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Part 2

Evaluating processes

5

Process evaluation

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LEARNING OBJECTIVES

After reading and reflecting on the content of this chapter you will be able to:

- Define what **process** evaluations are
- Explain why researchers use process evaluations
- Appreciate the role of process evaluations when integrated within an **impact evaluation** (such as a randomised controlled trial)
- Understand the three **process evaluation** domains of **implementation**, **intervention mechanisms** and **context**
- Describe the key components of each process evaluation domain, their main concepts and the methods employed
- Identify some of the specific considerations when undertaking a process evaluation in low resources settings
- Understand the value of methodological guidance when designing and conducting process evaluations

Reflexivity statement

We are an international group of researchers, all of whom bring different experiences of undertaking process evaluations.

JS is based in Wales, UK, where most of his research has been undertaken. A lot of his research focuses on school and family-based public health interventions, and he draws on this experience when designing and conducting process evaluations. BH is based in Belgium; much of her work focuses on the evaluation of interventions to improve access to sexual health services, particularly HIV prevention services in Zambia. As a white, cisnet woman, residing in a high-income country, she is cognisant of her privilege in her work. ND is based in the UK and draws on her experience of conducting multi-country large-scale evaluations to improve quality of care in maternal and newborn services in several countries in Africa and in Bangladesh. She leverages her lived experience as a member of a minoritised community to advocate for community inclusion in the evaluation process. BN is based in Ethiopia, where much of his work is grounded in strengthening health systems and advancing universal health coverage, particularly through primary health care and health financing reforms. With experience of working closely with national governments, international organisations and local communities, he is committed to ensuring contextually grounded, equity-focused evaluation processes. BN acknowledges how his position within a low- and middle-income country health system provides both valuable insight and structural limitations, and he actively strives to centre voices of underserved communities while navigating power dynamics inherent in global health partnerships. RP is based in England, UK, where she conducts most of her research. Her work focuses on evaluating school-based public health interventions, underpinned by a strong commitment to social justice and addressing health inequalities and their social determinants. She works to advance participatory, equitable, and transformative approaches to evaluation.

5.1 INTRODUCTION

This chapter introduces **process evaluations** and their role in understanding **intervention impact**. It begins by summarising what process evaluations are and their main aims, which address **implementation**, **intervention mechanisms**, and **context** (Section 5.2). Then, it describes why process evaluations are needed, including their role within **impact evaluations** such as randomised controlled trials (**RCTs**) (Section 5.3). Having set out the purpose of process evaluations, Section 5.4 explores how researchers undertake them. Taking the three domains of implementation, intervention mechanisms and context in turn, we describe the main components of a process evaluation, key concepts, and the methods they use to achieve their aims.

Specific considerations when undertaking process evaluations in low resource settings are covered in Section 5.5. In Section 5.6 we highlight the value of drawing on methodological guidance when designing and conducting a process evaluation. Section 5.7 provides a summary of the key points covered in this chapter.

5.2 DEFINING PROCESS EVALUATION

Process evaluations do not have a universal definition (McGill et al., 2020) and differ in focus and scope depending on the intervention being evaluated and the stage of the evaluation cycle at which they take place. However, methodological guidance on process evaluations produced by the Medical Research Council (MRC) defines a process evaluation as ‘a study which aims to understand the functioning of an intervention, by examining implementation, mechanisms of impact, and contextual factors’ (Moore et al., 2015). We use the MRC’s definition to guide this chapter.

The first aim of a process evaluation is to describe what was implemented and examine the factors that affected implementation. Secondly, they explore how and why interventions achieve their outcomes, investigating the mechanisms of impact. Third, process evaluations examine variation in implementation and intervention mechanisms of impact across contexts (for example, when interventions are delivered across places or by different groups of people). They consider the interaction between interventions and the contexts (for example, communities, schools or public health systems) into which they are introduced. Figure 5.1 provides a visual summary of the three process evaluation domains, the components that sit within each of them, and their key purpose. A process evaluation brings together the findings from each domain to provide a detailed account of what was implemented and why, how intervention mechanisms functioned, and how both sets of processes varied across contexts.

5.3 WHY AND WHEN WOULD WE USE A PROCESS EVALUATION?

5.3.1 Process evaluations within impact evaluations

A process evaluation can either form part of an impact evaluation or be conducted independently. Nested within an impact evaluation, process evaluations provide an in-depth understanding of how and why a public health intervention had an impact on the **primary outcome** of interest or why no impact was observed. For example, process evaluations can reveal whether failure to demonstrate impact was due to poor implementation of all or part of the intervention or due to an incorrect hypothesis of how it works. Process evaluations also provide information on who was reached by

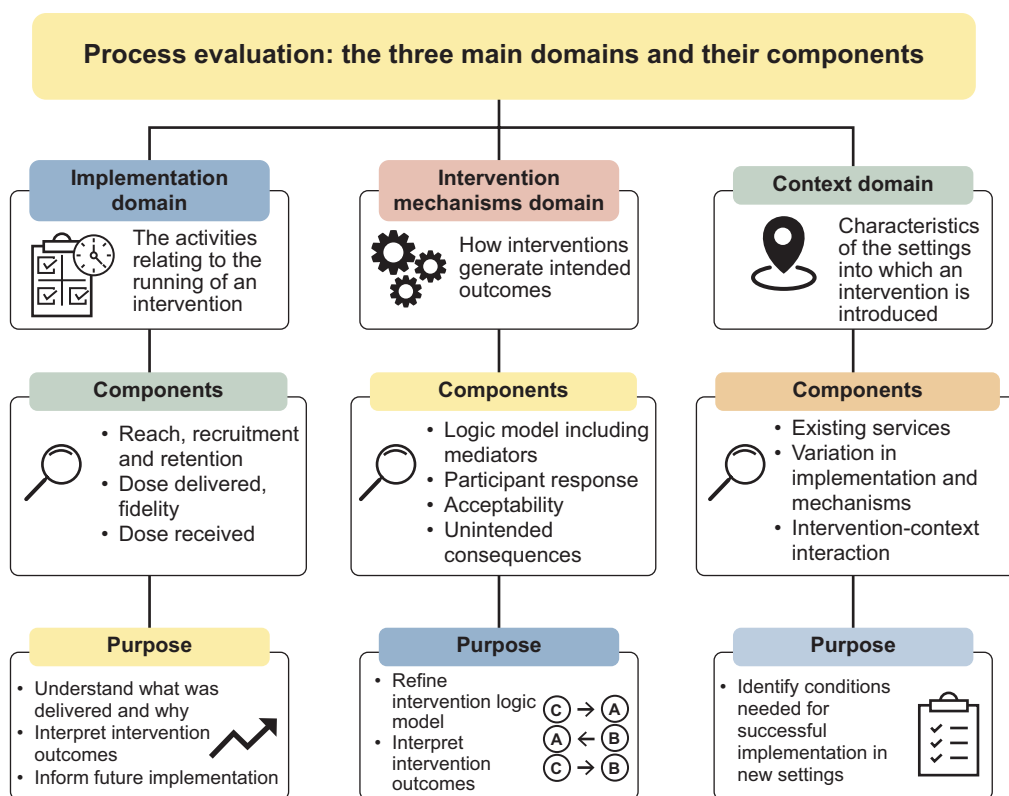


Figure 5.1 Process evaluation domains, their components and purpose. (Adapted from Moore et al., 2015.)

the intervention, and whether findings are likely to be reproducible at a different time and in other settings.

For example, a cluster-randomised trial of community-based, peer-led delivery of sexual and reproductive health services (the Yathu Yathu trial) in Zambia had an impact on knowledge of HIV status but not on met need for contraceptives, nor on the proportion of adolescent girls and young women reporting births in the last 12 months (Hensen et al., 2023). In the absence of a process evaluation, which explored issues of implementation and context, there would be limited understanding as to why the intervention had no impact on secondary outcomes. The process evaluation revealed that few adolescent girls and young women were aware of the availability of contraceptive services through the Yathu Yathu intervention; only a minority of those who initiated contraceptives returned for refills. When service delivery was interrupted in response to COVID-19, they were thought to have closed permanently.

5.3.2 Standalone process evaluations

As a standalone study, a process evaluation offers valuable information on implementation outcomes. It can inform whether these outcomes – such as the number of people reached from the intended population or how much of the intervention is delivered and received – are progressing as anticipated within a given timeframe. Process evaluation data may also inform whether intervention **adaptations** are necessary, for example, if **reach** is inequitable by specific characteristics of importance (for example, age, sex, ethnicity or relative wealth). Evidence of the influence of context on the implementation of, and participation with, the intervention can equally be assessed, with corrective measures implemented and aspects of context critical to implementation and/or participation documented.

5.3.3 When to undertake a process evaluation

Ideally a process evaluation would be planned prior to implementation of the intervention and alongside the impact evaluation (where one is being conducted). This ensures clarity and consensus on the intervention components to be implemented, the hypothesised **causal** pathway of the intervention, and contextual factors that a priori are anticipated to affect implementation of and participation in the intervention. Planning a process evaluation prior to implementation also facilitates data collection, by allowing certain process related indicators to be integrated into routinely collected data or in data collection tools that will be used to measure impact. For example, where a cross-sectional survey is used to measure impact, questions on exposure to the intervention are often nested within the questionnaire used as part of the survey. If a process evaluation was not planned prior to implementation, it can be conducted retrospectively. For example, routinely collected data (recorded by practitioners during delivery) might be used to measure the characteristics of participants reached and the extent to which the intervention is delivered as intended. **Qualitative** methods can also be used to understand factors that may have affected intervention implementation. For example, [Long et al. \(2019\)](#) conducted a retrospective process evaluation of an intervention that aimed to improve the detection and treatment of hereditary cancer syndrome. Qualitative interviews with intervention staff and ‘structured reflections’ completed by researchers were used to identify implementation outcomes (such as adoption of the new intervention by staff) and key challenges encountered, such as clinicians’ lack of time to interact with the intervention team.

There are, however, limitations to a retrospective process evaluation. **Quantitative** data on who the intervention reached (for example by age or sex), how much of the intervention was delivered and the attendance by participants, may not be available (or may be incomplete). Where qualitative data is collected after completion of the study, implementers and/or intended users may not remember how services were delivered

or received, or their perceptions regarding this process. A retrospective process evaluation is therefore limited in its ability to inform impact evaluation outcomes.

5.4 KEY COMPONENTS OF PROCESS EVALUATION DOMAINS – IMPLEMENTATION

In this section we explore the main components within each of the three process evaluation domains (implementation, intervention mechanisms and context). We describe the key concepts used to describe the components, their purpose within a process evaluation, and the main methods used. [Table 5.1](#) provides a summary of key

Table 5.1 Key components within process evaluations and their definitions

Component	Definition	Process evaluation domain
Reach	The number of individuals exposed to the intervention and which subgroups were reached	Implementation
Recruitment	The work that intervention staff do to identify, engage with and recruit participants	Implementation
Retention	The proportion of participants recruited who go on to receive the intervention in question	Implementation
Dose delivered	How much of the intervention is delivered	Implementation
Fidelity	The extent to which intervention activities are delivered as intended	Implementation
Dose received	The extent to which participants receive all of the intended intervention components	Implementation
Receipt	The minimum amount or ‘dose’ of the intervention which participants need to have received	Implementation
Mediator	How factors affecting intervention adoption and outcomes change as a result of exposure to the intervention – for example knowledge, attitudes, norms	Intervention mechanisms
Participant engagement and response	How participants engage with intervention content and messages	Intervention mechanisms
Structural context	How socio-economic, gendered and other factors encourage or impede implementation and uptake	Context
Temporal context	How political, environmental, economic and other events influence the intervention setting and environment, and how they encourage or impede implementation and uptake	Context

components and their definitions and indicates within what domain they are normally included.

Implementation comprises all the work relating to the running of an intervention. Its components therefore encompass **recruitment** of participants and the subsequent delivery of intervention activities. It also includes the organisational and practical tasks that are needed to enable the intervention to be delivered, for instance staff will often need to be trained, intervention materials printed and rooms booked (where appropriate). Process evaluations seek to understand *what* was implemented, and *how* and *why* implementation took place as it did. The role of quantitative data in **programme monitoring** is covered in more detail in [Chapter 6](#). Qualitative methods are discussed in depth in [Chapter 7](#).

5.4.1 Reach, recruitment and retention

Process evaluations describe and explore intervention recruitment rates. This information provides important insights into the extent to which an intervention has recruited (and retained) enough participants, and thus whether it is likely to be feasible to deliver in future. When undertaken as part of an impact evaluation, researchers will be able to use quantitative data on the rate of recruitment to the study. Baseline data collected from participants (for example, via questionnaires) can inform researchers whether those recruited are those the intervention intended to reach. For example, if a parenting intervention is targeted at those with high levels of need (for example, where there are significant challenges with family relationships), it is important to understand if these were indeed the people who were recruited. In such a scenario, if an intervention reached primarily parents with very low needs, this would raise questions about the **effectiveness** of the recruitment strategies, and the potential for negative consequences through exacerbating existing **health inequalities**. Administrative data collected by intervention delivery teams also provides important information on recruitment, and the extent to which participants are retained within an intervention (see [Chapter 6](#) for more detail on quantitative data and its use within evaluations).

5.4.2 Using mixed methods to assess recruitment and retention

A **mixed-methods** approach is often useful when process evaluations study recruitment (the use of qualitative and mixed methods within process evaluations is discussed in more depth in [Chapter 7](#)). Alongside quantitative and administrative data on how many people were recruited, and who they were, qualitative methods are used to explore recruitment processes. For example, researchers may conduct interviews with staff to understand how and why recruitment strategies were designed in the way they were, the factors shaping their implementation, and why they reached (or did not) those they intended to. Qualitative interviews or focus group discussions with study participants provide important insights into their

experience of the recruitment process, including where individuals were not retained until the end of the study. The use of a mixed methods approach enables process evaluations to understand some of the key factors which shape recruitment, and how potential barriers could be addressed in the future.

A process evaluation of the ICALM intervention (Interpersonal Counselling for Adolescent Low Mood) employed mixed methods to identify and explore barriers to recruitment and potential solutions (Katangwe-Chigamba et al., 2024). The **feasibility study** involved allocating young people at random to receive either interpersonal counselling plus treatment as usual (TAU) or TAU only (**control group**). Quantitative data from the trial demonstrated that, against a recruitment target of 60, the study succeeded in recruiting only 14 young people. The process evaluation, which was embedded within the larger study, also used qualitative methods – including interviews and **observation** – to describe how the interaction between the study and the delivery contexts in which it was conducted were key factors shaping recruitment challenges. The timing of the study (spring 2020, at the start of the COVID-19 pandemic in the UK) meant that there was high demand for mental health support, a focus on prioritising ‘urgent’ cases (linked to anxiety) and thus less capacity for staff to refer potential participants to the ICALM study (which was focused on low mood). Other challenges included complex or uncertain treatment pathways, and lack of familiarity with **randomisation** and other research processes. Based on these findings, the authors put forward several suggestions for future studies, including using innovative approaches to recruitment, e.g. ‘creating new referral pathways’, and considering an alternative trial design, such as the use of **cluster-level** rather than **individual-level** randomisation.

5.4.3 Dose delivered and fidelity

A key function of process evaluations is to describe the implementation of the intervention being evaluated and the extent to which it occurred as planned. Understanding this is important, because it helps interpret the main outcomes from an impact evaluation. For instance, where found to be effective, we need to be sure that the impacts achieved result from the delivery of the intended intervention content (rather than a heavily modified set of activities due to adaptations by practitioners during delivery). Equally, where interventions are found to be ineffective (or even harmful) implementation data tells us whether this is because the intervention in question is fundamentally flawed in some respect, or if the issue lies with a failure to deliver it comprehensively or in line with manuals and training. Many parenting interventions, for instance, are comprised of a series of structured group-based sessions, which have pre-defined content, with each session building on the next to achieve hypothesised outcomes. If the intervention content and structure is deviated from it may undermine the ability to achieve the hypothesised outcomes.

Process evaluations therefore seek to assess whether an intervention was delivered as intended. Though definitions and terms used vary, this encompasses two key dimensions. The first concerns how much of the intervention was delivered (for example, the number of sessions of a 10-week parenting intervention that took place) often referred to as **dose delivered**. As Carroll et al. (2007) suggest, the delivery of content may relate to the proportion of content delivered, and whether this content is delivered with the intended frequency and duration. The second dimension, **fidelity**, relates to whether intervention activities are delivered as intended. This includes whether planned activities took place (or were omitted for some reason), were modified in any significant way or if additional activities were added. Such changes are often referred to as adaptations. It is important that details of such adaptations are captured where possible (for example, via practitioner checklists) as they may alter how the intervention works (in other words, its change mechanisms).

Many interventions will define dose delivered and fidelity – that is, a minimum set of criteria which need to be met – to be able to say that an intervention has been delivered. Interventions that are highly standardised and structured will likely have a focus on fidelity of form (whether each activity is delivered in a uniform way). Other interventions may build some flexibility into *how* activities are delivered, as long as they are still achieving the same goals, which is known as ‘fidelity of function’. Process evaluations will seek to ascertain in advance how intervention developers conceptualise fidelity, and the extent to which the ‘form’ of activities varies across settings if practitioners have the autonomy to vary them (Hawe et al., 2004).

5.4.4 Methods for assessing dose delivered and fidelity

To assess dose delivered and fidelity, process evaluations collect quantitative data – often via implementation checklists completed by the practitioners delivering an intervention (see Chapter 6 for a more detailed account of the use of quantitative and intervention monitoring data within evaluations). These will capture the number of intervention sessions that took place, whether individual sessions included planned activities, and any changes made (for example, activities missed or additional material added). Sometimes researchers will observe delivery of the intervention to provide an independent assessment. However, researchers are unlikely to be able to do this for most intervention delivery, especially where implementation occurs across many settings simultaneously, hence the importance of self-completed checklists by practitioners.

Quantitative data of this kind therefore describes what was delivered and the extent to which activities took place as intended. Alongside this descriptive function, another key role of process evaluations is to explore influences on implementation, and why delivery took place as it did. Qualitative interviews with delivery staff and participants are a key way in which this is achieved. Observation of intervention

delivery will also enable researchers to understand factors affecting implementation (designing and using qualitative research methods is the focus of [Chapter 7](#)).

For example, a process evaluation of a group-based family substance misuse prevention intervention (the Strengthening Families Programme 10–14 UK) employed a mixed-methods approach – and used qualitative interviews to explore the factors which drove good fidelity (identified in quantitative checklists) ([Segrott et al., 2017](#)). The qualitative findings identified that practitioners faced several implementation challenges (such as recruitment of staff) but had succeeded in overcoming them. Key reasons included the fact that practitioners valued the intervention (and were therefore committed to it), that facilitator training provided staff with an understanding of why it was designed in the way it was, and the use of meetings which brought together teams to prepare for each group-based session. These findings would be useful for future implementation and scale up, as they indicate some of the conditions that promote good fidelity. Where practitioners have made local adaptations when delivering an intervention, qualitative interviews can explore why these were made (for example, to increase fit with local context) ([Hawe et al., 2004](#)).

5.4.5 Dose received and receipt

Process evaluators will also normally record how much of an intervention was received by participants. How this is measured will depend upon the nature of the intervention in question, but for manualised, group-based interventions, for instance, it will include the number of sessions that were attended. In many cases there may be some administrative data on the extent to which participants have received the intervention (**dose received**), as recorded by practitioners after each session. As with information on completeness of delivery and recruitment, data on dose received helps us interpret evaluation of effectiveness. If a significant proportion of participants only receive a small proportion of an intervention (or do not attend at all) this may explain the absence of intervention effects. Qualitative research plays an important role here by exploring why attendance rates may have been low, and how this could be addressed in the future. Intervention receipt refers to the minimum amount (or dose) which a participant needs to have received.

5.4.6 Methods for assessing dose received and receipt

To analyse dose received, interventions should determine up front how much of the intervention a participant needs to attend or receive for them to be considered as having ‘received’ the intervention (intervention receipt). Process evaluations can then use this definition to guide assessment and analysis of patterns in the data. The definition may encompass not only a simple proportion (for example, eight out of ten sessions) but also the need for certain specific content to have been received. For example, [Ondrušková et al. \(2024\)](#) conducted a process evaluation as part of a RCT

of the Stepping Stones Triple P intervention, which is delivered to parents of children who have intellectual disabilities. This intervention is nine weeks in length and comprises six group-based and three one-to-one sessions. Intervention receipt was defined as a parent attending at least four of the group sessions and two of the individual sessions. Quantitative data on attendance found that only 30% of parents had received this minimum dose. Qualitative interviews identified several factors that influenced intervention accessibility – including childcare responsibilities, access to transport and the switch to remote delivery (from face-to-face) during the COVID-19 pandemic, helping explain patterns in the quantitative data.

5.5 KEY COMPONENTS OF PROCESS EVALUATION DOMAINS – INTERVENTION MECHANISMS

Intervention mechanisms are the ways in which interventions (their activities, information, discussion, support) are expected to bring about intended impacts. Some mechanisms can be thought of as mediators, whereby initial changes in participants' knowledge or confidence lead to longer term changes in health outcomes or behaviours. Participant engagement with, and response to, intervention content and messages, form an important aspect of how intervention mechanisms operate.

5.5.1 Testing and refining intervention mechanisms

An important aspect of the development of a new intervention is to describe its **theory of change** (how the intervention is designed to bring about hypothesised **behaviour changes**). The building of theory of change is not usually considered part of process evaluation (theory of change is discussed in [Chapter 4](#)) but is vital for framing it. As such, designing a process evaluation will often involve working along the theory of change, through implementation processes and mechanisms to outcomes, to identify which factors and processes should be examined and measured.

The theory of change is often summarised in visual form through use of a **logic model**, which represents the **implementation theory** and articulates the goals and resources of the intervention ([Chapter 4](#) discusses the development of logic models). This sets out the ways in which intervention activities are designed to trigger mechanisms, which will produce key outcomes. For example, many family-based substance misuse interventions seek to prevent use of illicit drugs by young people in the future by strengthening protective factors such as parent-child attachment. Here, parent-child attachment can be thought of as a **mediator** of later prevention of illicit drug use. Many interventions aim to achieve their hypothesised impact through promoting some form of action or **behaviour change** by participants. Examples include interventions that teach parenting strategies and those which aim to increase

physical activity. The way in which participants engage with the information and messages they receive during an intervention may shape the extent to which they put the desired behaviours into practice, and in turn, whether key intervention impacts are achieved.

The role of the process evaluation is to help test the theory of change and logic model, and where appropriate to refine them. Process evaluators ask whether the planned intervention mechanisms have operated as intended, and if any other mechanisms may be in operation. For example, Knittle et al. (2016) conducted a process evaluation as part of an RCT to explore mechanisms of action of an intervention to promote physical activity among rheumatoid arthritis patients. The intervention comprised motivational interviewing and coaching in self-regulation and aimed to promote maintenance of physical activity over time. Intermediate outcomes (for example, hypothesised mediators of maintenance of physical activity) included motivation, self-efficacy and the use of self-regulation skills by participants. At post-treatment, the intervention arm reported higher levels of physical activity, but this was not mediated by any of the hypothesised mediators. However, maintenance of physical activity six months later was mediated by both motivation and use of self-regulation skills (but not self-efficacy). This quantitative data, therefore, helped to refine the understanding of how the intervention achieved its impacts on physical activity, and the extent to which hypothesised mechanisms operated as intended.

When process evaluations are embedded within early-stage work – such as **feasibility** studies – they may have a significant emphasis on helping to develop and refine the intervention's logic model. Once a research team embarks on an impact evaluation (such as an RCT) the process evaluation's primary role becomes to test the final version of the logic model (though it may often generate new insights).

5.5.2 Methods for exploring intervention mechanisms

To explore the function of intervention mechanisms, a process evaluation typically begins by reviewing the developed theory of change and logic model. It is also helpful to consult other relevant documents, such as training materials and practitioner manuals, to build up a good understanding of how the intervention is designed to work. As with the other dimensions of process evaluations, a mixed-methods approach is usually the most appropriate. Results from the impact evaluation tell us whether the intervention is effective (as measured by its primary outcome). Where the impact evaluation has collected data on the effectiveness of the intervention on short-term outcomes, which are designed to bring about longer-term change (mediators), this provides valuable insights into whether intervention mechanisms are working as hypothesised.

Process evaluations will also utilise qualitative methods to help explain whether and how intervention mechanisms have functioned as intended. Interviews or focus

group discussions with participants are an important tool for exploring how people engaged with and responded to intervention content. This includes understanding its **acceptability** and relevance to them, and the extent to which they have put new learning into practice. Interviews with intervention staff and participants can also shed important light on the extent to which interventions appear to be functioning as theorised (or reasons for their failure to do so). In some cases, researchers may be able to observe all, or part of the intervention being delivered, which can provide valuable insights into the delivery of activities and how participants respond to them. Where intervention mechanisms – including participant engagement – appear to be operating as intended, we are more confident that findings of effectiveness within the broader impact evaluation can be attributed to the intervention.

5.5.3 Unintended consequences and harmful intervention impacts

It is important to consider at all stages in a process evaluation, whether there are **unintended consequences** or unexpected mechanisms. There is always the possibility that an intervention may have harmful impacts. This might be through inadvertently exacerbating the problem it is trying to address. For example, a **cluster** RCT of a youth development intervention in England that aimed to reduce teenage pregnancies, found that rates were higher in the intervention group compared to the control. Process evaluation findings helped to identify potential explanations for what was an unexpected finding. It did not appear to be linked to implementation (which overall was as planned) or problems with recruitment (the aim of recruiting at-risk young people was achieved). Qualitative interviews suggested that the intervention (that is, the activities themselves) was viewed positively by staff and participants. It was therefore likely that the reason for the finding lay elsewhere. Possible reasons for the intervention's harmful impacts were thought to include the negative effects of labelling participants as 'problematic' (Wiggins et al., 2008; 2009) or potential 'network effects' of bringing together groups of at-risk young people.

5.6 KEY COMPONENTS OF PROCESS EVALUATION DOMAINS – CONTEXT

Context refers to factors external to the intervention that may influence its implementation and whether intervention mechanisms are triggered as intended. Key questions in this domain focus on how context affects implementation and intervention mechanisms. The theme of context, therefore, cuts across implementation and mechanisms, both of which can be shaped by contextual conditions.

When thinking about context, we look at the characteristics of the settings into which an intervention is introduced. These include socio-economic, gendered and other aspects of the structural context that may affect the uptake of an intervention by participants (such as aspects of the population and how these differ across places). Other characteristics relate to the broader systems that affect implementation and uptake, including political, environmental and economic factors. For example, the resources available to deliver a new intervention may vary across settings, as will the willingness of political leaders to support it. Temporal context relates to the way in which key influences on implementation vary over time (for example, changes in funding provision for a public health intervention).

5.6.1 How process evaluations consider context

When examining aspects of implementation (for example, recruitment, dose delivered, fidelity) process evaluations will look for any variations across different settings. For example, within a multi-site RCT, there may be variation in dose delivered (perhaps including which parts of an intervention were completed) and/or the level of fidelity. Practitioners in some settings may be more skilled in recruiting participants or have better financial or administrative support to do so. It is important not to overlook variations across context because they offer insights into the kinds of conditions needed for effective implementation, which may not be apparent when looking only at the overall results.

Many RCTs of school-based health promotion interventions, for instance, have identified variation in the extent and quality of implementation across settings. Embedded process evaluations within these RCTs have been able to identify which aspects of school context may have shaped implementation. [Hudson et al. \(2020\)](#) explored variation in implementation of a whole school mindfulness intervention and used the Consolidated Framework for Implementation Research (developed by [Damschroder et al., 2022](#)). The framework helps researchers to understand the contextual factors that may act as barriers to, and facilitators of, intervention implementation. Using the framework, Hudson and colleagues identified the characteristics that distinguished ‘high implementation’ schools from ‘low implementation’ schools. One of the most important contextual factors that influenced implementation was found to be school leadership – including the extent to which senior school staff engaged with the intervention. Other studies have similarly found that levels of support from senior staff in schools are critical to the implementation of new interventions. More generally studies have found that the extent to which an intervention has ‘fit’ with the needs of schools and how their systems work is important ([Bonde et al., 2018](#); [McIssac et al., 2019](#)). When undertaking a process evaluation, it is important to explore which potential aspects of context may be important, and to

understand how these may affect the fit between an intervention and the settings into which it is introduced.

5.6.2 Methods for exploring context

Quantitative and monitoring data (for example, recruitment logs and practitioner checklists) can be used to identify the extent of, and patterning in, variation, while qualitative methods provide the opportunity to explore with staff the factors shaping contextual influences. Indeed, sampling of participants for qualitative interviews or focus groups will typically seek to include perspectives of staff and participants from different types of settings, especially where quantitative data suggests variation in implementation processes. If it is known ahead of recruitment for the qualitative research that particular characteristics may shape implementation (for instance the size of an organisation, such as a school) this can be built into the sampling framework for data collection.

Interventions are introduced into existing systems. It is important to know what services and interventions are already being offered. Process evaluations often explore the extent to which a new intervention interacts with what is already being delivered. For instance, does it have a good fit with the needs of this local context (and is it therefore likely to be supported and sustained) or does it duplicate (or even take resources away from) existing provision? These questions can be addressed using qualitative methods. In the process evaluation of the Strengthening Families Programme ([Segrott et al., 2017](#)), for instance, high levels of support for the intervention were identified during qualitative interviews with practitioners. The intervention had a good fit with the existing system because it was perceived as filling a gap in services for children aged 10–14, and practitioners felt that it would assist them in performing their role. Surveys that ask key informants (practitioners and managers, for example) to summarise the provision of existing services can also be valuable in understanding the system into which a new intervention is introduced.

In relation to intervention mechanisms, process evaluations have begun to conceptualise intervention-context interactions in new ways, in which contexts are seen as active in shaping outcomes, rather than being a ‘passive’ backdrop for intervention delivery. The MRC guidance starts from the position that, rather than passively receiving interventions, participants (implementers and intended recipients) interact with interventions to produce outcomes. How implementers and potential beneficiaries receive and respond to interventions will inevitably have an impact on how they work. Participant responses can be examined in terms of the acceptability (or satisfaction) with an intervention. The level of acceptability of an intervention may indicate whether anticipated change pathways are likely to have been triggered.

Qualitative methods, such as interviews, can be helpful in exploring what shapes the acceptability of interventions to participants and how this may vary across contexts.

We can therefore conceptualise intervention mechanisms as operating through their interaction with contexts. Capturing the dynamics between interventions and context is important because it gives us important insights into how interventions' mechanisms of change function across different kinds of settings. It also increases the **transferability** and applicability of findings to other settings.

When designing process evaluations, it is important to build in questions from the start on variations across context and the role of intervention-context interactions. In some cases, researchers may a priori hypothesise ways in which these interactions could be important. For instance, where an intervention is delivered by different kinds of organisations, there may be some expectation that organisational cultures will influence take up of and support for it, and this can be built into the design of quantitative and qualitative data collection. Equally, some aspects of intervention-context interactions may not be predicted in advance, but surface during the evaluation, and can be explored through qualitative research. In a study of a physical activity intervention (Christiansen et al., 2021), qualitative interviews helped identify that schools varied in how they delivered and sustained their activities. An important driver of this variation was the extent to which school leaders framed the intervention as a long-term priority and allocated the necessary resources for its continued implementation.

Realist theory (examined further in Chapter 9) increasingly informs/underpins process evaluations, where the focus is on understanding how interventions work, for whom and in what settings, with a specific focus on how context shapes mechanisms to produce outcomes (**context mechanisms outcome configurations**). We might be interested in understanding the structures, resources and mechanisms through which implementation is achieved and the material, social and economic factors – aspects of context – that facilitate or hinder implementation. Understanding these factors is particularly important for assessing if and how a successful intervention could be implemented elsewhere, and in what kind of contexts success is most likely.

5.7 CONSIDERATIONS WHEN DESIGNING PROCESS EVALUATIONS AND THEIR METHODS IN LOW-RESOURCE SETTINGS

Designing process evaluations in low-resource settings requires careful consideration of multiple factors to ensure **feasibility** and accuracy. One key consideration is the context of resource availability, which can significantly influence the delivery and outcomes of an intervention. Limited resources, such as inadequate staffing and infrastructure, must be accounted for when measuring the **implementation strength** of interventions. Another important aspect is the complexity of health systems, where

interventions often interact with multiple layers of service delivery. The process evaluation should capture these interactions, as well as the dynamics of leadership and team structures, which are crucial in resource-constrained settings. Additionally, it is important to use mixed-method approaches, including both qualitative and quantitative data, to comprehensively assess how and why interventions succeed or fail. Given the unpredictability of intervention impacts, especially in low-resource settings, evaluators should also be prepared to integrate flexible and iterative methods, such as real-time feedback loops, to accommodate changes in intervention design based on ongoing findings.

5.8 METHODOLOGICAL GUIDANCE, FRAMEWORKS AND THEORIES FOR PROCESS EVALUATIONS

5.8.1 Medical Research Council guidance

When embarking on a process evaluation it can be helpful to draw on sources of methodological guidance. One of the most comprehensive and widely used is the MRC guidance on Process Evaluation of Complex Interventions ([Moore et al., 2015](#)) – which we have used to structure the present chapter. The authors draw on existing frameworks and theories to create a practical guide to designing, conducting and appraising of process evaluations. The guidance sets out the three core process evaluation domains: implementation; mechanisms of impact; and context. It describes in detail why we undertake process evaluations, summarises key theories and provides a ‘how to guide’, which can be used for individual studies. Using methodological guidance when undertaking a process evaluation can help you develop clear aims and objectives, identify which questions need to be asked, and support you to select the most appropriate methods and data collection tools. A framework of the type set out in the MRC guidance can also aid you in planning effectively and bringing together the different parts of a process evaluation into a coherent whole.

5.8.2 Other frameworks

While the MRC guidance provides a comprehensive overview of the key dimensions, questions and methods for process evaluation, it can sometimes be useful to consult more specialised frameworks that focus in depth on one aspect of a process evaluation. Implementation research, for example, is widely used to guide the assessment of intervention implementation in process evaluations. These frameworks are useful in helping to identify and refine the key implementation outcomes that will be measured and assessed.

For instance, based on a review of the literature and consultation with an expert working group of implementation scientists, [Proctor and colleagues \(2011\)](#) developed

a taxonomy of implementation outcomes to inform the assessment of intervention implementation. These comprise: acceptability; adoption; appropriateness; **costs**; feasibility; fidelity; **penetration**; and sustainability. The Consolidated Framework for Implementation Research (CFIR) is another influential framework that orients attention to the contextual factors that shape implementation. Based on a review of the existing theories and frameworks for implementation, CFIR (Damschroder et al., 2022) identifies five domains of influence on implementation. These are: the outer setting; the inner setting; individuals involved; the process; and the intervention. The CFIR has been widely used to guide the systematic assessment of potential barriers and facilitators to implementation in process evaluations. The process evaluation by Hadjistavropoulos et al. (2017) of cognitive behaviour therapy delivered online by community clinics provides a good example of the use of CFIR in practice. The authors constructed a survey (including closed and open questions) designed around the five CFIR constructs to explore barriers to and facilitators of implementation. Key facilitators of implementation included perceived characteristics of the intervention (for example advantages of online delivery) and the process (involvement of an external unit to support delivery). Barriers to implementation were located within the inner setting, including a lack of resources and the priority given to delivering other (face-to-face) services.

5.8.3 Using theories within process evaluations

Process evaluations will sometimes draw on theories to help understand why implementation succeeds or fails. For instance, Normalisation Process Theory (NPT) (May et al., 2009) provides a useful way of considering how interventions are taken up by people and integrated or ‘normalised’ within an organisation. NPT focuses specifically on the work people do to enable interventions to be implemented. Successful implementation is seen as a result of the action (or work) people do individually and together to achieve this. NPT conceptualises four key domains of influence on implementation. First, how practitioners perceive an intervention (is it valuable, does it make sense?). Second, whether commitment exists within an organisation to support delivery (and make it a recognised part of that organisation’s work). Third, the work done collectively within an organisation to enable the intervention to happen as planned (for example, logistical arrangements). Fourth, formal and informal assessments of the benefits and cost of the intervention will inform whether it continues to be implemented. Various versions of NPT have been used to structure process evaluations of healthcare interventions and increasingly in evaluations of policy and school-based interventions (see for example Meiksin et al., 2020; Sundaram et al., 2023; and Ponsford et al., 2024). Sometimes process evaluations will use theories at the analysis stage to help explain how influences on implementation operate (theories do not necessarily need to be identified at the start).

5.8.4 Using methodological guidance and frameworks within your process evaluation

No two studies are identical, but using some kind of guidance or framework from the very start can help you to design your process evaluation so that it asks the right questions and uses the best methods to answer these questions. Many published process evaluations utilise guidance/frameworks and they offer excellent ‘case studies’ of how to apply them to real-world studies. For example, [Rooijackers et al. \(2021\)](#) report the findings from a process evaluation embedded within an RCT of an intervention to promote independent living amongst older adults residing in the community. The three domains within the MRC guidance (implementation, mechanisms, context) are used to structure the process evaluation design and inform definitions and questions. The authors suggest that the use of the guidance helped them gain a deeper understanding of the intervention.

5.9 SUMMARY

In this chapter we have introduced process evaluations and their role in understanding intervention impacts. We began by defining process evaluations and describing when and why they are used. Whilst sometimes employed as standalone studies, we saw that process evaluations are frequently conducted as part of larger impact evaluations, such as RCTs. The three key domains of process evaluations – implementation, intervention mechanisms and context – were described. We examined the main components within each domain, the concepts which they employ and the methods used to achieve process evaluation aims.

We described the value of a mixed-methods approach, with quantitative methods capturing what was delivered and received, and qualitative methods exploring ‘how’ and ‘why’ interventions work (or fail to do so). The final section of the chapter highlighted the value of methodological guidance and frameworks in helping us design, structure and conduct process evaluations. In the field of public health, process evaluations generate crucial data about the implementation of interventions and how they work and play a central role in interpreting the results of impact evaluations, such as RCTs.

5.10 SELF-DIRECTED LEARNING EXERCISE

This learning exercise is designed to help you to think about and apply the three key domains of process evaluations: implementation, intervention mechanisms and context.

In 2019, Wyke and colleagues published the results of a randomised controlled trial of the European Fans in Training (EuroFIT) intervention (Wyke et al., 2019). It was an international study, taking place in the Netherlands, Norway, Portugal and the UK.

The intervention aimed to increase physical activity, reduce sedentary time and improve other aspects of participants' health, including diet and weight. Targeted at male football fans, the intervention was delivered by coaches in football stadiums and comprised 12 weekly 90-minute sessions for groups of participants. Additionally, participants wore a pocket device which monitored steps and sedentary time so that they could self-monitor these factors, and they could also access social support via a bespoke 'game-based app'.

Findings from the RCT indicated that '[p]articipation in EuroFIT led to improvements in physical activity, diet, body weight, and biomarkers of cardiometabolic health, but not in sedentary time' (Wyke et al., 2019).

Imagine that you have been asked to undertake a process evaluation (which would take place at the same time and alongside the RCT). Write down your answers to the following questions.

Questions

1. What would the aims of your process evaluation be?
2. What questions would you want to ask about: a) recruitment; b) reach; c) retention?
3. Which methods would you use to: a) assess dose delivered, fidelity and dose received; and b) explore the factors which influenced them?
4. Which were the main mechanisms through which the intervention was designed to achieve its intended outcomes on physical activity, sedentary time and diet?
5. Which aspects of context would the process evaluation consider, and why might they be important (in terms of their interaction with intervention implementation or mechanisms)?
6. How might the findings of the process evaluation be used to interpret those from the main trial (which assessed intervention effectiveness)?

Published findings from the process evaluation for this RCT can be found in Bunn et al., 2023.

For suggested solutions or answers to the exercise, please see the resources tab at <https://uclpress.co.uk/book/evaluating-public-health-interventions>

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