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.).

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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?