

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.

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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

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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.

1.2 Description and Purposes of Process Evaluation in Health Care

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

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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,

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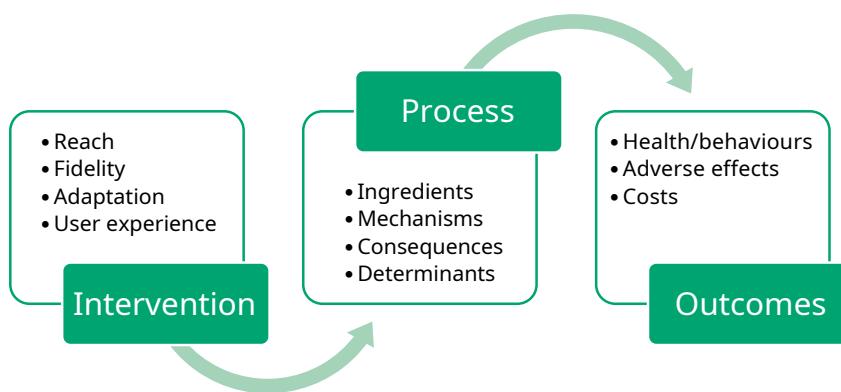


Figure 1.1 Relations between intervention, process and outcomes

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?

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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.

1.3 Outcome Evaluation in Relation to Process Evaluation

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

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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 it 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.

1.5 About this Book

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

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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

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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>

Bossert, J., Ludwig, M., Wronski, P., Koetsenruijter, J., Krug, K., Villalobos, M., Jacob, J., Walker, J., Thomas, M., & Wensing, M. (2021). Lung cancer patients' comorbidities and attendance of German ambulatory physicians in a 5-year cross-sectional study. *NPJ primary care respiratory medicine*, 31(1), 2. <https://doi.org/10.1038/s41533-020-00214-8>

Bossert, J., Wensing, M., Thomas, M., Villalobos, M., Jung, C., Siegle, A., Hagelskamp, L., Deis, N., Jünger, J., & Krug, K. (2020). Implementation of the milestones communication approach for patients with limited prognosis: evaluation of intervention fidelity. *BMC palliative care*, 19(1), 21. <https://doi.org/10.1186/s12904-020-0527-1>

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Krug, K., Bossert, J., Stooß, L., Siegle, A., Villalobos, M., Hagelskamp, L., Jung, C., Thomas, M., & Wensing, M. (2021). Consideration of sense of coherence in a structured communication approach with stage IV lung cancer patients and their informal caregivers: a qualitative interview study. *Supportive care in cancer: official journal of the Multinational Association of Supportive Care in Cancer*, 29(4), 2153-2159. <https://doi.org/10.1007/s00520-020-05724-2>

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Siegle, A., Villalobos, M., Bossert, J., Krug, K., Hagelskamp, L., Krisam, J., Handtke, V., Deis, N., Jünger, J., Wensing, M., & Thomas, M. (2018). The Heidelberg Milestones Communication Approach (MCA) for patients with prognosis <12 months: protocol for a mixed-methods study including a randomized controlled trial. *Trials*, 19(1), 438. <https://doi.org/10.1186/s13063-018-2814-1>

Villalobos, M., Siegle, A., Hagelskamp, L., Handtke, V., Jung, C., Krug, K., Bossert, J., Dies, N., Jünger, J., Wensing, M. & Thomas, M. (2019). HeiMeKOM (Heidelberger Meilenstein Kommunikation): Entwicklung einer interprofessionellen Intervention zur Verbesserung der Kommunikation bei Patient*innen mit eingeschränkter Prognose [HeiMeKOM (Heidelberg Milestones Communication): development of an interprofessional intervention for improvement of communication in patients with limited prognosis]. *Z Evid Fortbild Qual Gesundhwes*, 147-148:28-33. <https://doi.org/10.1016/j.zefq.2019.06.006>

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.

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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 Bundesauschuss 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>

1 Introduction

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?