

4 Determinants of Intervention Outcomes

Synopsis

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

4.1 Introduction

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

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

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

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

4.2 Intervention Theory on Determinants of Intervention Outcomes

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

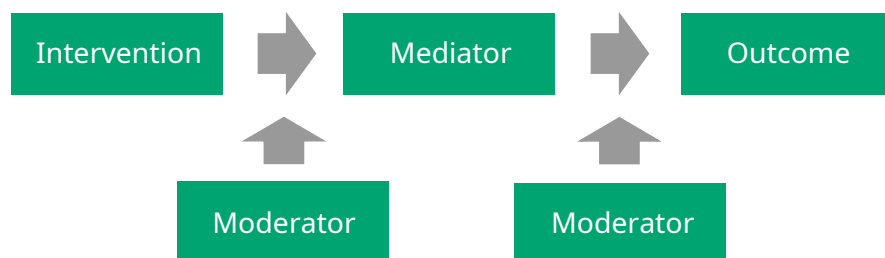


Figure 4.1 Mediators and moderators of interventions effects

4.2 Intervention Theory on Determinants of Intervention Outcomes

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

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

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

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

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

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

4.3 Types of Determinants

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

Box 4.1 Typical contextual factors that influence interventions in healthcare

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

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

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

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

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

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

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

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

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

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

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

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

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

4.4 Transferability of Interventions

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

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

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

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

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

4.5 Methods to Identify Relevant Determinants

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

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

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

4.5 Methods to Identify Relevant Determinants

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

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

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

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

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

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

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

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

4.6 Conclusions

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

Q & A Case Studies: Determinants of Intervention Outcomes

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

Q: What contextual factors were assessed?

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

Q: What were the main findings?

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

Q: Were all contextual factors covered by the research?

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

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

Q: All in all, do you think the intervention is transferable to other settings? And when, how?

A: The successful implementation seemed to depend on local clinical opinion leaders, which may provide a pre-condition for transferability to other settings.

Q: What did you learn concerning transferability of findings within the process evaluation?

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

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

Q: What contextual factors were assessed?

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

Q: *What were the main findings?*

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

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

Q: *Were all contextual factors covered by the research?*

A: Probably not. For instance, financial factors were not explicitly considered.

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Q: All in all, do you think that the intervention is transferable to other settings?

A: The practice networks provided a favourable setting for quality improvement interventions, but it is uncertain whether these can be transferred to other settings.

Q: What did you learn concerning transferability of findings within the process evaluation?

A: Regarding transferability, it has to be mentioned that the study setting in practice networks might have contributed to somewhat amplified effects. Future efforts to transfer the findings in ARena to routine care should also consider that participant age and significant work experience might limit transferability to younger and less experienced medical professionals.

Self-test Questions

- 1) What are the main reasons to consider contextual factors in process evaluation?
- 2) How do contextual factors fit in intervention theory?
- 3) Indicate which of the following refers to “how”, “why” and “when” of interventions performance:
 - a) a specific pain medication (analgesic) influences biological processes in human cells
 - b) a particular analgesic changes the recognition of pain signals in human cells
 - c) pain medication is only effective, if it is taken according to instruction
- 4) How would you choose a framework to guide the identification of contextual factors in the process evaluation of an intervention?
- 5) Context-mechanisms-outcome configuration can be examined in quantitative research? What is the difference with realist evaluation that is based on qualitative research?