

Process evaluation of complex interventions: a summary of Medical Research Council guidance

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This document provides a summary of new MRC guidance for process evaluation of complex interventions. The full guidance can be downloaded here:

<http://www.populationhealthsciences.org/MRC-PHSRN-Process-evaluation-guidance-final-2-.pdf>

Additional summaries are published in a new book on complex intervention methods, and in a Research Methods and Reporting article in the BMJ.

- Moore G, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, Moore L, O’Cathain A, Tinati T, Wight D, Baird J. (2015) Process evaluation of complex interventions: a summary of Medical Research Council guidance. In: Richards D, Hallberg IR, editors *Complex interventions in health: an overview of research methods*. Abingdon: Routledge.
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Introduction

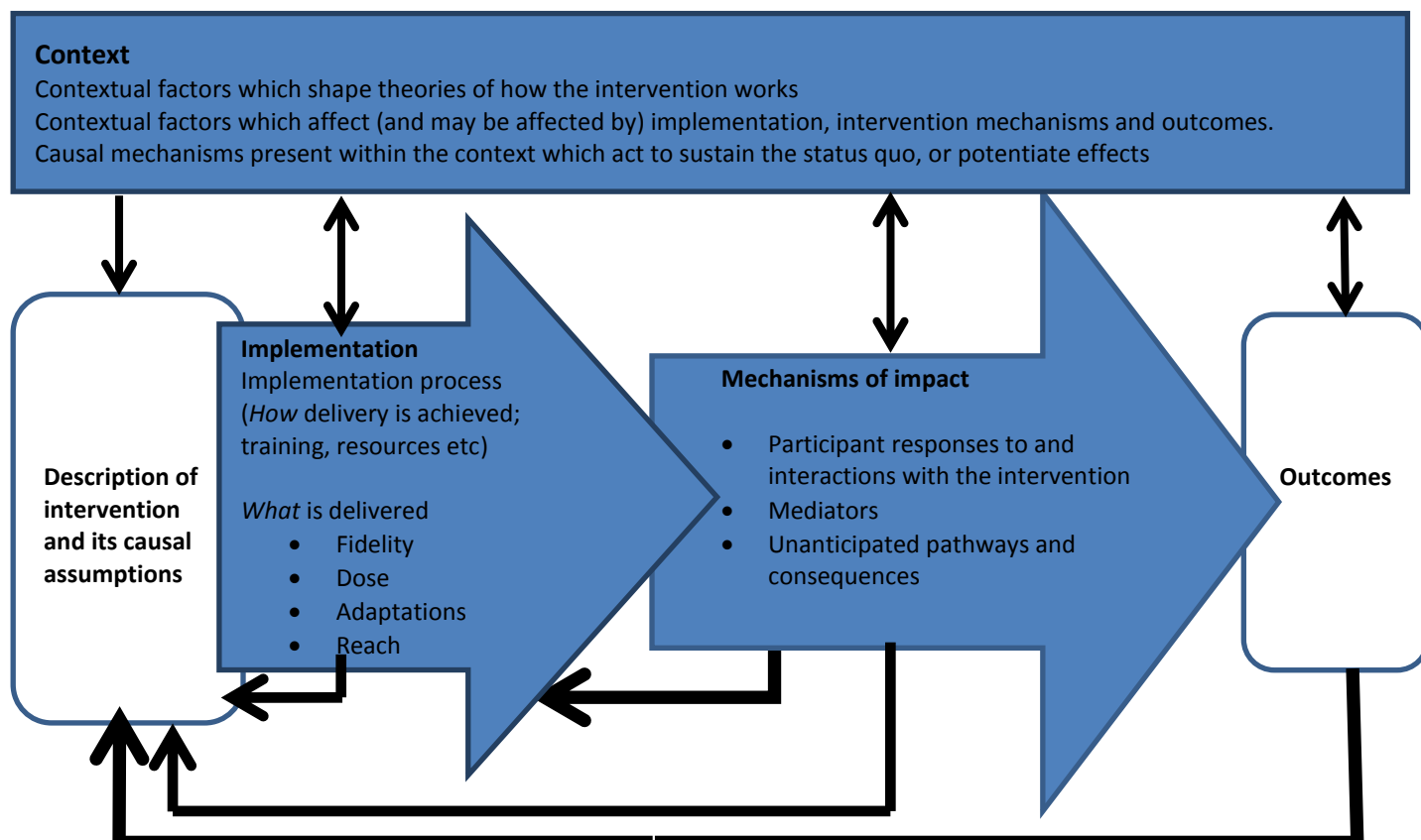
Attempts to address public health problems such as smoking and obesity, and to build evidence for ‘what works’, increasingly involve developing and evaluating ‘complex interventions’; commonly defined as interventions comprising multiple components which act in synergy to produce change.¹ They may target more than one cause simultaneously, including causes at multiple levels (e.g. individual, inter-personal, organisational), and will often be delivered in complex systems which respond unpredictably to intervention.^{2 3} While randomised controlled trials (RCTs) are typically regarded as the ‘gold standard’ method for establishing effectiveness (where randomisation is feasible), there are limits to the questions that outcomes evaluations can answer. Effect sizes do not provide policy-makers with information on how an intervention might be replicated in their context, or whether, if this is achieved, it will reproduce the outcomes observed in the trial. Earlier guidance for evaluating complex interventions focused on RCTs, making no mention of process evaluation.⁴ However, updated guidance published in 2008 recognised the potential value of process evaluation within outcome evaluations, stating that it ‘can be used to assess fidelity and quality of *implementation*, clarify causal *mechanisms* and identify *contextual factors* associated with variation in outcomes’ (⁵p12 our emphasis). While specifying three key functions, updated guidance provided little insight into how to conduct a process evaluation.

In 2010, a workshop funded by the MRC Population Health Science Research Network (PHSRN) discussed the need for guidance to fill this gap.⁶ There was consensus that researchers, funders and reviewers would benefit from guidance. Subsequently, a group of researchers with experience in evaluating public health interventions developed draft guidance drawing upon literature reviews, group discussions of case studies of process evaluations, workshops and discussions at several conferences and seminars, before circulating the guidance to academic, policy and practice stakeholders for comment. The original aim was to provide guidance on process evaluations of complex public health interventions (i.e. interventions focused on primary or secondary prevention of disease or positive health improvement, rather than health care). However, the guidance (<http://www.populationhealthsciences.org/MRC-PHSRN-Process-evaluation-guidance-final-2-.pdf>), is highly relevant to complex intervention research in other domains, such as health services and education. This document is a summary. The full guidance sets out the need for process evaluation, and presents a review of theories and frameworks which informed its development, before offering practical recommendations, and six detailed case studies. This summary provides an overview of the framework and its practical recommendations.

The MRC process evaluation framework

The three core themes for process evaluation described within the 2008 MRC complex interventions guidance⁵ form the basis for the new process evaluation framework (Figure 1). Our framework places explicit emphasis on using intervention theory to shape process evaluation. By theory, we are referring to causal assumptions regarding how the intervention will work in context. Such assumptions may be drawn from social science theory, although complex interventions will often also be informed by assumptions drawn from other sources such as past experience or ‘common sense’. An intervention as simple as a health information leaflet, for example, may reflect an assumption that ignorance of health consequences is a key modifiable cause of a health related behaviour, or that a reminder of health risks may be a cue to action. As will be discussed below, making these assumptions explicit helps to frame implementation assessments, and enables evaluators to test hypothesised mechanisms of impact and contextual influences, while also generating new intervention theory. The framework emphasises the dynamic nature of relationships between implementation, mechanisms and context, illustrated in Figure 1.

Figure 1: Key functions of process evaluation and relationships amongst them (blue boxes represent components of process evaluation, informed by the intervention description, which inform interpretation of outcomes)



Mechanisms of impact: how does the delivered intervention produce change?

Rather than passively receiving interventions, participants’ actively interact with them, with outcomes produced by these interactions, in context.¹³ Hence, understanding how participants

respond to and interact with complex interventions is crucial in attempting to understand how they work.¹⁴ Process evaluations may test the causal assumptions made by intervention developers through quantitative assessments of pre-specified causal pathways, while using qualitative methods to generate new theory.¹⁵

Context: how does context affect implementation and outcomes?

‘Context’ may include anything external to the intervention which impedes or strengthens its implementation or effects. Evaluators may need to understand how implementers’ readiness or ability to change are influenced by pre-existing circumstances, skills, organisational norms, resources and attitudes. Implementing a new intervention will often involve mutual adaptation, with the context changing to fit the intervention and vice versa.¹⁶ Pathways underlying problems targeted by interventions may differ from one context or subgroup to another.¹⁷ As a result, an intervention may have different effects in different contexts. Hence, context can influence implementation and mechanisms of impact. Even where an intervention is relatively simple, its interaction with its context may be highly complex.

Functions at different stages of evaluation

The emphasis upon each of the functions of process evaluation described above, and the means of investigating them, may vary according to the stage at which process evaluation takes place. Feasibility testing (exploring if it will be possible to implement and evaluate the intervention) and piloting (conducting a smaller version of the main study) should take place prior to fully powered evaluation of effectiveness.¹⁵ Insufficient feasibility testing and piloting may result in a subsequent evaluation failing to test the intended intervention because implementation structures are inadequate (implementation failure), or because the evaluation design proves infeasible (evaluation failure). Using process evaluation to explore the feasibility of the intervention, implementation processes, and key mechanisms of impact, should optimise the intervention prior to evaluating effectiveness. When evaluating effectiveness, emphasis shifts from attempting to shape the intervention and its delivery structures, towards examining the internal validity of conclusions about effectiveness by assessing the quantity and quality of what was delivered. However, new challenges emerge from increased scale, which leads to greater variation in participant characteristics and contexts of implementation. Process evaluation needs to understand how this greater diversity affects the implementation and functioning of the intervention.

Planning, designing, conducting and reporting a process evaluation

Given the diversity in types of complex interventions and uncertainties posed by them, not all process evaluations address the same aims or use the same methods. However, process evaluation involves thinking through common issues in order to arrive at the best possible solution for the

problem under investigation. Key recommendations within the new MRC guidance for process evaluation are summarised in box 1. The remainder of this paper expands upon these.

Box 1: Key recommendations and issues to consider in planning, designing and conducting, analysing and reporting a process evaluation

When planning a process evaluation, we recommend that evaluators:

- 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 as independent evaluators
 - Agree whether evaluators will play an active role in communicating findings as they emerge (and helping correct implementation challenges) or play a more passive role
- Ensure that the research team has the correct expertise. This may require:
 - Expertise in qualitative and quantitative research methods
 - Appropriate inter-disciplinary theoretical expertise
- 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

When designing and conducting a process evaluation, we recommend that evaluators:

- Clearly describe the intervention and clarify causal assumptions (in relation to how it will be implemented, and the mechanisms through which it will produce change, in a specific context)
- 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
- Select a combination of methods appropriate to the research questions
 - Use quantitative methods to measure key 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 with detailed data from smaller, purposively selected samples
 - Consider data collection at multiple time points to capture changes to the intervention over time

When analysing process data, we recommend that evaluators:

- Provide descriptive quantitative information on fidelity, dose and reach
- 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 received the intervention?)
- Integrate quantitative process data into outcomes datasets to examine whether effects differ by implementation or pre-specified contextual moderators, and test hypothesised mediators
- Collect and analyse qualitative data iteratively so that themes that emerge in early interviews can be explored in later ones
- Ensure that quantitative and qualitative analyses build upon one another (e.g. qualitative data used to explain quantitative findings, or quantitative data used to test hypotheses generated by qualitative data)
- Where possible, initially analyse and report process data prior to knowing trial outcomes to avoid biased interpretation
- 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)

When reporting process data, we recommend that evaluators:

- Identify existing reporting guidance specific to the methods adopted
- Report the logic model or intervention theory and clarify how it was used to guide selection of research questions and methods
- Disseminate findings to policy and practice stakeholders
- Where multiple journal articles from the same process evaluation are published, ensure that each article makes 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

Planning a process evaluation

As indicated in Box 1, key considerations in planning a process evaluation centre on the negotiation of relationships with policy and practice stakeholders, resources and staffing, and relationships between process evaluation and other evaluation components such as outcomes evaluation. Challenges and recommendations in relation to each of these issues are now discussed.

Working with programme developers and implementers

Achieving a high quality process evaluation requires good working relationships with stakeholders involved in developing or delivering the intervention. These relationships can be difficult to build due to professional or personal interests in portraying the intervention in a positive light, or because evaluation is seen as threatening. However, without them, close observation of the intervention can be challenging. While building these relationships is vital, evaluators also need to ensure that they maintain sufficient independence to observe the work of these stakeholders critically. Hence, transparently reporting the nature of relationships with policy and practice stakeholders, and remaining reflexive about how these affect the evaluation, is crucial. Occasional peer review by researchers external to the project may help to identify how researchers' positions have affected the evaluation. One key challenge in working with intervention stakeholders centres on structures for communicating emerging findings. That is, whether process evaluators will act as passive observers who feed findings back at the end, or play an active role in identifying and helping to 'correct' problems in implementation as and when they appear.¹⁸ Agreeing systems for communicating information to stakeholders at the outset of the study may help to avoid perceptions of undue interference, or that the evaluator withheld important information. Taking an active role is appropriate at the feasibility testing stage. However, when aiming to establish effectiveness under real world conditions, it will generally be appropriate to assume a more passive role in order to avoid compromising the external validity of trial findings.

Resources and staffing

Process evaluations involve prioritising from numerous potential research questions, combining quantitative and qualitative methods, and often, drawing together theories from multiple disciplines. Hence, there is a need to ensure that sufficient expertise and experience can be drawn upon to decide on and achieve the aims of the process evaluation. A process evaluation team will usually require expertise in quantitative and qualitative methods. The team should ideally also have a good understanding of relevant theory, drawing upon multiple disciplines (e.g. sociology and psychology) where appropriate. It is vital that the evaluation is overseen by a principal investigator who values all aspects of the evaluation. Sufficient resources should be costed to allow collection and analysis of large quantities of diverse data.

Relationships within evaluation teams

Process evaluation will typically form part of a study which includes outcomes and economic evaluation. Defining relationships between the components of an evaluation at the planning stage is crucial. Some evaluators choose to separate process and outcome teams, while in other cases the same people contribute to both process and outcomes evaluation. Some pros and cons of each model are presented in Box 2. Where allocated to separate teams, effective communications between teams must be maintained to prevent duplication or conflict. Where conducted by the same individuals, there is a need for openness and reflexivity about how this might influence the conduct and interpretation of the evaluation. Effective integration between components of an evaluation is more likely to be achieved where a team is assembled whose members respect and see value in one another's work, and where the overall study is overseen by a principal investigator who values integration.¹⁹

Box 2. Relationship between process evaluation and outcome evaluation teams: arguments for separation versus integration

Arguments for separation:

- Separation may reduce potential biases in analysis of outcomes data arising from feedback on the perceived functioning of the intervention.
- Where a controlled trial is taking place, process evaluators cannot be blinded to treatment condition. Those collecting or analysing outcomes data ought to be blinded where possible.
- Analysing process data without knowledge of trial outcomes prevents fishing for explanations and biasing interpretations. While it may not always be practical to delay outcomes analysis until process analyses are complete, it may be possible for these to be conducted concurrently without biasing one another where separate researchers are responsible for them.
- Process evaluation may produce data which would be hard for those who have vested in the trial to analyse and report dispassionately.
- Where there are concerns about a trial among implementers or participants, it may be easier for process evaluators to build rapport with participants and understand their concerns if they have a degree of separation from the trial.

Arguments for integration:

- Process evaluators and outcomes evaluators will want to work together to ensure that data on implementation can be integrated into analysis of outcomes, or that data on emerging process issues can be integrated into trial data collections.
- Data collection of intermediate outcomes and causal processes identified by process evaluators may be integrated into data collection of outcomes evaluation.
- If some relevant process measures are already being collected as part of the outcomes evaluation, it is important to avoid duplication of efforts and reduce measurement burden for participants.
- One component of data collection should not compromise another. For example, if collection of process data is causing a high measurement burden for participants, this may lead to lower response to outcomes assessments.

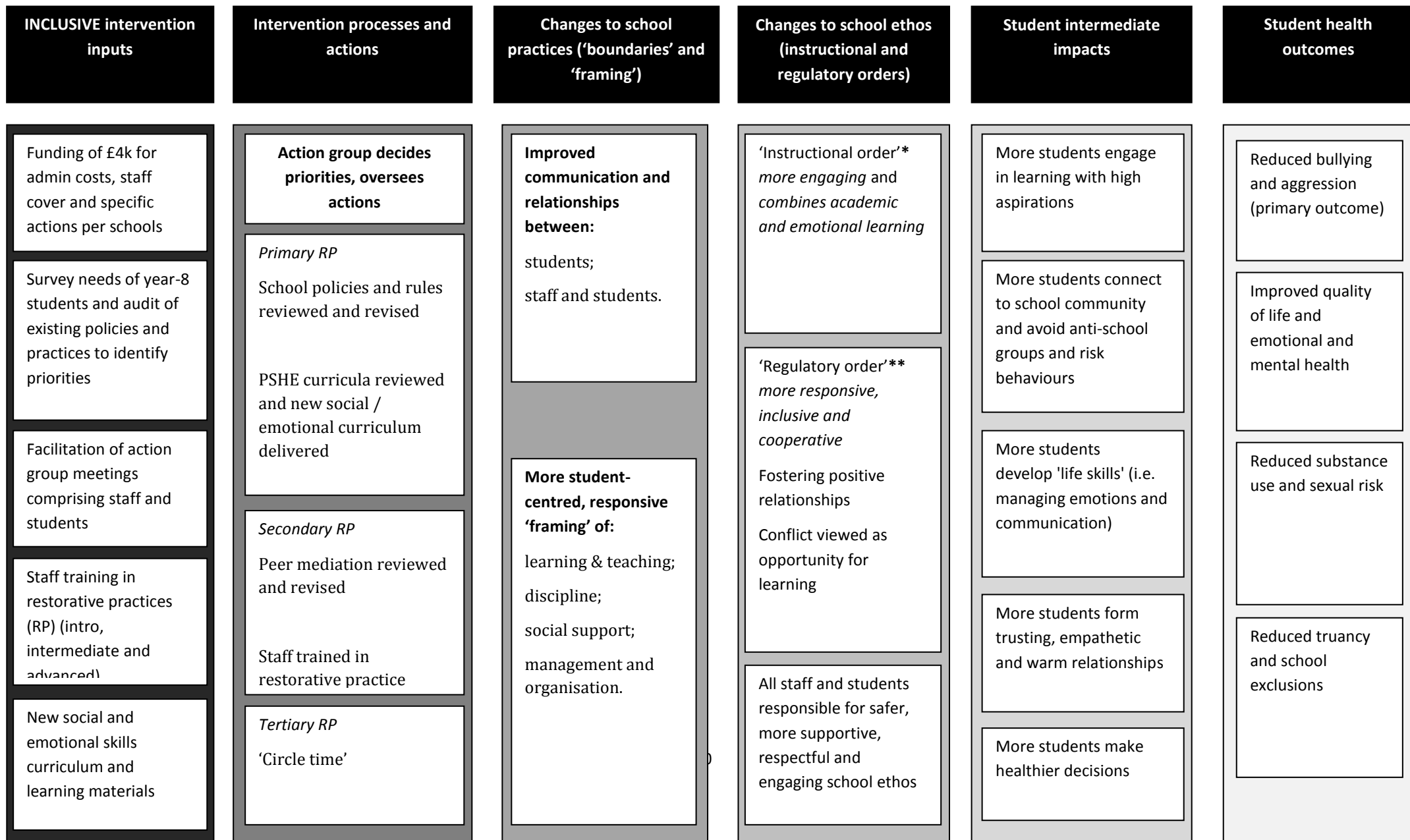
Designing and conducting a process evaluation

As indicated in Box 1, key challenges in designing and conducting a process evaluation centre on identification of the most important questions for process evaluation to address, and selecting appropriate methods to address them. Before evaluators can decide upon core questions, a clear description of the intervention and its underlying assumptions is vital.

Describing the intervention and clarifying causal assumptions

A clear description of the intended intervention, how it will be implemented and causal assumptions about how it will work in context may have been developed prior to evaluation. In such cases, designing a process evaluation will begin by reviewing these descriptions to decide what aspects of implementation, mechanisms of impact or context require investigation. However, where there is ambiguity over what the intervention is or how it is intended to work, working with intervention developers to generate a shared understanding of these issues is highly recommended. It is useful if interventions and their evaluations draw explicitly on existing social science theories, so that these can be tested and refined. However, focusing narrowly on inappropriate theories from a single discipline can be problematic. For example, psychological theory is useful for interventions which work at the individual level, though individual-level theorising becomes less useful when intervening with schools or communities.²⁰ Depicting the intervention and its causal assumptions in a logic model is highly recommended.²¹ Logic models take various forms, but typically set out the resources needed to deliver an intervention, intended intervention activities, and the anticipated processes linking these intervention activities to ultimate intervention goals. An example of a logic model is given for INCLUSIVE (Figure 2), a school-based intervention drawing upon sociological theory.²² The intervention aimed to improve student health through promoting ‘restorative practices’ across the whole school, and involved a set of standard structures and processes which aimed to trigger changes in organisational ethos and practice. Full implementation related to delivery of these key structures and processes, whereas activities delivered to students as a result of organisational changes varied by school.

Figure 2: Logic model for the INCLUSIVE intervention



* i.e. learning and teaching in school ** i.e. discipline, social support and sense of community in school

Learning from previous process evaluations.

When designing a new process evaluation, it is important to be mindful that at some point, the evaluation may be included in systematic reviews which aim to synthesise evaluations of interventions with similar theories of change. Process evaluation will provide the information on implementation and context which Waters and colleagues argue is a non-negotiable part of the review process, if reviews are to assist decision-makers.²³ It is helpful if process evaluations of similar interventions build upon one another's findings and use comparable methods to capture implementation and context, so that reviewers can make meaningful comparisons across studies. It is therefore useful to identify previous process evaluations of interventions with similar components or overlapping theories and consider whether it would be appropriate to replicate aspects of these studies and build on them.

Deciding core research questions

It is vital at the outset of a process evaluation to be clear about the questions it will aim to address. A lack of clarity may lead to collection of excessive data, or data which do not address the key questions. It is never possible to answer all potential questions. Furthermore, over-intensive engagement with providers and participants may artificially change how the intervention is delivered and experienced, particularly alongside an evaluation of effectiveness. It is better to answer the most important questions well than to try to address too many questions and do so unsatisfactorily. Process evaluation can offer important insights which advance intervention theory and practice, and raise questions for further investigation, drawing on a clear understanding of the current evidence base.

Core aims and research questions emerge from considering intervention assumptions and the evidence base for those assumptions. Evaluators may start by systematically listing causal assumptions within the intervention manual or logic model, before seeking agreement on the most important to be investigated, from both scientific and policy and practice perspectives. This will involve reviewing the literature, discussions within the research team, and consultation with policy and practice stakeholders. If, for example, there is limited evidence on how to implement some components, attention may be directed to the adequacy of structures to support implementation. If evidence for any anticipated mechanisms of impact is limited, evaluators might direct significant attention toward qualitatively and quantitatively capturing these mechanisms.

Complex interventions are inherently unpredictable. Evaluators may therefore identify additional questions during the course of their evaluation which need to be addressed. For example, the context may change in unexpected ways which have implications for the intervention. Hence, while a clear

focus from the outset is vital, designing process evaluations with sufficient flexibility to allow important emerging questions to be addressed is important.

Selecting methods

Commonly used methods in process evaluation

Once core questions are agreed, attention turns to selecting methods. Some common methods adopted by process evaluations are listed below in Figure 3. The merits of each of these methods need to be considered carefully in relation to the research questions. For example, self-completion diaries, audits or questionnaires may be cheap to administer on a large scale, but are subject to reporting biases. Process evaluations usually require a combination of quantitative and qualitative methods. For example, evaluators may need to quantify how much of certain components are implemented, while qualitatively capturing emerging adaptations. Qualitative investigation may allow exploration of participant responses, or pathways which are too complex to be captured quantitatively, and can generate theory regarding how an intervention works. Process evaluation can also use quantitative data to test pre-hypothesised causal pathways.

Sampling

A key consideration for process evaluation, particularly where embedded in a large scale trial, is sampling. Interviewing every implementer may lead to overwhelming volumes of data; theoretical saturation may be reached with far fewer interviews. Conducting observations in every site may be prohibitively expensive, and unduly influence implementation. Conversely, there are dangers in collecting data from only a few case study sites, and drawing conclusions regarding the intervention as a whole.²⁴ Hence, it is useful to combine data on key process variables from all sites/participants, with in-depth data from samples purposively selected along dimensions expected to influence the functioning of the intervention.

Timing

The intervention, participants' interactions with it, and the contexts in which these are situated may change during the course of an evaluation. Data collected during the early stages of the evaluation may reflect teething problems, rectified as the evaluation progressed. Implementers' perceptions of the intervention, and hence their practices, may change as they begin to receive feedback from the target audience. Hence, collecting data at multiple time-points to capture changes over time may be useful, although consideration needs to be given to whether this can be done without over-burdening respondents, or changing how the intervention is delivered.

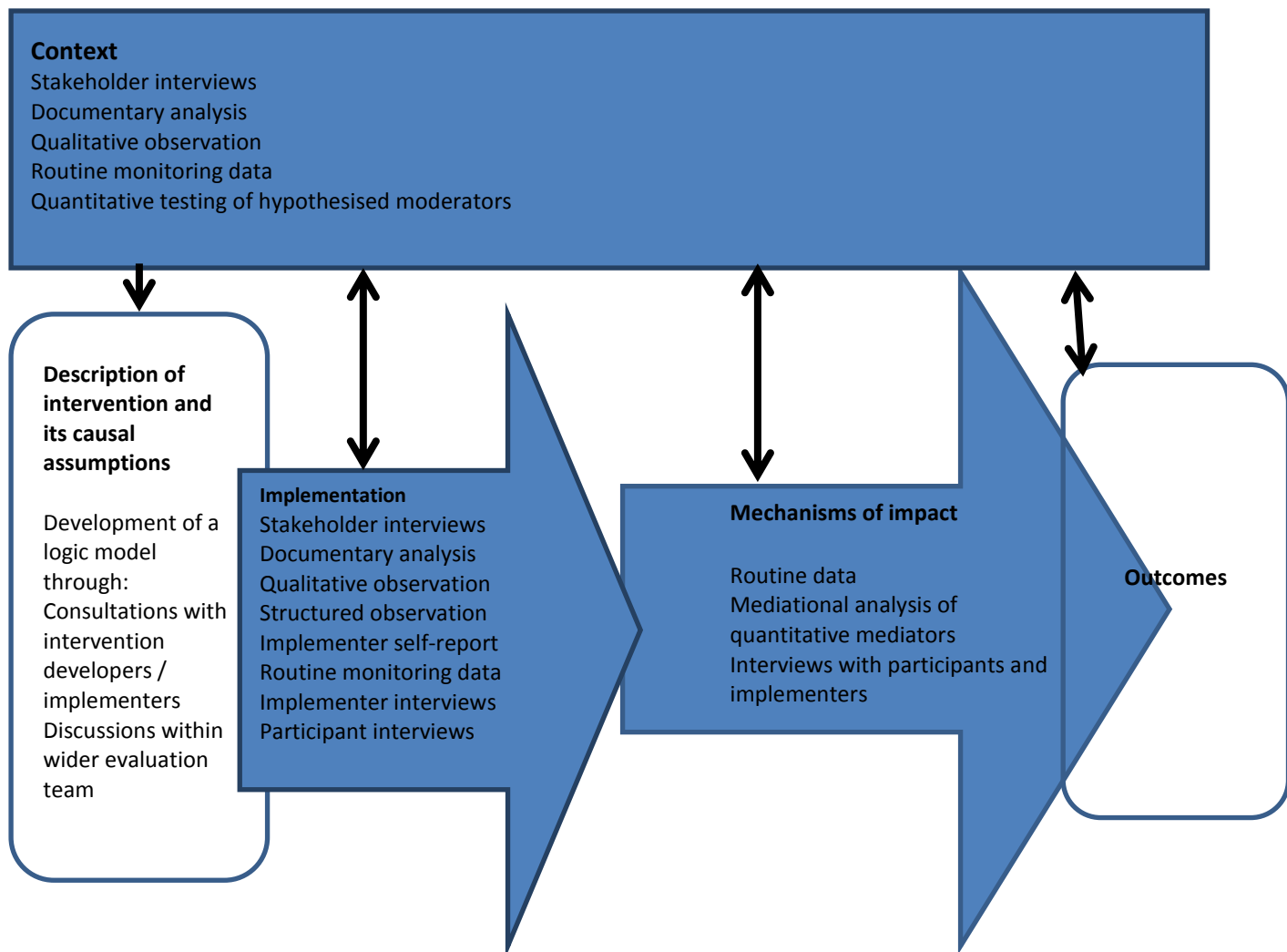


Figure 3: Some commonly used methods for process evaluation

Analysis

Quantitative analysis will likely begin with descriptive information on measures such as fidelity, dose and reach. Evaluators may also choose to conduct more detailed modelling to explore variations between participants or contexts in terms of process factors such as implementation and reach. Such analysis may start to explain issues such as how inequalities emerge or narrow at each stage of the intervention (i.e. whether the intervention only reaches certain groups, whether some groups are reached but drop out, or whether they complete an intervention but no effects are observed).

The flexibility and depth of qualitative data is a key strength, enabling evaluators to explore complex or unanticipated processes. Ideally, collection and analysis of qualitative data will be an iterative process. On a theoretical level, this means that emerging themes from earlier interviews can be investigated in later interviews. On a practical level, researchers will not complete data collection with a huge amount of data, and a short time for analysis and reporting. The length of time required for thorough analysis of qualitative data should not be underestimated.

Integration of process evaluation findings and findings from other evaluation components
Process evaluators should work with those responsible for other aspects of the evaluation to ensure that plans are made for integration from the outset and reflected in how the evaluation is designed. Where quantitative data are collected on process components such as fidelity and dose, hypothesised intermediate mechanisms (mediators) or contextual factors considered likely to influence effectiveness (moderators), it is helpful if these are collected in a way that enables associations with outcomes to be modelled in secondary analyses. Qualitative process analysis may serve predictive or post hoc explanatory functions in relation to outcome evaluation. That is, where analysed prior to outcomes analysis,²⁵ they may provide prospective insights into why evaluators might expect to see positive or negative overall intervention effects. Qualitative data may also lead to generation of hypotheses regarding how variability in outcomes may emerge; for example, whether certain groups of participants appear to have responded to intervention better than others. Qualitative process evaluation methods may, in some cases, inform the design of follow-up measures, with quantitative measures integrated into follow-up data collections in order to test emerging hypotheses from qualitative data.

Reporting findings of a process evaluation

What to report

Providing guidance on exactly what to report in a process evaluation is challenging because there is no one-size-fits-all method. Evaluators can draw upon a range of existing reporting guidelines relating to the specific methods adopted. A regularly updated database of reporting guidelines for health research is available on the EQUATOR network website (<http://www.equator-network.org/home/>). Key considerations include reporting relationships between quantitative and qualitative components, and the relationship of the process evaluation with other evaluation components. It is useful to report the theoretical assumptions underlying the intervention and to be explicit about how these informed the selection of questions.²⁶

Reporting to wider audiences

While process evaluation aims to inform incremental development of theory and contribute to a wider evidence base, it will also aim to inform actions of policymakers and practitioners. Hence, reporting findings in lay formats to stakeholders involved in the delivery of the intervention or decisions on its future implementation is vital. Presenting findings at conferences organised by service delivery organisations also offers a means of promoting findings beyond academic circles, providing an opportunity to summarise the evaluation as a whole and highlight links between its components.

Publishing in academic journals

Comprehensively reporting findings of a process evaluation will often require multiple peer-reviewed journal articles. A key challenge is dividing the process evaluation into components that stand alone, while not losing sight of the broader picture. Where process evaluation has been undertaken to interpret trial outcomes, interpretation needs to be clear in the published papers, with process evaluation data linked in discussion to trial outcomes. All journal articles should refer to other articles published from the study or at least to a protocol paper or report, which clarifies the relationship between the components of the evaluation (e.g. outcomes and process evaluation). Emphasising contributions to advancing intervention theory or methodological debates regarding how best to evaluate complex interventions, rather than focusing inwardly on the specifics of the intervention, may ensure that process evaluations have a broader appeal to journal editors.

Conclusion

This summary, and the full guidance (<http://www.populationhealthsciences.org/MRC-PHSRN-Process-evaluation-guidance-final-2-.pdf>), provide assistance in planning, designing and conducting a process evaluation, and reporting its findings. A framework is described for linking the core functions of process evaluation, enabling evaluators to accumulate a picture of the implementation and functioning of a complex intervention in context. It also argues for a systematic approach to designing and conducting process evaluations, drawing on clear descriptions of intervention theory, and identification of the key empirical uncertainties within it. While accepting that each process evaluation will be different, it is hoped that the guidance will assist in thinking through the key decisions which need to be made in relation to planning and conducting a process evaluation.

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