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 in- dividuals who are actually exposed to the intervention	Proportion of targeted health- care providers who are actually exposed to the intervention
Fidelity	Degree that the interven- tion 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' ex- periences 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)