2016

PROCESS EVALUATION

A reference for research teams evaluating hypertension interventions

GACD

GLOBAL ALLIANCE FOR CHRONIC DISEASES
AN ALLIANCE OF HEALTH RESEARCH FUNDERS

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GACD Process Evaluation in Hypertension Working Group

GLOBAL ALLIANCE FOR CHRONIC DISEASES

Process Evaluation in Hypertension Working Group

GUIDELINES

Process evaluation: A reference for research teams evaluating hypertension interventions

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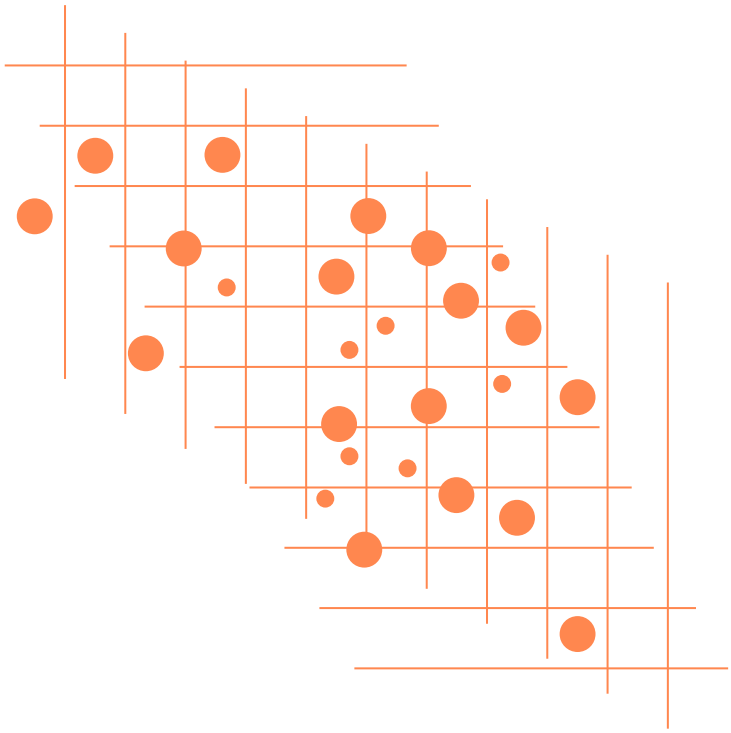
Contents

Aims of the guideline

These guidelines were written by the Global Alliance for Chronic Diseases (GACD) Process Evaluation Working Group, as a reference for research teams when considering the evaluation of their interventions. The working group was established in 2015 by members of the GACD Hypertension Programme, following the 2014 annual meeting at which it was felt better dissemination of process evaluation expertise was needed. The working group was tasked with producing a set of guidelines on process evaluation, and undertaking a review of the process evaluation approaches being used in the Hypertension Programme.

The guidelines are not meant as an exhaustive guide, more an initial starting point for those considering study design, outlining key concepts and key recommendations for each stage. They are drawn from the UK Medical Research Council guidelines (Moore et al, 2014).



Glossary

Complex intervention: An intervention comprising multiple components which interact to produce change. Complexity may also relate to the difficulty of behaviours targeted by interventions, the number of organisational levels targeted, or the range of outcomes.

Context factors: External to the intervention which may influence its implementation, or whether its mechanisms of impact act as intended. The study of context may include contextual moderators which shape and may be shaped by implementation, intervention mechanisms, and outcomes.

Implementation: The processes through which interventions are delivered, and what is delivered in practice. Key dimensions include:

> ***Implementation process:*** the structures, resources and mechanisms through which delivery is achieved.
>
> ***Fidelity:*** the consistency of what is implemented within the planned intervention.
>
> ***Adaptation:*** alterations made to an intervention in order to achieve better contextual fit.
>
> ***Dose:*** how much intervention is delivered.
>
> ***Reach:*** the extent to which a target audience comes into contact with the intervention.

Logic model: A diagrammatic representation of an intervention, describing anticipated delivery mechanisms (e.g. how resources will be applied to ensure implementation), intervention components (what is to be implemented), mechanisms of impact (the mechanisms through which an intervention will work), and intended outcomes.

Mechanisms of impact: The intermediate mechanisms through which intervention activities produce intended (or unintended) effects. The study of mechanisms may include:

> ***Participant responses:*** how participants interact with a complex intervention.
>
> ***Mediators:*** intermediate processes which explain subsequent changes in outcomes.
>
> ***Unintended pathways and consequences***

Process evaluation: A study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors. Process evaluation is complementary to, but not a substitute for, high quality outcomes evaluation.

Why is process evaluation necessary?

A high-quality evaluation of any intervention is crucial in allowing policymakers, practitioners and researchers to identify interventions that are effective, and to understand and learn how to improve those that are not.

Although outcome evaluations, such as randomised trials or natural experiments, are crucial to establishing the efficacy of any intervention, if assessed in isolation they can leave a number of unanswered questions:

If the intervention is effective in one context, how can we be sure that:

- Another organisation will deliver the intervention in the same way.
- The outcomes will be the same in new contexts.

If the intervention is ineffective in one context, how can we be sure that:

- The failure is attributable to the intervention itself, rather than to poor implementation of the intervention.
- The intervention doesn't benefit the target population.
- If the intervention was delivered in a different context it would be equally ineffective. With regard to systematic reviewers, without a process evaluation it can be difficult to:
    - Ensure that when comparing interventions they were implemented in comparable ways.
    - Understand why the same intervention had different effects in different contexts.

Furthermore, effective interventions can increase or decrease inequalities among sub-groups. Whilst an outcome evaluation can help identify whether inequalities are affected by an intervention, understanding how those equalities are affected requires a more detailed understanding of cause and effect than is provided by an outcomes evaluation.

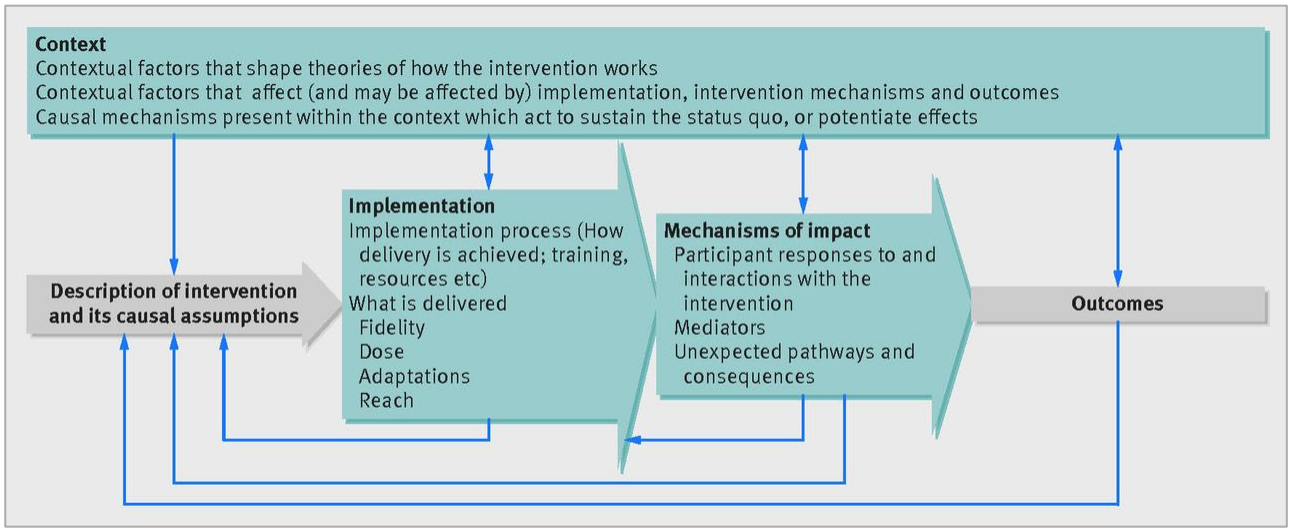
What is a process evaluation?

Process evaluations aim to provide the more detailed understanding needed to inform policy and practice (see Figure 1). They tend to assess:

- **Implementation:** the structures, resources and processes through which delivery is achieved, and the quantity and quality of what is delivered.
- **Mechanisms of impact:** how intervention activities, and participants' interactions with them, trigger change.
- **Context:** how external factors influence the delivery and functioning of the intervention.

Depending on the stage of the evaluation, a process evaluation will have different functions. During feasibility and pilot trials, a process evaluation will assess feasibility and acceptability of the implementation structures and proposed study design, and test any intermediate processes. During effectiveness studies, a process evaluation will test the fidelity of the implementation, investigate the mechanisms of impact, and any contextual influences on the implementation and outcomes.

Figure 1 Key functions of a process evaluation and the relationships between them (from Moore et al. 2015).



This figure was originally published in Moore GF et al. Process evaluation of complex interventions: Medical Research Council guidance BMJ 2015; 350 :h1258 doi:10.1136/bmj.h1258 and has been used in this guidance document with permission from the BMJ. Moore et al. (2015) is an Open Access article distributed in accordance with the terms of the Creative Commons Attribution (CC BY 4.0) license.

How to conduct a process evaluation

5.1 Planning a process evaluation

5.1.1 Relationships with intervention staff

Conducting a process evaluation will involve critically appraising the work of intervention staff. Maintaining good working relationships with staff, whilst remaining sufficiently independent to be able to credibly evaluate their work is a significant challenge. It is important to assess whether evaluators, due to having established relationships with intervention staff, are viewing the intervention too positively, or are being unduly critical. Occasionally introducing into the evaluation a researcher who is less invested in the project, to assess whether researchers are maintaining their independence, can be useful.

5.1.2 Addressing emerging issues

During a process evaluation it is likely that implementation issues will be identified that would be of interest to policymakers and practitioners, however careful consideration should be taken as to whether or not these findings are communicated. At the feasibility/pilot stage it is suggested that researchers play an active role in communicating such issues, but when attempting to establish effectiveness under real world conditions it is suggested otherwise. Providing excessive feedback can cause the lines between the evaluation and the intervention to become blurred. Agreement on the degree and nature of communication between the evaluators and intervention team should be agreed at the outset.

5.1.3 Relationships between evaluation teams

Normally a process evaluation will be conducted as one of a number of evaluation studies e.g. outcome evaluation and cost-effectiveness study. How these teams communicate and interact should be agreed from the outset, duplication and conflict minimised, and the evaluation as a whole should be overseen by a PI who values all aspects equally. Where process and outcomes evaluations are done by the same person, there should be openness about how this might affect data analysis.

5.1.4 Resources and staffing

Normally a process evaluation will be conducted as one of a number of evaluation studies e.g. outcome evaluation and cost-effectiveness study. How these teams communicate and interact should be agreed from the outset, duplication and conflict minimised, and the evaluation as a whole should be overseen by a PI who values all aspects equally. Where process and outcomes evaluations are done by the same person, there should be openness about how this might affect data analysis.

5.1.5 Public and patient involvement

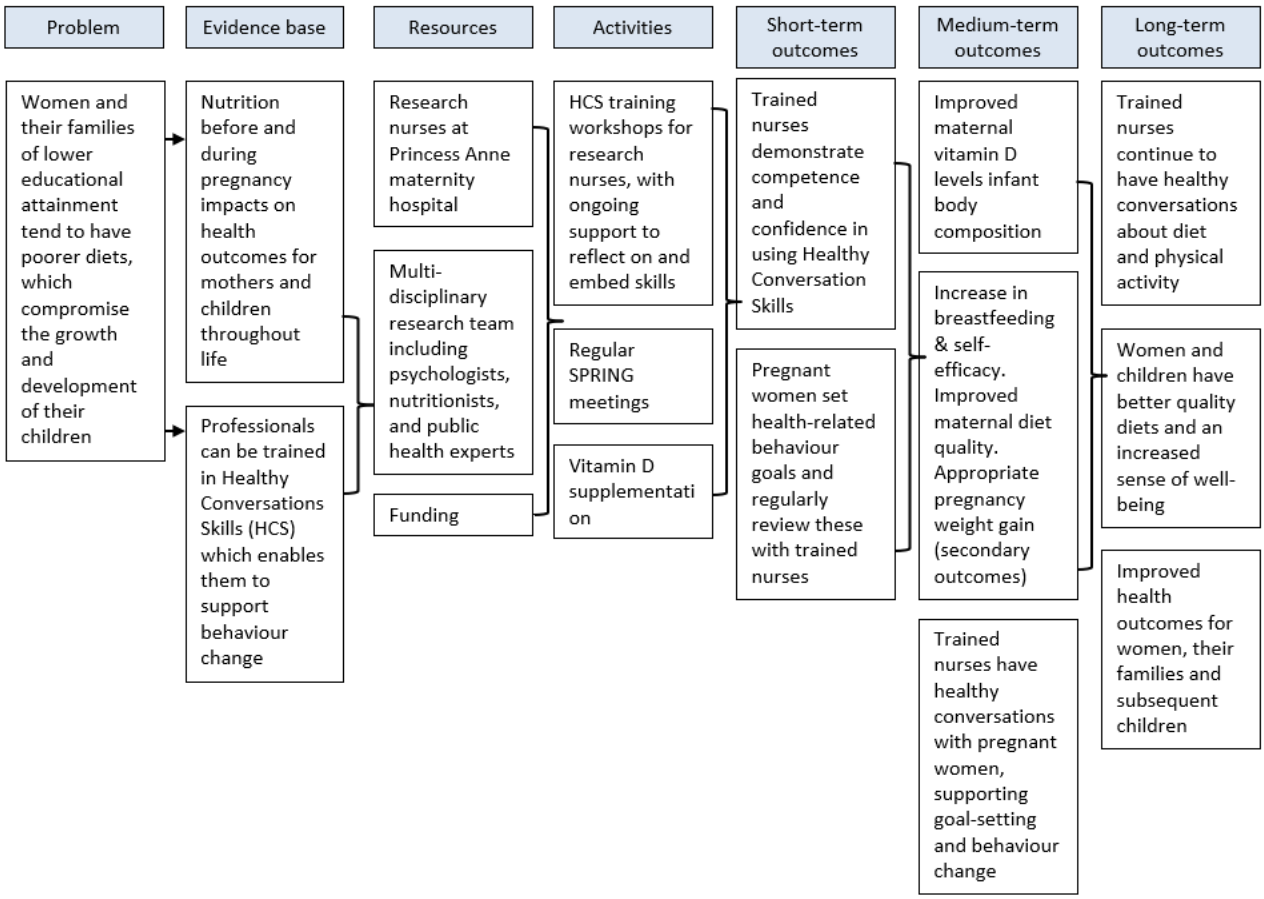
It is widely believed that increased attention to public involvement may enhance the quality and relevance of health and social science research. Research teams should spend time considering whether and how public involvement in the research project would be beneficial.

5.2 Designing and conducting a process evaluation

5.2.1 Define the intervention and key assumptions

Ideally by the time an evaluation begins the nature of the intervention should be fully understood, and its required structures, intended activities, and short- medium- and long-term outcomes detailed in a logic model (see Figure 2). A clear description of its causal assumptions should be in place, and it should be clear how these informed research questions and methods.

Figure 2 Logic model for the Southampton Pregnancy Intervention for the Next Generation study (from Moore et al. 2014)



This figure was originally published in Moore G et al. 2014. Process evaluation of complex interventions: Medical Research Council guidance. London, MRC Population Health Science Research Network. Available at: Process evaluation of complex interventions – UKRI

5.2.2 Current learnings and expected value

There should be an appreciation of the potential added value of the process evaluation, derived from an examination of the current literature. In doing so, there should be consideration of whether it is worthwhile repeating aspects of previous process evaluations of similar interventions, or whether it may be more appropriate to build on previous work.

5.2.3 Core aims and research questions

Given finite resources and time, a clear understanding of the core research questions should be in place from the outset. A focused process evaluation addressing fewer research questions, but questions of greatest import will likely give better results than a shallow disparate investigation. To establish the core questions, researchers can begin by listing the assumptions of how the intervention will be delivered and how it will work, before reviewing the evidence for the assumptions, and identifying the most important uncertainties. Time should be set aside to investigate unforeseen issues that may arise during the process evaluation.

5.2.4 Selecting appropriate methods

Most process evaluations will be mixed methods in design. The pros and cons of each method should be weighed carefully to select the most appropriate methods for the research questions. Common quantitative and qualitative methods are outlined below.

Common quantitative methods	Common qualitative methods
Structure observations	One-to-one interviews
Self-report questionnaires	Group interviews or focus groups
Secondary analysis of routine data	Non-participant interview

5.2.5 Sampling

While it may not always be possible or appropriate to collect all process data from all participants, care should be taken to not draw conclusions on the intervention as a whole from a small number of participants. It is usually most efficient to collect data on key aspects of the process from all participants, then conduct more in-depth data collection on a smaller sample. 'Purposive' sampling according to socio-demographic or other organisation factors that are expected to affect delivery or effectiveness can be a useful approach.

5.2.6 Timing of data collection

The intervention, participants' interaction with it, and the research context will likely change over time. Hence, attention should be given to the timing of data collection, and the nature of the issues that will be identified.

To capture both teething problems and established issues, teams may consider collecting data at various points throughout the period of the intervention to capture changes.

5.3 Analysis of data

5.3.1 Mixed methods

Process evaluations should be both mixed methods in design and in analysis. Though requiring different data and different skills, quantitative and qualitative data should be analysed in tandem. Often quantitative analysis will identify issues that require qualitative exploration, and qualitative analysis will identify issues that require quantitative assessment or confirmation. The amount of time required for thorough analysis of all data should not be underestimated.

Ideally collection and analysis of qualitative data should be carried out in parallel so that issues identified in early data can be addressed in later data collection.

5.4 Integrating process and outcome evaluations

The different teams who are responsible for the different aspects of the evaluation should ensure that plans are made for integration of all data, and that these plans are in the evaluation design. If key quantitative data is collected, these should ideally be collected in a way that allows their association with outcomes or cost-effectiveness data. Qualitative process evaluation data can be of use in assessing and explaining intervention outcomes, and could lead to the generation of causal hypotheses behind observed phenomena e.g. differential responses to intervention.

5.5 Reporting process evaluation findings

Reporting the results of process evaluations of complex interventions is complicated by the large quantities and diverse range of data generated. Key points that should be fully detailed are:

- The relationship between the qualitative and the quantitative components of the evaluation.
- The key assumptions being made by the researchers as to how the intervention will produce the intended effects (consider including a logic model).
- How the theory of the intervention drove the development of the key research questions of the process evaluation.

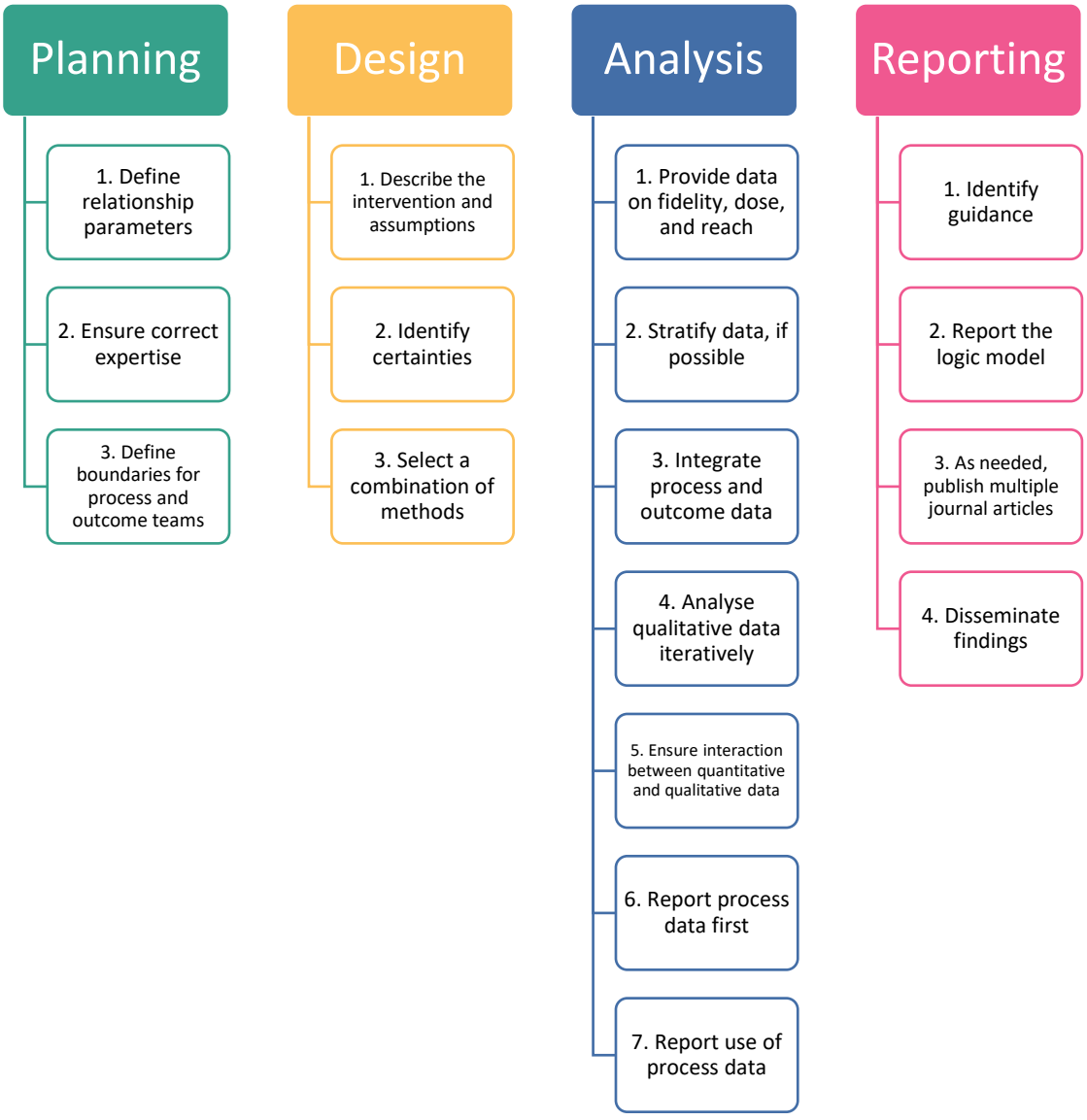
The results of process evaluations are often intended for relevant policymakers, practitioners, or stakeholders, and as such evaluation results should be presented in lay format to these audiences. Furthermore, researchers should consider reporting their formats to other policy and practice audiences whose work may be influenced by the findings.

Process evaluation findings should also be published in academic journals with full referencing to study protocol papers/websites. Though it is common for process data to not be published in journals, emphasising contributions to interpreting outcomes, intervention theory, or methodological debates regarding the interpretation of complex interventions, may increase their appeal to journal editors.

Key recommendations

Figure 3 outlines the key recommendations for process evaluation. Below the figure are details for each of the components.

Figure 3 Summary of key recommendations for process evaluation



Planning

1. Carefully define the parameters of relationships with intervention developers or implementers.
   - Balance the need for sufficiently good working relationships to allow close observation against the need to remain credible and independent.
   - Agree whether evaluators will play an active role in communicating findings as they emerge (and so help correct implementation challenges) or play a more passive role.
2. Ensure the research team has the correct expertise.
   - Expertise in qualitative and quantitative methods.
   - Appropriate inter-disciplinary theoretical expertise.

3. Decide the degree of separation or integration between process and outcome evaluation teams.
    - Ensure effective oversight by a principal investigator who values all evaluation components.
    - Develop good communication systems to minimise duplication and conflict between process and outcomes evaluations.
    - Ensure that plans for integration of process and outcome data are agreed from the outset.

Design

1. Clearly describe the intervention and clarify its causal assumptions in relation to how it will be implemented, and the mechanisms through which it will produce change in a specific context. A diagrammatic logic model will help to understand how the different component link to one another.
2. Identify key uncertainties and systematically select the most important questions to address.
    - Identify potential questions by considering the assumptions represented by the intervention.
    - Agree scientific and policy priority questions by considering the evidence for intervention assumptions and consulting the evaluation team and policy/practice stakeholders.
    - Identify previous process evaluations of similar interventions and consider whether it is appropriate to replicate aspects of them and build upon their findings.
3. Select a combination of quantitative and qualitative methods appropriate to the research questions.
    - Use quantitative methods to quantify process variables and allow testing of pre-hypothesised mechanisms of impact and contextual moderators.
    - Use qualitative methods to capture emerging changes in implementation, experiences of the intervention and unanticipated or complex causal pathways, and to generate new theory.
    - Balance collection of data on key process variables from all sites or participants where feasible, with detailed case studies of purposively selected samples.
    - Consider data collection at multiple time points to capture changes to the intervention over time.

Analysis

1. Provide descriptive quantitative information on fidelity, dose and reach.
2. Consider more detailed modelling of variations between participants or sites in terms of factors such as fidelity or reach (e.g. are there socioeconomic biases in who is reached).
3. Integrate quantitative process data into outcome datasets to examine whether effects differ by implementation or pre-specified contextual moderators, and test hypothesised mediators.
4. Collect and analyse qualitative data iteratively so that themes that emerge in early interviews can be explored in later ones.
5. Ensure that quantitative and qualitative analyses build upon one another, with qualitative data used to explain quantitative findings, and quantitative data used to test hypotheses generated by qualitative data.
6. Where possible, initially analyse and report qualitative process data prior to knowing trial outcomes to avoid biased interpretation.
7. Transparently report whether process data are being used to generate hypotheses (analysis blind to trial outcomes), or for post-hoc explanation (analysis after trial outcomes are known).

Reporting

1. Identify existing reporting guidance specific to the methods adopted.
2. Report the logic model or intervention theory and clarify how it was used to guide selection of research questions.
3. Publish multiple journal articles from the same process evaluation where necessary.
    - Ensure that each article makes it clear its context within the evaluation as a whole.
    - Publish a full report comprising all evaluation components or a protocol paper describing the whole evaluation, to which reference should be made in all articles.
    - Emphasise contributions to intervention theory or methods development to enhance interest to a readership beyond the specific intervention in question.
4. Disseminate findings to policy and practice stakeholders.

Further reading

Moore G *et al*. 2014. Process evaluation of complex interventions: Medical Research Council guidance. London, MRC Population Health Science Research Network.

Available at: www.ukri.org/publications/process-evaluation-of-complex-interventions/

Moore G *et al*. 2015. Process evaluation of complex interventions: Medical Research Council guidance. BMJ; 350:h1258 doi:10.1136/bmj.h1258.

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Pawson R and Tilley N. 1997. Realist Evaluation. SAGE Publications Ltd. ISBN: 978-0-7619-5008-0.

Readers may also be interested in the following publication from the **GACD Process Evaluation in Hypertension Working Group**:

Limbani F et al. 2019. Process evaluation in the field: global learnings from seven implementation research hypertension projects in low-and middle-income countries. *BMC Public Health*. 19(1):953. doi:10.1186/s12889-019-7261-8

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About the Global Alliance for Chronic Diseases

Who we are

The Global Alliance for Chronic Diseases (GACD) is the first collaboration of major research funding agencies to specifically address chronic, non-communicable diseases. Together, the members of the alliance represent 80% of global public funding for health research.

Our focus

Implementation science | Non-communicable diseases | Low- and middle-income countries and vulnerable populations in high-income countries

> "Implementation science examines what works, for whom and under what circumstances, and how interventions can be adapted and scaled up in ways that are accessible and equitable."
>
> ~ GACD Strategy Board

Our mission

To reduce the burden of chronic non communicable diseases (NCDs) in low-and middle-income countries, and in indigenous populations facing conditions of vulnerability in high-income countries, by building evidence to inform national and international NCD policies and contribute to the achievement of the Sustainable Development Goals.

Our strategic objectives

- Investing in impactful implementation science research.
- Building implementation science capacity and capability in relation to NCDs.
- Facilitating collaborations and partnerships to support GACD impact.

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