

“Relationship advice for trial teams integrating qualitative inquiry alongside randomised controlled trials of complex interventions”

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Introduction to this topic



Common language

Best efforts

...a little love



Understanding

Communication

Appreciation

The “relationship” between RCTs and qualitative research is developing.... **But** literature shows that when qualitative research is applied alongside an RCT, there are often *methodological shortcomings, and its use and findings are not fully utilised.*





Presentation objectives

- Provide a case study of a mixed-methods community randomised controlled trial
- Provide methodological and practical guidance for trial teams planning to utilise qualitative inquiry:
 - Advice on decisions on data collection & analysis
 - Advice on how to communicate these decisions to teams with limited experience in qualitative research (or evaluation!)

Look out for the
tips along the
way!





Presentation outcomes

- Increase comfort with qualitative research
 - Address concerns of methodological shortcomings & underutilisation of qualitative findings
- Promote understanding to strengthen relationships within multidisciplinary teams working across vastly different paradigms of explanation





Why is this important?

- With appropriate guidance qualitative inquiry can be useful and demonstrate quality and rigour.
- Synergies with quantitative findings can be achieved to add value to an RCT.
- Understanding the value each partner brings to the relationship, our different worldviews can complement each other and together **build stronger evaluations of more effective interventions.**





Before we start: **Definitions**

1. Evaluation
2. Randomised controlled trial
3. Complex intervention
4. Qualitative inquiry

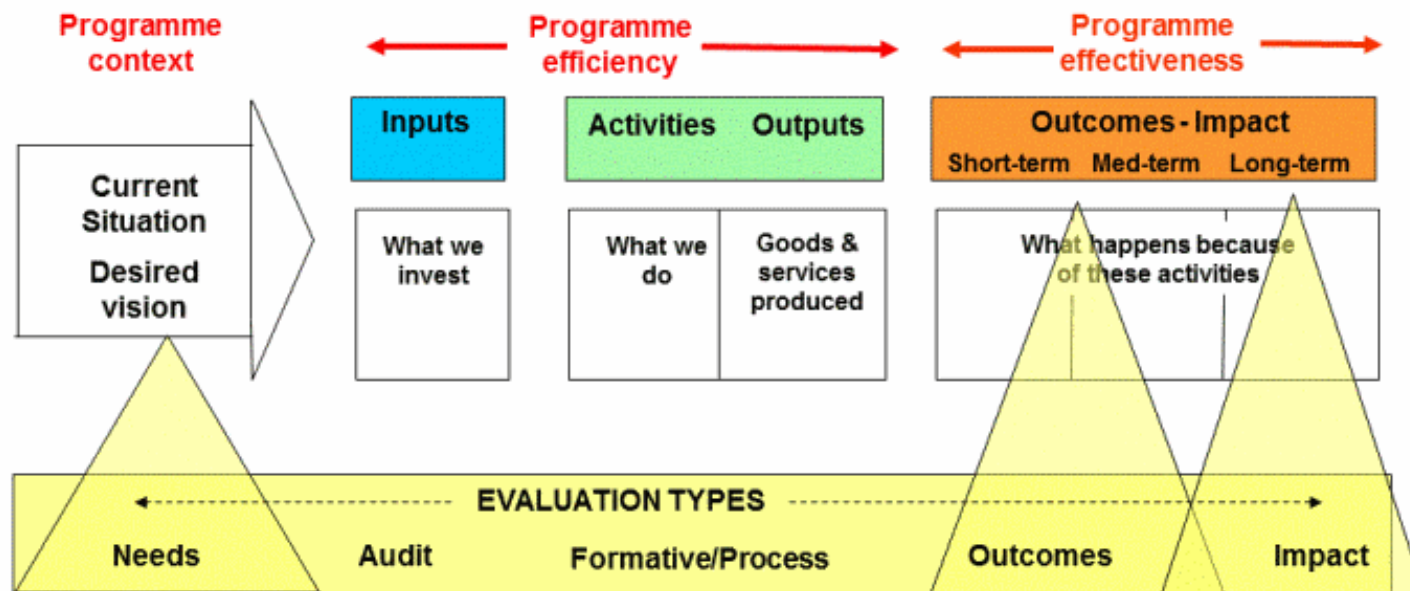




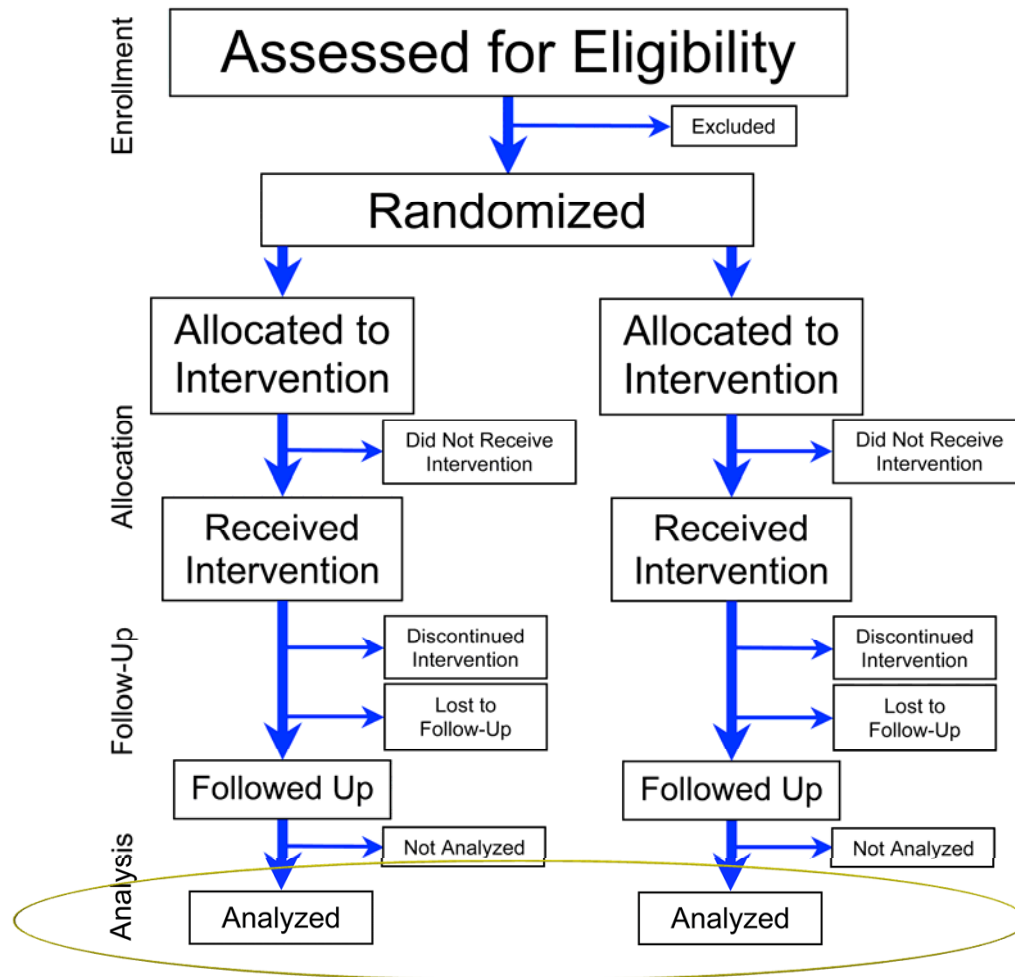
1. Evaluation (101)

Evaluations should help to draw conclusions about five main aspects of the intervention:

relevance, effectiveness, efficiency, impact, sustainability (OECD DAC)



2. Randomised Controlled Trials (RCTs)



Most rigorous scientific method for evaluating the effectiveness of health care interventions

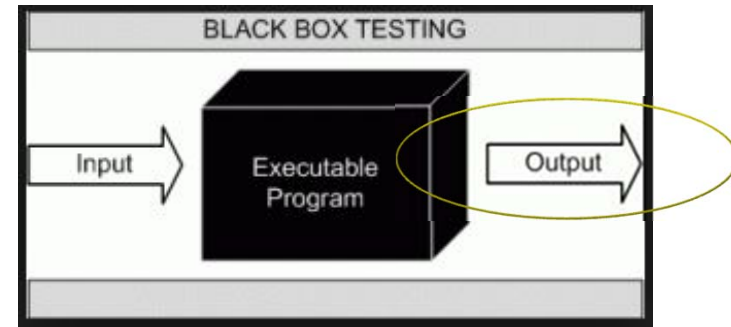
Effectiveness: extent to which project meets its intended outputs/objectives.

RCTs tell us whether (or not) an intervention results in changes... but little about the **causal mechanisms** that produce any change (Grimshaw, Zwarenstein et al. 2007)

2. Randomised Controlled Trials (RCTs)

Black box evaluation

Little attention to
“how” and “why”
impacts/outputs are
produced.



“Good RCTs” have:

- a high quality intervention
- adequate evaluation of the intervention and its delivery
- documentation of external factors that may influence outcome
- and a culturally sensitive intervention.

Thus, many RCTs would be **enhanced by an integral process evaluation** (Oakley, Strange et al. 2006).

2. Randomised Controlled Trials (RCTs)

“Gold standard” of research design – for **individual orientated interventions**. BUT its application to population health is more likely to encounter methodologic, pragmatic, and theoretical limitations.

Given the need for flexible, broad, and **complex interventions**, a focus on those that can be tested by RCTs may threaten the development and evaluation of innovative interventions with potentially significant public health consequences (*Sanson-Fisher, Bonevski et al. 2007*)





2. Randomised Controlled Trials (RCTs)

First tip!
Highlight that we
need each other.

Take home messages

- RCTs tell us about changes but nothing about causal mechanism of the change (hows and whys)
- RCTs are not always suitable for population-based health interventions (because they are more *complex*)

We need an integral **process evaluation** to compliment the RCT

“Hows” and “whys” are answered by **qualitative inquiry**

If RCTs *must* be used at population level, we need to treat them as “complex interventions”; thus need an appropriate design

Don't be critical of RCTs, instead focus on how to enhance them for the context



3. Complex Interventions

What makes an intervention complex?

- Number of interacting components within the experimental and control interventions
- Number and difficulty of behaviours required by those delivering or receiving the intervention
- Number of groups or organisational levels targeted by the intervention
- Number and variability of outcomes
- Degree of flexibility or tailoring of the intervention permitted

(Craig, Dieppe et al. 2008)





3. Complex interventions

Socially complex interventions (e.g. medical compliance) are characterised (under the 4 characteristics used to define **health service interventions**) by :

1. **Staffing arrangements:** that are complex and diverse;
2. **Protocol specificity:** ambiguous protocols - concepts are described theoretically but implemented subjectively;
3. **Subject involvement:** hard-to-define and differently motivated populations (subjects have many overlapping problems with uncertain origins and characteristics, have variable insight into their problems, and often challenge the goals of the intervention);
4. **Environment boundaries:** and permeable external boundaries in which the performance of the intervention is dependent on the social setting.

These characteristics create a number of difficulties when applied to RCTs” (Wolff 2001)





3. Complex interventions

Complex interventions = complex evaluations

There is likely to be too much 'noise' in the application of the RCT to complex interventions to meet standards of good science. However, this does not mean that we should disregard RCTs entirely, but **rather that they should be modified:**

- adding a comprehensive contextual evaluation based on mixed methods to the design, and
- using multiple sites.

(Wolff 2001 "Randomised trials of socially complex interventions: promise or peril?")





RCTs & complex interventions

Take home messages

RCT designs of complex interventions can be enhanced by:

- an integral process evaluation (to explain causal mechanisms); and
- adding a comprehensive contextual evaluation (to understand the “noise” affecting our intervention)

Show your decisions
are based on evidence
– use the literature



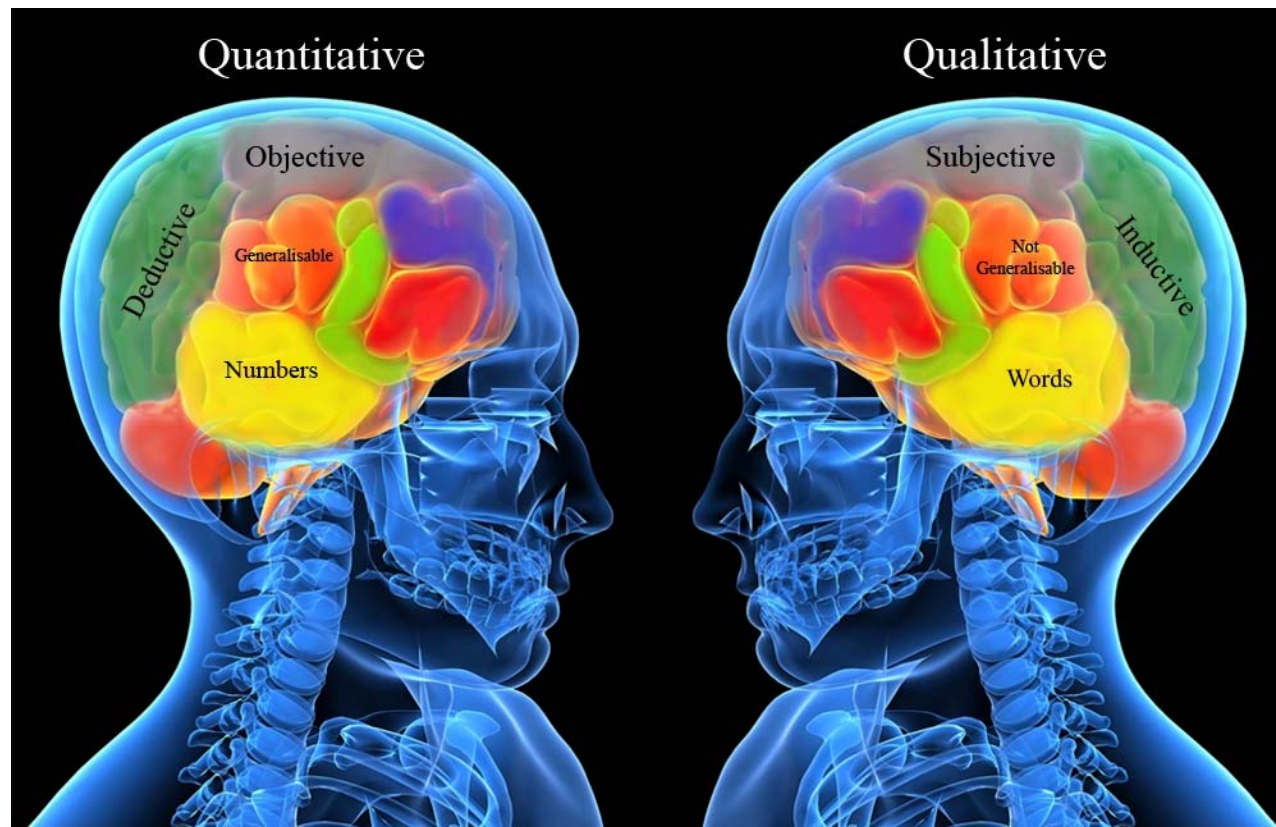


4. Qualitative inquiry

Qualitative research aims to **understand** and **explain phenomena** and their interrelationships in **non-numeric** terms, and variously incorporates such data collection and analysis methods as observation, individual and group interviewing, textual and visual data analysis. This form of inquiry depends primarily on matters of **quality** than quantity (e.g., an **in-depth understanding** of the form and **nature of a phenomenon** rather than its frequency, regularity or distribution).



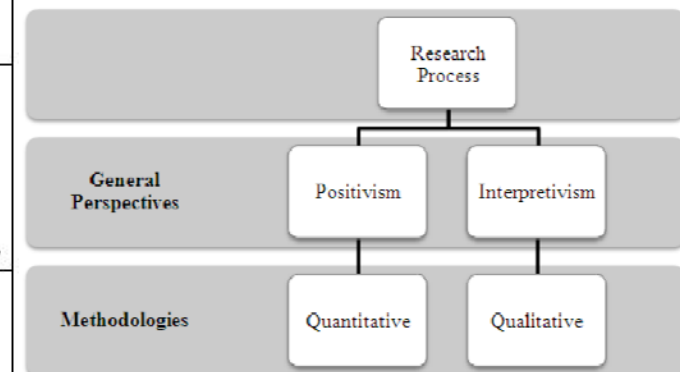
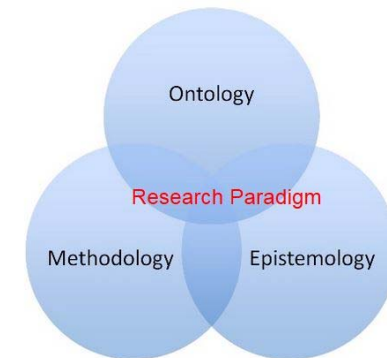
Working in multidisciplinary teams





Working in multidisciplinary teams

Paradigm				
	<i>Synonym</i>	Epistemology <i>What is truth?</i>	Ontology <i>What is real?</i>	Methodology <i>How do I examine what is real?</i>
Positivism	<i>Verify</i>	Objective dualism, the only knowledge is scientific knowledge which is truth	Realism, objective findings=truth	Experimental & manipulative: <i>Experiments & surveys</i>
Interpretivism/constructivist	<i>Understand/interpret</i>	Subjectivism, Co-created multiple realities and truths	Relativism, local, relative, co-constructed realities	Hermeneutic & dialectic: <i>Phenomenology, case study, ethnography, grounded theory</i>
Post-positivism	<i>Predict</i>	Modified objectivism, Findings approximate truth	Critical realism, findings=probably true	Modified experimental & manipulative: <i>Experiments, surveys, observation studies</i>
Critical theory	<i>Emancipate</i>	Subjectivism, Findings based on values, local examples of truth	Critical realism, Historical/virtual realism shaped by outside forces	Dialogic & transformative: <i>Action research</i>
Pragmatism	<i>Dialect</i>	Objective & subjective points of view	Symbolic realism, constructed based on the world we live in	Mixed-methods





Working in multidisciplinary teams

Reaching outside one's research paradigm can be uncomfortable...

- Qualitative studies in RCTs remain uncommon (n=30 out of 100) (Lewin, Glenton et al. 2009)
- **Poor understanding of the evaluation framework:** “these approaches are based on fundamentally different and unfamiliar paradigms of explanation” (Anderson 2008)





Working in multidisciplinary teams

Rigour of qualitative studies alongside RCTs is an important concern (Lewin, Glenton et al. 2009)

- Methodological shortcomings
- Underutilisation of qualitative findings
- Findings of the qualitative studies are poorly integrated with those of the trials





A good place to start!

- **Promoting understanding** of the evaluation framework amongst the team
- **Demonstrating rigour** in qualitative data collection and analysis

The following case study will provide example...





Complex intervention example

- The problem:
 - Poor medication compliance for rheumatic heart disease prevention (*injection every 21-28 days for 10 years or until the age of 21*)
- The aim:
 - To improve medication compliance by implementing and evaluating a sustainable, transferable, **systems-based** intervention at 10 Northern Territory health centres
- The intervention:
 - model of care designed to optimise health systems and community resources



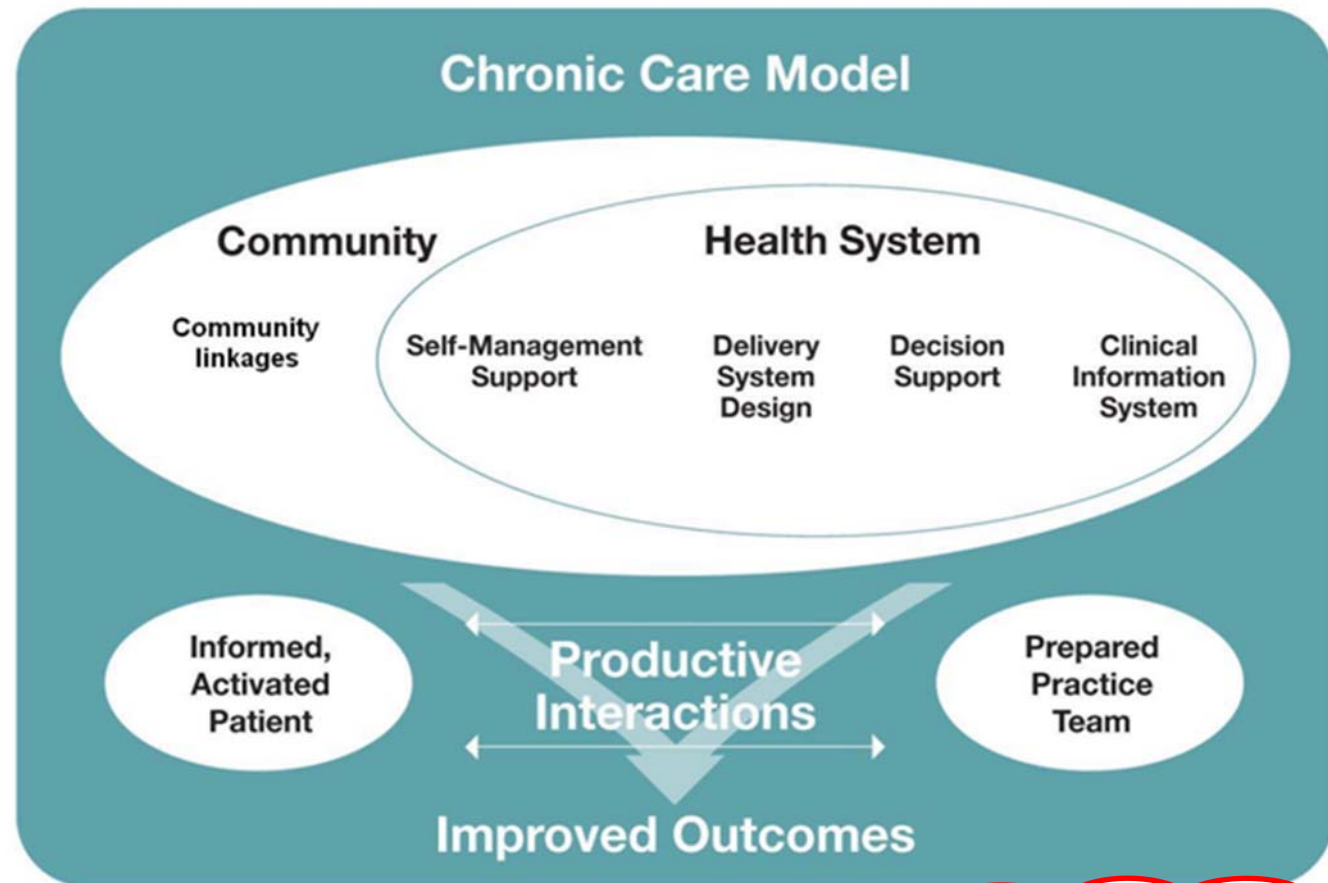


Intervention framework

♥ The Chronic Care Model (CCM) is a comprehensive systems-approach for chronic disease management

♥ It is a whole system model which promotes the client and the health service in a collaborative relationship

♥ It is also the current framework for the Northern Territory Chronic Disease Strategy.



Drawing on previous experience

EVALUATION CRITERIA

PROCESS & FIDELITY:

- What was the completeness and acceptability of implementation of the intervention package, and of individual items?
- What were the barriers and enablers of implementation?

- What were the barriers and enablers of organisational change?

EFFICIENCY: Degree to which inputs have been converted to outputs

- To what extent did health centres change their delivery of RHD care to align with the systems-based intervention?

PERFORMANCE:

- What were the factors associated with success in achieving organisational and client level improvements in SP for RHD?

EFFECTIVENESS: Degree to which project purpose has been achieved by the project outputs

- To what degree did adopting the systems-based intervention improve processes of RHD care and adherence to SP?
- Which elements of the intervention were most effective in activating change?

RELEVANCE & IMPACT: Degree to which the program design was right

- Did the intervention, (a model of care designed to optimise health systems), improve overall adherence to SP for RHD and minimise 'day at risk'?

STUDY LOGIC MODEL

BASELINE (3 months):

2-week site visit, interviews & development of customised action plans

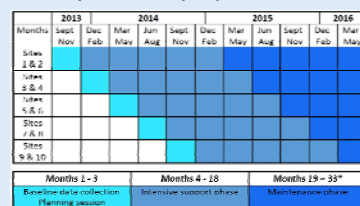
INTENSIVE (15 months):

Monthly site visits, review of action plan progress

MAINTENANCE (up to 15 months):

Monthly follow up, review of action plan progress

IMPLEMENTATION: Health centres commence the study at 3-monthly steps in random order



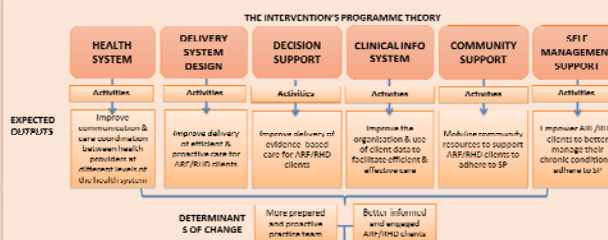
IMPLEMENTATION (Input)

MODERATORS

(factors that condition the intervention's effect on outcome)

THE INTERVENTION PACKAGE:

- Project Officers support health centres to develop and implement a customised set of activities aimed at improving penicillin delivery
- Activities are aligned under the elements of the Chronic Care Model (CCM)
- The intervention's Programme Theory is organised under the streams of the CCM & aim to activate "determinants" allowing for achievement of outcomes



INTERVENTION (Activities & outputs)

DETERMINANTS

OUTCOMES:

- Measured with generalised linear mixed models; Primary outcome with a logit link
- Outcomes measured at community level: McNemar's test for binary outcomes or a paired t test for normally distributed continuous outcomes

- OUTCOME MEASURES
- Proportion of clients receiving 80% or more of scheduled BPG injections over a minimum 12 month period
 - The proportion of scheduled injections that a client receives over a minimum 12 month period
 - The average number of days at risk
 - Proportion of clients receiving at least 90% of scheduled BPG injections over a minimum 12 month period
 - Proportion of clients receiving 50-79% and <50% of scheduled BPG injections over a minimum 12 month period
 - Recurrence rate and proportion of acute rheumatic fever (ARF) episodes that are recurrences, compared to non-participating communities and to the whole jurisdiction
 - Improvement in delivery of other services for RHD clients
 - Effect of the programme on delivery of other routine services
 - Impact of the intervention on RHD clients' experience of care including their perception and understanding of the disease and its management

OUTCOMES
Improved delivery and uptake of SP by ARF/RHD clients

IMPACT
Reduction in ARF recurrence

Introduce one concept at a time

Visual representation – a common language

SUSTAINABILITY: Durability of the benefits produced by the project after its completion

- Which of the activities and streams of the Chronic Care Model were sustained during maintenance phase?

IMPLEMENTATION (Input)

Break it down
into digestible
pieces

BASELINE (3 months):

2-week site visit, interviews & development of customised action plans

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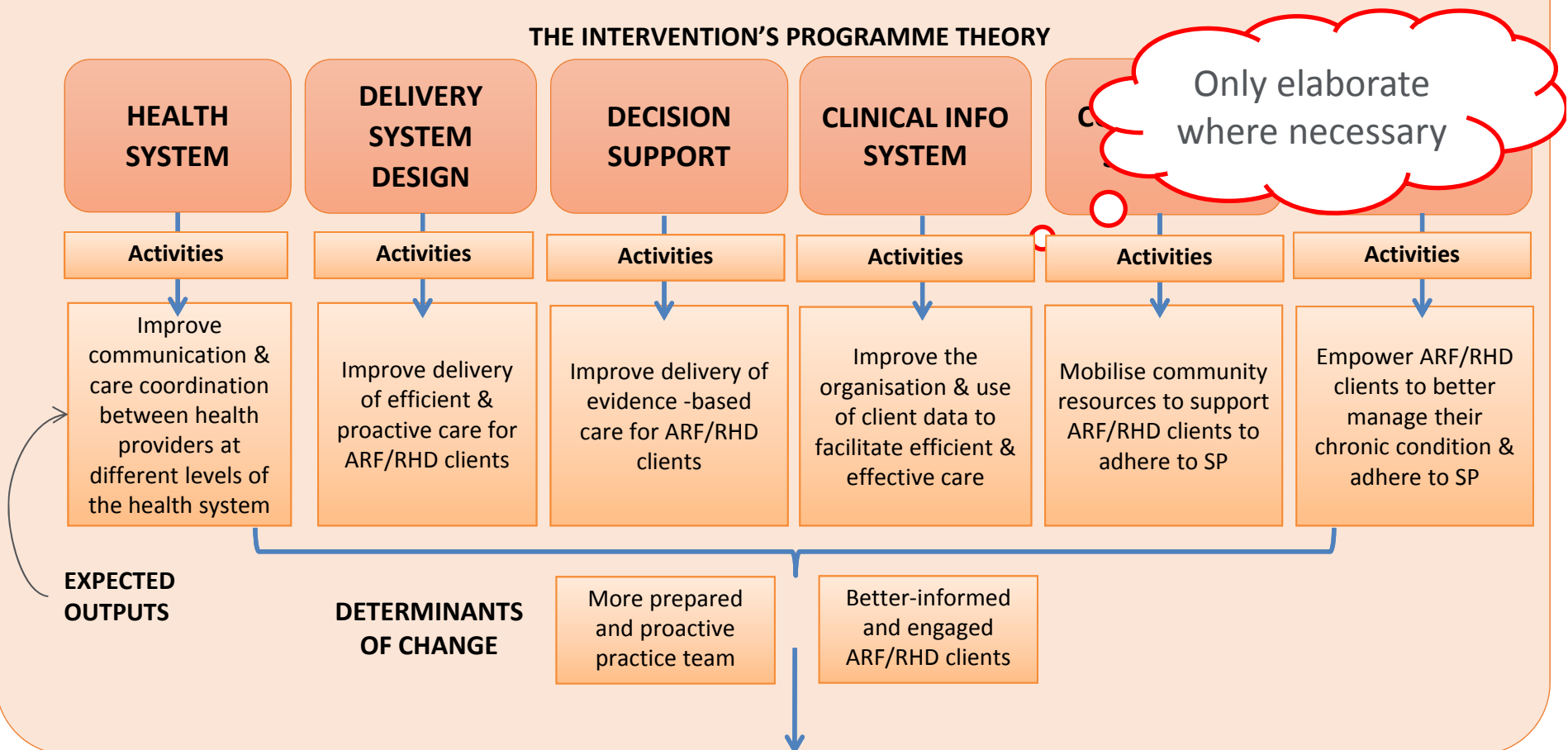
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	2013		2014				2015				2016	
Months	Sept-Nov	Dec-Feb	Mar-May	Jun-Aug	Sept-Nov	Dec-Feb	Mar-May	Jun-Aug	Sept-Nov	Dec-Feb	Mar-May	
Sites 1 & 2												
Sites 3 & 4												
Sites 5 & 6												
Sites 7 & 8												
Sites 9 & 10												

Months 1 - 3	Months 4 - 18	Months 19 – 33*
Baseline data collection Planning session	Intensive support phase	Maintenance phase

THE INTERVENTION PACKAGE:

- Project Officers support health centres to develop and implement a customised set of *activities* aimed at improving penicillin delivery
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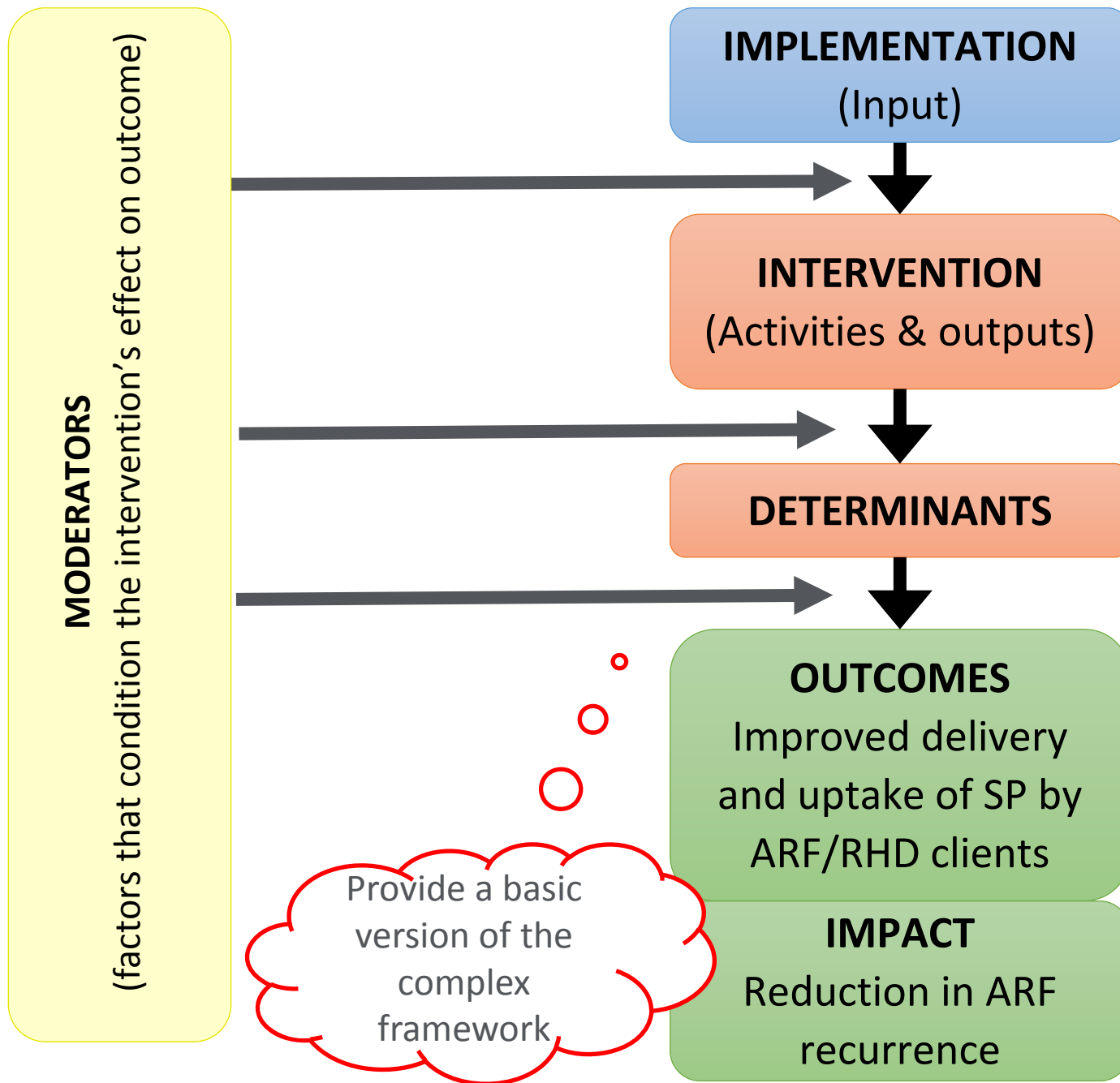
OUTCOMES:

- Measured with generalised linear mixed models; Primary outcome with a logit link
- Outcomes measured at community level: McNemar's test for binary outcomes or a paired t test for normally distributed continuous outcomes

OUTCOME MEASURES

- **Proportion of clients receiving 80% or more of scheduled BPG injections over a minimum 12 month period**
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Elaborate where necessary



EVALUATION CRITERIA

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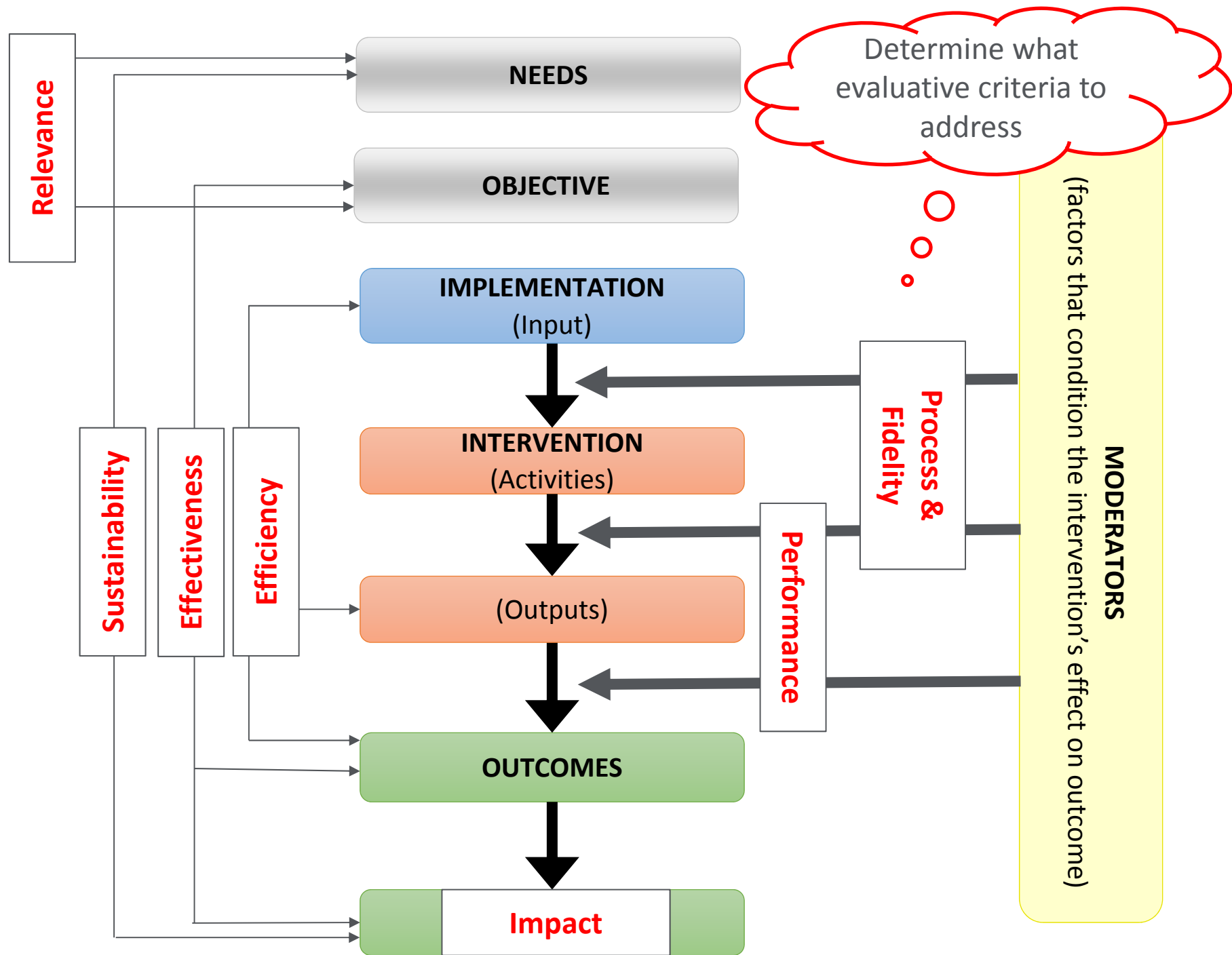
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Monthly follow up, review of action plan progress

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	2013			2014			2015			2016		
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From framework to practicalities

BEFORE YOU START!!!!

- Evaluative criteria guide your research questions
- Research questions guide your data collection (what to measure & how to measure it)
- *Data collection tool(s) are designed to answer our research questions (Deductive in nature)*



Evaluative measurements, indicators and means of verification for RHD SP Study

	RESEARCH QUESTION/ OBJECTIVE	OBJECTIVELY VERIFIABLE INDICATOR	MEANS OF VERIFICATION	
			Qualitative	Quantitative
EFFICIENCY	Evaluative criteria guide the research question		Research question guide the data collection	
EFFECTIVENESS				
IMPACT & RELEVANCE				
SUSTAINABILITY				
PROCESS & FIDELITY				
PERFORMANCE				

WHAT to measure

HOW to measure it



Ensure quality is maintained

Aspect	Qualitative Term	Quantitative Term
Truth value	Credibility	Internal Validity
Applicability	Transferability	External Validity or generalisability
Consistency	Dependability	Reliability
Neutrality	Confirmability	Objectivity

Different terms are used but we mean the same thing

Speak the right language for the right audience



Ensure quality is maintained

~An example of data collection procedure~

IMPLEMENTATION

PROCESS & FIDELITY:

1. Acceptability of implementation of the intervention package, and of individual items
2. **Barriers to and facilitators of implementation**
3. Completeness of implementation of the intervention package, and of individual items

Research question/ objective	Means of verification	Data collection procedure
What were the barriers and enablers of implementation	<p>PRIMARY SOURCES:</p> <ul style="list-style-type: none">• Project officer reports (observation)• Baseline and post-intensive interviews• Project journal <p>SECONDARY SOURCES:</p> <ul style="list-style-type: none">• Team meeting notes	<p><i>Example (Project officer reports):</i></p> <ol style="list-style-type: none">1. Project officers (2) prepare monthly reports at their respective sites in a predetermined report format.2. Project officers exchange reports and review, seeking clarification where necessary3. Project officer reports are reviewed by the project manager before being marked as “final”.





Ensure quality is maintained

~Data collection~

Do it right!,
demonstrate
rigour

Credibility	<ul style="list-style-type: none">• Peer debriefing• taking verbatim quotes• Use multiple data sources (data triangulation), methods (methodological triangulation), researchers (investigator triangulation)• Collect data for an extended period of time (prolonged engagement)
Transferability	<ul style="list-style-type: none">• document contextual background information & demographics
Dependability	<ul style="list-style-type: none">• Collect data until no new themes emerge (saturation)• Continuously analyze the data to inform further data collection (iterative data collection)
Confirmability	<ul style="list-style-type: none">• Audit trail: Document the steps and decisions taken in the research, and their motives





Ensure quality is maintained

~An example of analysis procedure~

IMPLEMENTATION

PROCESS & FIDELITY:

1. Acceptability of implementation of the intervention package, and of individual items
2. **Barriers to and facilitators of implementation**
3. Completeness of implementation of the intervention package, and of individual items

Research question/ objective	Data sources	Data analysis procedure
2. Descriptive summary of the barriers and enablers of implementation	<p>PRIMARY SOURCES:</p> <ul style="list-style-type: none">• Project officer reports (observation)• Baseline and post-intensive interviews• Project journal <p>SECONDARY SOURCES:</p> <ul style="list-style-type: none">• Team meeting notes	<ol style="list-style-type: none">1. Analyse project officer reports for intervention phase (collating information under the node: “barriers-implementation” and “facilitators: implementation”)2. Analyse baseline and post-intensive interviews (collating information under the node: “barriers-implementation” “facilitators: implementation”)3. Review project journal for supporting/additional information4. Interview project officers on implementation5. If required, consult secondary sources for supporting/additional information6. Use information at 1-5 (above) to <u>contribute to intensive phase report</u> for each HC (n reports=10)



Ensure quality is maintained

~Data analysis~

Credibility	<ul style="list-style-type: none">• Peer debriefing• independent analysis of data by more than one researcher• Use verbatim quotes• Use multiple data sources (data triangulation), methods (methodological triangulation)
Transferability	<ul style="list-style-type: none">• providing details of the study participants and contextual background• Make the findings meaningful to others by describing them and their context in detail
Dependability	<ul style="list-style-type: none">• Continuously re-examine the data using insights that emerge during analysis (iterative data analysis)
Confirmability	<ul style="list-style-type: none">• Peer debriefing: Discuss the research process and/or findings with peers/experts





Summary

~General advice~

- Don't drown in data!
- Ensure common expectations between partners
- Don't underestimate the time for analysis
- Don't forget the contextual background information (helps to inform transferability)
- DO remember your quality criteria!
- DO use a framework to guide development and implementation of evaluations
- DO explain concepts in a common language





Summary

- Provided a case study of a mixed-methods community randomised controlled trial of a complex intervention (*with definitions*)
- Provided methodological and practical guidance for trial teams planning to utilise qualitative inquiry
 - Advice on decisions on data collection & analysis
 - Advice on how to communicate these decisions to teams with limited experience in qualitative research (or evaluation!)





Good luck!

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