Lecture Notes
Medicine

Process Evaluation of Interventions in Healthcare

An Introduction to Concepts, Methods, and Practices

MICHEL WENSING/
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MICHEL WENSING AND CHARLOTTE ULLRICH

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HEIDELBERG
UNIVERSITY PUBLISHING

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Bibliographic information published by the Deutsche Nationalbibliothek
The Deutsche Nationalbibliothek lists this publication in the Deutsche Nationalbibliografie; detailed bibliographic data are available in the Internet at https://dnb.dnb.de.

Published by Heidelberg University Publishing (heiUP), 2025

Heidelberg University/Heidelberg University Library
Heidelberg University Publishing (heiUP)
Grabengasse 1, 69117 Heidelberg, Germany
https://heiup.uni-heidelberg.de
e-mail: ub@ub.uni-heidelberg.de

The electronic open access version of this work is permanently available on Heidelberg University Publishing's website: https://heiup.uni-heidelberg.de
urn: urn:nbn:de:bsz:16-heiup-book-1657
doi: https://doi.org/10.17885/heiup.1657

ISSN 2566-4816
eISSN 2512-4455

ISBN 978-3-96822-344-5 (PDF)

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1 Introduction

Synopsis

Process evaluation can be understood as a type of research that describes and explores the processes influencing the outcomes of an intervention. In health care, many of such interventions are either activities to improve patients' and population health ("health interventions") or strategies to implement such health interventions into practice ("implementation strategies"). To explore how, why and when health interventions work in practice, process evaluation examines whether an intervention has been taken up in practice as planned, and how it actually performs to achieve its outcomes. Thereby, the findings of a process evaluation help to interpret interventions' effects, optimize intervention design, and assess the transferability of interventions across settings.

1.1 Introduction

In healthcare, interventions might address both patients and health care providers. Health interventions aimed at patients include medical treatments, diagnostic procedures, screening procedures, health promotion programs, and patient education activities. The goal of these interventions is to improve the health of individuals and populations. Interventions aimed at healthcare providers include, for instance, educational programs for healthcare workers, organisational changes in healthcare institutions, and changes in the financial reimbursement of healthcare providers. Many of the interventions targeted at healthcare providers aim to implement specific health interventions into practice; they are described as implementation strategies. Such strategies also aim to improve the health of patients and populations, but they target health care providers to achieve this. Some interventions targeted at healthcare professionals have other aims, such as to enhance job satisfaction of healthcare workers, improve efficiency of healthcare delivery, or save costs. Some strategies targeted at health care providers involve patients or the public in their development or delivery, such as campaigns to enhance patients' active involvement in clinical consultations.

More generally, interventions can be understood as purposive, goal-orientated activities that aim at changing a status quo. This means, that interventions have a clear starting point in time, which distinguishes them from many other types of changes and developments. The explicitness, clarity and consistency of the goals of interventions vary. For example, the objectives of

a health system reform may remain implicit and change over time. In some cases, it can be debated whether something is an intervention as defined here, or a human-made development without coherent purpose and goal.

In healthcare, the concept *intervention* is understood in various ways. a) It might refer exclusively to medical interventions, i.e. clinical and prevention interventions, such as medication. This definition of interventions seems common among clinicians and clinical researchers. b) Alternatively, it may refer more broadly to a purposive change in current healthcare practice (i.e. anything that is planned by researchers to be different from routine practice). According to this definition, the delivery of a medical treatment in usual care is not an intervention, because it does not imply change from current practice. c) Finally, the concept intervention may cover any purposive, goal-orientated activity; this broad definition is used in this book. It includes health interventions, implementation strategies, and other goal orientated activities.

Any decision to deliver a specific intervention in health care (whether health intervention, implementation strategy, or other) should be taken carefully. Interventions require scarce resources, they may be ineffective, and some interventions involve risk of harm to individuals. Interventions may also have undesired consequences from an ethical point of view, such as increased inequity in access to healthcare. Data-based approaches to the evaluation of interventions can increase the degree of certainty and generalizability regarding their effectiveness.

Evaluation of health interventions has a long history: The 1747 scurvy trial by James Lind is assumed to be the first study in health, which has many features of modern clinical trials (Bhatt, 2010). In the 19th century, evaluation research developed into an activity of professional researchers. However, it was not until the 1930s, that the design and conduct of clinical trials were professionalized by establishing accurate methodology and standards such as randomization and replication. Since the 1960s, program evaluation as systematic empirical method to effectiveness and efficiency of policy programs was introduced. Nowadays, there is much attention for the evaluation of health interventions and evaluation research is part of the training of many healthcare professionals with higher education. This has various reasons: the attention for the health and well-being of the targeted individuals has increased; many interventions are less effective in real populations in routine practice than in controlled research settings, and the use of interventions requires resources (e.g., time of healthcare professionals) that could have been spent otherwise. Evaluation research helps to sort out which health interventions have relevant benefits, no or acceptable harm, and reasonable costs. It provides information that can support decision-making by healthcare professionals, patients, and payers of healthcare. In health policy context, this decision-making process has been described as deliberative policy-making (Baltussen et al., 2021). In healthcare practice, this approach to decision-making aligns with the principles of evidence-based healthcare.

This chapter will elaborate on the purposes of process evaluation (1.2), outcome evaluation as context of process evaluation (1.3) and the complex systems approach as conceptual foundation (1.4). The chapters conclude with an overview of the book (1.5).

1.2 Description and Purposes of Process Evaluation in Health Care

Process evaluation is mostly observational empirical research, based on qualitative and quantitative methods, regarding healthcare interventions in practice. Process evaluation is usually conducted in routine practice settings (rather than specialized centres or research laboratories), in which many contextual factors cannot be controlled, so interventions may work out differently than assumed. Besides the benefits, risks and costs of interventions, it is often helpful to examine the processes in practice that influence these outcomes. Research on these processes has been described as process evaluation, which is essentially the study of *how*, *why*, and *when* interventions work out in practice. Relevant processes include, for instance, to what extent the targeted population is actually reached, planned interventions are actually applied in practice, and which components of an intervention contribute to its effects. The findings of process evaluation help to interpret the effects (or absence of effects) of an intervention and to optimize the design of interventions. It can also provide deeper insight into the mechanisms that lead to effects, which contributes to scientific knowledge.

At a fundamental level, process evaluation can be related to the philosophical tradition of pragmatism, because it assumes knowledge is derived from and validated by observations of actions in practice (Brown & Tavory, 2024). The interest for process evaluation is also related to the increasing recognition of the value of pragmatic trials in health, which examine interventions under conditions that reflect routine healthcare rather than controlled conditions (Bhatt et al., 2019). Nevertheless, process evaluation researchers may also work in other epistemological approaches, such as positivism and social-constructivism.

In practice, process evaluation can serve various purposes. First, it can demonstrate to what extent an intervention is actually used as planned in a specific context and population. This is known as *intervention uptake* and covers various aspects, including reach of the targeted population, fidelity of intervention delivery, and adaptation of interventions during delivery. If the uptake of a health intervention is low, adaptation of the intervention and/or more intensive implementation activities may be required to achieve the intended effects. Information on intervention uptake can also help to

interpret effects that are lower or higher than expected: an intervention that is not well used in practice may not achieve its full effectiveness. This provides an important reason for process evaluation in trials of health interventions.

Second, process evaluation can provide insight into how the intervention works: its *active components*. This covers the identification of intervention ingredients, mechanisms and consequences. The focus on interventions' active components may relate to theories from various scientific disciplines. Insight into the mechanisms and consequences of interventions can contribute to the accumulation of scientific knowledge in a field. It may also help to drop or reduce specific intervention components, which contribute little to desired outcomes or which have adverse effects.

Finally, process evaluation can identify or examine *determinants of intervention outcomes*, with topics ranging from target group characteristics to organizational, financial and cultural factors. This can contribute to further insights into the mechanisms of action of an intervention and help to assess the transferability of an intervention to other settings. In this context, process evaluation helps to assess the potential for sustainment and scale-up of an intervention as these are strongly dependent on contextual factors.

In summary, process evaluation of interventions as research on how, why and when interventions work in practice can serve various purposes:

- Provide interpretation for lower or higher than expected effects of an intervention
- Focus on active intervention components in future use, drop or reduce other components
- Identify non-anticipated, positive or negative consequences
- Contribute to scientific knowledge on mechanisms and consequences of interventions
- Assess potential for sustainment, scale-up and transferability of an intervention.

Following from these purposes, a range of research questions can be phrased, which can be broadly categorized into three domains: a) uptake of interventions, b) interventions' active components, and c) determinants of intervention outcomes (see Box 1.1). Figure 1 integrates the various aspects of evaluation research, which apply to health interventions, implementation strategies and other intervention. Outcome and economic evaluation assesses changes in health and/or behaviours, adverse effects and costs. Process evaluations assesses, firstly, aspects of the uptake of interventions: reach, fidelity, adaptation, and user experience. This provides descriptive information, which is essential for the interpretation of intervention outcomes and further results of process evaluation. Secondly, process evaluation broadly explores the processes between intervention uptake and outcomes,

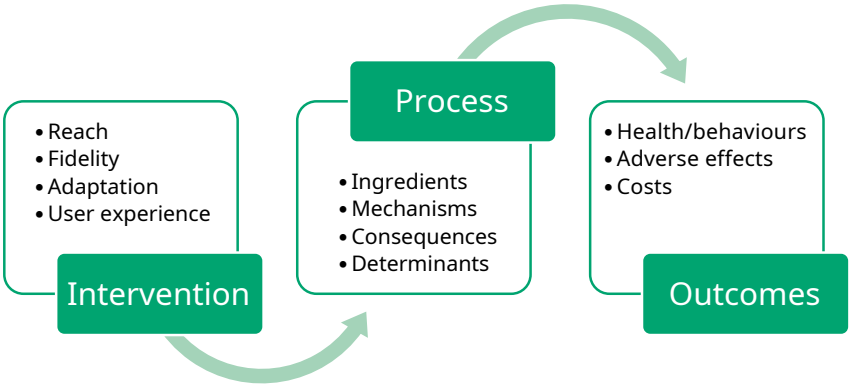

Figure 1.1 Relations between intervention, process and outcomes

covering interventions' active components: ingredients, mechanisms and consequences of interventions. Finally, process evaluation covers studies of determinants of outcomes.

Box 1.1 Research Questions in Process Evaluation

Uptake of interventions and user experiences
- Has the intervention been delivered as planned?
- Have the targeted individuals been exposed to the intervention?
- Has the intervention been adapted during use?
- What are the intervention users' experiences?

Interventions' active components
- What are the interventions' ingredients, which are assumed to result in change?
- What are the assumed intervention mechanisms, which are supposed change targeted outcomes?
- What are the observed intervention mechanisms?
- What are the non-anticipated consequences of the intervention, positive or negative?

Determinants of intervention outcomes
- Which factors are changed by the intervention and thus act as mediators in the pathway of intervention to outcomes?
- Which other factors are involved in this pathway as moderators of change?
- Which factors are relevant for the transferability of the intervention to other settings?

Process evaluation may concern a health intervention and/or an implementation strategy. It is important to distinguish the two, as they differ in how process evaluation plays out. A particular study can address both types of interventions: it then includes two process evaluations.

This can best be illustrated with an example: Within a hypothetical study a structured counselling on health-related lifestyle in patients (health intervention) is implemented by a communication skills training program of healthcare professionals (implementation strategy) (see Box 1.2): Looking at the health intervention "structured counselling", it assumes that a structured counselling method with specific features improves patients' lifestyles, such as physical exercise and diet (intervention theory). Intervention fidelity is assessed in terms of the proportion of eligible patients who receive structured counselling as designed. Potential mechanisms of effects concern time for counselling (more results in higher effects) and follow-up after counselling (more effects if present). A non-anticipated consequence may be an increased sense of professional identity among nurses, if they deliver the counselling and this implies a broader set of tasks. Several contextual factors influence the effects of the counselling intervention, including duration of consultations, presence of rooms for counselling by practice assistants or nurses, and reimbursement for counselling sessions.

Looking at the implementation strategy "communication skills training", a process evaluation study of the communication skills training for healthcare providers has a different profile. The intervention theory is that training with a number of features results in better counselling skills. Intervention fidelity is assessed in terms of the proportion of eligible healthcare providers who receive training as planned. A potential intervention mechanism is that role play with feedback enhances the increase of counselling skills. A non-anticipated consequence may be an increased sense of engagement with health-related lifestyles among healthcare providers. Several contextual factors influence the impact of the communication skills training, including accreditation of the training program, integration in a routine continuing education program, and planning of training outside regular consultation hours.

Concluding, it is recommended to distinguish between health interventions and implementation strategies in process evaluation research.

Box 1.2 Comparison of process evaluations of health intervention and implementation strategy in a lifestyle counselling intervention in primary care

Aspects of process evaluation:	Health intervention: Structured counselling on health-related lifestyles for patients	Implementation strategy: Communication skills training for healthcare providers
Intervention uptake	Proportion of eligible patients who receive structured counselling as designed.	Proportion of eligible primary care professionals who receive training as planned
Intervention ingredients and mechanisms	More time for counselling results in higher effects. Follow-up consultations increase effects.	Role play with feedback is essential for increasing counselling skills.
Non-anticipated consequences	Counselling by nurses enhances their professional identity	Healthcare professionals feel more engaged with patients' health-related lifestyles
Determinants of intervention outcomes	Duration of standard consultations; presence of rooms for counselling by practice assistants or nurses; reimbursement for counselling sessions.	Accreditation of the training program; integration in a routine continuing education program; planning of training outside regular consultation hours.

1.3 Outcome Evaluation in Relation to Process Evaluation

A process evaluation can be linked to a randomized trial or other outcome evaluation study, but it may also be a stand-alone research enterprise. Insight into intervention processes is most informative, if it can be related to known intervention outcomes. For instance, a moderate uptake of specific components of a planned intervention may explain its lowered effectiveness (if this was found) or have little relevance (if the intervention proved to be effective anyway). If the actual effectiveness is unknown, it is difficult to make sense of the observed moderate uptake of the intervention component. This does not imply that both outcomes and processes need to be measured in any single study. It may be possible to use results of previous outcome evaluations (or a systematic review of available evaluation research) for interpretation of a specific process evaluation.

The primary outcomes of health interventions are typically health-related, e.g., disease severity, health-related quality of life, and mortality. In addition, healthcare utilization and other aspects of resource use may be measured. The outcomes of implementation strategies (and other interventions on healthcare practice) are multi-folded and often include aspects of healthcare delivery (e.g., adherence to clinical guidelines) and experiences of targeted

individuals (e.g., patient experience in healthcare). Ideally, the outcomes can be organized in a chronological, potentially causal chain, for instance: changes in healthcare organisation and healthcare delivery lead to changes in people's health or other outcomes. Whether a specific factor is considered an outcome or a process, is to some extent a matter of perspective. In other words, a specific process evaluation study may focus on processes (e.g., adherence to clinical guidelines), that are considered outcomes in a different study (e.g., a trial of a program to implement the clinical guidelines).

A hypothetical (yet realistic) example demonstrates these different perspectives. Integrated care models for diabetes can be considered interventions on healthcare practice. They contain multiple components, such as a structured flow of clinical activities, multi-professional teamwork, support of patients' self-management, and optimal use of information sources. Anticipated outcomes include improved health of diabetes patients (e.g., better Hb1ac values) as well as reduced healthcare costs. Process evaluation would consider any process around application of various components of the integrated care models. Integrated care models can also be considered more narrowly as implementation strategies, which enhance the uptake of evidence-based clinical interventions that ultimately result in improved health outcomes. These clinical interventions include both medication and counselling on health-related life styles. In this context, uptake of these clinical interventions is the primary outcome of interest in an outcome evaluation and process evaluation would focus on processes that lead to uptake of recommended practices by health professionals. Health outcomes are not of interest in this context, or only as secondary outcomes.

The example above demonstrates that a given study may be designed in different ways: with a focus on health outcomes or with a focus on health providers' behaviours. Some studies have multiple aims: they assess both clinical effectiveness and implementation outcomes. These so-called hybrid implementation-effectiveness designs (Curran et al., 2012) have gained popularity in recent years, particularly among clinical trialists, but they also bring challenges. In particular, a bottle neck is the control arm: an implementation trial would require that the interventions of interest are available in the control arm, while a clinical trial usually has a control arm in which the interventions of interest are absent. In addition, assessment of implementation strategies requires a reasonably large sample of healthcare providers and a lower degree of control on the delivery of clinical and prevention interventions, as this reflects routine practice rather than a research laboratory.

1.4 Addressing Complexity of Healthcare

Calls for process evaluation have been linked to an awareness that healthcare is complex: health care has many structures and actors, which behave in ways that are difficult to predict (Livingood et al., 2011). Most interventions have multiple components, which influence each other. The effect of a specific treatment in an individual patient is often difficult to predict, even if it has shown beneficial effects in populations of similar patients. For instance, higher co-payments for patients tend to reduce healthcare utilization for both effective and non-effective treatments, which makes it hard to predict the overall impact on population health. Complexity may also relate to the difficulty of behaviours targeted by interventions, the number of organisational levels targeted, and the range of objectives. Complexity implies that processes may be non-linear (e.g., exponential), stochastic (i.e. there is random fluctuation), and recursive (e.g., causes can over time be affected by their consequences). There are major differences regarding the extent that processes are measurable, studied and understood across different domains of scientific research. In healthcare delivery, the complexity approach is often conceptual, but examples of quantitative modelling exist (e.g., mathematical models to predict utilization of intensive care units during the Covid-pandemic). It is, as yet, uncertain whether health interventions that were informed by a complexity perspective are more effective than other types of interventions (Brainard & Hunter, 2016).

Nevertheless, the complexity perspective reinforces the relevance of process evaluation, because it emphasizes the study of processes of change, adaptation of interventions during delivery, the possibility of non-anticipated effects, and the role of context on the implementation and effectiveness of an intervention. The complexity perspective also points to the possibility that interventions are not developed in a linear way, but in a cyclical process that involves repetition of earlier steps. The complexity approach has influenced prevailing guidance on process evaluation. The Medical Research Council (MRC) in the United Kingdom provided leading guidance on the evaluation of complex interventions in healthcare (Skivington et al., 2021). This emphasizes the role of process evaluation in addition to systematic intervention development and rigorous evaluation of intervention outcomes. The underlying perspective is that the development of intervention theory, refinement of interventions, and attention for context are considered essential in research on interventions. The guidance focuses on complex interventions, which have multiple components which interact to produce change (this covers most interventions in healthcare).

1.5 About this Book

This book focuses on the concepts and methods for process evaluation of interventions in healthcare, particularly health interventions and implementation strategies. This book relates to the final stages of the evaluation of health interventions (e.g., pragmatic clinical and public health trials), as well the evaluation of implementation strategies in healthcare settings. This implies a focus on routine healthcare delivery, so the topic can be situated within health services research. The focus on real-world practice also points to the behavioural and social sciences for concepts and methods.

There is a range of study types, which are close to and somewhat overlapping with process evaluation, which are not the primary topic of this book. *Program evaluation* is a broad concept of evaluation in applied social research, which covers outcomes, processes and costs (the word 'program' may be understood as 'intervention') (Rossi & Freeman, 1993). *Intervention development* may include research activities, such as pilots with interviews of users, which are also used in many process evaluation studies. However, the development of the intervention rather than its use and functioning in practice is of primary interest. Finally, this book is not about *implementation research* broadly. Implementation research covers a variety of studies, most particularly cluster randomized trials and other studies of the effectiveness of implementation strategies. Process evaluation of implementation strategies is among the study types and will be covered in this book.

When in comes to evaluation of complex interventions in health care, the UK Medical Research Council has provided guidance that is widely used. This guidance applies to evaluation of a wide range of interventions in health and points to the complexity of interventions and context in which these are applied. Why did we then write this book? One reason is that the UK Medical Research Council guidance does not explicitly consider implementation strategies, except as a final activity in evaluation research. In addition, it emphasises qualitative methods and realist evaluation for process evaluation, while we discuss a broader range of methods. Box 1.3 compares the book with the guidance of the UK Medical Research Council.

Box 1.3 Assessment of this book in relation to prevailing guidance, such as the UK Medical Research Council guidance on complex interventions (Moore et al., 2014; Skivington et al., 2021)

	Prevailing guidance	This book
Scope	Design and evaluation of complex interventions, covering design, pilot research, process and outcome evaluation, and implementation	Process evaluation of interventions in healthcare
Interventions of interest	All interventions in healthcare	Mainly health interventions and implementation strategies
Perspective	Points to complexity of interventions and role of context/systems	Points to complexity of interventions and role of context/systems
Phases	Specifies phases, not necessarily sequentially ordered	Allows for phases, not necessarily sequentially ordered
Predominant theories	Emphasizes theorizing, particularly in relation to complex systems	Emphasizes theorizing, not restricted to one particular theory
Methodology of process evaluation	Emphasis on realist evaluation, which leans toward qualitative research methods	Covers a range of qualitative and quantitative research methods, and discusses embedded research models
Knowledge transfer	Final phase of a research program (described as 'implementation')	Reporting and involvement of interest-holders in process evaluation research is considered

With this book we intend to provide an overview and guidance for students of process evaluation. It can be used in teaching programs and for self-study. Chapter 2 considers intervention uptake, covering reach, fidelity, adaptation and user experiences. Chapter 3 turns to interventions' active components, covering ingredients, mechanisms and consequences, including non-anticipated pathways and consequences. Chapter 4 focuses on the determinants of intervention outcomes, as well as the transferability of interventions across settings and populations. Chapter 5 elaborates on the design and methods of process evaluation studies, as well as reporting and involvement of interest-holders. The chapters complement each other and are therefore best read (or at last glance through) in the given order.

Starting with this chapter, throughout the book, we use case studies to demonstrate concepts and methods of process evaluation in some detail. In addition, we introduce two case studies – concerning a communication intervention in lung cancer care (MCA) and rational prescribing of antibiotics in ambulatory (ARena) (references of main publications are below) – to exemplify how process evaluation are applied in practice. The projects were chosen because they were comprehensive, have been well published, and

accessible as one the authors of this book had been involved. Both case studies were conducted at the Department of General Practice and Health Services Research at Heidelberg University. For educational purposes, self-test questions are provided at the end of each chapter.

Special thanks goes to our colleagues Katja Krug and Regina Poß-Doering who (more than once) answered our questions about the two projects MCA and ARena and thus also provided an insight behind the scenes of the research projects. Another big thanks goes to our research assistants Lea Hoffmann and Elisa Köhler for critical feedback, proof reading and checking the literature references. Last but not least we like to thank Heidelberg University Publishing for their competent and open support of this project. We did not use KI-based tools for writing or revising this book.

Q & A Case Studies: Introduction

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

Q: *Which problem was addressed in the study?*
A: Patients with advanced cancer face various challenges during the disease trajectory. Communication with patients is often not well planned and not adapted to the patient's information needs, which results in the experience that important topics are not timely addressed, too much or too little information is given too early or too late.

Q: *When was this project? Who conducted it? And how was it financed?*
A: The project was conducted between 2017 and 2020 at the Thoraxklinik in Heidelberg, in cooperation with the Department of General Practice and Health Services Research at Heidelberg University Hospital and the Institute of Medical and Pharmaceutical Proficiency Assessment in Mainz. The study was funded by the Federal Ministry of Health in Germany.

Q: *What was the goal of the project?*
A: The Milestones Communication Approach (MCA) for patients with lung cancer with limited prognosis aims to foster patient-centred communication with shared decision-making and facilitation of advance care planning, thus increasing patient quality of life and decreasing aggressive medical care at the end of life. To achieve this goal, physicians and nurses received a communication training, which addressed milestones

of the disease trajectory: diagnosis, stable phase, progression, and transition to best supportive care. Physicians and nurses conducted the milestone communication with patients and their caregivers as an interprofessional tandem to provide coherent care across the disease trajectory. It was assumed that the communication skills training and interprofessional coaching will improve the communication behaviour of healthcare providers and influence team communications and team processes. The communication concept was described in a manual, which also guided the training on MCA of physicians and nurses.

Q: *What was the design of the outcome evaluation?*
A: A randomized trial was conducted with questionnaire-based measurements at baseline and at 3, 6, and 9 months in outpatients with newly diagnosed lung cancer stage IV at a German hospital (Krug et al., 2021). A sample size of n=82 patients was planned to detect a meaningful effect on the primary outcome at 3-month follow-up. The primary outcome concerned patient reported need for information on healthcare, using a validated questionnaire. Secondary outcomes included measures of quality of life, functional status, depression, anxiety, and distress.

Q: *What were its main findings?*
A: At baseline, 174 patients were randomized, of whom 102 patients (MCA: n = 52; standard care: n = 50) provided data at 3-month follow-up. At this point in time, patients of the MCA reported lower information needs ($p = 0.03$). No effects were found for secondary outcomes. In conclusion, MCA lowered patient-reported information needs (=the primary outcome), but did not have other observable effects on patients.

Q: *When was the process evaluation planned, and how did it look like?*
A: The study included a process evaluation, which was planned as an explicit part of the study right from the beginning. It aimed to document and explore intervention fidelity, potential intervention mechanisms, and contextual factors associated with impact. Data for the process evaluation were collected through interviews and surveys among healthcare providers, and extraction of data from patient records.

Q: *What was the impact of the project on healthcare practice?*
A: The results of the MCA project provided the basis for a contract with the main health insurer to arrange reimbursement for the additional services (“Selektivvertrag”). However, the MCA approach did not spread to other hospitals, despite efforts to achieve this. The process evaluation in the MCA project did not play an explicit role in achieving impact, but

it supported the argument that interprofessional care was strengthened. Although communication with the interprofessional tandem was appreciated by the patients, they struggled with prognostic information and advanced care planning. Healthcare providers need to balance the duty of providing information and the patient's wish of not knowing.

Q: *How would you describe the study in one sentence?*
A: A project that implemented a structured and interprofessional approach to communication in one hospital, which improved cancer patients' experience with care.

Case Study 1: Main Publications

Bossert, J., Forstner, J., Villalobos, M., Siegle, A., Jung, C., Deis, N., Thomas, M., Wensing, M., & Krug, K. (2020). What patients with lung cancer with comorbidity tell us about interprofessional collaborative care across healthcare sectors: qualitative interview study. *BMJ open*, *10*(8), e036495. https://doi.org/10.1136/bmjopen-2019-036495

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

Q: *What problem was addressed in the study?*
A: Antibiotics are an important treatment option for bacterial infections. Unnecessary prescribing should be avoided whenever possible to prevent the development of resistance among micro-organisms which enables weakening or completely neutralizes the effect of antibiotics. An important cause of resistance development is uncritical prescribing.

Q: *When was this project? Who conducted it? And how was it financed?*
A: The project was conducted between 2017 and 2020 by a consortium that involved practice networks from Bavaria and North Rhine-Westphalia, public health insurers, and research institutes (including the Department of General Practice and Health Services Research at Heidelberg University Hospital). It was funded by the Federal Joint Committee Innovation Fund (Innovationsfonds Gemeinsamer Bundesausschuss G-BA; funding code 01NVF16008) in Germany.

Q: *What was the goal of the project?*
A: ARena is a comprehensive quality improvement program that aimed to enhance rational prescribing of antibiotics in ambulatory care in Germany (Kamradt et al., 2018). Its aim was to optimise the appropriate use of antibiotics in patients with acute non-complicated infections (respiratory tract infections, such as bronchitis, sinusitis, tonsillitis and otitis media), community-acquired pneumonia and non-complicated cystitis, in order to counter the advancing antimicrobial resistance development. In practice, this means that the aim was to reduce the number of unnecessary antibiotics prescriptions and thus implement recommendations of prevailing clinical guidelines.

Q: *What was the design of the outcome evaluation?*
A: ARena was conducted as a three-armed cluster randomised trial in 14 primary care networks in two German federal states with 196 practices (Poss-Doering et al., 2021). The outcome evaluation was based on claims data of health insurers and referred to established performance indicators. Each arm received a slightly different set of implementation strategies. Arm A received a standard set, comprising of e-learning on communication with patients and quality circles with data-based feedback for physicians, information campaigns for the public, patient information material and performance-based additional reimbursement. Arm B received this standard set plus e-learning on communication with patients and quality circles with data-based feedback tailored for non-physician health professionals of the practice team and information material for tablet computers. Arm C received the standard set as well as a computerised decision support system and quality circles in local multidisciplinary groups. Primary and secondary outcomes related to prescribing of antibiotics and were analysed in multivariate regression models.

Q: *What were the main findings?*
A: Significantly lower prescribing rates were observed for all study arms (20.1 %, 18.9 % and 23.6 %) compared to matched standard care (29.4 %).

No difference between intervention arms was detected. An observational comparison suggested improvement in all arms compared to usual care outside the trial.

Q: *When was the process evaluation planned, and how did it look like?*
A:The ARena process evaluation was included in the original project plan. It was based on repeated interviews and large-scale surveys among the participating healthcare providers and accompanied the trial.

Q: *What was the impact of the project on healthcare practice?*
A: The ARena project did not have a direct follow-up project, but its components may be integrated in subsequent projects of the involved practice networks. The funder actually recommended a transfer into standard care and asked associations of Statutory Health Insurance Physicians for comprehensive statements regarding a potential implementation of approaches used in ARena in contractual agreements and quality improvement measures. Institutional stakeholders were asked to provide statements regarding an integration of the educational material used in ARena in further educational campaigns for the general public and ambulatory healthcare workforce.

Q: *How would you describe the study in one sentence?*
A: A project that applied a comprehensive quality improvement program in primary care practices, which seemed associated with lowered rates of unnecessary antibiotics prescribing.

Case Study 2: Main Publications

Kamradt, M., Kaufmann-Kolle, P., Andres, E., Brand, T., Klingenberg, A., Glassen, K., Poß-Doering, R., Uhlmann, L., Hees, K., Weber, D., Gutscher, A., Wambach, V., Szecsenyi, J., & Wensing, M. (2018). Sustainable reduction of antibiotic-induced antimicrobial resistance (ARena) in German ambulatory care: study protocol of a cluster randomised trial. *Implementation science: IS*, *13*(1), 23. https://doi.org/10.1186/s13012-018-0722-0

Poss-Doering, R., Kamradt, M., Glassen, K., Andres, E., Kaufmann-Kolle, P., & Wensing, M. (2020). Promoting rational antibiotic prescribing for non-complicated infections: understanding social influence in primary care networks in Germany. *BMC family practice*, *21*(1), 51. https://doi.org/10.1186/s12875-020-01119-8

Poss-Doering, R., Kamradt, M., Stuermlinger, A., Glassen, K., Kaufmann-Kolle, P., Andres, E., & Wensing, M. (2020). The complex phenomenon of dysrational antibiotics prescribing decisions in German primary healthcare: a qualitative interview study using dual process theory. *Antimicrobial resistance and infection control*, *9*(1), 6. https://doi.org/10.1186/s13756-019-0664-6

Poss-Doering, R., Kühn, L., Kamradt, M., Stürmlinger, A., Glassen, K., Andres, E., Kaufmann-Kolle, P., Wambach, V., Bader, L., Szecsenyi, J., & Wensing, M. (2020). Fostering Appropriate Antibiotic Use in a Complex Intervention: Mixed-Methods Process Evaluation Alongside the Cluster-Randomized Trial ARena. *Antibiotics (Basel, Switzerland)*, *9*(12), 878. https://doi.org/10.3390/antibiotics9120878

Poss-Doering, R., Kronsteiner, D., Kamradt, M., Kaufmann-Kolle, P., Andres, E., Wambach, V., Bleek, J., Wensing, M., ARena-Study Group, & Szecsenyi, J. (2021). Assessing Reduction of Antibiotic Prescribing for Acute, Non-Complicated Infections in Primary Care in Germany: Multi-Step Outcome Evaluation in the Cluster-Randomized Trial ARena. *Antibiotics (Basel, Switzerland)*, *10*(10), 1151. https://doi.org/10.3390/antibiotics10101151

Poss-Doering, R., Kronsteiner, D., Kamradt, M., Andres, E., Kaufmann-Kolle, P., Wensing, M., ARena-study group, & Szecsenyi, J. (2021). Antibiotic prescribing for acute, non-complicated infections in primary care in Germany: baseline assessment in the cluster randomized trial ARena. *BMC infectious diseases*, *21*(1), 877. https://doi.org/10.1186/s12879-021-06571-0

Queder, A., Arnold, C., Wensing, M., & Poß-Doering, R. (2022). Contextual factors influencing physicians' perception of antibiotic prescribing in primary care in Germany – a prospective observational study. *BMC health services research*, *22*(1), 331. https://doi.org/10.1186/s12913-022-07701-3

Kühn, L., Kronsteiner, D., Kaufmann-Kolle, P., Andres, E., Szecsenyi, J., Wensing, M., & Poss-Doering, R. (2022). Implementation fidelity in a multifaceted program to foster rational antibiotics use in primary care: an observational study. *BMC medical research methodology*, *22*(1), 243. https://doi.org/10.1186/s12874-022-01725-3

Self-test Questions

1) In what ways do outcome, economic and process evaluation relate to each other, and what are the differences?

2) Consider which of the following interventions are health interventions, and which are implementation strategies or related interventions:
   a) a structured counselling intervention to enhance patients' self-management in coping with chronic disease
   b) a reorganisation of an ambulatory practice to meet the requirements for structured chronic care
   c) a financial incentives scheme, which rewards healthcare delivery that is consistent with evidence-based recommendations

3) Consider which of the following is typically covered by process evaluation: adverse events, intervention costs, intervention fidelity, working mechanisms, user experiences, contextual influences, non-anticipated consequences?

4) Why are the following theoretical perspectives aligned with process evaluation of interventions: evidence-based practice, pragmatism, complex systems?

2 Uptake of Interventions

Synopsis

Process evaluation examines the uptake of a planned intervention in terms of the reach in the targeted population, the fidelity and the adaptation of the interventions of interest. *Intervention reach* primarily addresses the degree that a targeted population is exposed to an intervention. *Intervention fidelity* indicates the degree that a planned intervention is delivered and used as planned. *Adaptations* are changes that occur after intervention delivery, which may be made by the users of the intervention. Finally, the experiences of users with the intervention regarding perceived value, emotional response, and feasibility can be assessed.

2.1 Introduction

An important (and sometimes the only) component of process evaluation is an assessment of the uptake of planned interventions: the degree that interventions are actually applied as planned in practice. Insight into intervention uptake helps to interpret interventions' outcomes and may point to ways for improving the intervention itself. Assessment of the uptake of interventions should be included in all process evaluation, because it provides descriptive data that is essential for interpretation of intervention outcomes and further process evaluation findings. The measurement of the uptake of interventions is often straightforward and based on structured questionnaires, self-registration forms, or extraction of data from computer systems. Few standardized measures have been developed for intervention uptake, so new measures have to be developed in most cases, linked to the interventions of interest. This chapter will focus on conceptual aspects of research on the uptake of interventions.

This chapter will elaborate on the uptake of interventions in practice, covering reach in the targeted population (2.2), fidelity of intervention delivery (2.3), adaptations of the intervention (2.4), and user experiences (2.5) in both, health interventions and implementation strategies.

Box 2.1 provides a summary of these central aspects of process evaluation as they apply to health interventions and implementation strategies. The remaining of the chapter will elaborate on these aspects.

Box 2.1 Uptake of health interventions and implementation strategies

Aspects of uptake	Health interventions	Implementation strategies
Reach	Proportion of targeted individuals who are actually exposed to the intervention	Proportion of targeted healthcare providers who are actually exposed to the intervention
Fidelity	Degree that the intervention is delivered and used as planned by patients and populations	Degree that the strategy is delivered and used as planned by healthcare professionals and organisations
Adaptation	Changes in the health intervention during its use	Changes in the implementation strategy during its use
User experiences	Patients' or individuals' experiences with the health intervention	Healthcare professionals' and other users' experiences with the implementation strategy

2.2 Intervention Reach

Interventions are targeted at a specific population (patients, healthcare professionals, or others), so the extent that they actually reach this population is a relevant factor that contributes to the interventions' overall impact. Intervention reach can be conceptualized in terms of exposure to and/or awareness of the intervention of interest, actual start of its use. For instance, the reach of a health app on smartphones may be: a) the targeted population is *exposed* to the app, i.e. it can be downloaded, b) the targeted population is *aware* of the app, i.e., its existence is known, c) the targeted population has started to *use* the app, i.e. it has been downloaded and installed. With respect to interventions' effectiveness, it is probably most relevant whether the targeted population has been exposed to the intervention. This matches with the intention to treat principle, which is common in outcome evaluation research. Actual use of an intervention is better captured as aspect of intervention fidelity, which is elaborated below (section 2.3).

For adequate operationalisation of intervention reach, the targeted population needs to be defined in order to determine a proportion that is reached. However, the total number of eligible individuals (within a given time window) may be unknown or uncertain. For instance, the number of eligible patients may be high in a providers' administrative database, but lower among actual visitors of a healthcare provider. Exclusion of individuals for use of an intervention (e.g., patients' co-morbidities, language or digital skills) can further reduce the effective population. It is often informative to calculate both a gross and net reach, considering a theoretical (large) targeted population and a realistic (smaller) population in routine practice.

Box 2.2 provides an example that demonstrates the challenges in the assessment of intervention reach.

Box 2.2 Reach within a physical exercise program in oncology (Blütgen et al., 2025)

Physical exercise can reduce symptoms in cancer patients. The Move-Onko project aims to connect cancer patients to available evidence-based physical exercise interventions in patients who receive treatment for cancer. To achieve this, a clinical pathway that points patients to exercise interventions was defined, supported by a computerized information system, and exercise oncology guides were appointed. The primary aim of the project implies a focus on reach of eligible patients, but identification of the targeted population proved to be challenging. Net reach in the project is influenced by resource constraints: combination of available staff (hours) and time for recruitment and counselling. Therefore, several approaches were planned: a) extraction of numbers from administrative systems regarding numbers of patients in the participating hospital departments (to calculate gross reach), b) documentation of the number of eligible patients who could be approached by the exercise oncology guides for information on physical exercise interventions, given the available staff time for recruitment of patients (to calculate net reach).

Some authors have conceptualized intervention research more narrowly. In the Reach-Effectiveness-Adoption-Implementation-Maintenance (RE-AIM) framework, a widely used framework for classifications of outcomes in public health research (Glasgow et al., 2019), reach refers to patients or populations only. In this book, we propose to apply reach to healthcare providers as well. In studies of the implementation of practices, they may be the primary population to reach.

In some studies, reach in a targeted population is the primary outcome of interest (i.e. how many individuals were offered vaccination). Intervention reach is similar to penetration of an innovation in a targeted population, which has also been conceptualized as an implementation outcome (Damschroder, Reardon, Opra Widerquist, & Lowery, 2022; Proctor et al., 2011). Regardless of the conceptualisation, intervention reach is a precondition for impact as it is a logical step in the causal chain that leads to changes in the targeted outcomes.

2.3 Intervention Fidelity

Intervention fidelity is the degree that an intervention is delivered and adopted as planned in practice. This definition applies to health interventions as well as to implementation strategies. In the context of clinical trials, it has also been described as intervention integrity. Intervention fidelity is an observable degree of use of intervention components, which may be categorized (e.g.: full, partial, little use) or measured on a continuous scale (e.g., percentage of attended sessions). For instance, intervention fidelity may refer to the use of medication as prescribed (in terms of dose and time of intake) in a clinical trial. Thus, intervention fidelity differs from user experience, acceptance, attractiveness, feasibility, satisfaction, intended use, and other constructs that express subjective assessments. Intervention fidelity concerns observable behaviours rather than cognitions. Intervention fidelity can be documented for each user of an intervention, using questionnaires, self-registration forms or other measures (e.g., medication boxes that register that they are opened).

In the evaluation of health interventions, intervention fidelity is often subject of process evaluation since the outcome evaluation primarily focuses on health outcomes. In contrast, when evaluating implementation strategies, the fidelity of the intended health intervention is often the primary outcome, while health outcomes are of secondary interest. In this context, process evaluation primarily relates to the fidelity of implementation strategies in practice. So, the fidelity of health interventions and implementation strategies in practice can be differently positioned in evaluation studies, depending on the focus in these studies.

Reach of an intervention might be considered as one aspect of its fidelity, but for conceptual clarity intervention fidelity is better defined in terms of use of an intervention by individuals who were actually reached. For instance, a structured diabetes program might reach 80 % of the targeted population and in this population, 90 % of recommended clinical procedures might be performed; thus, 72 % of all diabetes patients effectively receive recommended procedures. Lower intervention fidelity may be due to the fact that some intervention components are not used, partly used, or less intensively used than planned. It may also be due to adaptations of the intervention by users or delivers of the intervention (see section 2.4). In the RE-AIM framework, reach and maintenance may cover aspects of intervention fidelity by patients and populations, while the domains adoption and implementation are related to healthcare providers and others who deliver interventions (Glasgow et al., 2019). In this book, we argue that all domains of the RE-AIM may relate to patients/populations as well as to healthcare providers.

Approaches to the Measurement of Intervention Fidelity

Most interventions in healthcare are complex as they have multiple or many components, and are applied in natural settings with a high degree of complexity. For instance, medication is often accompanied by other interventions, such as counselling and monitoring, which makes medication a complex intervention. It is usually not feasible to document the fidelity of all intervention components comprehensively, so a selection of most relevant and best measurable components has to be made. In many cases, the number of intervention components in the assessment should not be too high (e.g., fewer than 15 items) to keep data-collection reasonably feasible. For some well-elaborated interventions, measures of intervention fidelity may be available or can be easily composed. These are usually questionnaires for healthcare providers or patients. Box 2.3 provides an example of the measurement of intervention fidelity, which used a validated questionnaire.

Box 2.3 Fidelity of community mental health teams (Roth et al., 2021)

> Community Mental Health Teams (CMHTs) deliver healthcare that supports the recovery of people with mental illness. A study explored to what extent team members of five CMHTs newly implemented in five countries perceived that they had introduced aspects of the recovery-oriented, strength-based approach into care. A quantitative survey was administered among 52 health professionals (21 nurses, 13 psychiatrists, 9 psychologists, 8 social workers) and 14 peer workers. The questionnaire included various standardised, validated measures. The study showed that all teams had the perception that they provide recovery-oriented practice to a moderately high degree after a training week on recovery-oriented care (mean scores between 3.85–4.46 on a five-point scale).

The development of tailored measures of intervention fidelity may be guided by frameworks, which provide broad domains or concepts that can guide the choice of specific measures. The framework in Box 2.4 is a brief set of domains, which are ideally described for any intervention. It was developed by a group of health researchers.

Box 2.4 Aims, Ingredients, Mechanism, Delivery (AIMD) framework (Bragge et al., 2017)

- **Aims**: specification of the aims or targeted outcomes of an intervention, which may be categorized in various ways (e.g., primary versus secondary, intermediate versus final)
- **Ingredients**: the active components of an intervention, usually in terms of observable activities or materials
- **Mechanisms**: ideas on how an intervention (and its ingredients) has effect on the targeted outcomes, which may comprise of proposed causal chains with intermediate and final outcomes
- **Delivery:** the way the intervention ingredients is delivered (e.g., education may be delivered in written format, in educational meetings, or as e-learning module).

It may be noted that the ingredients, mechanisms and delivery formats in AIMD are linked, while others cannot be combined (e.g., financial incentives cannot be delivered as educational materials).

Another source for orientation of measures of intervention fidelity evaluation are reporting guidelines for complex interventions. An example is the Template for Intervention Description and Replication (TIDieR) (Hoffmann et al., 2014) (Box 2.5). As compared to the AIMD framework, the TIDIER framework is more focused on practical detail of the intervention. Therefore, both frameworks complement each other very well.

Box 2.5 Template for Intervention Description and Replication (TIDIER) Checklist

The template aims to provide recommendations for a comprehensive description of an intervention. It covers the following aspects:

a) Why: rationale, theory or goal of the intervention
b) What: procedures and materials of the intervention
c) Who: individuals who delivered the intervention
d) How: modes of delivery
e) Where: locations of intervention delivery
f) When and how much: duration, number of times, and intensity of ntervention delivery
g) Tailoring: adaptation of the intervention to individual users
h) Modifications: adaptation of the intervention over the course of the study
i) How well: describe intervention fidelity

In studies with a control arm, that is not exposed to interventions of interest, intervention fidelity is usually only measured in the intervention arms. In this way, the control arms are not pointed to the intervention of interest, which helps to maintain the contrast between study arms. Nevertheless, it can be relevant to document what interventions were used in the control arm of a study. For instance, the control arm may receive 'usual care', which is often remains a 'black box' if there are no measurements in this study arm.

The assessment of intervention fidelity is often close to the documentation of resource use, which is an essential component of economic evaluation. For instance, the resources may include healthcare providers' time, rooms and materials that are used. However, it is uncommon to monetarize the documented resources in process evaluation: they remain expressed in natural units, such as number of meetings or hours spend.

2.4 Adaptation of Interventions

Adaptation of interventions (as compared to the planned or designed intervention) during its delivery and use in practice occur frequently. For instance, the format or duration of an educational program may be changed, the number of contacts with healthcare providers may be higher or lower than planned, and specific intervention components may be dropped. Adaptation may be done by intervention deliverers (e.g., teachers) as well as by the recipients (e.g., healthcare professionals). By definition, adaptation means lowered intervention fidelity. Changes in the intervention may be done across the board or by individual users, resulting in variation in the actual intervention across users. Adaptation is often done to facilitate the uptake of the intervention in practice, given the constraints of the setting in which it is applied. Adaptations to interventions can reduce their effectiveness, if they alter core components or disrupt key mechanisms of action. However, they can also increase the effectiveness, if the intervention is better matched to specific characteristics of the targeted population and setting. What is adapted, and how this plays out, is therefore an important topic of process evaluation and should thus be documented and analysed.

A framework for adaptation of interventions can be used to guide the research. Box 2.6 presents a widely used framework, which describes a range of ways that health interventions may be adapted to specific populations or settings. These domains are also relevant for adaptation of implementation strategies.

Box 2.6 Framework for types of adaptions in health interventions (Wiltsey Stirman et al., 2019)

1) when and how in the implementation process the modification was made,
2) whether the modification was planned/proactive (i.e., an adaptation) or unplanned/reactive,
3) who determined that the modification should be made,
4) what is modified,
5) at what level of delivery the modification is made,
6) type or nature of context or content-level modifications,
7) the extent to which the modification is fidelity-consistent,
8) the reasons for the modification, including (a) the intent or goal of the modification (e.g., to reduce costs) and (b) contextual factors that influenced the decision.

Box 2.7 Adaptation of an intervention to implement cardiovascular prevention (Huntink et al., 2016).

A comprehensive intervention program was developed and tested to implement recommendations for cardiovascular prevention in primary care practices. It included various components, such as training on counselling skills, e-learning program, information materials, and specific recommendations for patients with depressive symptoms. The choice of components was based on preceding research on the needs of primary care practices. The program was tested in a cluster randomized trial with 34 primary care practices. The process evaluation in the intervention arm (n=16 practices) showed that most intervention components were rarely used, because the participants perceived the package of interventions as a menu from which they could choose. Also, they indicated that they would have liked more practice support and reminders (although these interventions had not been mentioned in the preceding research on needs).

Adaptation of health interventions and implementation strategies is actually very common. A documented example is presented in Box 2.7. Interventions may also be adapted to the targeted individuals and setting *before* they are applied. This has frequently been described as tailoring rather than adaptation (Wensing, 2017), although the concepts “adaptation” and “tailoring” are not consistently used in the literature and may show overlap. Within this book, the concept ‘tailoring’ mostly refers to an activity during intervention development (before its delivery in practice) (see also Wensing, 2017).

Tailoring may be a component of the intervention theory, or underly the intervention theory. Tailoring implies that factors associated with intervention impact are identified, followed by procedures to link intervention components to the identified factors. It is often based on interviews or surveys in samples of the targeted individuals, which are methods that are also frequently used in process evaluations.

2.5 User Experiences

The assessment of fidelity and adaptation of an intervention may be combined with an assessment of user experiences. This may cover various aspects, such as: a) the perceived value of intervention components, e.g., acceptability and perceived benefit, b) the emotional response to intervention components, e.g., attractiveness and satisfaction, c) the perceived feasibility of intervention components in the setting of interest, e.g., resources required and match with prevailing practices. In addition, an overall assessment of the intervention may be done, which can provide a quick impression of the overall users' experiences with an intervention. In some cases, assessment of user experiences is the only topic of process evaluation. This may have value at an early stage of intervention design, but it does not fully realize the potential of process evaluation as outlined in this book. For instance, it does not cover intervention mechanisms, non-anticipated consequences, or determinants of intervention outcomes.

2.6 Conclusions

Concerning intervention uptake in both health intervention and implementation strategies, the documentation of reach, fidelity and adaptation of interventions is a central component of process evaluation. There are few standardized measures that can be taken of the shelf, because measures have to be tailored to a specific intervention. Documentation and analysis are often largely descriptive.

Q & A Case Studies: Uptake of Interventions

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

Q: *How was reach of the intervention achieved and, subsequently, evaluated?*
A: In the Milestones Communication Approach (MCA) project, the intervention of interest concerned guidance for clinical conversations. Each conversation was expected to involve a physician, a nurse, a patient and often also a patient's relative. As reported by the research team, a total of 483 patients were screened to include 171 patients (35 %). Initially, this screening was not systematically performed und unsuccessful, so a study nurse was involved to enhance the reach of the intervention. Patients dropped out for various reasons, including declination of participation, not in treatment at the hospital (but visiting for a second opinion), and no further treatment in the hospital. Some of these reasons might be considered ineligibility for the intervention, which would reduce the numbers in the targeted population and increase the percentage of intervention reach.

Q: *Was the MCA intervention recognized by participants in the study?*
A: Healthcare professionals who were part of the MCA tandems obviously knew the intervention. Interestingly, although healthcare professionals not directly involved in the intervention knew about the study in general, they were not aware of its specific aims and the intervention details. Therefore, the study was introduced and reported on in various team meetings at the Thoraxklinik, both in departments that were involved and that were not involved in the study. Thus, patients did not receive contradicting information about study and intervention from different sources within the clinic.

We cannot tell how far patients were aware of being part of an intervention. They knew they were part of a study since they had agreed to take part but maybe they did not know if they were part of the intervention or the control group. For them, the intervention may have felt like standard care, although they especially praised the care by the tandem which was an integral part of the intervention.

Q: *How was intervention fidelity assessed?*
A: A prospective observational process evaluation study was conducted to document the fidelity of the MCA in conducted clinical conversations.

The source of data was written records of the conversations, which are part of the routine documentation during conversations and follow-up calls. Adherence to key aspects of the manual was documented on structured checklists during the training period at the beginning of the implementation of the MCA (t1) and after 6 months (t2). All conversations during those two chosen time periods were included. Differences between the two assessment periods were analysed with chi-square tests. A total of 133 conversations (with 54 follow-up calls) at t1 and 172 conversations (with 92 follow-up) at t2 were analysed. The recommended topics were not identified in all documented conversations. For instance, advance care planning was discussed in 26 % of conversations at t1 and 13 % of conversations at t2. For the topic 'prognostic awareness', these figures were 31 % and 47 %. Nevertheless, the uptake of recommended topics was considered substantial, given the novelty of the MCA. The figures need to be considered with a view on methodological limitations, particularly the possibility that topics were discussed yet not documented.

Q: *What do you think of this methodological approach? Would you do something differently the next time?*
A: The documentation of the clinical conversations was not explicitly introduced for the MCA study but part of standard routine. New was the documentation by the MCA nurses in the patient files. Especially at the beginning of the study, physicians and nurses had to find a "common language" for the documentation, so that both regularities for documentation were fulfilled but also the team work enhanced by providing a common knowledge base in the patient files. To assess intervention fidelity in more detail, a documentation system for study purposes would have been needed which would have led to higher workload for the participating healthcare professionals. Conversations could also have been recorded and analysed which would have led to more than 300 recordings, which is both unfeasible and highly prone to the Hawthorne effect since they are acutely aware of their being observed. With these arguments in mind, the analyses of the documentation as it was conducted within this study was probably the most pragmatic approach but could have been supplemented by focussed interviews with healthcare professionals and patients.

Q: *Concerning intervention uptake, what can be learned from these findings?*
A: The program led to a big step towards the aspired communication practices, but it was probably naïve to think that it would be directly fully adopted.

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

Q: *How was reach of the intervention reach achieved and, subsequently, evaluated?*
A: In the ARena project, the intervention comprised of a package of quality improvement strategies for primary care practices. The targeted population of practices was given as they were all participants in 14 organized practice networks. They were all exposed to the planned strategies.

Q: *Was the quality improvement intervention recognized by the study participants?*
A: We do not have data on this, but the participating healthcare professionals were probably aware of the intervention. On the other hand, patients probably did not recognize the intervention.

Q: *How was intervention fidelity assessed?*
A: In a prospective process evaluation conducted alongside the delivery of these strategies, the fidelity of the program was documented. This study was based on data generated in a three-wave survey of 312 participating physicians and on documentation of their attendance to the planned sessions. Measures concerned persistence of participation in the program and adherence to intervention components (thematic quality circles, e-learning, basic expenditure reimbursements, additional bonus payments and a computerized decision support system). Participants' views on five domains of the program were also measured. Regression analyses were used to explore which views on the implementation were associated with participants' adherence to quality circles and use of additional bonus compensation. The analysis of fidelity showed overall high persistence of participation in the intervention components across the three intervention arms (90 % to 97 %), but practices did not use all strategies at all times. For instance, 56 % of physicians attended the maximum of four quality circles. Participants' views on participant responsiveness, context and culture of shared decision-making were associated with attendance of the planned quality circle sessions. Of all eligible practices, 84 % used the available performance-based additional bonus payment; they used it for 52 % of eligible patients. Participants' views regarding participant responsiveness and context were associated with use of bonus payment.

Q: *What do you think of this methodological approach? Would you do something differently the next time?*
A: With a profound theoretical conception, this methodological approach strengthened the appraisal of intervention fidelity and feasibility in the ARena program. It also facilitated quantifying of influences of participant views with intervention engagement. Combining attendance and survey data served data triangulation and ensured a holistic view on fidelity regarding core components.

Insights into favorable dosages of intervention components could not be provided since the initially intended matching with data of the primary outcome analysis on practice level was not possible due to German data protection law. Since no qualitative data was integrated in this approach, not all results could be explained in depth. Reasons for the level of bonus size achievements were not explored.

Q: *Concerning intervention uptake, what can be learned from these findings?*
A: Not all strategies for improving practice may be used by the targeted individuals. It remains unclear whether this reduces the effectiveness of the quality improvement interventions.

Self-test Questions

1) What is the difference between intervention fidelity and user experiences with an intervention?

2) What is the relation between fidelity and adaptations of interventions?

3) In a study, patients receiving cancer treatment are advised to attend a physical exercise program, as it can help reduce symptoms (see also Box 2.2). What would you measure to assess reach in this study?
   a) patients who received advice of all eligible patients attending targeted hospitals
   b) patients who received advice of all eligible patients, given available staff time for advice
   c) patients who attend physical exercise programs of all cancer patients attending targeted hospitals
   d) patients who attend physical exercise programs of all cancer patients who received advice

4) What aspects of user experience with an intervention may be examined?

5) Define some aspects of intervention fidelity/adaptation for the following interventions:
   a) a program that uses facilitators who visit ambulatory practices to support the implementation preventive activities in defined cohorts of patients
   b) a program that arranges direct access to physiotherapists (with reimbursement by health insurers) in a healthcare system (as an alternative to referral by physicians)

3 Interventions' Active Components

Synopsis

An important role of process evaluation is to explore how interventions work. Specification and assessment of the ingredients, mechanisms and consequences of interventions is essential in this respect. In this context, it is helpful to specify *intervention theory,* which may build on broader scientific theories on change in individuals and populations. The identification of intervention ingredients, mechanisms and consequences often builds on theoretical analysis of the planned intervention as well as qualitative interviews with intervention developers, deliverers and recipients. As many health interventions and implementation strategies aim to achieve change in populations, complexities in the aggregation of individual changes need to be considered.

3.1 Introduction

All interventions are based on ideas on how the planned intervention may work, and what consequences they have, whether implicitly or explicitly (McIntyre et al., 2020). These ideas concern the active ingredients, mechanisms of change, consequences of interventions, and related contextual factors. In process evaluation research, such ideas or theories may be elaborated, tested and adapted to explore mechanism and consequences of interventions. This research can help to examine and, if necessary, to adapt pre-specified ideas underlying the intervention. This helps to understand why the effects were lower, higher or different as compared to expectations. In addition, positive or negative consequences beyond the aspired outcomes of an intervention can be monitored. This can lead to optimize the effectiveness of an intervention over time through better activation of working mechanisms, or adding intervention components. In addition, this kind of research might enhance the certainty that can be attached to the observed effects (or absence of effects) in an outcome evaluation. This is relevant, because many outcome evaluations suffer from methodological limitations that reduce the certainty of their findings. More generally, this kind of research contributes to scientific knowledge on mechanisms of change in a specific domain.

This chapter will elaborate on intervention theory (3.2), typical ingredients and mechanisms of interventions in healthcare (3.3), consequences of interventions (3.4), and approaches to the identification of ingredients, mechanisms and consequences (3.5.).

3.2 Intervention Theory on Intervention Mechanisms and Consequences

Ideas on how an intervention is expected to have impact on the targeted outcomes, what consequences the intervention has, and which contextual factors are relevant, can be described as "intervention theory". Such theory may be based on broader scientific theories, which have been examined in other situations. Nevertheless, an intervention theory may be incorrect, incomplete or not applicable in a given context. In practice, the theory underlying an intervention is not always readily available. Therefore, many process evaluators start their work with elaboration of an intervention theory, collecting data to test the theory, and adapt the intervention theory if required. Alternatively, the researchers may take an explorative approach and develop an intervention theory on the basis of data that are collected in the context of intervention delivery.

All individuals – e.g., intervention developers, deliverers, recipients – may hold beliefs about interventions, including scientists. In science, however intervention theories are interpretations or deductions from systematically collected data, ideally across a range of studies. Their plausibility depends on features of the underlying theory and on the rigour of the research methods that were applied. An element of a theory has a higher degree of certainty, if it has been examined in a rigorously designed and conducted study, if alternative explanations are unlikely, and if it is consistent with broader scientific theory, that is relevant to the population and setting of interest.

Intervention theory is an umbrella term, under which several related concepts are subsumed in this book, including theory of change, logic model, and program theory. All have in common that they specify ideas on how an intervention works in a systematic way.

- **Theory of change** is a flexible, comprehensive concept with roots in program evaluation (Silva et al., 2014). A "theory of change" describes the processes and contextual factors that result in change. In this context, "theories of change" are typically developed in collaboration with stakeholders and adapted on the basis of the findings of evaluation research.
- **Logic model** is a graphical description of intervention components, intermediate and ultimate outcomes. It can be considered simple and visualized theory of change.
- **Program theory** is linked to realist evaluation, which aims what works, how, for whom, in what circumstances and to what extent (Coleman et al., 2020). The specification of program theory is typically the first step in realist evaluation, which is a methodological approach that seeks to identify patterns of contextual factors, working mechanisms, and outcomes.

The various concepts for intervention theory have not been consistently defined and overlap considerably. Logic models may be most used in health-related research, because they are simple and visual representations of intervention theory.

Regarding its scope, intervention theory is a narrowly focused theory targeting a specific intervention. Nevertheless, it may borrow concepts and ideas from a wider spectrum of more general theory, covering middle range and grand theories. For instance, an intervention theory of a training program may refer to theoretical concepts from psychology and educational science to conceptualize learning behaviours. Some attempts have been made to map the use of such theoretical concepts in health research, e.g., regarding social prescribing (see Box 3.1. for an example). As many interventions in healthcare practice are only partly understood, carefulness is generally recommended. In the health field, there are many examples of interventions that seemed effective in early studies but proved to be less effective (and sometimes harmful) in later research. Over time, the findings of theory-orientated process evaluation research can also lead to adaptation of such broader theories.

Box 3.1 Theoretical concepts used in intervention theories on social prescribing (Evers et al., 2024)

> Social prescribing is a short phrase for various interventions that link patients to community resources outside the healthcare system to improve their health and well-being. These resources may include physical activity, arts and culture, nature-based activity, and life-related coaching. A scoping review of the literature was conducted to identify intervention theories of social prescribing. Four broader theories were identified regarding how social prescribing generates outcomes: theory on salutogenesis, self-determination theory, social cure theory, and social innovation theory. Three further theories were identified that aim to explain differences across individuals regarding the outcomes of social prescribing: theory on social capital, theory on synchronicity in time, and theory on candidacy. Other theories concerned the implementation of social prescribing into practice, including normalisation process theory, critical systems thinking, theory on boundary-spanners, and theory on social capital. The identification of 1 intervention theories in total demonstrates that the social prescribing may be based on various intervention theories.

For specification of an intervention theory, ideas on the ingredients and mechanisms of health interventions and implementation strategies may be derived from a variety of scientific disciplines. Many health interventions

are based on insights from human biology and/or clinical psychology. The behavioural and social science provide ideas on how interventions perform in practice, which is the focus of process evaluation.

3.3 Types of Intervention Ingredients and Mechanisms

Regarding ingredients and working mechanisms of interventions (the "how" of interventions), many theories are available. Many interventions in healthcare involve change of individual behaviours: patients may need to adhere to treatment and change life-styles, health professionals may have to adopt recommended procedures or change their collaboration with other professionals. Looking first at individual behaviour change, potential ingredients and mechanisms of interventions can be derived from the behavioural sciences (psychology and related disciplines). For instance, a systematic synthesis of scientific publications identified 93 distinct behaviour change techniques, which could be categorized in 16 groups (see Box 3.2). Trained academics were able to apply these categories with a reasonably high degree of consistency in characterising behaviour change interventions (Michie et al., 2015). Behaviour change techniques are active ingredients of interventions that are associated with specific mechanisms of action such as knowledge and behavioural regulation (Michie et al., 2021). In this approach, mechanisms of action are equivalent to factors associated with change, which are elaborated in chapter 4.

Box 3.2 Groups of individual behaviour change techniques (Michie et al., 2015)

1) goals and planning
2) feedback and monitoring
3) social support
4) shaping knowledge
5) natural consequences
6) comparison of behaviour
7) association (as in operant conditioning)
8) repetition and substitution
9) comparison of outcomes
10) reward and threat
11) regulation
12) antecedents (restructuring context)
13) identity
14) scheduled consequences
15) self-belief
16) covert learning

Change in populations of individuals is conceptually more complex. Organisational leaders and political actors, who decide on changes in organisation or societies, are individuals who are subject to the same set of individual change mechanisms as described above. For individuals in a targeted population,

behaviour change may be thought of as the result of restructuring of context (item 12 in Box 3.3). This actually covers a wide range of strategies. For instance, many implementation strategies would fall in this category, e.g., finance strategies, restructure strategies, quality management strategies, and attend to policy context strategies (Powell et al., 2015). Therefore, further taxonomies to specify working mechanisms that relate to restructuring of context are required.

Change in populations may be simply the aggregation of behaviour change of individuals in the population, e.g., the proportion of patients who respond to individual treatments. However, the link between individual and collective change can also be more complex. There may be complexities in the aggregation of individual changes to change in populations, if they involve non-linear, probabilistic and recursive relationships. For instance, a population may be protected for an infectious disease, if a certain percentage is vaccinated (e.g., 90 %). Likewise, a hospital may perform suboptimal, if only a few key healthcare providers perform poorly. There may be a quantitative 'tipping point' in the aggregation of individual changes, at which features of the population, organisation or society at large changes qualitatively (Petticrew et al., 2019). These qualitative changes influence individuals (by enabling options, posing restrictions, or influence attitudes), also if they individually did not contribute to the change at macro-level.

The social sciences (sociology and related disciplines) provide further ideas on the linkage between change in individuals and change in populations. A part of social science views organisations and societies as units with autonomous dynamics, in which individual behaviours are shaped. Another part of social science starts from behaviours and interactions of individuals, and postulates that (stable) shared ideas and social configurations emerge and influence actors in reverse. In both approaches, social factors have a degree of independence from individual behaviours, which needs to be considered in studies of change in populations. In health care, organisational and societal entities may be contextual factors for an intervention of interest, but they may also be the target of change for interventions. For instance, organisational culture is defined as a characteristic of organisations and can be subject of interventions (Scott et al., 2003).

3.4 Consequences of Interventions

By definition, interventions are designed to realize specific consequences, usually described as "outcomes", which may be measured in outcome evaluations. In evaluation research, they are often categorized into primary and secondary outcomes. In addition, adverse events may be assessed in outcome evaluation, particularly in studies of health interventions. However, the

assessment of consequences in outcome evaluation is often incomplete as there may be non-anticipated consequences of an intervention, which are mostly not covered by outcome evaluation research. Assessment of further consequences of interventions beyond planned outcomes is therefore an important goal of process evaluation. Process evaluation can also be used to collect additional information on primary and secondary outcomes.

In some cases, intervention consequences (subject of process evaluation) and secondary outcomes (subject of outcome evaluation, additionally to primary outcomes) is not consistently made. For instance, structured questionnaires may be used to measure aspects of clinical team functioning. This may be listed as secondary outcome or be an intermediate consequence in process evaluation. If there is collaboration between process and outcome evaluators, demarcation of the boundaries between the two might not be relevant. In other situations, it may be necessary to coordinate the measurements of intermediate consequences across process and outcome evaluation research.

Non-anticipated consequences may be positive or negative for study participants and other stakeholders. For instance, a quality improvement may not achieve its planned outcomes but unexpectedly improve team functioning and job satisfaction among participating clinicians. Negative consequences include adverse effects, which may be monitored in the context of a clinical trial. This results in overlap between process evaluation and risk management in trials of interventions. Given the fact that non-anticipated consequences are initially unknown, they can only be identified through the use of measures that allow for unexpected findings. Suitable research methods include open-ended questions in interviews or questionnaires, analysis of documents, and direct participant observation. Box 3.3 provides an example of a qualitative study that measured non-anticipated consequences of an implementation strategy.

Box 3.3 Adverse effects of audit and feedback to healthcare providers (Catlow et al., 2022)

Audit of procedures and feedback to healthcare providers is an overall effective strategy to improve professional performance and outcomes of healthcare. However, it may also have adverse effects. In a qualitative study, endoscopists involved in colonoscopy procedures in England were interviewed. They indicated that negative feedback reduced their confidence, if there was no problem to improve. The reduced confidence increased anxiety and reduced their performance, which contributed to the consideration of false documentation of patient comfort and the removal of insignificant polyps to improve detection rates. The authors describe this process as a dark logic model of the audit and feedback strategy.

3.5 Identification of Ingredients, Mechanisms and Consequences of Interventions

In practice, new ideas on the intervention may emerge or change during its delivery. Therefore, process evaluation researchers often find themselves in the role of (co-)developers of the intervention theory (see Box 3.4 for an example). Process evaluators may use interviews with intervention developers (and other stakeholders) to specify the intervention theory in the early phase of a process evaluation. The specification of intervention theory helps to make ideas on the intervention explicit, which guides measurement and analysis. The specification of intervention theory can also contribute to the accumulation of scientific knowledge, particularly if the theory relates to concepts of underlying scientific theories.

Box 3.4 Exploring mechanisms of practice facilitation in healthcare (Kilbourne et al., 2023)

> Practice facilitation is a widely used strategy to implement changes in healthcare practice. It can be described as a dynamic process in which facilitators apply diverse methods in a supportive relationship among healthcare workers to achieve performance improvement. The working mechanisms of practice facilitation were explored in a Delphi procedure with experts in the field. In the first phase, participants identified and reviewed key publications to develop a logic model. In the second phase, they responded to vignettes to elaborate the logical model. In the final phase, a map was designed based on the data. Many factors and processes were identified and categorized in this way, including staff engagement, role clarification, coalition-building through peer experiences and identifying champions, capacity-building through problem solving barriers, and organizational ownership of the implementation process.

For the identification and analysis of intervention ingredients, mechanisms and consequences, a combination of theoretical analysis and qualitative research can be used. If elaborated descriptions of interventions are available, these can be examined against the background of one or more theories. This can identify the planned mechanisms and the consequences that may be expected. Such theoretical analysis requires in-depth knowledge of the theory of interest. Alternatively, empirical research can be used to identify mechanisms and consequences of interventions. In this context, particularly qualitative research among intervention developers and/or intervention users can be helpful. This can be used to document and categorize ideas on intervention mechanisms and consequences. A particular strength of qualitative methods is that it may also identify non-anticipated consequences,

which are not included as primary or secondary outcomes in an evaluation. Researchers can use these and other qualitative data to develop interpretations that point to mechanisms and consequences of an intervention. In this qualitative analysis, they may use theories of interest. An iterative approach for the analysis, described as 'theorizing', has been recommended (Kislov et al., 2019). This goes beyond mechanistic use of conceptual frameworks, which are often lists of factors that are derived from multiple scientific theories. The credibility of findings may be further harnessed by making systematic comparisons between subgroups in the data, such as low and higher performers, and patients with low and high health literacy.

As the role of various intervention ingredients and mechanisms may change over time, data-collection needs to be carefully timed. It seems most informative to collect data, when participants have collected some experience with the intervention, although perhaps not closely before the end of an intervention period. In addition, it may be relevant to collect data at an earlier stage to document early experiences. The measurements may themselves have (desired or undesired) impact on the intervention delivery and outcomes, which would imply a risk of bias in the evaluation of intervention outcomes. This risk needs to be balanced with the benefits of insight into intervention processes. In many studies, the control arms are excluded from process evaluation for this reason.

An issue is the use of process evaluation data for adapt, optimize or change intervention mechanisms. This has been described as participatory research, which implies that researchers become partners of study participants rather than distant observers (Hoekstra et al., 2020). Related terms for this approach are co-creation and stakeholder participation in research. Participatory research is related to embedded research (see chapter 5). As a consequence of the participation, the intervention and the underlying intervention theory may be adapted on the basis of the researchers' experiences. Proponents argue that this enhances the implementation and effectiveness of interventions. On the other hand, it may introduce bias in the conceptualization of the intervention.

3.6 Conclusions

Research on active ingredients, working mechanisms and consequences of interventions starts with the specification of intervention theory, which may relate to broader theories on change in individuals and populations. Qualitative research among intervention developers, deliverers and recipients can be helpful in this context. A participatory research approach implies adaptation of the intervention during its delivery, which has benefits and disadvantages.

Q&A Case Studies: Interventions' Active Components

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

Q: *What were the primary outcomes of the intervention?*
A: Previous studies and clinical experience had shown that patients with advanced lung cancer require different information along the disease trajectory. Therefore, the primary outcome of the MCA was the extent of addressed and satisfied information needs as assessed by patients.

Q: *What did the intervention theory in the MCA-project look like?*
A: An elaborated intervention theory was not formulated. The research team developed a pragmatic logic model that broadly described the intervention components and how the intervention was expected to perform. This model also included context factors that were considered essential for conducting MCAs, i.e. providing a room and blocking time for physicians and nurses so they were able to talk undisturbed with the patients.

Q: *How were intervention mechanisms assessed?*
A: The Milestones Communication Approach (MCA) included guidance for clinical conversations with patients who have advanced lung cancer with a limited life expectancy. A qualitative study used face-to-face semi-structured interviews with patients and informal caregivers to explore potential working mechanisms in practice (Krug et al., 2022). The 25 interview transcripts were coded deductively into themes related to the components of sense of coherence and emerging sub-themes. All data was managed and organised in MAXQDA.

Q: *What were the main findings?*
A: In the interviews, a sense of coherence was referred to with all three components: "comprehensibility" was supported by information conveyed suitably for the patients; "meaningfulness" was addressed as accepting the situation; and "manageability" led to advance care planning the patients were comfortable with. So, this study found evidence for mechanisms related to sense of coherence among patients and informal caregivers.

Q: *How were non-anticipated consequences assessed?*
A: To assess potential non-anticipated consequences of the MCA-intervention, a qualitative interview study with patients and informal caregivers was conducted (Bossert et al., 2020). Data analysis was performed using qualitative content analysis to structure data into themes and subthemes.

Q: *What was found?*
A: In 15 interviews, participants reported that cross-sectoral collaboration functioned well, if treatments occurred as planned. However, treatment gaps were experienced, especially regarding medication and regimen. As a result, participants felt insecure and obliged to take responsibility for the coordination of healthcare. Patients reported to be in favour of an active patient role but felt that healthcare coordination should still be a responsibility of a care provider. A more intensive information exchange, potentially by using an electronic platform, was expected to strengthen cross-sectoral collaboration. Overall, patients felt uncertain about their role in the coordination of treatment and care across healthcare sectors.

Q: *What was in your opinion surprising?*
A: As we recognized in putting together the pragmatic logic model of the MCA, the intervention included a lot of components and targeted and supported change on both healthcare provider and patient level. Although especially nurses reported a gain in patient care by applying the MCA, these effects did not generally transfer to patients. Yes, they felt better informed and could identify aspects related to and strengthening sense of coherence. Other outcomes which were thought to be influenced were not changed by the MCA, e.g., mood or quality of life. It could be that the intervention was delivered too shortly – just in a few highly selected conversations with just two healthcare professionals of a larger provider team, which maybe hampered spilling effects on outcomes not directly addressed.

Q: *What can be learned from these findings?*
A: The communication model was a big step towards more structured care, but healthcare providers outside specialized cancer care need to be involved in the future.

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

Q: *What were the primary outcomes of the intervention?*
A: The primary outcome in ARena was the percentage of patient cases with acute non-complicated infections who received a prescription for antibiotics without testing for pathogens when they consulted primary care practices. Cases referred to adult patients with acute bronchitis, or sinusitis, and young patients with otitis media (>2 years), upper respiratory tract infections (>1 year), or tonsillitis (>1 year). The outcome evaluation was based on quarterly claims data and aimed to examine and compare the change of prescribing rates for these cases in the ARena intervention arms and compare prescribing rates to matched non-participating standard care.

Q: *What did the intervention theory in the ARena project look like?*
A: An elaborated intervention theory was not formulated. The research team developed a pragmatic logical model that listed the (hopefully active) ingredients of the intervention program.

Q: *How were intervention mechanisms assessed?*
A: In the ARena project, interviews were conducted with a purposive sample of physicians to identify factors relevant to primary care physicians' decision-making when prescribing antibiotics for acute non-complicated infections (Poss-Doering et al., 2020). The Dual Process Theory was applied to provide understanding of individual health professional factors that are associated with prescribing decisions.

Q: *What were the main findings?*
A: One of the key findings was that physicians developed habits in decision making on antibiotics prescribing based on medical and organizational considerations. They perceived to prescribe antibiotics for acute, non-complicated infections in situations in which they experienced uncertainty regarding the diagnosis, prognosis, continuity of care, patient expectations, or when they did not know the patient prior to the consultation. Another key finding was that educational interventions may only change prescribing behaviours if they result in active rational rather than routine-based decision-making on antibiotics prescribing.

Q: *What was in your opinion surprising?*
A: Findings in the ARena process evaluation indicated that practice networks as a study setting fostered necessary changes by placing the responsibility for change from the individual physician to the collective setting. Combined with the audit and feedback and quality circles components, this contributed to making the value of the study very tangible for the participants. Also, physicians acknowledged that they became aware of their own misinterpretations regarding patient preferences through participating in ARena and actively engaging in communication about patient expectations. Some physicians considered strategies which include monetary incentives as a key element for behaviour change, yet uptake of this component in ARena did not match this perception. This heterogenous result might be explained by an expectation of increased administrative work or inadequate understandings of the component, yet cannot be supported by the collected data.

Q: *How were non-anticipated consequences assessed?*
A: These were not assessed in the ARena project.

Q: *What can be learned from these findings?*
A: The interventions in the ARena project addressed only a small range of all factors that influence antibiotics prescribing. Conclusions drawn from the process evaluation findings indicate that approaches targeting health literacy competencies and clinician's therapy decisions at the same time perhaps need to be specifically tailored to the needs of respective targeted groups, and that audit and feedback reports combined with provision and discussion of evidence-based information in quality circles should be established in primary routine care to reduce overuse of antibiotics.

Self-test Questions

1) What are mediators and moderators of intervention effects?

2) What are some concepts for mechanisms of individual behaviour change?

3) Which of the following items are typically part of process evaluation?
   a) side effects of medical treatment
   b) effects on patients' satisfaction with care and well-being
   c) effects of a medical treatment on the staff time that is required for delivery the treatment
   d) effects on interprofessional collaboration

4) Which research methods can be used to examine intervention mechanisms?

5) How can qualitative and quantitative methods be combined in a "mixed-methods" study in a way that increases the credibility of research findings?

4 Determinants of Intervention Outcomes

Synopsis

Determinants that influence the outcomes of an intervention include characteristics of the targeted individuals, organisational characteristics of the setting in which the intervention is applied, characteristics of the broader healthcare system, and other concurrent interventions. Some of these setting characteristics, also called contextual factors, may be changed by the intervention of interest, which explains why the intervention might have consequences within a study setting. Some factors influence an intervention when it is adopted and effective in the setting of its application, thus determine the transferability of an intervention to other settings. In process evaluation research, a range of quantitative and qualitative methods for exploration of determinants of outcomes is available.

4.1 Introduction

All interventions are applied in a specific context, that is shaped by a set of social, organisational, economic and cultural conditions as well as a population of individuals with various characteristics. In process evaluation, this context of an intervention can be broadly and pragmatically defined as anything within the intervention setting that is not the intervention itself. Some aspects of context are determinants of intervention outcomes, because they are changed by the intervention of interest. Process evaluation can help to unravel the ways that interventions result in effects, thus explain "why" an intervention has impact. The term "contextual factors" may be misleading, because some of these factors relate to the mechanisms of interventions. For instance, an intervention may change specific characteristics of an individual (e.g., physical fitness) and thus impact on outcomes of an intervention (e.g., surgical procedure).

Many interventions are matched or tailored to some aspects of the context in which they are applied, such as the characteristics of the targeted individuals (e.g., medical diagnoses of patients). In addition, specific contextual factors influence "when" an intervention is adopted and effective in practice. In other words, they are pre-conditions for adoption and impact. For instance, a sufficiently high degree of health and digital literacy may be needed to be able to use a health-related smartphone application, and thus

determine the transferability of findings of a study in users of the application. So, contextual factors influence how interventions play out, thus they should be considered in the assessment of the transferability of interventions across settings.

This chapter will elaborate on intervention theory in respect to determinants of intervention outcomes (4.2), different types of determinants (4.3), transferability of interventions (4.4) and approaches for identification of relevant determinant factors (4.5).

4.2 Intervention Theory on Determinants of Intervention Outcomes

Intervention theory describes the ideas on the active ingredients, mechanisms and consequences of an intervention. Besides a description of these components, it may specify the causal pathway of intervention components to outcomes. This points to factors or determinants, which play a role as preconditions, mediators or moderators in the processes or mechanisms that result in (proximal and distal) outcomes (see Table 4.1. for definitions of these terms). A determinant can have multiple roles in a change process, e.g., be mediator in one process and moderator in another process. There may be different theories of a particular process. In particular, the targeted individuals may have a different intervention theory than those who deliver the intervention. Mediators can be understood as factors that transfer the effect of an intervention (or preceding factor) on the outcome (or subsequent factor), while moderators are factors that impact on such chain of effects (see figure 4.1). Many further types of explanatory models can be specified, for instance models with multiple determinants and outcomes. The linkages need not be linear, but may be exponential or otherwise specified.

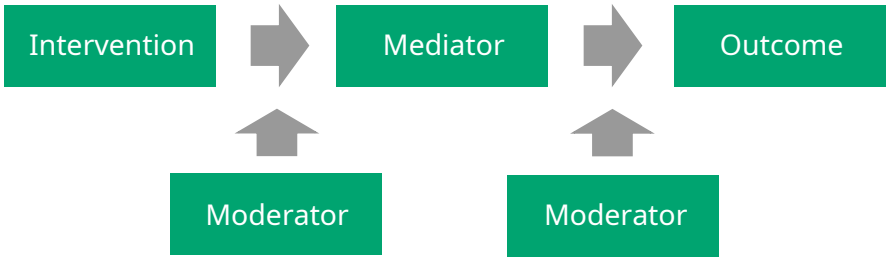

Figure 4.1 Mediators and moderators of interventions effects

Table 4.1 Terms related to causal mechanisms (adapted version of Lewis et al., 2020)*

Given elements	
Precondition	Factor that is necessary in order for an intervention mechanism to be activated.
Intervention	Methods used to achieve change in behaviours or processes in healthcare.
Determinant	Also referred to as 'barriers' and 'facilitators', a factor that enables or hinders the intervention from eliciting the desired effect.
Process-related terms	
Mechanism	Process or event through which an intervention operates to affect desired intervention outcomes.
Mediator	Intervening variable that may account for the relationship between the intervention and the outcome.
Moderator	Factor that increases or decreases the level of influence of an intervention.
Outcome-related terms	
Proximal outcome	The product of the intervention that is realised because of its specific mechanism of action; the most immediate, observable outcome in the causal pathway.
Distal outcome	Outcome that the intervention processes is ultimately intended to achieve; not the most immediate outcome in the causal pathway.

*The original table is focused on implementation strategies, which is adapted to generalise to interventions in healthcare. This table is taken from: Wensing M, Ullrich C., Chapter 3 Use of theories in health services research. In: Foundations of Health Services Research. Principles, Methods, and Topics. Springer, Cham Switzerland, 2023. The content is licensed by Springer Nature Customer Service Center GmbH.

In process evaluation research, moderators and mediators of intervention impacts are often distinguished. If factors are changed by an intervention of interest, they may be mediators in the chain of effects that lead to desired outcomes. Specification of effect mediators is a logical component of intervention theory. Changes in mediators are caused by intervention mechanisms, which describe "how" change is achieved. For instance, social comparison may be a mechanism in the chain of effects of an intervention, which changes attitudes towards a practice – a mediator in the pathway to intervention outcomes. In contrast, moderators speed up or slow down the unfolding of the working mechanisms of interventions, and thus influence outcomes. In its most extreme case, they may be preconditional for these working mechanisms: if a factor does not have a specific value, the working

mechanisms will not unfold. This has implications for the generalizability and transferability of research findings. For instance, a specific degree of pre-existing knowledge may be required to achieve learning effects through an educational program. In this case, the program is not transferable to individuals who lack this knowledge (e.g., an education program for neurologists may not be effective in cardiologists). Insight into effect moderators is relevant for the transferability of an intervention across settings and populations. Ideally, they are also specified in an intervention theory.

Some contextual factors may influence outcomes, but not interfere with the working mechanisms and effects of an intervention. So, they are neither moderators nor mediators of intervention effects. Insight into the role of such factors helps to place the effectiveness of an intervention in context: some interventions may be of little value, given the impact of contextual influences.

4.3 Types of Determinants

In many process evaluation studies in healthcare, four types of determinants frequently play a role in the pathway of intervention to outcome (see Box 4.1): a) competencies and attitudes of the targeted individuals, b) organisational characteristics of the setting, c) characteristics of the broader healthcare system and d) other parallel interventions – either within in usual care or specific programs

Box 4.1 Typical contextual factors that influence interventions in healthcare

	Examples
Competence and attitudes of targeted individuals	healthcare professionals' attitudes regarding clinical guidelines and patients' ability to manage clinical interventions
Organisational characteristics of the setting	leadership styles, communication behaviours, and perceptions of professional roles
Characteristics of the broader healthcare system	the reimbursement system for healthcare providers, the degree of fragmentation in the healthcare system, and cultural beliefs regarding healthcare
Other interventions	treatments in usual care or concurrent programs to improve practice

To examine these types of factors determining interventions, various theoretical approaches can be used. Some of the approaches address one type of factor (e.g., either the individual or the organisation), other approaches might have broader scope. Process evaluation can build on approaches and concepts

from behavioural and social sciences and might use structured compilations or frameworks of such approaches, e.g., as suggested by implementation science.

Looking at individual behaviour change, many theories within behavioural science offer concepts for individual states that can influence the performance and outcomes of interventions. Psychologists developed the Theoretical Domains Framework, a structured list of such psychological factors, which was derived from a synthesis of psychological theories (see Box 4.2). These factors have also been described as mechanisms of action (Michie et al., 2021). The framework can be used to choose behaviour change techniques to address specific factors, for instance "goal setting" to enhance behavioural regulation, or "social comparison" to influence subjective norms (see chapter 3). The framework can also be used to assess existing interventions with respect to their psychological ingredients and mechanisms.

Box 4.2 Theoretical Domains Framework (Cane et al., 2012)

In a structured process with experts, which started with 128 constructs from 33 theories, the so-called Theoretical Domains Framework (TDF) was developed (Cane et al., 2012). It contains 14 domains: 1) knowledge, 2) skills, 3) social/professional role and identity, 4) beliefs about capabilities, 5) optimism, 6) beliefs about consequences, 7) reinforcement, 8) intentions, 9) goals, 10) memory, attention and decision processes, 11) environmental context and resources, 12) social influences, 13) emotion, 14) behavioural regulation. Each of these domains covers several concepts, which are thought to influence behaviour and behaviour change, whether it concerns patients, healthcare workers, or others. Linkages between the concepts are not specified in the Theoretical Domains Framework; it is a straight list of items, which may be measured with structured questionnaires or used to categorize qualitative data.

The TDF-Framework is currently the best available synthesis of concepts on individual behaviour change, but it should not be considered exhaustive or final. The framework includes social and organisational factors (mainly in TDF-domains 11 and 12), but it does not specify these in great extent as the focus is on individual behaviour change. Many theories within the social sciences describe social, organisational and cultural and economic factors that influence change of behaviours. A panel of organisational and implementation scientists extracted 70 constructs from 9 organisational theories with a focus on the implementation of practices, which they then categorized in a systematic procedure (Birken et al., 2023). The resulting Organizational Theory for Implementation Science (OTIS) organizes concepts in 6 domains: organizational characteristics, governance and operations,

tasks and processes, knowledge and learning, characteristics of a population of organizations, and interorganizational relationships. Like in TDF, the framework should not be considered exhaustive or final.

Ideas about social and organisational factors can also be derived from other frameworks for implementation science (Strifler et al., 2018). For instance, the Consolidated Framework for Implementation Research (CFIR) has three domains that relate to context: individuals, inner setting, and outer setting (Damschroder et al., 2022). A total of 27 items is included in these domains of context, varying from information technology infrastructure to innovation recipients. Based on this framework, a pragmatic context assessment tool was developed (see Box 4.3).

Box 4.3 A pragmatic context assessment tool (Robinson & Damschroder, 2023)

Linked to the Consolidated Framework for Implementation Research (CFIR), a pragmatic context assessment tool was developed in a systematic procedure that involved a think-aloud process with users. The tool (available as supplement to the paper) involves 14 items to assess 10 constructs in 4 domains of the CFIR-framework. Each item is assessed by health workers regarding presence and impact on implementation. The items are:

1) People here regularly seek to understand the needs of patients and make changes to better meet those needs
2) I have open lines of communication with everyone needed to make the change.
3) I have access to data to help track changes in outcomes.
4) The change is aligned with leadership goals.
5) The change is aligned with clinician values.
6) The change is compatible with existing clinical processes.
7) The structures and policies in place here enable us to make the change.
8) We have sufficient space to accommodate the change.
9) We have sufficient time dedicated to make the change.
10) We have other needed resources to make the change (staff, money, supplies, etc.).
11) People here see the current situation as intolerable and that the change is needed.
12) People here see the advantage of implementing this change versus an alternative change.
13) Higher level leaders are committed, involved, and accountable for the planned improvement.
14) Leaders I work with most closely are committed, involved, and accountable for the planned improvement.

There is a broad range of other theories, frameworks and models that may help to understand determinants of intervention outcomes. This book only shows a number of examples.

4.4 Transferability of Interventions

Process evaluation can have the purpose to assess transferability of an intervention beyond a specific setting and time period. This question, on how an intervention might work within a different setting, is also discussed using related concepts, such as sustainment, transportability, and scale-up (Hayes-Larson et al., 2024; Milat et al., 2020; Munthe-Kaas et al., 2020). These concepts show much overlap, and the differences are not discussed here. In the context of a specific project, transferability often relates to a hypothetical situation, because in most projects the observations are often limited to specific settings and time period. The assessment of transferability may point to required adaptations of the intervention, but it is often mainly focused on contextual factors: legal, financial, organisational and cultural pre-conditions for long-term and widescale use of an intervention.

Many frameworks for assessment of the transferability of interventions in healthcare have been proposed (Birken et al., 2020). These are structured lists of domains and factors, which largely overlap with other frameworks from implementation science. For instance, a review and analysis of frameworks suggested seven domains for investigating transferability (Nadalin Penno et al., 2019):

a) innovation, such as its benefits and adaptability;
b) adopters, including individuals' and stakeholders' commitment and competencies;
c) leadership and management, particularly management engagement and approaches;
d) inner context, covering infrastructure support, cultural, political and financial factors;
e) inner processes, such as communication, education, and change strategies;
f) outer context, e.g., economic stability and external support;
g) outcomes, which is not further specified.

In conclusion, an assessment of the transferability of an intervention is largely an assessment of contextual factors that moderate adoption and effectiveness of the intervention. Various frameworks can be used to guide the identification of factors that influence the transferability of inteventions in health. The frameworks provide broad concepts, which need to be specified

for a given intervention. Depending on the state of research on a specific intervention, this may require new (qualitative or quantitative) research. Adaptation of the intervention may be proposed to address lowered transferability due to hindering contextual factors. For instance, an intervention may be simplified to address a lower level of competences in a new target population.

4.5 Methods to Identify Relevant Determinants

The identification of relevant determinants of intervention outcomes is often challenging, and rarely achieved in a single study. As a first step, it is generally helpful to specify the most relevant causal pathways in sufficient operational detail. A basic model related to interventions is: intervention → determinant → implementation outcome → health outcome. Lewis et al. (2020) provide a range of extensions of this basic model.

For testing or exploration of the specified pathways, empirical research is required. For quantitative research, many structured measures of many types of factors are available. These are typically questionnaires, which are completed by patients, healthcare providers or managers. An example is the readiness for change in an organisation, for which a range of questionnaires is available (Weiner et al., 2020). A large number of quantitative analysis methods can be used to explore the role of (potential) determinants of outcomes. These may be categorized from relatively simple to complex methods: 1) cross-tables with associated statistics, 2) multivariate analysis methods, such as regression analysis, and 3) advanced methods, such as pattern recognition through machine learning. Many other textbooks provide introductions to these methods. Box 4.4. provides an example, which used regression analysis to explore the mediating role of continuity of care in an intervention. Regardless of their complexity, the interpretation of findings of quantitative analysis is restricted by the design and sample of the underlying study. For instance, a cross-sectional study does not facilitate causal interpretation, while random allocation of participants to study arms controls for known and unknown confounders.

Under specific conditions, which mainly concern analytical study design and data-analysis approach, these associations may be plausibly interpreted as causal effects. Criteria for causal associations according to Kazdin (cited in (Lewis et al., 2020)) are: a) strong association between intervention, mechanism and outcome, b) specificity: plausibility of explanation of change, c) consistency: replication across studies, d) experimental manipulation: direct manipulation of strategy or factor results in change of outcome, e) timeline: determinants precede outcomes in time, f) gradient: dose-response relationship, g) plausibility or coherence: the mechanism matches with other knowledge.

The latter requires knowledge of the content of the research, including theories and previous studies, and cannot be derived from the data.

Box 4.4 The role of continuity of care for impact of strong primary care (Wensing et al., 2021)

High continuity of care is a key feature of strong general practice. A broader evaluation study aimed to assess the effect of a programme for enhancing strong general practice care, in which this study on the effect of continuity of care on hospitalization patterns was integrated. The study had an observational design, involving patients who received a strong general practice care programme (n = 1.037.075) and patients who did not receive this programme (n = 723.127) in the year 2017. Data were extracted from a health insurance database. The cohorts were compared with respect to three measures of continuity of care (Usual Provider Index, Herfindahl Index, and the Sequential Continuity Index), adjusted for patient characteristics. The effects of continuity in general practice on the rates of hospitalization, rehospitalization, and avoidable hospitalization were examined in multiple regression analyses. Compared to the control cohort, continuity in general practice was higher in patients who received the programme (continuity measures were 12 to 24 % higher). Higher continuity of care was independently associated with lowered risk of hospitalization, rehospitalization, and avoidable hospitalization. Higher continuity of care may be one of the mechanisms underlying lower hospitalization rates in patients who received strong general practice care, but further research is needed to examine the causality underlying the associations.

In addition to quantitative methods, qualitative approaches can be used for the identification of relevant contextual factors. These are essentially similar to the methods for the exploration of intervention ingredients and mechanisms, which were described in chapter 3. A specific approach is realist evaluation, which aims to explore which interventions work, for whom and under what circumstances (Bonell et al., 2012). The approach aims to identify combinations of contextual factors, mechanisms and outcomes. The configuration of context, mechanisms and outcomes may be based on perceptions of study participants, derived from systematic comparison of settings or outcomes, and/or linked to scientific theory. While the realist approach is associated with specific assumptions about science, it is also applicable if these assumptions are not shared. Realist evaluation has been mostly associated with qualitative research, but it might also include quantitative analysis. Another useful design is a comparative case-study, which

combines detailed qualitative and quantitative data from relatively few units (e.g., hospitals).

Combine the findings of quantitative research with those of qualitative research, which has been described as mixed-methods research, is generally a way to strengthen research (e.g., (Rijnhart et al., 2021; Zawadzki et al., 2023)). The study in Box 4.5 provides an example of purposeful combination of qualitative and quantitative methods.

Box 4.5 Mixed methods with a realist evaluation and structural equation modelling to explore context and mechanisms of change (Söling et al., 2023)

Computerized decision-support and other digital tools can improve quality of care for patients who use many sorts of medication, but these tools are not well adopted in German primary care. Physicians in an intervention trial (n=218) were subjects in this process evaluation in three steps: (1) a realist inquiry approach, which involves the description of a context-mechanism-outcome configuration; (2) a belief elicitation approach, which involves qualitative content analysis and the development of a quantitative latent contextualized scale; and (3) a mediation analysis using structural equation modelling based on quantitative survey data from physicians. The study found that physicians' beliefs regarding the effectiveness of the aspired pharmaceutical management practices mediated the impact of organisational readiness to implement change on physician intention to adopt the aspired computer tools. In other words, physicians' beliefs depended on organizational factors and, at the same time, influenced their behavioural intentions.

4.6 Conclusions

A wide range of factors beyond intervention characteristics determine intervention outcomes. Some factors also influence the transferability of an intervention to other populations and settings, thus influence sustainment and scale-up of intervention programs. A range of quantitative methods and some qualitative methods are available to assess determinants of intervention outcomes.

Q&A Case Studies: Determinants of Intervention Outcomes

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

Q: *What contextual factors were assessed?*
A: In the MCA project, the attitudes of physicians and nurses regarding interprofessional collaboration of professions (an important component of the approach) were explored (Krug et al., 2022). In a longitudinal study, a validated questionnaire on interprofessional collaboration was applied in a survey prior to implementation of MCA (t0) with follow-up data collections at 4 months (t1), 10 months (t2) and 17 months (t3). In addition, interviews and focus groups on implementation and interprofessional collaboration in the context of MCA were conducted with healthcare providers. The topics were analysed deductively, guided by the Professional Interactions factor of the Tailored Implementation for Chronic Diseases (TICD) framework.

Q: *What were the main findings?*
A: The survey study with 87 providers (44 nurses, 13 physicians, 12 psycho-social providers, 7 therapists, and 11 others) found heterogeneous attitudes. 'Communication and Teamwork' and 'Interprofessional Relationships' were characterized by primarily positive attitudes. Neutral attitudes to 'Interprofessional Interaction' were indicated by the majority of respondents. Fifteen providers participated in the interviews and focus groups. The main interprofessional interaction factors associated with implementation concerned the knowledge of the MCA and the impact of the intervention on team roles, on information sharing and on transfer processes between wards. Adaptive processes led to a shift in the perception of responsibilities and interprofessional collaboration. Overall, attitudes regarding interprofessional care were neutral to positive, which provides a reasonably favourable climate for the implementation of MCA.

Q: *Were all contextual factors covered by the research?*
A: The organisational context was not subject of systematic research. The research team learned anecdotally that a number of physicians, who were trained on MCA, had rotated to other clinical sites before the intervention period started. This is common practice in academic

clinical centres, but seemed a substantial barrier for implementation of innovations. Some physicians who were involved in MCA-conversations had not formally been trained. In addition, recruitment of patients and planning of conversations proved to be challenging in the beginning. A dedicated study nurse was then appointed to organize this locally, but this was initially not very successful. However, the recruitment of patients improved substantially, after a different study nurse with more additional support took on the role.

Q: *All in all, do you think the intervention is transferable to other settings? And when, how?*
A: The successful implementation seemed to depend on local clinical opinion leaders, which may provide a pre-condition for transferability to other settings.

Q: *What did you learn concerning transferability of findings within the process evaluation?*
A: Experiences with the study revealed various challenges which have to be considered when trying to transfer MCA to other settings. Not only dedicated leaders and healthcare professionals are needed, but other context factors also have to be considered in advance such as: how can conversations be planned to allow smooth processes for healthcare professionals and patients, are there suitable facilities available, which resources in staff and time can be allocated, which strategies foster the interprofessional work of the tandem and strengthen the role of the nurse?

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

Q: *What contextual factors were assessed?*
A: The ARena project comprised extensive elaboration of contextual factors associated with impacts. In a nested mixed-methods approach, a three-wave study-specific survey for participating physicians and medical assistants assessed potential impacts and uptake of the complex intervention program (Poss-Doering et al., 2022). Stakeholders received a one-time online questionnaire to reflect on network-related aspects. Semi-structured, open-ended interviews, with a purposive sample of physicians, medical assistants and stakeholders explored the acceptance and perceived sustainability of interventions.

Q: *What were the main findings?*
A: Survey data in the ARena process evaluation showed that the organized practice networks were seen as a major facilitator of the sustainable adoption of new routines, including the recommendations on antibiotics prescribing. Thematic analysis of interview transcripts was conducted to explore social influences and provided further insights into the role of organized practice networks (Poss-Doering et al., 2020). All interviewed physicians (n = 27) considered their network to be a strong support factor for daily routines, introduction of new routines, and continuity of care. They utilized network-offered training programs focusing on best practice guideline-oriented use of antibiotics and considered their networks supportive in dealing with patient expectations. A shared attitude combined with intervention components facilitated reflective management of antibiotic prescribing. Non-physician health professionals (n = 11) also valued network peer exchange. Stakeholders (n = 7) expected networks and their members to be drivers for care optimization. Thus, primary care networks seemed to play a crucial role in providing a platform for professional peer exchange, social support and reassurance. The organized practice networks seemed to facilitate and amplify quality improvement programs by providing a platform for refreshing awareness, knowledge and self-reflection among care providers. These mechanisms of change exist beyond the quality improvement strategies int he ARena project, which is the reason to consider these contextual factors.

Analyses of the physician survey data (Queder et al., 2022) found that work experience, practice network environment, structural conditions, environment of existing processes, and externally defined general conditions were associated with physicians' perceived impact of participating in the ARena project on decision-making regarding antibiotic prescribing. In the final regression models, only work experience showed a significant influence. Longer work experience appeared to be a significant influencing factor to be considered in antimicrobial stewardship programs. It may be noted that nearly all physicians in this study had positive views about the role of organized practice networks (thus reducing variation), which may explain the fact that the influence of this factor was overruled by a different factor.

Q: *Were all contextual factors covered by the research?*
A: Probably not. For instance, financial factors were not explicitly considered.

Q: *All in all, do you think that the intervention is transferable to other settings?*
A: The practice networks provided a favourable setting for quality improvement interventions, but it is uncertain whether these can be transferred to other settings.

Q: *What did you learn concerning transferability of findings within the process evaluation?*
A: Regarding transferability, it has to be mentioned that the study setting in practice networks might have contributed to somewhat amplified effects. Future efforts to transfer the findings in ARena to routine care should also consider that participant age and significant work experience might limit transferability to younger and less experienced medical professionals.

Self-test Questions

1) What are the main reasons to consider contextual factors in process evaluation?

2) How do contextual factors fit in intervention theory?

3) Indicate which of the following refers to “how”, “why” and “when” of interventions performance:
   a) a specific pain medication (analgesic) influences biological processes in human cells
   b) a particular analgesic changes the recognition of pain signals in human cells
   c) pain medication is only effective, if it is taken according to instruction

4) How would you choose a framework to guide the identification of contextual factors in the process evaluation of an intervention?

5) Context-mechanisms-outcome configuration can be examined in quantitative research? What is the difference with realist evaluation that is based on qualitative research?

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,

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?

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Recommended Literature

Frameworks used in process evaluations

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*Framework for structured description of interventions.

Damschroder, L. J., Reardon, C. M., Opra Widerquist M. A., & Lowery, J. (2022). Conceptualizing outcomes for use with the Consolidated Framework for Implementation Research (CFIR): the CFIR Outcomes Addendum. *Implementation Science, 17*(1), 7. https://doi.org/10.1186/s13012-021-01181-5
*Framework for outcomes of interventions, which differentiates between (anticipated and actual) outcomes of implementation strategies and outcomes of innovations (i.e. health interventions).

Glasgow, R. E., Harden, S. M., Gaglio, B., Rabin, B., Smith, M. L., Porter, G. C., Ory, M. G., & Estabrooks, P. A. (2019). RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review. *Frontiers in Public Health, 7,* 64. https://doi.org/10.3389/fpubh.2019.00064
*Framework for categorization of outcomes of public health interventions. The domains "adoption" and "implementation" refer to the uptake of interventions.

Frameworks and theory for process evaluations

McIntyre, S. A., Francis, J. J., Gould, N. J., & Lorencatto, F. (2020). The use of theory in process evaluations conducted alongside randomized trials of implementation interventions: A systematic review. *Translational Behavioral Medicine, 10*(1), 168–178. https://doi.org/10.1093/tbm/iby110
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*Influential guidance on process evaluation of complex health interventions.

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*Framework for structured classification of adaptations of interventions in healthcarew

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Process evaluation is research that describes and explores the processes that influence the outcomes of interventions. In health care, many interventions aim at improving the health of patients and populations, or at implementing desired practices by healthcare providers. Process evaluation concerns the uptake of interventions, their active components, and the determinants of their outcomes. The findings of process evaluation help to interpret interventions' effectiveness, optimize intervention design and delivery, and assess the transferability of interventions across settings. This book provides a concise introduction to the concepts, methods and practices of process evaluation in healthcare settings.

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