health emergencies (e.g. suicide risk) or other crisis situations for example homelessness 12. Motivation and Readiness —which would include willingness to engage in the intervention 13. HIV status 14. Occupation e.g. sex worker may face different risk
What was the purpose/goal?	➤ Please state where present 1. Increase reach or engagement — adapting to increase the number of people engaging with the intervention 2. Increase retention – adapting to increase the number of people completing the full intervention (i.e. reduce drop-offs) 3. Improve feasibility – adapting to fit with resource constraints, HRH availability 4. Improve fit with recipients—adapting to fit with the needs and preferences of recipients a. To address cultural factors a subdivision of improving fit, when adaptation specifically to address cultural norms and beliefs b. To improve fit within the wider context of school/community/region/national setting (not necessarily just fit with recipient) 5. Improve effectiveness/outcomes – adapting to improve desired outcomes (not specifically just to increase engagement like code above) 6. Reduce cost 7. Increase satisfaction
Were adaptations planned	➤ Planned/proactive – planned adaptation embedded into scale-up of intervention e.g. quality improvement methods such as plan-do-study-act cycles embedded into implementation ➤ Planned/reactive – planned adaptation that occurs in response to circumstances and events as scale-up progresses e.g. in response to feedback from stakeholders or new data which was not foreseen from the outset ➤ Unplanned – adaptations which occur without thoughtful planning, unsystematic in its process

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
When did adaptation occur	*Note interested in adaptations in scale-up or sustainment phases* If additional adaptations occurred in other phases can document if deemed relevant to future adaptation during scale-up phase (i.e. pre-implementation, implementation, scale-up, maintenance/sustainment)
Actions Definitions and Coding for Stage 2	
Action	Definition
Identification of intervention theory, core elements, components, functions or minimum standards	The identification of intervention theory, core elements, components, functions or minimum standards to support adaptation and implementation. These could be identified at intervention development stage with the purpose of future adaptations during scale-up (e.g. intervention theory developed with core components) or at a later stage during the rollout of scale-up as needs arose (e.g. a minimum contraceptive method mix to address supply chain issues)
Providing guidance to sites	Guidance provided to sites which could for example be in the format of: written guidance (e.g. manuals), technical assistance (e.g. access to a support team), online guidance (e.g. webinars) or facilitating guidance from peers (e.g. through learning collaboratives)
a. Providing guidance on the intervention components	Guidance on intervention theory, core elements, components, functions or minimum standards provided to sites
b. Providing guidance on the implementation and adaptation process	Guidance on the implementation and adaptation process provided to sites. This could include steps to take to adapt or evaluate changes to the intervention
c. Providing examples of tried and tested adaptations	Provision of guidance on tried and tested adaptation examples from past sites as a way to encourage cross-site learning
Local decision making	Autonomy was given to local stakeholders to make decisions on adaptations for local fit within their setting. This could occur at varying levels within the system for example at provincial, regional, district, community, health facility levels, by frontline providers or the recipients themselves
a. Regional, Provincial or District Levels	When local decision making for adaptations occurred during scale-up at regional, provincial and/or district levels
b. Community or Health Facility Level	When local decision making for adaptations occurred during scale-up at community or health facility level. This could include CBOs and school level. This could also include the use of formalised community partnerships
c. Frontline Provider Level	When local decision making for adaptations occurred during scale-up by frontline providers delivering the intervention
d. Recipient Level	When local decision making for adaptations occurred during scale-up by the recipients of the intervention
Using an adaptive scale-up design	Where an adaptive scale-up design was used to incorporate flexibility allowing for large scale change as learning occurred and contexts change over time
Creating peer learning opportunities	Where proactive opportunities to learn from peers were created allowing for cross-site learning. This could include sharing lessons learned through implementation and adaptation. This could be through in person opportunities (e.g. learning collaboratives), and/or through dissemination of materials (e.g. change packages). Peer learning is understood to be learning from those at the same or similar levels of the system e.g. between frontline providers at differing sites, as opposed to top down support and guidance

Adaptations definition and coding (based on Stirman and colleague's taxonomy of modifications (1, 15, 369))	
Ongoing Assessment of the Wider Political, Socioeconomic, Cultural and Organisational Context to Inform Adaptations	This could include ongoing assessment of the wider political, socioeconomic and cultural context to inform adaptations. For example to capture dynamic political situations that may affect the intervention e.g. unsupportive policy change. It may also include ongoing assessment of the organisational landscape and resource availability
The Use of Data to Assess Progress and Inform or Evaluate Adaptations	The use of data, for example through monitoring and evaluation processes, to assess progress of health or implementation outcomes which may inform adaptations throughout the scale-up. It may also include use of data to evaluate chosen adaptations
Use of QI methods	Where formalised QI methods were utilised such as: the breakthrough series model (BTS), learning collaboratives and the model for improvement (MFI) during the course of the scale-up to inform adaptations

APPENDIX G. Document Types For Each Case Example Phase Three

Table G 1 Included Documents for Phase Three: Document types, Primary Focus of Document and Whether Methods Reported on

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
CE1	(230)	Peer reviewed article	Process of scale-up	Yes	Developed from a systematic literature review on the scale-up, data from Demographic and Health Surveys (DHS) and semi-structured interviews with a range of relevant stakeholders (in UN, MoH, CSO, MoE). Expandnet framework used for reporting. Transparency of methods and appear appropriate for overall findings
CE2	(197)	Peer reviewed article	Process of scale-up	Yes	Developed from a literature review on the scale-up from both published and grey literature sources (including plans and reports from implementing agencies), in addition to interviews with key informants. ExpandNet framework used to synthesise and report findings. Transparency of methods and appear appropriate for overall findings
	(310)	Peer reviewed article	Process of scale-up	Yes	Article exploring what strategies used to implement sexuality education in a conservative context. Document review on the implementation of sexual education in Pakistan by the two organisations who scaled-up programs. Thematic analysis to develop questions of interest which were then further explored with key informant interviews from the implementing organisations (Aahung and Rutgers Pakistan). Transparency of methods and appear appropriate for overall findings
	(309)	Grey literature. Report	Process and outcomes	Yes	Evaluation of Life Skills Based Education (LSBE) programme from 2006-2010 in Pakistan. Mixed methods study which included: document review, in-depth interviews with principals, implementing partners and district education departments, focus group discussions with students and teachers, Knowledge Attitudes and Practices (KAP) questionnaire completed pre and post LSBE course in five randomly selected districts (to note for one year 2008 due to data set errors sample was conveniently selected). Transparency of methodology and range of stakeholders consulted at all levels for qualitative component. Methods appear appropriate for findings
CE5	(228)	Peer reviewed article	Process of scale-up	Yes	Article developed by leaders of project and ExpandNet experts. Reflections from authors used along with: baseline, midterm and endline surveys, rapid assessments, monitoring data and service delivery statistics. Site visits completed along with key informant interviews from; health authorities, community health workers, providers, recipients and community members. Article developed further over online communication and a one week workshop with project leaders and Expandnet experts. Project funded by philanthropic agency Bill and Melinda Gates foundation

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
	(267)	Grey literature Newsletter	Newsletter	No	Source of newsletter is from The Tupange project. Updates, news and examples from the project shared in newsletter. News stories on the project contained quotes from local health workers and community members. Contains details of adaptations made
CE6	(270)	Expandnet book chapter	Process of scale-up	Yes	Authors were part of the NGO that scaled-up the project in the public sector. Article reports information came from six main sources including: participant observation over ten years of implementation; published and unpublished papers and reports; qualitative assessment in municipalities during project renewal; meetings and interviews with MoH, state and municipal officials; official reports, laws, guidelines from MoH; literature on wider health sector reform and decentralisation in Brazil. Transparency of methods and appear appropriate for overall findings
	(311)	Expandnet book chapter	Process of capacity building	Yes	Book chapter outlining the Retropolina project training and capacity building approach across three countries. Written by the SRH trainers and is based on their experience, focus groups with newly trained trainers (six groups in Brazil), and in-depth interviews with municipal and local government health authorities (11 in Brazil), along with project statistics of training programs conducted. Transparency of methods and appear appropriate for overall findings
	(129)	Grey literature, ExpandNet resource	Process of scale-up	No	Case vignette in much larger report on scaling-up from Expandnet. Some further details are available as needed but primarily book chapter above is main source
CE7	(268)	Expandnet book chapter	Process of scale-up	Yes	Authors roles stated as involved in the scale-up as researcher, MoH management, technical assistance team members, project implementer and representative from women's union. Use of routine service data and observations on implementation by team members. Note that this scale-up was the precursor to development of the strategic approach for strengthening reproductive health systems (122). Transparency of methods and appear appropriate for overall findings and the perspective presented in the paper
CE8	(16)	Expandnet book chapter	Process of scale-up	No	Does not discuss methods or specific sources for development of chapter. It does report the three authors were directly involved in the scale-up as the project manager of the Copperbelt study, the director of the Copperbelt Provincial Health Office, and a technical adviser from the Population Council
	(312)	Grey literature. Project report	Process of scale-up	No	Population council report on the scale-up. While a lot of overlap with the above chapter this report does provide some further background information for context. Methods for development of report not specifically stated. Written by member of population council who provided technical support and with assistance of those involved in the project. However further details not given. MoH data used for contraceptive coverage rates

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
CE10	(231)	Peer reviewed article	Equal focus on process and outcomes	No for process of scale-up. Yes for outcomes	Article discusses both the process and evaluation of KMC in four regions in Ghana. While the article discussed the methods of the evaluation (outcome data for implementation coverage with evidence of practice in settings). It did not discuss methods for description of the process of implementation. It does note a process evaluation was completed (this included qualitative data from steering committee members and workshop feedback) however there was minimal details in the results for this. It does describe that all authors were involved in execution of project
	(226)	Peer reviewed article	Outcome focused	Yes	Further details on the methods and results for the implementation outcome evaluation which was also reported in study above
	(314)	Grey literature. Report	Process and outcome focused	Yes	Description of KMC training process and evaluation of implementation outcomes in upper east region. Gives details of how progress monitoring was carried out with use of monitoring model used in articles above
	(313)	Grey Literature. Workbook	Process focused	n/a	Workbook given to steering committees members. Provides background of the context/resource of implementation guidance given to local decision makers
CE11	(257)	Grey literature	Process of scale-up	Yes	Report on lessons learned. Report led by project director with key informant interviews (MoH, National Catholic Health Service Leaders, project partners, scale-up team) and data from DHS surveys used. To note did not appear to have frontline providers included in development of report. Transparency of methods and appear appropriate for overall findings
	(232)	Peer reviewed article	Process of scale-up	Yes	This article had rich description of the process of QI methods within this scale-up. Collected data on implementation indicators, change ideas and health outcome indicators from facility registers and clinical registers. QI teams collected indicators specific to their change ideas (e.g. number of phone calls midwives received). Qualitative data was also taken from QI team documentation on change ideas. Ghana's national community based surveillance data also used for reporting of births and deaths for health outcomes. Transparency of methods and appear appropriate for overall findings
	(315)	Peer reviewed article	Outcome focused	Yes	Observational study of postnatal care for mother and baby in first seven days and how interventions were implemented using QI methods over a three year period in three of the ten regions. This is a subset of the wider national study above. Used point of care data collected from health facilities for outcomes (skilled delivery, neonatal mortality and postnatal care received) and routine health service statistics. Used time series analysis. Demonstrates change ideas tested having positive impact on indicators. Contains outcome and context/resources information, but as primarily quantitative outcome data less information on potential mechanisms

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
	(262-266)	Grey literature	Newsletters	No	Newsletters (five in total included), which included vignettes of examples and lessons learnt which had been distributed to sites. Contains examples of adaptations
	(233)	Peer reviewed article	Outcome focused	Yes	Impact evaluation of wider project. Can be used for extra information on wider health outcomes as needed. Data from health facility registers
	(316)	Peer reviewed article	Outcome focused	Yes	Impact evaluation. Time series analysis used on data from health facility registers from 2009-2013 (primarily from wave 2 of scale-up). Primarily outcome data for key MCH indicators
	(317)	Peer reviewed article	Outcome focused	Yes	Impact evaluation for hospitals in Southern Ghana in Wave 4. Primary outcomes on neonatal and postnatal infant and under five mortality. Time series analysis used on routine data from district health management systems. Primarily outcome data
CE14	(236)	Peer reviewed article	Determinants of implementation	Yes	Overview of path from efficacy and effectiveness studies to scale-up. The implementation study focused on identification of determinants of implementation. Data for this was developed from surveys of a random sample of schools using Likert scales to ask about specific implementation factors (with overall good response rates). To note, descriptive study without much rich information for CMOC formation
	(318)	Peer reviewed article	Outcomes of scale-up	Yes	Mixed method study with cross sectional survey and focus groups with teachers and principals. Survey captured self-reported implementation. Focus group captured challenges to implementation
	(319)	Peer reviewed article	Process of intervention development	Yes	Describes methods for intervention development of 'Action Schools!' and its evaluation along with how this influenced changes in intervention over time. Written by intervention developers. Provides wider context of the intervention as needed
CE16	(207)	Peer reviewed article	Process focused	Yes	Process focused with evaluation of two specific sites. Multiple data sources used: observation, informal communication, formal meetings, discussions and interviews with key informants. Interpretations were confirmed with site leadership and supervisors. Data analysed on theoretical framework with confirmation or divergence noted, feedback and consensus was made through group discussion and written communication. Two case studies selected: Jersey City Public Schools (JCPS), New Jersey and Mercy family centre, New Orleans, Louisiana. Sites were selected based on successful uptake and representativeness of service delivery models for 'CBITS', which also had sufficient information on implementation processes present to answer research questions. Transparency of methods and appear appropriate for overall findings
	(238)	Peer reviewed article	Process focused	No	Reflections paper, lack of clarity as authors do not explicitly state their role. Through author searching, identified their role as part of intervention development and technical support
	(320)	Peer reviewed article	Process focused	Yes	Qualitative study using key informants from multiple school stakeholders across three regions in the USA (11 purposefully sampled schools in total: 51 participants ranging from regional

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
					implementing support to teachers, clinicians and parents). Explores how organisational characteristics influenced the adoption, implementation and sustainment of the intervention. To note intervention implemented through different pathways between the regions. Explores how organisational processes differed between regions. Does not focus on adaptation, more of a focus on wider implementation success. Can be used for background as needed. Transparency of methods and appear appropriate for overall findings
	(321)	Peer reviewed article	Outcome and process focused	Yes	This article is a description of the methods used to implement the 'CBITS' intervention across one state in addition to reporting on implementation outcomes and child level outcome data. Methods for outcome data are reported however it does not state the methods for development of the process information in the article. However appears written from perspective of implementers. Two authors are from a scale-up supporting agency (Child Health and Development Institute)
	(322)	Peer reviewed article	Description of intervention	No	This article describes the components of the 'CBITS' intervention and history of its initial development. Provides background information on the components of the intervention
CE17	(239)	Peer reviewed article	Adaptation and fidelity focused	Yes	Qualitative study of 34 CBO staff across 22 organisations in LA county who had implemented and adapted the DEBI interventions. Transcribed: two coders with reported good inter-rater reliability with open (for adaptations in particular) and closed coding used. To note primarily focused on delivery element of fidelity and self-report of adaptations
	(62)	Peer reviewed article	Adaptation and fidelity focused	Yes	Survey and semi-structured interviews with key informants from 61 CBOS implementing the intervention (thematic analysis used). In the survey elements such as fidelity to core elements, why adaptations were made, and facilitators and barriers were captured. Further in-depth interviews were made with five CBOs based on their reporting of unique or interesting adaptations. To note primarily focused on delivery element of fidelity and self-report of adaptations
	(240)	Peer reviewed article	Process focused	Yes	Reflections paper. Authors report the reflections in article are from their expertise in HIV prevention and experience working with minority groups, along with literature on community-researcher partnerships
	(281)	Peer reviewed article	Process focused	Yes	Lessons learnt paper. General information on where evidence for these lessons came from but not specific information on how it was analysed. Data from training assessment, quality assurance activities, user acceptability tools, implementation monitoring instruments, database of technical assistance requests, CDC site visits and website utilisation. Reports this was combined with reflections from experts' experiences and feedback from end users. Overall this article is more overarching lessons of dissemination. Provides a wider background only

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
	(323)	Peer reviewed article	Fidelity focused	Yes	For Mpowerment intervention. Data collected from 69 CBOs implementing this intervention nationally. Baseline data on fidelity for Mpowerment intervention. Further article (324) provides more details on evaluation of implementation supports. All implementing organisations invited to be part of longitudinal cohort study. Semi-structured interviews with coordinators of the intervention and group members every 6 months (over 18 month period). Self-reported fidelity to core elements and if modifications made were asked to describe in more detail. Methodological considerations: no sampling bias as all agencies contacted, self-report on fidelity, reporting to agency who provided training and technical assistance so may be some element of social desirability bias. Overall transparency of methodology and findings appear appropriate once these considerations made
	(324)	Peer reviewed article	Process focused	Yes	Feedback on implementation supports (technology exchange system) for Mpowerment intervention as part of Translating Research to Practice Study (TRIP). All CBOs using the technology exchange system invited to participate in study and followed up over two years. Study described uptake of the supports, perceptions and issues that arose for the implementation support system. N=329 participants interviewed over 6, 12 and 24 month time period. Methodological considerations: no sampling bias as all agencies contacted, self-report on uptake of implementation supports, reporting to agency who provided training and technical assistance so may be some element of social desirability bias. Overall transparency of methodology and findings appear appropriate once these considerations made
	(280)	Peer reviewed article	Process focused	Yes	This is another article on the TRIP longitudinal study. Data for this study was gathered from semi-structured interviews of staff and group members implementing Mpowerment interventions in CBOs. All CBOs implemented were invited into study. In addition to interviews technical advisor notes of sessions were used. Framework analysis of barriers and facilitators to implementation was completed with 13 themes emerging. Some direct quotes in text. Methodological consideration: interviews were reporting to agency who provided training and technical assistance so may be social desirability bias to be considered. However both positive and negative elements reported and described. Overall transparency of methodology and findings appear appropriate once these considerations made
	(325)	Peer reviewed article	Process focused	No	Case report of the implementation of DEBIs in Maryland and Massachusetts states. Authors were involved in the initiative for both states in the AIDS administration and Dept. of Public Health HIV/AIDS bureau respectively. Does not report how information for this article was compiled. Assume from experience of authors and their roles. Provides wider background only

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
	(326)	Peer reviewed article	Process focused	No	Descriptive article on the Development of technical assistance and training of facilitators for VOCE/VOICES intervention. Outcomes for training was the level of implementation three months post training and questionnaires/feedback at end of trainings. Gives one case report of successful implementation in AIDS services of Austin. Gives wider background of project
CE18	(241)	Peer reviewed article	Process focused	Yes	Explores implementation from 2008-2012 in one province. Compared initial planned activities with findings. Mixed methods: qualitative data from in-depth interviews and focus groups, inductive thematic analysis; quantitative data from routine monitoring. Triangulated findings. Transparency of methods and appear appropriate for overall findings
	(242)	Peer reviewed article	Process focused	Yes	More details on the qualitative part of the study incorporated into mixed methods study above. Can use any additional information present in this paper as needed
	(327)	Peer reviewed article	Intervention focused	Yes	Qualitative data from multi-site evaluation. At time of study CAGs had scaled to a further 69 sites nationally. Focus group discussions with CAG members from 10 randomly selected sites, with key informant sampling. Transparency of methods and appropriate for findings. To note, study focused on PLHIV experience of the CAG intervention. Not focused on implementation or scale-up. Provides wider background on intervention
	(243)	Peer reviewed article	Process focused	No for process of scale-up. Yes for outcomes	Programme data from routine data collection and chart review. Methods for generation of implementation process data unclear. Does not clearly state role of authors in scale-up, although from affiliations appear to have been part of implementation. Reports on provincial scale up and first stage of national scale
	(328)	Peer reviewed article	Process and outcome focused	No for process of scale-up. Yes for outcomes	Description of implementation in Tete Province and reporting of outcomes. Used routine monitoring data for outcomes. Process descriptive information can provide wider background
	(329)	Peer reviewed article	Outcome focused	Yes	Routine data was used for all clinics to retrospectively examine retention of adult CAG members from 2008-2012. Transparency of methods and appropriate for findings. Provides outcome data on retention in groups but does not have much process information
CE19	(244)	Peer reviewed article	Outcome focused	Yes	Article focused on evaluating and discussing implementation outcomes. Document review (n=32) with deductive thematic analysis under implementation outcome headings (acceptability, appropriateness, adoption, feasibility, implementation cost, coverage and sustainability). Did not critically analyse or quality appraise documents, more a narrative synthesis under pre-defined headings. Transparency of methods which appear appropriate for overall findings. Reference list of document review screened for relevant articles and included below
	(245)	Peer reviewed article	Process focused	Yes	Mixed methods study of 12 facilities in Cape town area. Used observations, interviews (n=45) with recipients, frontline staff, local managers and senior policy-makers and managers,

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
					document review from AC club documents and policies, in addition to use of routine monitoring data. Data triangulated through multiple sources as described. Used complex adaptive systems framework to analyse and discuss. Transparency of methods and appear appropriate for overall findings
	(330)	Grey literature. Report	Process focused	Yes	Report which has further details from the study (245) above. Report provides further details on reduced mentoring and shared learning which took place
	(246)	Peer reviewed article	Outcome focused	No for process of scale-up. Yes for outcomes	Included in document review above (244). However more details present as needed. Article describes how outcome descriptive data collected (routine data collection sources). Describes process of implementation but not how data gathered for this part of article or of relationship of authors to project
	(247)	Peer reviewed article	Outcome focused	Yes for outcome	Retrospective observational cohort study to assess patient outcomes and effectiveness of intervention
	(248)	Peer reviewed article	Outcome focused	Yes for outcome	Evaluation of patient outcomes and loss to follow-up. Use of anonymised routine clinic data. Does not have details on process of scale-up, outcome data present as needed
	(249)	Peer reviewed article	Description of intervention	No	Short overview of intervention from pilot to wider implementation. Can be used for background of the content of the intervention itself. Written by the author who was part of the development for the adherence club intervention. Also includes some details on QI methods used in early phase
	(331)	Peer reviewed article	Intervention evaluation	Yes	RE exploring health systems conditions that affect the AC clubs. Transparency of methods and appear appropriate for findings. Mixed methods used to complete theory testing and refinement across three cases (health centres). Not specific to scale-up but can be used for wider background as needed
	(332)	Peer reviewed article	Intervention evaluation	Yes	RE of the AC club intervention. One of the case studies in more detail from (331) above. Transparency of methods and appear appropriate for findings. Mixed methods used to complete theory testing and refinement in a health care centre in Western Cape. Not specific to scale-up but can be used for wider background as needed
	(333)	Peer reviewed article	Intervention evaluation	Yes	RE of the AC club intervention. One of the case studies in more detail from (331) above. Transparency of methods and appear appropriate for findings. Mixed methods used to complete theory testing and refinement in a health care centre in Western Cape. Not specific to scale-up but can be used for wider background as needed
	(334)	Peer reviewed article	Intervention evaluation	Yes	RE of the AC club intervention. One of the case studies in more detail from (331) above. Transparency of methods and appear appropriate for findings. Mixed methods used to complete

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
					theory testing and refinement in a health care centre in Western Cape. Not specific to scale-up but can be used for wider background as needed
	(335)	Peer reviewed article	Process focused	No	Descriptive short case studies from four QI initiatives using the IHI BTS approach. Minimal information present however one of which was based on Cape Metro district Cape town for ART clubs
CE20	(271)	Grey literature	Process focused	Yes	Report exploring service delivery models of ART in Western Cape, South Africa. Transparent methods and appear appropriate for findings. Five sites purposively selected representing differing delivery models. Report developed by data from exit interviews with recipients, interviews and focus group discussions with providers, observations in clinics and reviewing of counsellor diaries
	(260)	Grey literature	Process focused	Yes	Report exploring approaching to ART delivery in three provinces across 16 sites. Transparent methods and appear appropriate for findings. Sites purposively selected representing differing delivery models. Utilised key informant interviews, focus group discussions, exit interviews with recipients, use of routine data, record reviews, CHW diaries and staff questionnaire
	(250)	Peer reviewed article	Process focused	Yes	Transparency of methods and appear appropriate for perspective put forward. Utilised data from operational research and reports (260, 271). In addition to this the authors worked in public health appointments for Western Cape and Guateng provinces and used observations from their experience along with published accounts of the implementation processes from programme managers and advocates. Paper was also reviewed by two HIV experts with knowledge of implementation in South Africa. Transparency of methods and appear appropriate for perspective put forward
CE21	(251)	Peer reviewed article	Process focused	Yes	Narrative description of process of scale-up and how data was used to inform changes at provincial and district levels. Article reported was developed with contributions from those involved in implementation at multiple levels of the system (including technical working group members, steering committee members at national and provincial levels, health facility staff, community members). Some evaluation data directly from one district. Further articles can be used for evaluation data from other districts as needed
	(258)	Peer reviewed article	Process and outcome focused	Yes	Describes QI methods (including BTS) in Cape Metro area in early phases. For outcomes of BTS/QI approach reports on changes made in area. For data on overall PMTCT outcomes this was taken from routine monitoring data. Article written by those who implemented the BTS in this area (from IHI and DoH South Africa. Lacking depth of analysis of process however describes actions taken and outcomes achieved

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
	(336)	Peer reviewed article	Process and outcome focused	Yes	Mixed methods study using national health statistics for quantitative data and qualitative synthesis of workshop reports for all districts nationally from 2016 & 2017. Did not complete any primary qualitative data, however these reports give some perspective of district level planning
	(259)	Grey literature	Examples of adaptations	Yes	The A-Plan report compiled by DoH to share tried and tested adaptation ideas developed in local sites. Provides examples of tried and tested adaptations
	(337)	Grey literature	Examples of adaptations	Yes	Report compiled by DoH to share tried and tested adaptation ideas developed in local sites. Provides examples of tried and tested adaptations
	(252)	Peer reviewed article	Process focused	No	Article gives a brief overview from pilot projects to national scale detailing the use of QI methods; however, it does not discuss how methods of this article developed. Appears written from perspective of implementers, however this is not explicitly stated. Reference list search of the case studies/districts cited completed and direct sources used instead
	(253)	Peer reviewed article	Process focused	No	Narrative overview of lessons learnt throughout implementation. Does not state methods for development of article, references other studies for data which were screened. Written from perspective of implementers however explicit roles within the scale-up not stated. Can provide wider context as needed
	(254)	Peer reviewed article	Process focused	Yes	This article provides further details and methods of how the A-Plan (259) was developed and tested in subdistricts with examples of successful adaptations
	(255)	Peer reviewed article	Outcome focused	Yes	Operational research to assess outcome of implementation approach in one district (across 18 clinics). Data gathered from interviews, observations, and use of routine data sources. Article can provide more detail as needed but does not focus on the scale-up itself
CE22	(256)	Peer reviewed article	Process focused	No	Case report of lessons learnt in scale-up, however does not state sources or methods used to develop. Through author search the role of author clarified. Lead author part of the scale-up team and worked directly with implementing agencies, article based on their reflections and perspective over the years of scale-up. Note philanthropic funded project (Bill and Melinda Gates Foundation; with role of funders mentioned). Further documents identified (below) to support individual CMOCs to provide further background information and perspectives
	(338)	Peer reviewed article	Process focused	No	Case study written by scale-up team and Bill and Melinda Gates Foundation. Does not report methods for development of article. Reflections style piece. Focusing on lessons learnt from using a participatory style approach. Provides some more background information
	(339)	Peer reviewed article	Process focused	Yes	Delphi study exploring participants opinion of management approaches which contributed to success in the Avahan scale-up. Three rounds within study with 38 invited participants of varying positions including from staff from scale-up team and Bill and Melinda Gates Foundation, staff of state level and lead implementing partners from local and international NGOs, along with

Case Ref	Citation	Type of Document	Primary Focus of Document	Were Methods Reported?	More Details on Document*
					members of expert technical panel who provided support throughout the programme. Number of participated with response rates of 25 participants with 61%, 71% and 41% from each group respectively appear credible. Reports consensus achieved in findings. Methods appear appropriate to support findings
	(307)	Peer reviewed article	Ethnographic study	Yes	Ethnographic study exploring the Avahan project and peer workers in Karnataka state. Two authors report a background of ethnographic and applied health research projects regarding HIV in South India. They reported a close partnership with one of the lead implementing organisations of the Avahan programme which provided point of entry for research. Explored how the Avahan project influenced how peer workers and community members framed thinking and problem-solving. Observations from meetings, field sites where community outreach occurred and areas where sexual minorities congregated for sex. Direct participation of the researchers in mapping studies with peer workers gave insight into this element
	(340)	Grey literature. Report	Process and outcomes	No	Project report. Has background context and some information on local data capturing methods as needed. Can provide wider contextual background information
	(341)	Grey literature. Report	Process and outcomes	No	Project report. This included more details on the interventions within programme. Provides details on methods used for data capturing by peer workers. In particular tools used for workers with literacy issues
	(342)	Grey literature. Report	Process and outcomes	No	Earlier project report which can provide wider context

*More details on document heading provides a brief overview only. Rigour was decided based on the piece of evidence taken from a document and not necessarily the document as a whole. This is discussed in the methods for Chapter 6, and in the results section where for each synthesised CMOC considerations of rigour specific to the pieces of evidence used are discussed in the supporting evidence table for the relevant programme theory.

APPENDIX H. Working Definitions to Assist in CMOC Extraction for Phase Three

Table H 1 Working Definitions to Assist in CMOC Extraction for Phase Three

Working definitions for review to help guide CMOC Formation Phase Three		
Notes: what is categorized as resource, context, mechanism or outcome in one instance may be categorized under another heading in another CMOC depending on the configuration. For example, ownership may be an outcome in one CMOC and a context in another. Please categorize under whichever heading is appropriate for the CMOC. Reasoning can be documented as needed.		
Resources	Local decision making	Involvement of: local service users, providers, community, local organisational or government HR for decision making for adaptations. Autonomy given to local level for adaptations
	Clarity of Intervention content e.g. intervention theory, core elements, components, functions or minimum standards	The identification of intervention theory, core elements, components, functions or minimum standards. This could involve purposeful selection of an intervention where these are known or seeking out this information for the selected intervention
	Guidance to sites on intervention components	Providing guidance to local sites on intervention theory, core elements, components, functions or minimum standards
	Guidance to sites on implementation and adaptation process	Providing guidance to local sites on a process of implementation and how to adapt intervention the specific intervention
	Providing examples of tried and tested adaptations	Examples of adaptations from sites shared with others. This could be through written formats (e.g. guidance documents) or through peer learning platforms
	Community partnerships	Formalised partnerships with the community to directly influence changes to the content of interventions
	The development of accessible data for use at local levels	This could include simplifying the data collection or analysis for use at local level, which may also have been accompanied with capacity building at local levels for its use
	Use of data to inform or evaluate adaptations	When a data driven approach was used to inform or evaluate adaptations
	Use of QI methods	QI Methods used to assist in adaptations during scale-up for example BTS, MFI and Plan-Do-Study-Act cycles
	Creating peer learning opportunities	This could be through a formalised process such as a learning collaborative or through mandated collaboration between sites
	Positive visibility of results	Local decision makers see the positive results of adaptations, or implementation made
Contexts	Conservative religious context	Where context was identified as a conservative religious setting where social norms and beliefs may have affected adaptations to interventions
	Political environment	The presence or absence of political support at national or local levels which affected adaptations to interventions
	Community Partnerships	This could be between community and an organisation.

Working definitions for review to help guide CMOC Formation Phase Three		
	Readiness	Where the organisation (or community) are ready for intervention and implementation, for example with resources, capacity in place, community sensitized to intervention, buy-in for intervention exists etc. This could also capture a lack of readiness or rushing to scale
	Resources	Resources or lack of resources such as: financial, logistical or human resource availability. This could include a stressed health system with under resourced HRH
	Leadership	This could relate to strong leadership, or a lack of leadership which may influence adaptation and scale-up. This includes level of support by management
	Funder support	The level of support and understanding by funders for intervention and adaptations
	Organisation flexible and responsiveness to local needs	Organisation flexible and responsiveness to local needs. This could relate to where the organisation is open to receiving and acting on feedback or an adaptive scale-up design
	Make-up of local decision-making team	The composition of experience of local decision-making team e.g. diverse range vs bias on one or more professional groups
	Encouragement and flexibility to adapt	Where the scale-up team or higher levels of system provide encouragement and flexibility to adapt. Linked to leadership support
	Culture of respect	Culture of respect between individuals, or within an organisation. This could include placing value on the knowledge and opinions of those in the local setting
	Culture of trust	Culture of trust between individuals, or within an organisation. This could also relate to a history or relationship of trust built over time.
	Power imbalance	Power imbalance between individuals or organisations. This could relate to a power imbalance within a community setting limiting individual's participation, or could relate to top-down/bottom-up power imbalance between funders and an organisation, or between different levels of the health system
	Capacity to adapt interventions	Capacity to carry out actions needed to adapt and/or implement interventions
	Factors relating to make up of the intervention	For example: relative advantage, compatibility, complexity, trialability and observability. This could also include whether the intervention was simple or complex
Mechanisms (Response)	Awareness	"Knowledge or perception of a situation or fact"(348). This could relate to the local context, the need to adapt, the intervention itself or the scale-up or adaptation process. To note the level this occurred at i.e. awareness by scale-up team, community, local providers etc.
	Sensemaking	Giving meaning to circumstances by forming a plausible explanation based on local understanding which can lead to a proposed action (344, 347)
	Problem solving	Finding solutions to difficult or complex issues (348)
	Belief of relative advantage	Recognising that an intervention or approach may be preferable to the norm or another approach

Working definitions for review to help guide CMOC Formation Phase Three		
	Belief of intervention compatibility	Where there were beliefs of intervention compatibility or lack of compatibility in local setting
	Discomfort	Discomfort with intervention components based on social norms or individual beliefs
	Trust	"Firm belief in the reliability, truth, or ability of someone or something" (348). Trust could relate to the intervention itself, the scale-up or adaptation process or trust between actors e.g. service users, organisation, implementers etc.
	Motivation	Intrinsic or extrinsic motivation towards the intervention, its adaptation or scale-up. Motivation is an internal process that may cause a desire or willingness(348) towards something this is not seen, however relating actions could be visible
	Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in
	Commitment	"The state or quality of being dedicated to a cause, activity, etc." (348). This could relate to a commitment to the problem (e.g. addressing the health problem), the intervention, adaptation or scale-up process. This differs from support as it relates to dedication or engagement and so it is more active than support alone. A proxy for this could be mobilisation of resources for intervention or adaptation
	Confidence	"The feeling or belief that one can have faith in or rely on someone or something." (348). Confidence relates more to self-assurance(7) or certainty in an ability of oneself or others. This could be confidence in the ability to adapt or implement the intervention, in the intervention itself or of other people's ability to complete actions or goals for scale-up
	Empowerment	The process of becoming more powerful or confident in the ability to do something (348). This can include authority or power given to someone to do something
	Feeling valued, respected, appreciated	Where local decision makers feel valued, respected or appreciated
	Sensemaking and problem solving	Where local decision makers apply tacit knowledge to problem solve and adapt or implement what makes sense for their setting
	Pride	Local decision makers experience a sense of pride in achievements
	Fear of repercussions	Fear of negative consequences for adapting or implementing intervention or components. This could also include fear of negative consequences of reaching out for further assistance
	Perceived stigma of incompetence	Where local decision makers perceive they will be seen as incompetent for example by highlighting their need for support
	Pressure to adapt	Where stress placed on local decision makers to conform to adaptations as requested by others
	Overwhelmed/overburdened	Local decision makers feel overwhelmed by demands placed on them
	Sensitised to intervention	Local decision makers familiarised to intervention or components which may increase awareness and comfort with intervention

Working definitions for review to help guide CMOC Formation Phase Three		
Outcomes	Buy-in and Support	This may capture support from an individual, community or organisation. They may approve of or encourage the intervention, the adaptation or scale-up process. This may also capture the concept of buy-in. A proxy of support could be participation in the adaptation process or champions for intervention.
	Ownership	A feeling or sense of ownership of the intervention and/or scale-up or adaptation process by an individual, community or organization. A proxy of ownership could be engagement with the adaptation process by development of a local action plan.
	Adaptations with local fit (e.g. acceptability, feasibility)	Adaptations made which are acceptable and/or feasible in local settings
	Adaptations with fidelity to intervention components (positive)	Demonstrated examples of adaptations where intervention theory, core elements, components, functions or minimum standards remained intact. This could be through formalised fidelity assessment or example given of adaptation in practice
	Adaptations with loss to fidelity to intervention components (negative)	Where adaptations were reported with loss to fidelity of intervention theory, core elements, components, functions or minimum standards
	Time sensitive adaptations	Adaptations occurred in real time as needs emerged or with reduced time needed to complete
Outcomes (Distal)	*Note these distal outcomes will have multiple contributing factors and so only document if a direct link was reported	
	Scale up with local fit	Intervention is scaled-up across sites with local fit where intervention is acceptable and/or feasible
	Sustainability	Intervention is continued to be delivered at sites or the outcome of the intervention is sustained at sites over a time. This intervention may be continually adapted and does not need to remain the same

APPENDIX I. Publication Standards

Table I 1 Publication Standards for Realist Review along with where Standard can be found in Thesis. Adapted from (151)

Heading		Description from Publication Standards	Where Standard Can be Found in Thesis
Title			
1		"In the title, identify the document as a realist synthesis or review"	Title page
Abstract			
2		"While acknowledging publication requirements and house style, abstracts should ideally contain brief details of: the study's background, review question or objectives; search strategy; methods of selection, appraisal, analysis and synthesis of sources; main results; and implications for practice"	Abstract
Introduction			
3	Rationale for Review	"Explain why the review is needed and what it is likely to contribute to existing understanding of the topic area"	Chapter 2, Literature Review. Chapter 4, Section 4.2.2
4	Objectives and focus of review	"State the objective(s) of the review and/or the review question(s). Define and provide a rationale for the focus of the review"	- Rationale for focusing of review present in; clarifying scope sections of Chapter 4 (Section 4.2.2) and Chapter 5 (Section 5.5) - Objectives of review outlined in Chapter 3 (Section 3.5) - Research question and objectives also presented as they are refined in each empirical chapter (Chapter 4, Section 4.2.2; Chapter 5, Section 5.5)
Methods			
5	Changes in the review process	"Any changes made to the review process that was initially planned should be briefly described and justified"	- Clarifying scope Sections in Chapter 4 (Section 4.2.2) and Chapter 5 (Section 5.5) discuss rationale for focussing of question - Search terms updated in phase two and changes discussed in Chapter 5 (Section 5.2)
6	Rational for Using Realist Synthesis	"Explain why realist synthesis was considered the most appropriate method to use"	Chapter 3, Section 3.3

Heading		Description from Publication Standards	Where Standard Can be Found in Thesis
7	Scoping the Literature	"Describe and justify the initial process of exploratory scoping of the literature"	Chapter 4, Section 4.1
8	Searching processes	"While considering specific requirements of the journal or other publication outlet, state and provide a rationale for how the iterative searching was done. Provide details on all the sources accessed for information in the review. Where searching in electronic databases has taken place, the details should include, for example, name of database, search terms, dates of coverage and date last searched. If individuals familiar with the relevant literature and/or topic area were contacted, indicate how they were identified and selected"	- Chapter 4, Section 4.1 (Phase one) - Chapter 5, Section 5.2.1 and 5.2.2 (Phase two) - Chapter 6, Section 6.1.3-6.1.5 (Phase three)

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