5 Methods of Process Evaluation

Synopsis

In the design and conduct of process evaluation studies, many decisions need to be made regarding research objectives, theoretical concepts, sampling, data-collection, data-analysis, involvement of interest-holders, and researchers' participation. Challenges of the design and conduct of process evaluation relate to the combination of different intervention types, restrictions set by outcome evaluation, absence of standardized measures, little or superficial use of theory, predominance of descriptive analyses, and handling conflicts of interests. Comprehensive reporting is essential for meaningful communication on process evaluation studies.

5.1 Introduction

Process evaluation does not require unique research methods, as it uses common methods in a specific context, which brings specific challenges that are elaborated in this chapter. Process evaluation is usually observational research, based on interviews, questionnaires, clinical observation forms, and available documents. It may be connected to outcome evaluation (e.g., a randomized trial), which facilitates a meaningful interpretation of the findings of process evaluation. In such cases, the outcome evaluation is often considered the main study, which implies that its design and conduct have priority over the process evaluation. Therefore, the design of process evaluation does not always receive extensive attention. Nevertheless, careful preparation enhances the relevance and methodological rigour of any study.

The design of process evaluation involves the specification of several aspects, including: a) research objectives, b) theoretical concepts, b) methods for sampling, data-collection and -analysis, c) involvement of interest-holders, and d) researchers' participation in intervention delivery.

Regarding *research objectives*, it is generally relevant to examine aspects of the uptake of interventions. Further objectives can be added (e.g., explorations of intervention mechanisms), depending on relevance, interest, available time and resources. A balance needs to be found between addressing a few objectives in much detail with high certainty and addressing many objectives more broadly with less detail and lower certainty. Even if a study has many objectives, it may be required to put emphasis on specific ones. For instance, a study on antibiotics prescribing might focus on patients' expectations, although many more factors play a role (e.g., physicians' habits,

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patients' health literacy, and organisation of care). The emphasis in a study is determined by a range of factors, such as the research funders' program, interests of stakeholders, previous research on the topic (what is new?), expertise and preferences of the research team.

If the mechanisms and consequences of interventions are examined, the choice of *theoretical concepts* is another topic for process evaluators. For instance, a focus on intervention users may place psychological concepts in focus, while an interest in contextual factors may point to sociological concepts. The use of theory in process evaluation can enhance its informativeness, because it relates a study to the broader body of scientific knowledge. As the applicability of specific theory is often uncertain, it is recommended to plan explorative components in the process evaluation at all times. This is particularly relevant if the population or setting is less familiar to the researchers.

In many process evaluation studies, the *methods for sampling, data-collection and data-analysis* are largely common approaches for applied health research, e.g., semi-structured interviews with qualitative analysis, or written surveys with quantitative analysis. Nevertheless, they come with specific challenges and limitations in the context of process evaluation. The choice and timing of measurements, the study sample and its recruitment, as well as the data-analysis approach, need to be carefully designed and applied. Particularly decisions on the content of measures can be challenging. For instance, complex interventions often involve numerous components and potentially relevant contextual factors, not all of which can be examined in detail. It requires time to make a thoughtful selection of items that are included in a process evaluation.

The *involvement of interest-holders* – members of the targeted population, deliverers of the intervention, researchers, and others – is often central in process evaluation. Intervention users (one group of interest-holders) are often the main study population in process evaluation. Other interest-holders (e.g., authorities or payers of healthcare) may be involved as well, for instance to elaborate sustainment and scale-up of intervention programs. Interest-holder involvement may be further strengthened by the involvement of interest-holders in a steering board of a study or in the research team. In larger research projects (with multiple work packages alongside the process evaluation), this is usually arranged for the entire project rather than process evaluation separately.

The *participation of researchers* in the delivery of an intervention varies on a continuum from not at all to very active involvement. Scientific studies often require a certain distance from researchers, which can inhibit the adaptation of interventions during their delivery. However, the early findings of process evaluation may be used to adapt an intervention. Some researchers use participatory approaches, assuming that they increase the relevance and impact of the research (Slattery et al., 2020). A balance needs to be found between distance to the intervention to facilitate valid observations and the provision of

contributions to optimize the intervention of interest. For instance, researchers may contribute to the development of the intervention in an early phase and refrain from contributions in a later phase. Alternatively, monitoring and adaptation of the intervention may be organized separately from the process evaluation (e.g., different work packages and different teams of researchers).

This chapter elaborates on study designs in process evaluation (5.2), sampling and data-collection methods (5.3), and embedded research approaches (5.4). Next, it will summarize some main challenges of process evaluation and ways to overcome these (5.5) and provide recommendation for documentation (5.6).

5.2 Study Designs in Process Evaluation

The methodological design of process evaluation studies (e.g., cross-sectional, longitudinal, or experimental) is not always described, but it is usually observational (i.e., without researcher-controlled interventions). Process evaluation can use qualitative and quantitative research methods in cross-sectional or longitudinal designs. Qualitative research focuses on the qualities of phenomena, while refraining from quantification, using interviews, analysis of available documents, and direct observation of activities. Quantitative research uses quantification of phenomena to provide descriptions and explanations, using questionnaires, registration forms, clinical and administrative databases.

In practice, process evaluation is often restricted to measurements in the intervention arms of a study. The use of control arms or cohorts for comparison is not common in process evaluation, but it can strengthen the study design. In many situations, there are concurrent interventions in use that are similar to the intervention of interest, but not under the control of the research team. For instance, patients may be exposed to alternative messages in a study of an educational program. It is also possible that other research projects test similar interventions in parallel. Examination of such concurrent interventions help to determine the added value or unique features of the intervention of interest. A control arm or additional cohort may be the same as the one in an outcome evaluation, but it may also be a different one (independent of the outcome evaluation). The latter has the advantage that the control arm in the outcome evaluation is not contaminated by measurements for the process evaluation.

Furthermore, an independent study within a trial (SWAT) can be planned as part of the design of a process evaluation (Arundel et al., 2024). This is a study with aims and methods that are largely independent of the intervention study, but which makes use of the infrastructure for sampling and data-collection of the intervention study. Such study may have an experimental design.

For instance, the preparedness to pay for a specific intervention among potential users may be explored in discrete choice experiment among trial participants, using vignettes as interventions. Preparedness to pay may be relevant for the sustainment and scale-up of an intervention, which can be one of the research questions in process evaluation. SWATs may also be more distant from the process evaluation of an intervention. For instance, methodological studies on recruitment procedures or studies to validate questionnaires may also be conducted as SWATs.

Process evaluation of interventions requires resources during a period of time, particularly for research staff. Most data-collection is usually done at the end of the intervention period (when participants have gained experience with the intervention), followed by data-analysis and reporting. In earlier phases, the empirical research needs to be prepared and an initial round of data-collection may be conducted, for instance shortly after start of the intervention to document early experiences. In addition, data may be collected at intervention start to get insight into the early phase of intervention use. This implies that process evaluation requires activities from some months before the intervention starts until several months after the intervention ends, but with a potentially quiet period in the middle if the intervention lasts for an extended period (e.g., more than a year).

Like in all empirical research, protection of participants' welfare, maintaining integrity of data, and handling conflict of interests are essential components (Wensing & Ullrich, 2023). For instance, process evaluation can identify issues in an early stage of the delivery of an intervention, which may give individuals the feeling that these will be addressed by the research team. Depending on the institutional context, approval of the study by an independent ethics board may be required.

5.3 Sampling and Data-Collection

The study population of process evaluation is typically composed of users of an intervention (typically patients/service users and healthcare professionals). The size of this population is often given by the outcome evaluation. The number of healthcare professionals can be small, which usually implies that all eligible participants are invited to an interview study or survey for process evaluation (full census). Exceptions include large programs with many participants, which use a sample of selected participants for process evaluation. Participation rates vary across studies, and seem to be higher in clearly defined projects or studies as compared to programs with continuous enrolment of participants. Participants in control groups of outcome evaluations can also be of interest to process evaluation, but they are often

not accessible to avoid bias in the outcome evaluation through additional attention.

If process evaluation is linked to outcome evaluation (e.g., a trial), the sample often consists of all subjects in the outcome evaluation. This may imply that the sample size is small, particularly regarding the number of healthcare providers (e.g., lower than 20 individuals) and therefore a full census is used instead of a sampling approach. Another implication is that process evaluation has the same limitations as the outcome evaluation, although the selection bias may play out differently in the process evaluation. For instance, the characteristics of a sample of patients may be predictive for the health outcomes, but not necessarily for the uptake of recommended interventions or contextual factors that influence outcomes.

If sampling from a broader population is applied, the methods are those of sampling in research generally. In qualitative research, purposive sampling is a common strategy in health research, which is also frequently used in process evaluation. In quantitative research, this implies that random sampling provides the highest certainty that the sample is unbiased, at least if the sample is reasonably large. A random sampling procedure may involve specific restrictions, such as stratification and clustering. Alternatives to random sampling can be positioned on a continuum from close to far from random sampling: systematic sampling, consecutive sampling, snowball sampling and convenience sampling. Participation rates in research vary, which introduces further risk of bias.

Process evaluation research often implies data-collection that involves time of healthcare providers and others. This can be challenging, particularly if the outcome evaluation requires their time as well. If questionnaires or interviews are used, individuals may be unwilling to participate, even if they previously agreed to participate in a project. Furthermore, participants may provide incomplete data, which reduces the informativeness of the data. There is a range of methods to enhance participation, varying from reminders to involvement of peers. For instance, sending reminders to people who do not respond to a postal invitation seems to increase the participation rate somewhat in the context of trials (Treweek et al., 2018). The effects of other methods were found to be small or inconsistent.

Alternatively, data may be derived from routine documentation systems (e.g., computerized patient records) or systems that are part of the intervention of interest (e.g., a software application) or the evaluation of its outcomes. Access to these sources may be facilitated by the integration in a broader evaluation project. These sources can provide more comprehensive datasets, but they are usually not designed for evaluation purposes and may thus not cover specific issues of interest. In addition, participants need to provide informed consent for use of data for other purposes than originally planned (certainly under the European Data Protection law). Nevertheless, the use

of available data is generally recommended, because it implies less burden for participants and higher efficiency of data-collection.

Data-collection in process evaluation may also be based on direct observation of behaviours or processes as these are in the focus of interest, but this seems less common. Informed consent needs to be provided, but the burden on the observed people seems otherwise low. The main disadvantage of this approach is that it requires much time of the researchers. On the other hand, the time investment for qualitative interviews (and their analysis) should not be underestimated either.

In the coming years, broader developments in data science may change the nature of process evaluations. Advanced data-analysis approaches, which may use artificial intelligence and machine learning procedures, have become available. Large amounts of text data (e.g., from patient records) can be analysed with new methods. Nevertheless, these new methods require concepts for analysis and interpretation, as well as large amounts of data. The availability of data is often limited in research of healthcare interventions, both regarding number of measured variables and numbers of cases. New technological tools, such as sensors and smartphone-based questionnaires, may change this in the coming years.

5.4 Embedded Research

Many applied health studies involve collaboration between researchers and users of the research findings, such as clinicians, managers and policy makers. This is particularly relevant for process evaluation, because it puts high value in the users' experiences. In some cases, the collaboration involves participation of researchers in the setting of their research (healthcare practice or institutions in the healthcare system). This has been characterized as 'embedded research', which is defined by "researchers who work inside host organisations as members of staff, while also maintaining an affiliation with an academic institution" (Vindrola-Padros et al., 2016). For instance, they may work as healthcare providers in the institutions, which are also the setting of their academic research. A review of embedded research activities in the field of healthcare and public health of published cases identified an even broader range of embedded research types: 1) classic embedded model, with academic researchers embedded in practice/policy settings, 2) reverse embedded model, with practitioners and policymakers embedded in academic organisations, 3) remote embedded model (based on online work, with little physical co-location), 4) models with low levels of embeddedness (Kneale et al., 2024).

Embedded research is a model of research that aims to bridge the gap between research and the use of knowledge in practice. The promise is that

the research is better grounded in the priorities of users, and therefore more impactful, as compared to other research models. For researchers it can result in the development of close relationships, learning of new skills and career opportunities (Reen et al., 2022). A framework specified a number of features of embedded research (Kneale et al., 2024), including a) researchers have a dual affiliation covering a research organisation and a host organisation in practice or policy; b) host organisations can influence and direct the work of embedded researchers (this makes it different from ethnographic research); c) there is two-way learning between the research organisation and the host organisation. In practice, not all features may be present in a case of embedded research. Empirical analysis of embedded research models in health research found variation in many aspects of goals, structures and processes (Ward et al., 2021). Embeddedness in healthcare may be globally characterized on a range from deep immersion and partial embedded to collaborative link-up and dichotomized research-practice (Churruca et al., 2019).

The embedded research model has a number of potential consequences, which include both benefits as well as risks (see Box 5.2). It is wise to reflect on these consequences and to plan mitigating strategies, if necessary. This is particularly relevant for process evaluation studies, because in most cases many decisions are taken throughout the conduct of the research. For instance, preliminary findings of the process evaluation may be reported to intervention deliverers in order to improve the intervention. Additional research questions may emerge during a process evaluation study, which lead to additional measures or analyses. Involvement in the research setting makes it more likely that decisions on these matters are influenced by the expectations and interests of people in the settings in which the study takes place. This can improve the quality and relevance of the research, but it may also result in suboptimal approaches, and even biased results, if the validity or generalizability of research findings is sacrificed.

Box 5.2 Potential benefits and risks of collaboration between researchers and healthcare professionals

Aspect of collaboration	Benefits	Risks
Choice of topic and questions of research	Higher relevance for research users in the setting of research	Lowered scientific relevance, e.g., questions may have low relevance of already been answered
Choice of study design and methods	Higher feasibility of research in the setting of research	Increased risk of bias, if design is scientifically suboptimal
Recruitment of participants and data-collection	More successful and faster recruitment and data-collection	Risk of bias if methods are not optimal
Analysis and interpretation of data	More meaningful and richer findings	Risk of bias if focus is narrow or guided by interest-holders
Dissemination of research findings	More effective dissemination among interest-holders	Findings may be reported selectively if guided by self-interests
Other considerations	Better understanding of roles and restrictions in all settings; time investment for exploration of research setting is lowered	Initial time investment may be high; conflicts of roles or loyalties may emerge; complimentary authorships may be more likely

Empirical research demonstrated some of these benefits and risks. In an interview study in a sample of embedded researchers in the United Kingdom, they expressed experiences that often related to common themes concerned intended outcomes, power dynamics, scale, involvement, proximity, belonging, functional activities, skill and expertise, relational roles, and learning and reflection (Ward et al., 2021). Researchers and practitioners may have different priorities which need to be balanced: researchers are inclined to conduct studies to the highest standards of rigour, whereas practitioners require more immediate action often in the face of regulatory and organizational pressures (Reen et al., 2022). Another concern is that researchers may have less time available to develop core research skills, such as research ethics, peer review, and (advanced) data analysis. Time pressures as a result of multiple obligations to the organization and university can make it difficult to meet career goals, for example, publishing papers or applying for grants (Reen et al., 2022).

The embeddedness of research may play out somewhat differently in studies of health interventions and implementation strategies. In the first case, colleagues of the embedded researchers may be involved in the

recruitment and data-collection in patients or populations. The recruited patients receive care within the same institution or team, although not necessarily by the embedded researcher in the role of care provider. In the second case, the colleagues may be research subjects and requested, for instance, to respond questionnaires and participate in interviews. Thus, they are the primary research subjects as their work-related behaviours are the focus of research.

5.5 Challenges in the Design of Process Evaluation

Challenges in the design process evaluation reduce the certainty of findings of process evaluation studies and the accumulation of knowledge across studies (see box 5.3).

Box 5.3 Challenges and potential approaches

Challenges	Potential approaches
Mixing or ignoring intervention components	Pay separate attention to intervention components and types in the evaluation
Restrictions set by outcome evaluation	Create or find a control/comparison arm outside the outcome evaluation; negotiate with evaluators of outcomes
Lack of standardized measures	Use available measures; develop new measures
Little or superficial use of theory	Train and/or specialise researchers
Mainly descriptive analyses	Train and/or specialise researchers
Conflicts of interests	Disclose and reflect on conflicts of interests; organize independence regarding the intervention of interest
Uncertain transferability	Include variety of settings; favour multicentre studies with large samples

Mixing or ignoring intervention components. Many intervention programs contain various components, particularly combinations of health interventions and implementation strategies. This is not always recognized by intervention recipients and researchers, who may hold different views on what are intervention components. Process evaluation is most informative, if it pays separate attention to these intervention components from the start. A specific example is presented by recruitment and intervention delivery problems in many clinical trials. These are typically addressed by adaptation or additions to the planned implementation strategies, e.g., additional support by the

research team. Such planned implementation strategies (usually deviations from the study protocol) may be overseen, if a separate process evaluation of the implementation strategies was not planned.

Restrictions set by outcome evaluation. Insight into the effects of an intervention helps to interpret the findings of process evaluation, but outcome evaluation frequently sets restrictions. For instance, interviews or surveys among participants in the control arm of an outcome evaluation are often not possible in order to reduce the risk of bias. Nevertheless, insight into the processes in the control arm would help to assess the additional or unique features of the processes in the intervention arm. It may be possible to create a control or comparison arm, which is independent of the outcome evaluation. In addition, there may be limitations regarding the frequency or timing of measurements in the intervention arm, if this is perceived to imply a burden for participants that is considered unacceptable. This is often an area of negotiation with the evaluators of intervention outcomes.

Absence of standardized measures. There are few standardized measures for process evaluation, for instance for measuring intervention fidelity or contextual factors. Exceptions exist for specific interventions, such as the uptake of community mental health teams for delivery of recovery-orientated care to people with severe mental illness (Roth et al., 2021). There are some generic measures for perceptions of acceptability, feasibility and appropriateness of psychosocial and educational interventions in healthcare (Weiner et al., 2017). Rather than developing new measures for each specific intervention, it may be efficient to develop generic measures or measures for specific groups of interventions (e.g., health apps or psychotherapy interventions).

Mainly descriptive analyses. Many process evaluation studies report descriptive analyses (e.g., frequencies or accounts of themes), while more advanced qualitative or quantitative analysis approaches could provide further insights. While this problem is related to the absence of an explicit theoretical perspective in many process evaluation studies, it also applies if theory is not explicitly involved. Some researchers have good skills in one set of methods, but lack the competencies to apply other methods. Training of researchers in advanced methods for qualitative and quantitative analysis is required to overcome this problem.

Little or superficial use of theory. Some process evaluation studies use conceptual frameworks (e.g., lists of factors), but few are clearly guided by theory to design measures and interpret findings. Health researchers may be unaware of such theories, or have a narrow understanding of potentially useful theories. Others apply frameworks mechanistically by treating them as lists of factors or hypotheses, without considering the underlying assumptions and perspectives. This situation reduces the informativeness of process evaluation and inhibits the accumulation of knowledge over time. Training of researchers and perhaps also specialisation of specific researchers on theory-informed process evaluation research may help to overcome this problem.

Uncertain transferability. As a consequence of previous issues, the transferability of the findings of many process evaluation studies is uncertain. Studies in academic or specialized settings may not be generalizable to other settings. In addition, many intervention studies involve small samples and few sites, which further adds to the uncertainty of transfer. Multi-centre studies with attention for contextual factors as well as systematic synthesis (using established methods of systematic reviews) are ways to overcome this problem. Systematic reviews of qualitative studies on interventions provide an example of rigorous synthesis of process evaluation research, which can provide further clues to the transferability of interventions.

Scientific integrity. Most process evaluations depend on the cooperation with intervention users and other interest-holders. Researchers are also interest-holders and their interests are complex, if they are embedded in practice settings. This implies that the scientific integrity may conflict with the interests or expectations of people involved. Some process evaluations are designed to support the development and optimization of interventions, which may intensify this conflict. These potential conflicts or tensions need to be reflected on and, if necessary, addressed by mitigating procedures.

Conflicts of interests. Evaluation of interventions usually involves interest-holders with financial or non-financial interests, including the research team. For instance, the process evaluators may also be involved in intervention development and outcome evaluation. Disclosure of interests is now standard practice in research reports, but it is not sufficient to guarantee the integrity of research. Particularly studies that involve the developers, investors or implementers of an intervention may have high risk of bias. As a minimum, researchers should reflect on conflicts of interests and discuss in what direction it may bias the research findings. Ideally, evaluators do not have direct interests in the findings of their research. Even this is achieved, many depend on projects to fund their work, which implies a conflict of interests.

5.6 Reporting and Impact

The findings of process evaluation are most informative, if the effects of the intervention of interest are known. This implies that the results of the outcome evaluation need to be available (and ideally also published after peer review) before the reports on the process evaluation are finalized and published. However, the results of process evaluation tend to be available earlier than the results of a trial or other type of outcome evaluation. Therefore, the findings of process evaluation are often published before the findings of outcome evaluations are available. The limited time within most projects and the requirement of publications for scientific qualification are factors,

which contribute to this practice. Unfortunately, this implies that many published process evaluations do not well contextualize the results with respect to intervention outcomes.

In all research, comprehensive reporting is essential for meaningful communication. For process evaluations, reporting guidelines that are used for specification of the interventions of interest (e.g., TIDIER) and for the outcome evaluation (e.g., CONSORT) can serve as orientation. However, as process evaluation concern additional issues, many of which were covered in this book. Therefore, we have developed a checklist for reporting of process evaluation studies in healthcare (see Box 5.4).

Box 5.4 Checklist for reporting process evaluation studies in health care

What type of intervention is examined? (more than one may apply)
a) Health intervention
b) Implementation strategy
c) Other

Focus, purpose and a priori specifications
1) A short name or description of the intervention of interest is given.
2) The effects of the interventions of interest are known and described.
3) The specific objectives of the process evaluation are presented.
4) An intervention theory is specified before intervention start.

Aspects of process evaluation design
5) The overall study design and methods for process evaluation are described.
6) The conceptual framework used for the process evaluation is described.
7) It is clear how are interest-holders are involved in the design and conduct of process evaluation.
8) The relation between researchers and research subjects has been clarified.
9) Management of conflicts of interests of researchers goes beyond disclosure.

Sampling for process evaluation
10) The study population(s) of interest to process evaluation are described.
11) The sampling procedure (e.g., full census, random, purposive) is described.
12) The participation rate among targeted individuals is presented.

Box 5.4 *Continuation*

Data-collection for process evaluation

13) The type and content of measurements are described (e.g., interviews, surveys, clinical databases, computer generated user files).
14) The timing of measurements is described (e.g., before start of intervention, throughout intervention period, at end or after of intervention period).

Data-analysis for process evaluation

15) If relevant, the qualitative analysis approach (e.g., thematic analysis) is described.
16) If relevant, the quantitative analysis approach is described (e.g., descriptive statistics, multivariate analysis, simulation modelling).
17) If both qualitative and quantitative methods, it is clear whether and how these were integrated (e.g., methods of triangulation).

Like in all studies, dissemination beyond scientific reports is relevant for process evaluation. The interest in process evaluation may initially be limited among interest-holders, when a project or evaluation is designed. However, many intervention projects have problems in the recruitment of participants and many interventions show little, small or mixed effects. These phenomena often increase interest in the findings of process evaluation, because these may help to identify issues in the use of an intervention and possibly show positive effects, which have not been integrated in the outcome evaluation. Given the relevance of the findings of process evaluation, they may be conveyed in meetings with decision-makers and reports or reports for a broader audience.

The use of research findings in practice and policy is overall mixed and moderate, and there is no reason to believe that this is different for process evaluation research. In the early phase of a research project, the interest is mostly on the outcome evaluation, but this often changes in the course of a study. Practical experience suggests that process evaluation findings are appreciated, if an intervention shows little effect in the outcome evaluation and the process evaluation shows positive experiences. Furthermore, the findings of process evaluation are frequently earlier available than the findings of outcome evaluation, which is in principle favourable for use in practice and policy. In some cases, authorities decide to implement an intervention on the basis of process evaluation findings and in the absence of results of the outcome evaluation. A risk is that the findings of a process evaluation study are selectively used to meet the interests or views of stakeholders.

Research impact is not only dependent on its quality or timeliness of delivering research findings. Many other factors influence impact, which go beyond the control of the individual intervention user. It is often required to build a coalition of relevant political stakeholders and arrange the financial and legal conditions. These activities are largely outside the scope of scientific research, but some might be supported by research that is part of process evaluation. For instance, a project may include analysis of the changes in laws and regulations that are required for implementation of an intervention (e.g., broadening of professional autonomy of nurses for active involvement in health care). Such legal analysis may be informed and accompanied by interviews with stakeholders, which could be part of process evaluation.

5.7 Conclusions

The design of process evaluation comes with challenges, which are to some extent specific for this type of research. Careful preparation is recommended, but not always practised. In many projects, priority is given to the outcome (and economic) evaluation. The methodology for outcome evaluation, particularly for randomized trials and quasi-experimental designs, has been much elaborated in recent decades. In comparison with this advancement, the methodology for process evaluation lags behind, but interest in this has grown in recent years.

Q&A Case Studies: Methods of Process Evaluation

Case Study 1: Milestone Communication Approach in Lung Cancer Care (MCA)

Q: *How was the study designed?*
A: The project was designed as intervention development, testing and dissemination. Elaboration of the intervention theory (mainly in terms of an educational manual) was the first phase of the project. The research component (phase 2) comprised a mixed-methods evaluation study, based on questionnaires and interviews in patients, physicians and nurses. After it had become clear that the capacity would be insufficient

to include all eligible patients in the MCA-guided conversations, the decision was made to allocate them on the basis of a randomization procedure. Thus, a randomized trial was designed and conducted, but it did not dominate the research enterprise. The emphasis was mostly on collecting data concerning patients' experiences (using several validated questionnaires) and to lesser extent on healthcare providers views. In addition, documentation of the consultations was analysed. The organisational context seemed relevant for the implementation of MCA, but scientific data to provide insight into this were hardly collected.

Q: *Would you change the design, if the study could be done again?*
A: More data on organisational aspects could be collected, although the study was essentially a single-centre project, which limits the generalizability.

Q: *How was the relation between researchers and subjects of research?*
A: The research team in the MCA-project involved several practicing academic clinicians and other researchers employed at the hospital, which was the setting of the study. They had invested substantially in preparatory research and lobbying to facilitate the project, and placed high priority on a training manual for healthcare providers and non-scientific audiences to facilitate spread of the MCA-intervention. So, they were deeply immersed in the host organisation. The research team also involved researchers, who had not previously been involved in the development of the intervention. Their goal was to conduct rigorous research, which could be published in scientific journals and contribute to scientific qualification. All research meetings were at the hospital, in which the study took place. These external researchers had close collaboration, but they were not embedded in the study setting. They were able to conduct and publish their research without restrictions, also facilitated by the generally favourable results.

Q: *What were the benefits of this relationship?*
A: The main benefit was easy access to clinical practice for recruitment and data-collection. The clinical expertise also supported the choice of measures and interpretation of findings in the study.

Q: *What were the interests of participants, and how were these handled?*
A: In the MCA-project, the intrinsic motivation of a few practising clinicians led to an interest to develop a dedicated contract with health insurers to arrange reimbursement for the additional services. The main

health insurer had an interest in strengthening interprofessional care and patient-centredness in healthcare. Therefore, both parties had an interest in positive results of the evaluation research. This was handled by including an independent research team for conducting the evaluation. Nevertheless, the clinical team expressed high expectations of the intervention, which may have influenced the researchers. However, it seemed that both healthcare providers and health insurers mainly had the outcome evaluation in mind as the process evaluation seemed largely non-affected. On-site researchers gathered additional feedback from participating physicians and nurses after conclusion of the MCA study. Since they knew the setting and had established a stable relationship with the healthcare professionals, they received honest and valuable additional information to further improve the intervention in this specific setting apart from the study.

Q: *What was done to enhance the scientific integrity of the process evaluation?*
A: After the project had received funding, the budget for the research teamwas transferred to a separate account and thus guaranteed, independent of study results. The research team regularly discussed the study among themselves (without the clinical team) to maintain scientific standards.

Case Study 2: Rational Prescribing of Antibiotics in Ambulatory Care (ARena)

Q: *How was the study designed?*
A: The three-year, externally funded ARena project was designed as a large cluster randomized study using random allocation of 14 participating networks. Randomization rather than observational comparison was proposed by the research team and ultimately accepted by the practice networks. However, the contrast between the randomized study arms was limited as all arms received a comprehensive package of quality improvement strategies. These features implied that interpretation of the effects was challenging. A comprehensive process evaluation on the basis of surveys and interviews with healthcare providers was planned from the start. Given the absence of validated measures, most were newly developed for the purpose of the study. The project provided the data for several theory-guided analyses that go beyond descriptive research. These studies were initiated during the study by

the process evaluation researchers, although not planned in the original research plan.

Q: *Would you change the design, if the study could be done again?*
A: The randomization was a big methodological improvement compared to the originally proposed observational study design, but a new study might be able to randomize at a lower level of aggregation (e.g., practices). The process evaluation was rather comprehensive, but an option could be to add surveys and interviews in practices outside the project. This would provide a reference for the findings of the current process evaluation.

Q: *How was the relation between researchers and subjects of research?*
A: In terms of set-up, the ARena project was a traditional project in which the research team was physically and mentally separated from the practice setting. While several project meetings involved researchers and practitioners, their roles were clearly different. This constellation was enforced by the funder, who expected independent evaluation research. Nevertheless, the leading organisation (which was independent of the research team and the practice setting) placed high value on a constructive working relationship. Thus, there was a degree of collaboration between researchers and practitioners in the project. This may explain the content of messages in various dissemination activities, which prioritized the observational comparison with usual care that suggested a large effect of the quality improvement program.

Q: *What were the benefits of this relationship?*
A: The distance of the research team to the practice networks facilitated scientific independence. Participation in data-collection was arranged in written contracts, which led to reasonably good participation rates (50–75 %) in the surveys and interviews with healthcare professionals.

Q: *What were the interests of participants, and how were these handled?*
A: The ARena project involved clinicians, health insurers and an independent research team. However, the clinicians were represented by an agency, which negotiated and managed contracts with health insurers and others for them. This provided a transactional setting, in which services (here: participating in quality improvement and data-collection) were provided for reimbursement. This may imply that the results of the evaluation were not directly of interest of clinicians, although they might influence contracts in the future. For health insurers, evaluation was important to justify the financial investment in the project. Like in

the MCA project, it seemed that both parties mainly had the outcome evaluation in mind.

Q: *What was done to enhance the scientific integrity of the process evaluation?*
A: The budget for process evaluation was transferred to the account of the research team and guaranteed, independent of the findings. The research team regularly met to discuss decisions regarding the research.

Self-test Questions

1) Which of the following research approaches and methods are typically used in process evaluation research: observational research, controlled designs, qualitative methods, questionnaires, direct observation, qualitative analysis, statistical testing?

2) Many process evaluation studies are based on samples of participants, who are exposed to the intervention of interest (e.g., the intervention arm in a controlled trial). What are the limitations and the alternatives?

3) What types of measurements are typically used in process evaluation studies, and what might be innovative measures for aspects of process evaluation?

4) How do SWATS (studies with trials) relate to process evaluation?

5) Some researchers are also healthcare providers? What are the potential benefits and risks?