7 The CeHRes Roadmap

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Introduction

eHealth technologies are being used in different kinds of settings, for example in public, somatic, consumer, and mental health. There are often high expectations of these technologies. However, these expectations are often not met in practice – a lot of them stop being used because they are, for example, hard to understand for the user, require too much effort or time, do not have clear added value for users, or are simply too expensive. One explanation for these issues can be found in suboptimal development, implementation, and evaluation processes, in which insufficient attention is paid to the interrelationships between people, context, and technology. Even though more research is necessary, findings point to the fact that a holistic development, implementation, and evaluation process increases the chances of successful sustained use of effective eHealth technologies, thus increasing the likelihood of achieving the desired impact on health and healthcare. These processes are complex and multifaceted and are thus ideally guided by specific frameworks or models. This chapter is specifically focused on one of such models, which is especially suitable due to its focus on eHealth, interdisciplinary nature, and holistic, iterative approach towards development, implementation, and evaluation: The CeHRes Roadmap.

In this chapter, the CeHRes Roadmap – a framework for eHealth development, implementation, and evaluation – is explained. The Roadmap consists of six main phases: The contextual inquiry, value specification, design, operationalization, summative evaluation, and formative evaluation. The chapter starts with an explanation of the rationale behind the Roadmap. After that, each phase is explained, its objectives are stated, relevant concepts, methods, and activities are explained, and the types of outcomes one might expect from each phase are given. Furthermore, references to other chapters that provide more in-depth information and cases are provided. After reading this chapter, you will be able to:

- Explain the need for a holistic, iterative, and interdisciplinary development, implementation, and evaluation approach for eHealth technology;
- Describe and explain the pillars that underpin holistic eHealth development, implementation, and evaluation;
- Describe and define the six main phases of the CeHRes Roadmap, state their main objectives, and explain the rationale behind each phase;
- Explain how the phases of the CeHRes Roadmap are interrelated and why an iterative, agile development approach is important;

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- List several suitable models and methods for eHealth development, implementation, and evaluation and explain the added value of a multi-method, interdisciplinary approach for each phase.

Holistic eHealth Development, Implementation, and Evaluation

Pillars Underpinning eHealth Development, Implementation, and Evaluation

Before presenting the different phases of the CeHRes Roadmap, we will first present the five pillars that underpin it (Figure 7.1). They are based on a review about existing eHealth frameworks (van Gemert-Pijnen et al., 2011), and updated with over a decade of experience with eHealth research guided by the CeHRes Roadmap (Kip et al., 2022), and frameworks, models and insights from different relevant disciplines such as human-centred design, implementation science, and psychology. Given this broad foundation, the methodologies, approaches, and underlying principles of these pillars are not just relevant for those working with the CeHRes Roadmap, but for any eHealth-related process, regardless of the specific framework that is used. An overview of the five pillars is provided below, after which they are explained in more detail.

eHealth development, implementation, and evaluation processes:

- Are ongoing and intertwined rather than phases containing separate and sequential activities;
- Require a holistic approach, focused on a fit between technology, people, and context;
- Require a multi-method, iterative approach with continuous evaluation cycles;
- Require constant active involvement of stakeholders;
- Are based on an interdisciplinary approach.

eHealth development, implementation and evaluation processes are ongoing and intertwined rather than phases containing separate and sequential activities

While it might sound like development, implementation, and evaluation are separate, consecutive stages, this is not the case: They are intertwined, interrelated activities that are all relevant from the start (Mohr, Lyon, Lattie, Reddy, & Schueller, 2017). The same goes for the phases of the CeHRes Roadmap: While, for overview purposes, they are visualized as separate activities, in reality the development, implementation, and evaluation are all intertwined (van Gemert-Pijnen et al., 2011). To illustrate: Too often, implementation is seen as a post-design activity, while attention should be paid to it from the start, for example by identifying potential implementation issues as early as possible to ensure that they can be accounted for during development. Furthermore, development activities of eHealth can also take place during evaluation, for example when new insights and points of improvement arise. Additionally, the evaluation process can already be initiated during

Figure 7.1 Pillars of the CeHRes Roadmap.

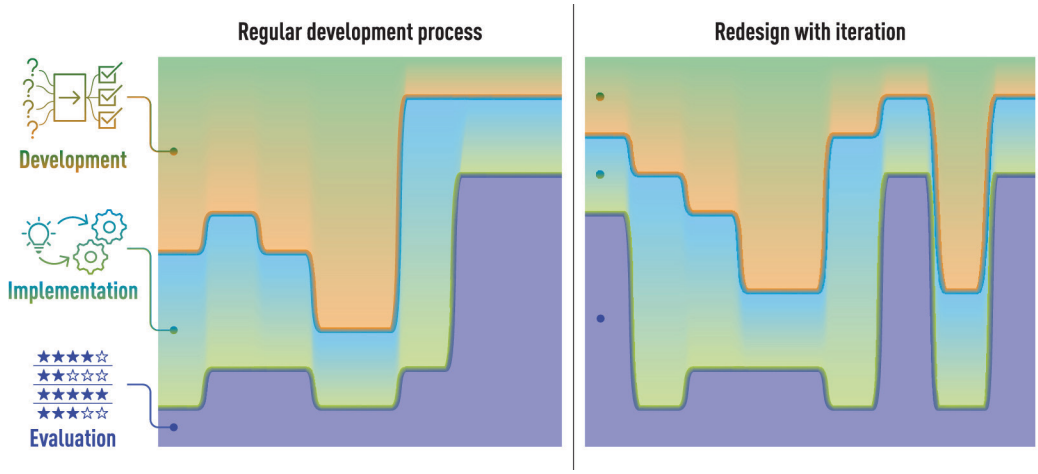

Figure 7.2 Illustration of two different ways of how development, implementation, and evaluation are ongoing and intertwined.

development, for example when a functioning prototype is used to first evaluate its underlying working mechanisms with a different target group, such as students, before it is further developed to optimally fit the intended (and more vulnerable or hard to reach) target group, e.g., psychiatric patients. Furthermore, goals that evaluation research should focus on are ideally specified during development. It is also possible to first conduct thorough evaluation studies to prove effectiveness before fully diving into implementation. During the entire process, a different process will be predominant, but activities from other stages will also be relevant to a lesser extent, as is visualized in Figure 7.2.

As the explanation above already illustrates, it is important to note that eHealth development, implementation, and evaluation processes are never really finished: There will always be room for improvement or updates of the content or design of a technology, there will almost always be a need for more and better implementation strategies, and new questions for evaluating the impact and uptake of a technology will always keep arising. However, this does describe an ideal situation. In practice this is often difficult because of limited resources such as time or money, because a (research) project ends, or because a technology is not of added value and further investments are not considered worthwhile.

eHealth development, implementation, and evaluation processes require a holistic approach, focused on a fit between technology, people, and context

Regardless of the type or goal of an eHealth intervention, there are interrelationships between the design and content of a technology, the needs and preferences of the people involved, and the context in which it is used. While more research is necessary, it seems that a good fit between technology, people, and context increases the chances of successful adoption and sustained use (Nielsen & Mathiassen, 2013 Kip et al., 2019). These interrelationships warrant a holistic approach, in which different elements are all interdependent and part of one whole instead of separate constructs. Because individual elements in a complex system are determined by the relation they have to other elements, separate analysis of its parts should be avoided (James, 1984).

With regard to eHealth, technology, context, and people are interrelated and should not be viewed (and studied) as separate elements. First, technology and the behaviour of people are interrelated. The introduction and sustained use of technology ideally influences the way end-users behave, resulting in, for example, better health outcomes or increased well-being. To enable this behaviour change, users should be adherent, which means that eHealth should be used as intended – this can be viewed as usage behaviour. In order to promote the successful use of eHealth, it is important to investigate and improve the way in which people use and interact with – in other words, behave within – a technology. Concepts such as engagement – the extent to which someone is involved or occupied with an eHealth technology from an emotional, behavioural, and cognitive perspective – are important to account for to ensure adherence and behaviour change (Kelders, Van Zyl, & Ludden, 2020). Second, the use of eHealth is never isolated, but influences and is influenced by the context in which it is used. The introduction of eHealth creates novel structures and processes for healthcare delivery; an adapted or new ecosystem for healthcare emerges (Eysenbach, 2001). Examples of these changes are a shift from hospital- to home-based care enabled by remote patient monitoring systems, or the emergence of shared decision making in healthcare enabled by the rise of personal health records. Furthermore, since a technology is never finished, its design and content ideally change over time to increase the fit with the context and/or incorporate changes (Mohr, Weingardt, Reddy, & Schueller, 2017). To illustrate: After introduction in practice, the content of Internet-based interventions can be rephrased and shortened to better fit the cognitive skills of users, or content can be adapted to be in line with revised treatment guidelines.

eHealth development, implementation, and evaluation processes require a multi-method, iterative approach with continuous evaluation cycles

In order to do justice to the holistic, multifaceted, and complex nature of eHealth, its development, implementation, and evaluation should not be viewed as linear processes with consecutive steps: They are iterative, flexible, and dynamic, with constant changes to the process and products (Hekler et al., 2016; Patrick et al., 2016). This is in line with an agile approach, which currently is common practice in software development. Such an approach is characterized by the division of large tasks into rapid, shorter phases and constant adaptations of plans based on the outcomes of evaluations. Core values are close collaboration, a 'lean' mentality to minimize unnecessary work, active stakeholder involvement, and the acceptance of uncertainty (Dingsøyr, Nerur, Balijepally, & Moe, 2012). In order to apply an agile approach to eHealth, a multi-method approach is key. Researchers need to be able to draw from a broad toolkit of both qualitative and quantitative research methods and products, and select the method that best fits their research objective, the practical demands from the context, and the characteristics and needs and wishes of the participants (Kip et al., 2022). It is important to ensure that the selected methods fit within the entire process and are related to each other. To ensure such a coherent approach and to prevent the project team from 'getting lost', there is a need for continuous formative evaluations in which outcomes of activities are critically analyzed, evaluated, and adapted (Michie, Yardley, West, Patrick, & Greaves, 2017). Constant evaluation in which stakeholders are actively involved can also ensure a good fit with the stakeholders and their context. Within each method, the project team should always strive to gain insight into the perspective and characteristics of the context and users. Moreover, it is important to carefully consider the combination of different methods and to check if and how findings from different methods are consistent with and build upon each other. This can take on different forms, for example, verifying outcomes of a phase with users, checking if outcomes still match the outcomes of previous phases, or gathering stakeholders' opinions on a specific idea for a next phase.

An agile approach might seem like a contradiction to a rigorous scientific approach in which all research activities are meticulously planned (and sometimes even published) in advance. While agile science can indeed be challenging and complex, it is not a synonym for unstructured or

messy: It is a way to shape systematic, structured yet dynamic high-quality research processes that are able to deal with changes and new insights (Dingsøyr et al., 2012). Consequently, while a broad research plan with potentially suitable methods can of course be developed, it might be necessary to deviate from this plan based on outcomes of specific methods or new insights regarding the needs of stakeholders or possibilities of a technology. However, as is the case for any scientific activity, it is important to remain transparent: The project team should carefully map all steps, choices, and reasons for that, also to ensure that others can learn from their experiences (Kip et al., 2022).

eHealth development, implementation, and evaluation processes require constant active involvement of stakeholders

In order to create eHealth that meets the needs and wishes of users and other stakeholders, a participatory approach is recommended, in which stakeholders are actively involved throughout the entire process (Bartholomew et al., 2006; Beerlage-de Jong, Wentzel, Hendrix, & van Gemert-Pijnen, 2017; Wentzel et al., 2014; Yardley, Morrison, Bradbury, & Muller, 2015). Participatory development goes beyond merely involving end-users such as patients or healthcare providers, because this might cause a dominance of the user perspective and might lead to overlooking the needs of other stakeholders (Bødker, Kensing, & Simonsen, 2009). Stakeholders such as managers, healthcare insurers, and technology developers should be involved as well to ensure a holistic approach (van Woezik, Braakman-Jansen, Kulyk, Siemons, & van Gemert-Pijnen, 2016). Amongst other things, stakeholders can provide input when identifying problems where technology can be of added value, improving the design of a technology, or identifying boundary conditions for integration in existing healthcare systems. In participatory development, the roles of a stakeholder can range from an informant that mostly provides input on products when invited by researchers, to a co-creator that is actively involved in creating ideas and products (Scaife, Rogers, Aldrich, & Davies, 1997). Stakeholders can (or should) also be part of an interdisciplinary project team that coordinates the entire eHealth process.

A participatory approach is not just important for development: Stakeholders should also be actively involved in implementation processes, for example in setting implementation objectives, identifying strategies, designing implementation material, and evaluating the progress and outcomes of an implementation. Additionally, different groups of stakeholders should also be actively involved in evaluation: To ensure a value-based approach in which technology is aligned with the needs of stakeholders, it is important to evaluate with instead of for the target group (O'Cathain et al., 2019). This means for example that the values that were formulated in close collaboration with stakeholders during the development process should be evaluated. Finally, participatory development does not always have to be about creating new technologies, since existing technologies can be redesigned and reused in different contexts as well, which also requires active stakeholder involvement. As a final note, it is important to emphasize that stakeholders should only be involved when it is necessary: Merely involving end-users for the sake of involving end-users is not of added value and takes up valuable time of participants and researchers (van Velsen et al., 2022). This requires careful consideration and clearly set objectives by the project team.

eHealth development, implementation, and evaluation processes are based on an interdisciplinary approach

In order to capture the complexity of eHealth, an interdisciplinary approach towards research and development is required (Michie et al., 2017). In such an approach, theories, methods, and models from different disciplines are combined and ideally merged, resulting in new approaches, concepts, and models. It is important to make the distinction with a multidisciplinary approach. In a multidisciplinary approach, input is provided by different disciplines, but this is done independently from each other – there is not much integration of different methods, approaches, or theories and people remain working within the boundaries of their discipline. In an interdisciplinary approach, input

from different disciplines is actively integrated, aiming to create a synergy that goes beyond the sum of individual contributions. To achieve this, interdisciplinary teams actively work together and aim to blend their approaches. Ideally, eHealth development, implementation, and evaluation are interdisciplinary since their holistic nature requires an integrated approach.

There are multiple paradigms that are relevant for an interdisciplinary approach towards eHealth, a (not exhaustive) overview of which is given in Table 7.1.

Table 7.1 An overview of (some of the) disciplines that are relevant for eHealth development, implementation, and evaluation.

Discipline	*Importance*	*Example contribution*	*Further reading*
Psychology	Accounting for the behaviour, emotions, and cognitions of end-users and other stakeholders.	Theories from, for example, health psychology can be used to explain the behaviour that needs to be changed and support behaviour change (Michie et al., 2013); research methods grounded in psychology such as interviews can be used as well (Bonten et al., 2020).	Chapter 2, Chapter 16
Human-centred design	Ensuring that the eHealth technology fits with the needs, skills, and characteristics of its end-users and other stakeholders.	Methods (e.g., usability tests) and products (e.g. prototypes) from human-centred design can be used to design and evaluate a technology that has the best user experience and usability, which will increase the chances of implementation and impact in practice (Giacomin, 2014; Göttgens & Oertelt-Prigione, 2021).	Chapter 11
Persuasive technology	Developing a technology that increases chances of behaviour change.	Specific persuasive features (e.g. feedback, personalization) can be integrated into a design to increase the chances of adherence and resulting attitude- and behaviour change (Fogg, 2002; Kelders, Kok, Ossebaard, & van Gemert-Pijnen, 2012; Oinas-Kukkonen & Harjumaa, 2009).	Chapter 12
Engineering	Designing and evaluating eHealth with methods and approaches that account for the characteristics of technology.	Methods such as agile science, requirement engineering, and log data analysis can be used to develop and evaluate eHealth technologies (van Velsen, Wentzel, & van Gemert-Pijnen, 2013). It is recommended that behavioural scientists understand the basics of these models and other technology-related aspects (e.g., coding) to ensure that they speak the language of developers.	Chapter 3, Chapter 9
Implementation science	Systematic planning and evaluating implementation of eHealth to ensure integration in practice.	Implementation frameworks such as the CFIR and NASSS, that account for implementation factors in different levels – the intervention, the people involved, and the inner and outer contexts (Damschroder, Reardon, Widerquist, & Lowery, 2022; Greenhalgh et al., 2017), can be used to shape implementation processes.	Chapter 13
Business modelling	Ensuring that a technology is financially feasible and of added value for its context.	Business models such as the Business Model Canvas can be used to determine a value proposition early on and ensure that it is operationalized during implementation (Osterwalder & Pigneur, 2010; van Limburg, Wentzel, Sanderman, & van Gemert-Pijnen, 2015).	Chapter 10
Domain-specific theories	Making sure that the eHealth technology is consistent with guidelines and up-to-date knowledge of the specific domain.	Domain-specific theories and models such as guidelines for cognitive behavioural therapy (CBT) in mental healthcare and knowledge about risk factors for disorders such as depression can be used when developing interventions for that specific context.	Not applicable – depends on domain

The interdisciplinary nature of eHealth is also important when composing the project team that coordinates the development process. Putting together a team with members from different disciplines is deemed essential to ensure that all relevant perspectives are actively involved in the development, implementation, and evaluation and to prevent tunnel vision (Feldman, Schooley, & Bhavsar, 2014; O'Cathain et al., 2019). Two different types of people can be involved: Professionals with knowledge on eHealth development, such as designers, project managers, researchers, and engineers, and people who are expert on the domain in which the eHealth intervention will be used, such as patients, healthcare professionals, or managers (Kip, Kelders, Bouman, & van Gemert-Pijnen, 2019).

The CeHRes Roadmap

eHealth has multiple proven and potential benefits, but there are still many barriers. As mentioned before, thorough development, implementation, and evaluation of eHealth can (partly) help to overcome these barriers. In 2011, a review on the potential and limitations of existing eHealth frameworks was conducted to investigate their value in overcoming these barriers (van Gemert-Pijnen et al., 2011). An important outcome was that it was assumed that barriers can mostly be avoided by applying a participatory development process that creates a good fit between technological, human, and contextual factors. However, most existing frameworks were found to have a rather conceptual approach instead of practical guidelines, were sequential as opposed to iterative, and lacked the stakeholder-driven approach. Consequently, based on this review, the pillars and phases of the CeHRes Roadmap were developed.

The CeHRes Roadmap (Figure 7.3) serves as a guideline for the development, implementation, and evaluation of eHealth technology that fits the people and their context. It assists the project team in planning, coordinating, and executing the sustainable creation of eHealth technologies (van Gemert-Pijnen et al., 2011). This can refer not only to 'new' technologies that are developed from scratch, but also to the improvement of existing technologies – or even the critical analysis of an already conducted development, implementation, and/or evaluation process. The Roadmap consists of five interrelated phases and connecting cycles. These phases are the *contextual inquiry*, *value specification*, *design*, *operationalization*, and *summative evaluation*. Connecting all these phases are continuous *formative evaluation* cycles which can also be viewed as a phase in itself. It ensures that activities during a phase are related to the stakeholder perspective, the context, and outcomes of previous phases. In this chapter, an updated version of the Roadmap is presented. The

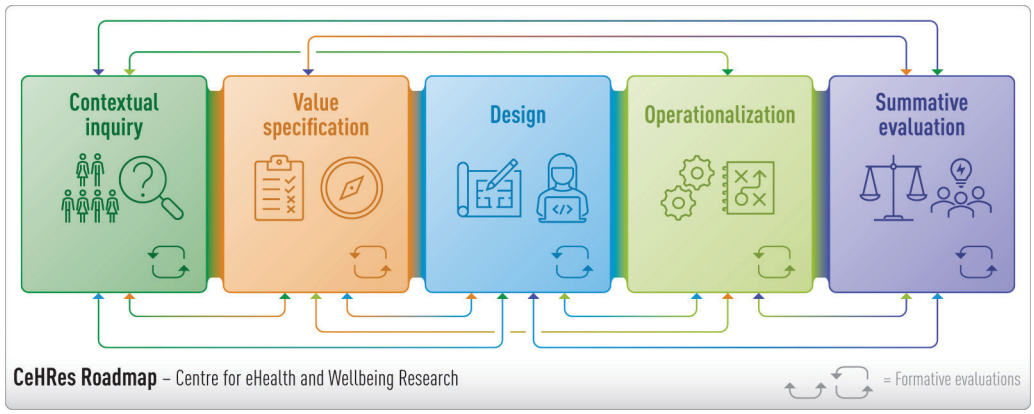

Figure 7.3 The CeHRes Roadmap.

phases have remained the same as in the original version, but their main objectives and accompanying methods and frameworks are revised and updated based on new insights from research and over a decade of experience with working with the CeHRes Roadmap.

Strictly speaking, the first three phases of the Roadmap are related to development of eHealth, operationalization fits best with implementation, and summative and formative evaluation are most aligned with the evaluation phase. However, this distinction is made for visualization and overview purposes – in reality the phases overlap and are intertwined. Furthermore, as is the case with any roadmap, the CeHRes Roadmap is not a checklist or step-by-step approach for developing, implementing, and evaluating eHealth technologies. It is a visualization of an approach and a tool to help researchers and practitioners in shaping their own, unique processes. Finally, the CeHRes Roadmap is not the only model that can be used for eHealth development. There are different types of these models, such as Intervention Mapping (Bartholomew et al., 2006), the person-based approach (Yardley et al., 2015), and the Accelerated Creation-to-Sustainment model (Mohr et al., 2017). These models have some differences, but also many similarities with the Roadmap. Depending on the skills and preferences of the project team, other models can be used, partly supplemented with elements of the Roadmap, or a combination of both models can be generated.

Organization of this Chapter

The upcoming sections of this chapter are focused on the phases of the CeHRes Roadmap. For each phase, the following aspects will be described in separate sections:

- **Description of the phase**
  In this section, a brief description of the phase, its background, and its relation with the entire development process is provided;
- **Objectives**
  This paragraph briefly states the objectives of that phase, which logically arise from the description of the phase;
- **Concepts, methods, and activities**
  This paragraph is structured by the previously stated objectives. For each objective, relevant concepts, methods, and/or activities are described to give an idea of how the objectives of the phase can be reached. Concepts can be models, theories, or approaches. They have to be understood to get a good idea of the rationale behind the methods and activities that can be used.

How Should this Chapter be Read?

The methods presented in this chapter are not an exhaustive list: Other methods might also be used if they are relevant and suitable. Consequently, this chapter's main goal is to provide the reader with insight into the main objectives of the phases of the CeHRes Roadmap and does not provide a step-by-step approach for eHealth development, implementation, and evaluation. In case more in-depth information is required, this book contains chapters that elaborate on the disciplines, methods, and principles introduced here, as can be seen in the table below.

Contextual Inquiry

What is the Contextual Inquiry Phase?

The first step in any eHealth development project is a thorough investigation of the context in which it will be used. In order for an eHealth technology to be successful, it should provide a solution for relevant issues, it should be accepted by (groups of) people such as the users, funders,

Table 7.2 Phases of the CeHRes Roadmap and accompanying chapters.

Phase	*Chapter(s)*
Contextual inquiry	8 – The Contextual Inquiry
Value specification	9 – Activities for Value Sensitive eHealth Design
	10 – Business Modelling
Design	11 – Human-centred design
	12 – Persuasive Health Technology
Operationalization	13 – Innovation, Improvement, and Implementation – Conceptual Frameworks for Thinking through Complex Change
	14 – Sustainable eHealth Implementation: A Practical Perspective
Summative evaluation	15 – Engagement
	16 – eHealth Evaluation

and policy makers, and it should fit the physical, social, and cultural environment in which it will be used (Glasgow, Phillips, & Sanchez, 2014; Michie et al., 2017). Consequently, a contextual inquiry is necessary to paint a complete picture of the current situation and to pinpoint the most relevant points of improvement that could potentially be addressed with an eHealth technology. A contextual inquiry assists in keeping a focus on the people and their environment from the start (Holtzblatt & Jones, 2017; Wentzel, 2015). In order to achieve this, first an identification and analysis of relevant stakeholders – i.e. (groups of) people who affect or are affected by the potential eHealth technology – has to be conducted.

When an initial list of stakeholders is completed, an overview of the current situation and points of improvement must be created. This overview is created by means of multiple methods, allowing the project team to gain a good understanding of prospective users' daily lives or work routines, the perspectives and ideas of other involved stakeholders, their environments, and any practical organizational constraints such as rules and regulations (Sjöström, von Essen, & Grönqvist, 2014). Besides merely describing a situation, points of improvement for which an eHealth technology could be of added value have to be mapped as well. The outcomes of the contextual inquiry serve as the foundation for the rest of the development, implementation, and evaluation process.

Objectives of the Contextual Inquiry Phase

The contextual inquiry has several main objectives:

1. To identify and gain insight into the roles and activities of relevant stakeholders;
2. To analyze the current situation regarding the involved people's daily lives and behaviour, organizational characteristics and structures, relevant policies and legislation, and potentially useful existing technologies;
3. To identify the main point(s) of improvement for which an eHealth technology could be a solution.

Concepts, Methods, and Activities in the Contextual Inquiry Phase

1. Stakeholder identification and analysis

During every phase of eHealth development, stakeholders should be actively involved. That is why one of the first activities that should be undertaken is a stakeholder identification. There are many different kinds of stakeholders, for example, users, researchers, policy makers, funders, insurance

companies, and designers. To make sure every stakeholder is identified, multiple methods can be used and combined (van Woezik et al., 2016). Some commonly used methods are:

- *Literature study*. Stakeholders can be identified by systematically reviewing or rapidly scanning the literature, for example, about stakeholder theories or involved stakeholders in development of similar eHealth technologies;
- *Expert recommendations*. Experts from the field can be asked to nominate stakeholders they consider relevant;
- *Snowball sampling with stakeholders*. Once a preliminary list of stakeholders is created, it is valuable to ask them to supplement the list.

Once an initial overview is created, the stakeholders should be analyzed. There are several ways to conduct a stakeholder analysis (van Woezik et al., 2016). One frequently used framework is that of stakeholder salience (Mitchell, Agle, & Wood, 1997). In this approach, stakeholders can be mapped based on their power, legitimacy, and urgency. They can be ranked by both the project team and other stakeholders (also see Chapter 8). Based on this analysis and – if necessary – other methods, *key stakeholders* can be selected. The main reason for this is that not every stakeholder will be equally important for the eHealth technology, and intensively involving each stakeholder requires too many resources. The selection of key stakeholders can be made solely by the project team (which should of course include stakeholders), but also by letting a group of stakeholders who are not part of the team decide on who the key stakeholders are (van Woezik et al., 2016). It is important to keep in mind that the initial overview of stakeholders is definitely not final, since it should be updated throughout the remainder of the process.

2. Analysis of the current situation

To ensure that the project team knows for whom and for what context they are creating eHealth, a thorough understanding of the current situation is essential. The exact context is part of the contextual inquiry as well. Besides the perspectives and opinions of the stakeholders on the current situation, the context can include the rules, regulations, organizational culture, ethical issues, and other important matters that have to be considered during the development (Sjöström et al., 2014). Examples of broad research questions related to people, the context, and technology are:

- What is (and is not) part of the context within this project?
- What does the delivered care look like? What is the patient journey, and what (treatment) protocols are used by healthcare providers?
- What rules, regulations, guidelines, and ethical themes play a role within the relevant organizations?
- What does the behaviour of the intended end-users look like? What are the determinants of their behaviour, and what theories can be used to analyse and explain their behaviour?
- What are important domain-specific theories, frameworks, or models?
- What technologies are used within the context and what are the users' experiences?
- What is known about potentially useful technologies in terms of technological possibilities, working mechanisms, and experiences in other contexts?

Throughout this entire process, it is important to integrate scientific and grey literature, theories and frameworks, and the perspective of the involved people because combining multiple sources results in a more comprehensive overview. An overview of potentially useful methods is provided in the next section.

3. Identification of points of improvement

Merely describing a context does not suffice: The project team needs to gain insight into points of improvement that can be addressed by the to-be-developed eHealth technology. When doing this, it is important to specifically describe the behaviour that needs to be improved and identify accompanying determinants that can be targeted with an intervention (also see Chapter 2). A (simplified) example of a behaviour is the prescription of antibiotics, and accompanying determinants that arise from literature and theories might be knowledge and attitudes of healthcare providers. Besides using research and theory, it is essential to thoroughly involve the stakeholders. By combining methods, insight can be gained into what needs to be changed from an individual and organizational perspective. This also helps in identifying the initial conditions for implementation, which shows that implementation is relevant from the start of a development process. Implementation barriers such as limited financial resources or low literacy skills of prospective end users can be identified in the contextual inquiry to ensure that they are accounted for in upcoming phases. Examples of methods that can be used in the contextual inquiry are (Kip et al., 2022):

- *Desk research*. This method is useful to map existing, non-scientific documents such as protocols, news articles, or internal communication about relevant topics, such as a specific situation, regulations, or technology;*Systematic literature review.* A systematic search of scientific literature can be conducted to find out about the current state of affairs of a specific topic from a scientific point of view. Examples are determinants for the behaviour that has to be changed, an overview of eHealth interventions within a specific field, or possibilities and working mechanisms of a specific eHealth technology that is considered to be developed;
- *Focus groups*. Structured group discussions with one or multiple groups of stakeholders can be organized to, for example, identify problems and strong points of the current way of delivering care;
- *Interviews*. Interviews, guided by an interview scheme, can be conducted with stakeholders to identify their individual perspectives on a certain situation, for example about problems with current use of technology;
- *Observation*. Observing daily practice within a context can reveal relevant, ecologically valid information about the designated end users of the eHealth technology and their daily tasks, issues, and preferences.

It is important to note that these methods are often combined and complement each other, and are often also used for both this and the previous phase (i.e., to analyze the situation and immediately also identify points of improvement). As is the case for any part of eHealth development, there is not one correct way to conduct this process. The selected methods should fit the research questions, skills, and needs of the participants (e.g., lower cognitive skills, stigma regarding the disorder), and practical limitations of the context (e.g., shortage of staff, geographical distances). The better the researcher understands their stakeholders, the better they can select suitable methods, which is another advantage of paying much attention to getting to know the context (Schouten et al., 2022).

Outcomes of the Contextual Inquiry Phase

In line with the three objectives, a well-performed contextual inquiry has three main outcomes. The first is an overview of stakeholders, which can be visualized in a stakeholder map. In this

map, similar stakeholders can be grouped together, key-stakeholders can be pointed out, and relationships can be visualized. Second, an overview of the current situation should be created. The way this is documented, presented, and summarized will differ per project, one example of this is a patient journey. Third, the main points of improvement for which a technology might be of added value should be described. This can range from one to multiple relevant issues. The identified points of improvement can be related to, for example, *efficiency*, *effectiveness*, timely delivery of care, or safety of healthcare.

The contextual inquiry lays the groundwork for the remainder of the development, implementation, and evaluation processes. The choices that are made in the contextual inquiry regarding the issue(s) that a technology should address will be elaborated on and made more specific and concrete in the value specification. The design phase is also grounded in the contextual inquiry, since the technology should address the problem(s) and accompanying behaviour that were described in the contextual inquiry, it has to fit within the organizational structures, and should be in line with the needs of the identified stakeholders. In the operationalization phase, implementation strategies should be designed with and for the stakeholders and with a keen eye on their fit within the specific context. For example, the foundation for an implementation plan can already be created in the contextual inquiry by identifying elements that need to be accounted for when using a technology within a specific organization – i.e., an initial identification of implementation factors such as limited resources or the importance of integration in treatment protocols (Kip et al., 2019). Finally, in the summative evaluation phase, it should be determined whether the identified point(s) of improvement(s) were actually improved, again by involving relevant stakeholders. While it is often overlooked or underestimated, a contextual inquiry provides the foundation for any eHealth development process by ensuring insight into what is needed to enable a good fit between the people, organization, and technology.

Value Specification

What is the Value Specification Phase?

The outcomes of the contextual inquiry provide a broad, general idea of the added value that a certain technology might have. However, these outcomes are not concrete enough to specify what is needed from or asked of an actual technology. In the value specification, the identified topics are narrowed down and translated into specific requirements for a technology. This is again done in close cooperation with stakeholders that were identified in the contextual inquiry – but in addition to that new stakeholders might pop up in this phase. The value specification supports the project team in becoming as precise and concrete as possible in terms of what a technology should do and look like. In order to achieve this, several activities have to be performed. As is almost always the case, these activities are often performed in parallel to each other, can be combined, and are related to activities of earlier or later phases.

The name of this phase already indicates that values have to be formulated to summarize the needs, ideals, and interests of all key-stakeholders. Besides the stakeholder perspective, it is also important to consider evidence-based elements that can be added to a technology to support behaviour change. In addition to that, in this stage the identified values are used to formulate requirements to specify what the technology should do, look like, and how it should be delivered. Furthermore, the project team needs to initiate the development of a business model to plan and operationalize the integration of an eHealth technology in practice. In the value specification, first versions of these products are generated to gain insight into the added value of the technology. The value specification phase is quite complex, but also essential for good eHealth development, since the goals and scope of the technology should be clear before it is actually designed and used in practice.

A comprehensive overview of values is pivotal for further stages since they support the project team in constantly checking whether the technology is still in line with these values.

Objectives of the Value Specification Phase

The value specification has several objectives:

1. To formulate and prioritize values from all identified key-stakeholders and set concrete goals based on these values;
2. To select initial behaviour change techniques (BCTs) and persuasive features that fit with the values and needs of the key-stakeholders features;
3. To translate the values into specific requirements to describe the to-be-developed eHealth technology;
4. To create a first version of a business model for the eHealth technology.

Concepts, Methods, and Activities in the Value Specification Phase

1. Formulate and prioritize values and objectives

While there are many definitions of values, in relation to value-sensitive design, values can be viewed as things that are important to people in their personal lives, related to for example ethics and morality (also see Chapter 9). Relating this to eHealth, values also incorporate what stakeholders find important regarding the technology from their own, personal perspective. In other words: Values represent ideals or interests of stakeholders and summarize what they find important on an abstract level (van Velsen et al., 2013). They assist the project team in specifying what stakeholders want to achieve or improve via a technology, which implies that values are aligned with the point(s) of improvement that were identified in the contextual inquiry. Values can be related to social, behavioural, cognitive, emotional, economic, or healthcare issues. Examples are saving costs, personalized care, increasing efficiency of care, increasing access to healthcare, improved decision-support for healthcare professionals, autonomy, improving specific health-outcomes, or improved self-image (Asbjørnsen et al., 2020; Kip, Kelders, & van Gemert-Pijnen, 2019). Since values can remain quite abstract, it is important to add specific definitions to ensure a shared understanding (Kip, Kelders, & van Gemert-Pijnen, 2019).

Values can be uncovered through several methods, such as interviews or focus groups. Combining multiple methods can be helpful to paint a complete picture of the values of all key-stakeholders. When collecting data, it can be helpful to discuss concrete examples of existing or potential technologies, since discussing values in an abstract way can be very complex. This is also an illustration of overlap with the design phase, because prototypes of potential eHealth technologies are often used in both phases (Kip, Kelders, & van Gemert-Pijnen, 2019). Since multiple stakeholders should be involved in this process, conflicting values might arise. For example, managers might have different interests than patients: They might emphasize cost-saving, while patients require a very personalized approach that could be quite expensive. Such conflicting values should be identified as early as possible and can be discussed with an interdisciplinary project team to make a decision on what to prioritize.

Values can be used as a foundation for specific objectives that should be reached by the eHealth technology. These objectives are ideally formulated in a SMART way (specific, measurable, achievable, realistic, and timely) and serve as the basis for the evaluation of the technology. Connecting values to objectives helps to ensure that the stakeholder perspectives are involved in the goals of the project and the accompanying evaluation studies. Of course, these objectives can (and should)

be further defined throughout the process, but explicitly formulating them early on helps to keep the process focused.

2. Select behaviour change techniques and persuasive features

eHealth interventions almost always aim to support behaviour change. However, this has appeared to be very difficult to achieve, not just because changing behaviour in itself is difficult, but also because it is challenging to ensure that users remain engaged and adhere to the intervention. In order to increase the chances of adherence, engagement, and behaviour change, behaviour change techniques (BCTs) and persuasive features can be integrated in the technology. BCTs are derived from behaviour change theories from psychology and can be defined as a general technique to influence or create changes in the predictors of specific behaviour (Michie et al., 2013), also see Chapter 2. In the free BCT taxonomy app, 93 evidence-based BCTs are described, which are divided into multiple overarching categories, such as Goals and planning, Social support, Feedback and Monitoring, and Reward and Threat. Persuasive features are part of the Persuasive System Design (PSD) model and are divided into four categories (Oinas-Kukkonen & Harjumaa, 2009), also see Chapter 12: Primary task support, Dialogue support, Credibility support, and Social support. Furthermore, it might be relevant to also use domain-specific theories that were identified in the contextual inquiry. To illustrate: According to existing models on risk assessment and management for treatment of offenders, risk factors such as impulsiveness or intoxication play an important role in treatment of delinquent behaviour, which means that they could be integrated into eHealth interventions that target that specific behaviour.

BCTs partly overlap with persuasive techniques since they both target behaviour change, but the main difference is that the PSD is specifically aimed at technology, while BCTs are applicable to any kind of behaviour change intervention. Furthermore, BCTs are explicitly linked to psychological behaviour change theories. BCTs and persuasive features can be combined since they can complement each other. For example, the BCT 'feedback and monitoring' can be combined with the PSD 'tunnelling', in which the user is guided through a system/process, to facilitate the user experience.

To be able to select the most appropriate BCTs, persuasive techniques, and other features based on domain-specific theories, it is important to clearly identify the main objectives of a technology and the values of its user. Getting from these values to specific behaviour change mechanisms is an iterative process that will also play an important part in the design and evaluation phases of the Roadmap. However, the foundation for this is laid in the value specification phase. An important reason for this is that behaviour change mechanisms should be aligned with user needs, and not just be selected by researchers, as is often the case (Asbjørnsen et al., 2019). For example, the identified values can rule out some BCTs or persuasive features, e.g., a value related to cooperation might rule out the persuasive feature competition. Additionally, values can also provide insight into how to apply specific BCTs or features to a technology. For example, if 'privacy' is an important value and comparison of behaviour seems to be an effective BCT, it is important to do this without sharing personal information. The identified values can be connected to an initial set of suitable BCTs and persuasive features. For example, the value 'Feeling supported' can be identified in focus groups, via quotes such as '*It is really important that the technology motivates and supports me to keep up*'. Based on this value and accompanying quotes, the BCT 'feedback and monitoring' can be used, as well as the persuasive feature 'praise', to ensure a positive, motivating approach (Asbjørnsen et al., 2020). Previously collected data on values, e.g., quotes from interviews, can help the project team in selecting and operationalizing suitable BCTs. Consequently, identifying values, connecting them to BCTs and persuasive features, operationalizing them in a prototype, and updating and fine-tuning them is an iterative process. The project team has to be aware of the fact that the initially identified BCTs and persuasive features will probably change throughout the

remainder of the process: It is possible that some techniques are not feasible to integrate in a technology, new ideas for features might arise during the design process, or something might not be technically feasible.

3. Formulate specific requirements

Requirements describe what an eHealth technology should do, what data it should store or retrieve, what content it should display, and what kind of user experience it should provide. In other words, they are the instructions for developers that tell them how to create a technology that provides value to the end-user (also see Chapter 9). The following types of requirements can be identified: Functional and modality; Service; Organizational; Content; and Usability and user experience requirements.

As is the case with most eHealth activities, there is no clear step-by-step approach that can be followed to develop requirements. Usually, requirements are formulated by the project team, based on, for example, previously or newly conducted focus groups, interviews, questionnaires, literature reviews, card sorting, or comparable studies. Regardless of the methodology, it is always necessary to thoroughly involve the stakeholders, build upon earlier identified outcomes, and add at least one source to show on what data the requirement is based. Since values are more abstract, they can be used to group specific requirements to verify whether all important values are represented in the requirements. The other way around, groups of requirements can also be used to formulate values. As is the case with most eHealth-products, this is an iterative, dynamic process for which no step-by-step guideline is available.

A specific product that can help to design for the end-users and facilitate requirement formulation, is a persona. Personas are 'hypothetical archetypes of actual users' and are presented by means of a short biography with a photo and the goals they have in life or with regard to their work or medical condition (LeRouge et al., 2013; Ten Klooster et al., 2022). Personas can also include the previously identified values. One or more personas can be created to offer a concrete way to keep the end-user in mind when formulating requirements – but they are of course also useful for further steps. However, personas only describe end-users, but do not link them to the technology. This is where scenarios can be useful. Scenarios describe the potential, envisioned use of an eHealth technology by the end-users. Scenarios can contain information about how the end-user uses a technology in relation to their characteristics and values, what activities are supported by a technology, which steps a user follows, in which context this happens, and what the main functionalities that a technology offers are (Rosson & Carroll, 2002). There are of course other types of products that can support developers in formulating requirements, such as use cases or card sorting, depending on the skills and preferences of the project team.

4. Create a first version of a business model

Many eHealth projects suffer from the 'field of dreams' syndrome, in which a project team simply presupposes that users will show up spontaneously as soon as the technology is made available (van Limburg, Wentzel, Sanderman, & van Gemert-Pijnen, 2015). This shows a lack of understanding of important implementation issues like reimbursement dynamics, how much money to ask for the technology, or consumers' willingness to pay for the service (Miron-Shatz, Shatz, Becker, Patel, & Eysenbach, 2014). To prevent this, it is important to start developing a business model as soon as possible. A business model can be defined as 'the rationale of how an organization creates, delivers, and captures value' (Osterwalder & Pigneur, 2010). It can guide the implementation processes and clarifies the costs and benefits (values) for stakeholders. It is important to note that values in relation to a business model often have a narrower (and monetary) definition than those used during value specification activities, which again highlights the importance of using clear definitions and reaching a shared understanding about what values are, amongst the project team.

A frequently used method to create a business model is the business model canvas (Osterwalder & Pigneur, 2010). A business model consists of nine blocks. One block is focused on the value proposition – which is the eHealth technology. The three blocks on the left side (key partners, key activities, and key resources) show the required organizational aspects that are necessary to deliver the value to practice. Three other blocks help the team to identify who the main customers or users are, and what the best way of interacting with them is (customers, customer relationships, and channels). Finally, two blocks represent the financial aspects of the product and help to explain how to account for the costs that are related to offering the intended value (costs and revenues).

Because the project team has to account for implementation from the start, the creation of the business model should also start early in the development process, so it will be relevant in the value specification phase. Of course, it can (and should) be adapted throughout the entire process to ensure that it is in line with recent insights from the stakeholders and context. Multiple methods should be used to create the business model (e.g., interviews, focus groups, desk research), and information from the contextual inquiry and value specification is used to ensure consistency with earlier activities. Since a business model provides a more generic overview instead of a set of predetermined activities, the way it is filled in depends on the skills and preferences of the project team.

Design

What is the Design Phase?

The output of the contextual inquiry and the value specification serves as the blueprint for the eHealth technology, which is actually developed in the design phase. This is again not a hard transition: Often, activities of these phases overlap. The design phase is an extremely dynamic, iterative, creative, and collaborative phase during which there is an active collaboration between end-users, other stakeholders, researchers, designers, behaviour change experts, content experts, and perhaps even funders.

The final technology should not be developed all at once, since chances are that if that does happen, a lot of important problems may be missed and arise only after it has been introduced in practice and thus wasting a lot of time and effort. That is why multiple prototypes – visual representations of the to-be-developed technology – have to be developed based on the requirements. Prototypes are used to visualize and elaborate on initial ideas, using an iterative approach in which changes to the prototype are being constantly made, based on stakeholder input (Beerlage-de Jong et al., 2017; Wentzel et al., 2014). These prototypes have to be based on the requirements and thus also incorporate behaviour change techniques and persuasive features (see also Chapter 12). By creating prototypes and evaluating them with users, the project team can remove any critical issues, add elements that are thought of by the stakeholders, identify potential factors that need to be taken into account during implementation, and adapt the design to preferences and new insights.

Objectives of the Design Phase

The design phase has several main objectives.

1. Both low-fidelity (lo-fi) and high-fidelity (hi-fi) prototypes of the eHealth technology are developed;
2. Persuasive elements, behaviour change techniques, and/or domain-specific theories are operationalized and integrated into the design of the eHealth technology;
3. Usability tests of the prototypes have to be conducted with end users, experts, and other stakeholders.

Concepts, Methods, and Activities in the Design Phase

1. Developing low- and high-fidelity prototypes

When developing prototypes, it is especially important for every member of the project team to have a good understanding of the end users. For starters, the products from the value specification, such as requirements, personas, and values, should be used throughout the entire prototyping process to structurally incorporate the end-user perspective. Ideally, a first step in the prototyping process is to come up with initial ideas by means of ideation. However, in practice, a project team often already has some ideas of what they want to design, based on the earlier phases. These ideas are being constantly specified throughout the prototyping process. It can also be beneficial to involve a professional design company in the prototyping process since user experience (UX) designers have specific expertise and skills to translate requirements into prototypes.

A rough distinction can be made between low-fidelity (lo-fi) and high-fidelity (hi-fi) prototyping. The design process usually starts with very lo-fi prototypes: Prototypes that do not have to resemble the final technology but are mostly used to communicate about the overall goal and most important elements. An advantage of lo-fi prototypes is that they can be drawn up relatively quickly by people with little to no technical skills. There are several methods to create lo-fi prototypes, of which some examples are:

- *Paper-based prototyping/sketching.* Paper prototypes can be created with different kinds of materials such as pencils, paper, paint, sticky notes, cards, or paint. This can range from very basic sketches to more detailed drawings;
- *Digital prototyping.* Computer programmes like PowerPoint or Figma can be used. These programmes can be used to make clickable, interactive lo-fi prototypes;
- *Storyboarding.* Storyboards are sequences of images that clarify how the technology can be used by the user;
- *3D prototyping.* This method uses materials such as cardboard, foam, wood, plastic, clay, and building blocks.

Of course, other methods are possible as well. In addition, these methods are not solely used for lo-fi prototyping, but can also be used for hi-fi prototypes. While the distinction isn't that black-and-white, hi-fi prototypes have a higher resemblance to the final version of the eHealth technology, enable the user (to some extent) interact with it and are suitable for testing specific details of the technology. Developing them requires more technical expertise. The method to develop the hi-fi prototype depends on the technology that is being developed and the skills of the designer. More information on prototypes can be found in Chapter 11.

Often, the project team should also know which kind of information should be provided and how this has to be structured. This can be achieved in multiple ways, for example by using existing (treatment) protocols as the foundation for the content of a technology. Furthermore, Delphi studies can be conducted with experts to gain insight into which information a technology should contain (Yap et al., 2017). Furthermore, experts can be asked to create a first version of the technology's content. A way to structure the content of technologies that contain much information and to gain insight into the desired information structure, is by means of a card-sorting study. Participants are invited to cluster cards with information in whatever way they consider it to be logical. By analyzing these 'card clusters', the information or the menu structure of a certain website can be structured in a way that fits the end users' needs (Wentzel, Müller, Beerlage-de Jong, & van Gemert-Pijnen, 2016).

2. Integrating behaviour change theories and persuasive features in the design

In the value specification phase, initial choices for relevant behaviour change techniques, persuasive features, and possibly also features based on domain-specific theories were made and integrated into the requirements. However, since behaviour change is extremely complex, the set of behaviour change techniques will most likely be adapted throughout the process. Consequently, in the design phase, attention should again be paid to behaviour change. This can be done by collecting new data via interviews, focus groups, or questionnaires, and by using scientific literature on behaviour change techniques or features that are specifically relevant for a certain target group or behaviour (Asbjørnsen et al., 2020). Furthermore, these behaviour change techniques should be operationalized and integrated into prototypes. There is not a single, straightforward way to do this. On the contrary, it requires an iterative and creative approach. Techniques can be integrated in a prototype in multiple ways, amongst other things through brainstorming sessions with stakeholders, by involving experts on design and behaviour change, by investigating working mechanisms in similar technologies, and via co-creation sessions with end-users. Once these mechanisms are integrated into prototypes, they should be presented to stakeholders and experts to investigate if they are potentially effective and fit the skills and preferences of end-users. Again, this is an iterative process, which means that it will probably take some time to identify the most suitable techniques and integrate them in the most optimal way.

3. Conducting usability tests with stakeholders and experts

Prototypes have to be tested with stakeholders to gain insight into overall opinions, points of improvement, and recommendations. This can be done by means of *usability testing*. Usability tests can be used to study how someone interacts with the system, to test the ease of use and user-friendliness of the technology, or to assess whether behaviour change mechanisms and requirements are correctly translated into the design. Very broadly speaking, there are two ways of testing usability: Involving usability experts or involving users.

Some studies indicate that the best results occur when both kinds of usability testing are combined. Some examples of methods for usability testing are (Jaspers, 2009):

- *Think-aloud method.* In this method, intended end-users are provided with a scenario in which they have to use a prototype, and while doing this, they are asked to think aloud, i.e., verbalizing their thoughts about the system while using it;
- *Heuristic evaluation.* In this method, design experts assess the usability of the system by exploring it using a set of recognized usability principles, called heuristics. Examples of heuristics are visibility of system status, recognition rather than recall, and aesthetic and minimalist design (Nielsen, 1995);
- *Cognitive walk-through.* In this type of usability testing, experts are asked to execute tasks that a user would want to perform to identify usability issues (Wharton, Rieman, Lewis, & Polson, 1994). This method can also be used by experts on content.

Operationalization

What is the Operationalization Phase?

Operationalization refers to the planning and actions for the introduction, dissemination, adoption, and internalization of the technology in the intended context. In this phase, the technology is launched, marketing is set into motion, and organizational working procedures are put into practice. This phase is part of implementation, but the main difference between operationalization and

implementation is that implementation is more overarching and already begins in the contextual inquiry, while operationalization is mostly focused on the actual rollout of plans that are necessary for the use of a technology within a specific context.

In this phase, the business model should be completed and applied to practice using the input from earlier phases, but also by collecting new data. Additionally, previously collected data and new research has to be combined into a concrete implementation plan with specific activities, ideally structured by means of an implementation framework. This plan needs to be holistic, i.e., it should pay attention to the involved people, the organizational and wider context, and the eHealth technology that has to be implemented. Operationalization is very complex and should not be underestimated. A participatory approach is also necessary in the operationalization phase, to identify relevant implementation factors and set obtainable objectives, and the input of stakeholders is also needed for the development of implementation strategies and accompanying materials.

Objectives of the Operationalization Phase

The operationalization phase has three main objectives.

1. Finalize the business model with input of the stakeholders and put it into practice;
2. Create an overview of implementation barriers and facilitators, using input from the previous phases, new data, and implementation frameworks;
3. Developing a concrete implementation plan based on the previously identified implementation factors, including implementation outcomes, objectives, strategies, and materials, and apply it to practice.

Concepts, Methods, and Activities in the Operationalization Phase

1. Complete the business model

In the value specification, a start was made with the development of a business model by, for example, filling in the business model canvas or a similar method (also see Chapter 10). A business model was further specified alongside the development process and should be finalized and rolled out in the operationalization phase. Concrete plans on how to deal with the nine blocks of the business model canvas have to be created, again in close cooperation with stakeholders (Osterwalder & Pigneur, 2010). By means of methods like desk research, focus groups or interviews with stakeholders, a plan to implement the business model should be drawn up. Documented information from the scientific or grey literature on comparable operationalization processes might be used as well. Again, there are no step-by-step guidelines, since the way to do this depends on the context, the technology, and the preferences and competences of the team. This implies that the project team has to make deliberate, well-substantiated decisions and should of course constantly cooperate with stakeholders. It is important to determine whether the business model will focus on one organization, or if it will be organization-overarching, e.g., focusing on a network of different hospitals. While the business model should be as complete as possible, this does not mean that the model is finished: Chances are that it will have to be updated constantly, in line with, for example, new insights, policy changes, new customers, or new ways of financing.

2. Create an overview of implementation barriers and facilitators

Too often, implementation is underestimated or seen as a post-design activity. As became apparent in the pillars and previous phases, implementation starts alongside the development process. Consequently, throughout the process, insight will already have been gained into factors that

are important for implementation. In the operationalization phase, additional attention needs to be paid to such implementation factors. Examples of studies that can be conducted are systematic reviews on similar implementation processes, interviews or focus groups with stakeholders, or questionnaires to ask a larger group of people about their perceived implementation barriers. Previous and new research should lead to a clear and comprehensive overview of implementation factors that may bolster or hinder implementation success.

Implementation frameworks are useful tools for identifying and structuring these barriers and facilitators – and thus are also broader and more comprehensive than business models. These frameworks can also be used to evaluate existing implementation processes and learn from them for future implementation processes for to-be-developed technologies (Kip, Sieverink, van Gemert-Pijnen, Bouman, & Kelders, 2020). Examples of much-used models in eHealth research, are the Consolidated Framework for Implementation Research (CFIR) and the Nonadoption, Abandonment, Scale-up, Spread, and Sustainability (NASSS) frameworks. The CFIR is a comprehensive implementation model that is based on an exhaustive review of literature on multiple existing implementation theories (Damschroder et al., 2022). To take the different levels of implementation into account, the CFIR incorporates different domains with several accompanying constructs: (1) the Innovation domain (e.g., evidence base, relative advantage); (2) Outer Setting domain (local attitudes, policies, and laws); (3) Inner Setting domain (e.g., tension for change, available resources); (4) Individuals domain (e.g., implementation facilitators, characteristics); and (5) Implementation Process domain (e.g., planning, tailoring strategies). The NASSS framework is specifically focused on value-based technology in healthcare (Greenhalgh et al., 2017). This model incorporates elements related to the seven main domains and includes several sub-categories: (1) Condition (e.g., nature of condition or illness, comorbidities); (2) Technology (e.g., material features, knowledge needed to use); (3) Value proposition (supply-side value, demand-side value); (4) Adopters (e.g., staff and patient); (5) Organisation (e.g., capacity to innovate, extent of change needed to routines); (6) Wider system (political, socio-cultural); and (7) Embedding and adaptation over time (e.g., scope for adaptation over time, organizational resilience). While there are differences between these models, they both pay attention to the people involved, the characteristics of the intervention, and the context in which a technology is used, in line with a holistic approach.

A final note is that there are of course other frameworks that might be suitable and the choice for the framework depends on different elements, such as the preferences and skills of the involved researchers. Often, models such as the Technology Acceptance Model (TAM) model are used (Venkatesh & Bala, 2008). Individual differences, system characteristics, social influence, and facilitating conditions are part of the model, but most emphasis lies on perceived usefulness and perceived ease of use, which are viewed as predictors for intention, which in turn is considered to directly influence usage behaviour. While these types of models can be relevant for specific research questions, it is important to note that most focus lies on the individual implementation factors, and less attention is paid to the wider context and characteristics of the eHealth intervention. Furthermore, intention is viewed to be a direct predictor of actual usage behaviour, while there is a huge intention-behaviour gap in implementation behaviour (Kip et al., 2020). Too often, implementation research focuses only on one aspect of implementation, so when using these models, it is essential to carefully ensure that all levels of implementation are taken into account – i.e., the people, the organization, wider context, and the technology.

3. Developing and rolling out an implementation plan with objectives and strategies

Based on the previously identified factors (i.e., barriers and facilitators), a concrete plan on how to implement the eHealth technology in a sustainable way should be developed. Based on the factors, specific objectives can be set. These objectives help the team in ensuring that the implementation plan remains focused and allows for evaluation of the success of the implementation process.

These objectives can also be related to implementation outcomes, again to ensure that all relevant elements of implementation are accounted for. Proctor et al. (2011) identified the following implementation outcomes: Acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, and sustainability.

Besides the factors, outcomes, and objectives, there is also a need for specific strategies that are drawn up to reach the set objectives and thus address the identified factors (Kouijzer et al., 2023). Implementation strategies are activities that are undertaken to realize the adoption, dissemination, and sustainable integration of eHealth in healthcare (Powell et al., 2012). Examples are training of healthcare providers, changes in an organization's infrastructure, management support, development of technology-enhanced protocols, practical support of clinicians in using the intervention, or information flyers for patients (Varsi et al., 2019). It can be difficult to translate objectives into specific strategies that fit within the context. This requires creativity, but also active stakeholder involvement and highlights the importance of a participatory approach in which implementation materials and activities are co-created. Service modelling can be used to support this process. Such a model describes how an end-user will receive and use a technology in context and can be used to specify what is needed to achieve this (also see Chapter 9). Furthermore, since implementation often requires behaviour change from the involved stakeholders, the aforementioned BCTs might be useful when designing implementation strategies as well (Kouijzer, Kip, Bouman, & Kelders, 2023).

Finally, when designing implementation processes, it is important to be aware of the different types of adopters. The Diffusion of Innovation theory makes a distinction between innovators, early adopters, early majority, late majority, and laggards (Rogers, 2010). While this distinction may primarily be a paper truth and isn't black-and-white, it does help in understanding that not all stakeholders will be very enthusiastic about adopting a new eHealth technology. This implies that when designing implementation, one has to take these differences into account. To illustrate: Innovators might serve as project champions and can take on an active role from the start of the implementation process, while the late majority and laggards first need to see that an innovation works for their peers before using it. This shows that different groups of people require different, tailored implementation approaches.

Summative Evaluation

What is the Summative Evaluation Phase?

A holistic vision on eHealth in which technology, context, and people are intertwined, is essential for the entire process, including evaluation. However, often, a monodisciplinary view is applied, and attention is paid to only one type of outcome measure, using only one type of research method. Thorough eHealth evaluation should not be viewed as a post-development or -implementation activity, but as an iterative, multi-method process that is focused on a broad range of objectives, in line with the holistic view on eHealth. In evaluation processes, the project team has to check whether the eHealth technology succeeds in addressing the objectives formulated in previous phases, and during evaluation, development, and implementation activities can also still take place.

For overview purposes, a rough distinction can be made between three aspects of eHealth evaluation – even though they overlap. First, the impact of eHealth on its users, other stakeholders and their context should be investigated. This type of evaluation aims to measure the effects on different types of outcomes, e.g., clinical, organizational, and behavioural. However, evaluation should not only be focused on *if* a technology works; it also should provide insight into how, for whom, when and why it is of added value. Consequently, a second focal point of eHealth evaluation is related to the uptake, in other words: How was the technology used? To illustrate: If an impact evaluation shows no effects, a reason might be that a technology was hardly used, or not in

the right way. This does not become apparent if no attention is paid to the way in which the users navigated through the technology. Third, evaluation methods can be used to provide insight into working mechanisms – why does an eHealth technology work? This can relate to constructs such as engagement, but also to effective persuasive features or BCTs such as personalization. These types of evaluations do not just provide insight into why eHealth works, but also provide valuable points of improvement for design and implementation.

These three elements of eHealth evaluation are not separate but should be viewed as aspects of a larger evaluation process. An example of a suitable framework for this approach is the Multiphase Optimization Strategy (MOST) framework, that consists of three phases: Preparation, Optimization, and Evaluation (Collins, Murphy, & Strecher, 2007). In the Preparation phase, the groundwork is laid: A conceptual model for the intervention – including pilot testing, identification of 'core components', and determining the main outcomes – is developed. As you may notice, this overlaps with multiple phases of the CeHRes Roadmap. In the Optimization phase, different types of research designs are used to investigate which components of the intervention are effective. In the Evaluation phase, studies are conducted to determine the effectiveness of the eHealth technology and reach consensus about which components have to be incorporated. While there are other useful approaches for eHealth evaluation, the example of the MOST framework shows that evaluation is a multi-method, iterative process.

Objectives of the Summative Evaluation Phase

The summative evaluation phase has three main objectives:

1. Determining the impact of an eHealth technology on the users, other stakeholders, and their context, based on the predetermined values;
2. Analyzing the uptake of an eHealth technology in terms of adoption or use of the technology by its intended users;
3. Investigating relevant working mechanisms that explain why an eHealth intervention is (not) effective for its users.

Concepts, Methods, and Activities in the Summative Evaluation Phase

1. Determining the impact of an eHealth technology

Since there are many different types of technologies with a broad range of goals, there is not one set of research questions that should be answered. In any case, they should be closely related to the values of the stakeholders. Examples of research questions for evaluating the impact of an eHealth technology are provided below.

- To what extent does the eHealth technology influence patient or consumer health and well-being?
  - Clinical values (e.g., blood pressure, depression)
  - Quality of life (e.g., general well-being, mental health)
  - Lifestyle behaviours (e.g., alcoholic beverages, steps per day)
  - Cognitions (e.g., attitudes, knowledge, intentions)
  - Treatment fidelity (e.g., treatment adherence, therapeutic relationship)
- To what extent does the eHealth technology influence the delivery of healthcare?
  - Accessibility (e.g., availability of healthcare, independent of place and time)
  - Efficiency (e.g., utilization of healthcare services, time savings, cost savings)
  - Safety (e.g., errors by healthcare professionals, increased privacy)

- Communication (e.g., contact moments, improved communication)
- Quality of care (e.g., patient and healthcare professional satisfaction).

In order to assess the impact of eHealth, multiple methods should be used to paint a broad, comprehensive picture of the influence that the technology has on the context and stakeholders (Bonten et al., 2020). It is important to note that there is not one gold standard for evaluating eHealth: The suitability of the method always depends on the fit with the research question, target group, and practical considerations such as the available time of participants and the budget of the study. Some commonly used examples are provided below.

- *Randomized controlled trials (RCTs)*. RCTs can be used to evaluate the outcomes of an eHealth technology in an experimental way. RCTs are used to assess whether the experimental group of patients who used the eHealth technology had better health outcomes after using the intervention, compared to a control group that did not use the technology;
- *Interviews/focus groups*. Interviews or focus groups with stakeholders can be conducted to gather qualitative data on their perspective on the technology, for example, on the experienced benefits and influence on their context. Often, qualitative data is combined with quantitative data in a mixed- or multiple-method approach to paint a broader picture of the impact of a technology;
- *Single-case experimental designs (SCEDs)*. SCEDs are experimental research designs in which individual participants are monitored for a longer period of time, for example with experience sampling apps. In SCEDs, the eHealth intervention is systematically introduced after a baseline and withdrawn. There can be one or more intervention phases;
- *Health Technology Assessment (HTA)*. HTA is a broad form of evaluation and refers to the evaluation of properties, effects, or impacts of health technology. It is a multidisciplinary process to evaluate several issues of an eHealth technology, such as social, economic, or ethical.

2. Analysing the uptake of an eHealth technology

Just as for impact, uptake also can be measured in multiple ways, using different types of research methods. The following types of questions can be answered when studying the way in which an eHealth technology is used:

- How often did the users log in and for how long did they use the technology?
- How often was the technology used by different organizations/teams?
- How often was the technology used over time?
- What features of the system were used and in what combination?
- Who are the 'hardcore' users and who are the dropouts?
- Are there differences in usage between adherent and non-adherent users?

There are multiple ways to investigate uptake, yet log data analysis is a commonly used method for doing so (Sieverink, Kelders, Poel, & van Gemert-Pijnen, 2017). Log data represents the actual use of the different elements of the technology. Examples of log data are the number of website visitors, the times during which users log in, or the frequency of use of the functionalities used.

3. Investigating working mechanisms of an eHealth technology

Most outcomes of impact- or uptake-related studies are not very generalizable: They mostly give insight into the effectiveness and usage of a single eHealth technology within a specific context. Understanding why an eHealth technology achieves a certain effect, can provide insight into

how behaviour change can be achieved, thus contributing to creating (health) impact. Therefore, investigating *why* an eHealth technology is (not) effective provides relevant knowledge for other researchers and eHealth developers as well, and can be used to make future interventions more effective. Examples of questions that can be answered are:

- Is the level of a user's adherence (the extent to which a technology is used as intended) related to effectiveness?
- To what extent is engagement a predictor of adherence and effectiveness?
- Which persuasive features/BCTs are related to effectiveness?
- Are certain usage patterns related to the success of the eHealth technology?

Important for all these questions is that they attempt to take on a broader perspective relating the effectiveness of an intervention to a certain concept (or working mechanism) that may play a similar role in other interventions. Therefore, it is important to check the validity of these outcomes in various studies with various eHealth technologies. Questions like these can be integrated in different study designs such as RCTs or factorial designs (also see Chapter 16). Factorial designs are a specific method that can be used to investigate the effectiveness of elements such as persuasive features or BCTs (Collins et al., 2007). In such a design, every user is exposed to different variations of an intervention, e.g., a version with or without personalization, and with or without feedback. By means of this, the researcher can screen for the effects of specific features of an intervention by searching for differences in effects between variations of an intervention. Furthermore, a combination of interviews with log-data or a larger-scale RCT can be used to acquire qualitative in-depth understanding of certain outcomes, in close cooperation with stakeholders. In addition to that, interviews can help to identify subjectively experienced working mechanisms.

Formative Evaluation

What is the Formative Evaluation Phase?

Formative evaluation is not a separate development phase, but a principle that is intertwined throughout all stages of the eHealth development process. It is very important to note that its place at the end of this chapter does not mean that it is the final phase. Within the CeHRes Roadmap, it is visualized as the cycles that are connected to all five phases, and thus is relevant within each phase. As was emphasized in the third pillar and throughout this chapter, eHealth development, implementation, and evaluation processes are not linear, but iterative and dynamic. Formative evaluation cycles are a good example of this proposition. The basic presumption of formative evaluation is that ongoing information on how to improve the process and eHealth technology is collected. This information assists the project team in ensuring that there is a constant focus on the context and people involved. In this way, formative evaluation can be seen as creating by evaluating.

Formative evaluation is twofold: It can be used within and between phases of the Roadmap. First, formative evaluation within phase refers to activities that support the project team in ensuring that there is a fit between their activities or output and the perspective of the stakeholders and context, for example by actively involving and verifying results with stakeholders. These kinds of activities should be conducted in every phase of eHealth development, and thus are the activities that were described for each of the previous phases. Second, formative evaluation between phases refers to ensuring that outcomes of phases are consistent with each other. At the 'end' of a phase, the team has to check whether the outcomes of a previous phase have been accounted for

and haven't been forgotten along the way. Besides this, decisions also have to be made on whether changes in the outcomes of previous phase are required.

Objectives of the Formative Evaluation Phase

The formative evaluation has two main goals, both related to the development process:

1. Using methods to gather information from the stakeholders and context to continuously include their perspectives within the phases of the CeHRes Roadmap (within phase);
2. Checking whether the outcomes of previous phases of the CeHRes Roadmap have been accounted for in the current phase and ensuring that the outcomes of all phases are related to each other (between phases).

Concepts, Methods, and Activities in the Formative Evaluation Phase

1. Evaluation within phases by gathering input from the stakeholders and context

The formative evaluation does not entail separate methods since it is an overarching approach that refers to principles behind eHealth development, implementation, and evaluation. However, to illustrate and further clarify this, some practical examples of methods that convey the principles from formative evaluation within a phase are provided below.

- In the *contextual inquiry* phase, snowball sampling is used to ask existing stakeholders to identify missing stakeholders. This is an example of formative evaluation, since it assists in validating whether the list of stakeholders is complete and reflects the actual context;
- In the *value specification* phase, lists of *requirements* are often verified by stakeholders once they are drawn up. This supports the team in ensuring that the requirements they derived from focus groups and interviews make sense to the stakeholders;
- In the *design phase* of the technology, a straightforward example of formative evaluation is usability testing among end-users via the think-aloud method. This method aims to make sure the technology fits the user's needs;
- During the *operationalization* phase, the involvement of stakeholders in completing the *business model* and making a plan on how to operationalize the model is an example of formative evaluation;
- The *summative evaluation* phase also contains formative evaluation cycles, for example by asking users to explain the outcomes of a randomized controlled trial or log data analysis in a mixed-methods approach.

2. Evaluation between phases by checking whether phases are related to each other

This element of formative evaluation mainly focuses on ensuring that there is a clear relationship between the content and output of the separate phases. For example, in the design phase, the project team has to make sure that the designed technology incorporates the requirements and addresses the values. No concrete methods are prescribed for this; the approach used depends on the nature of the project and the preferences of the project team. However, it is essential for team members to be aware of the decisions that are being made and to, if necessary, involve external stakeholders. Another requirement is that thorough, transparent documentation of the activities and outcomes of each phase in an eHealth development project are created. If the documentation isn't clear, it is hard to retrieve what the main outcomes of previous phases were, and what the grounds for specific

decisions were. Deciding on whether the outcomes of the current phase match those of previous phases can be achieved by means of, for example, meetings with the project team or focus groups with stakeholders.

Summary

As can be seen in this chapter, the CeHRes Roadmap is a framework – consisting of five phases, underpinned by pillars – that can be used to shape the development, implementation, and evaluation of eHealth technologies (see Figure 7.4). While the Roadmap provides a broad overview, it should not be seen as a step-by-step template: A tailored process that fits the context, technology, and users is essential. This highlights the importance of an experienced, interdisciplinary project team that can set clear objectives, use suitable research methods, and ensure a coherent process. While each eHealth development, implementation, and evaluation processes are unique, a systematic, iterative approach is key. Ultimately, a good fit between the eHealth technology, the involved people, and their context should be reached to increase the chances of making an impact with eHealth. The take-home messages for this chapter are:

- The CeHRes Roadmap is a set of principles that are combined in a framework for overview purposes, so in practice, the different phases overlap and the way in which they are executed will differ per project;
- In line with a holistic view, attention should constantly be paid to the interrelationship between the behaviour and preferences of stakeholders, the healthcare context, and the features of a technology;
- eHealth development, implementation, and evaluation are all iterative, highly interdisciplinary processes, which require active collaboration between researchers with flexible and creative mindsets;
- During each development phase, multiple methods should be used. Which methods are used should depend on the research question that was posed by the project team, the skills and preferences of the participants, and the practical preconditions from the context;

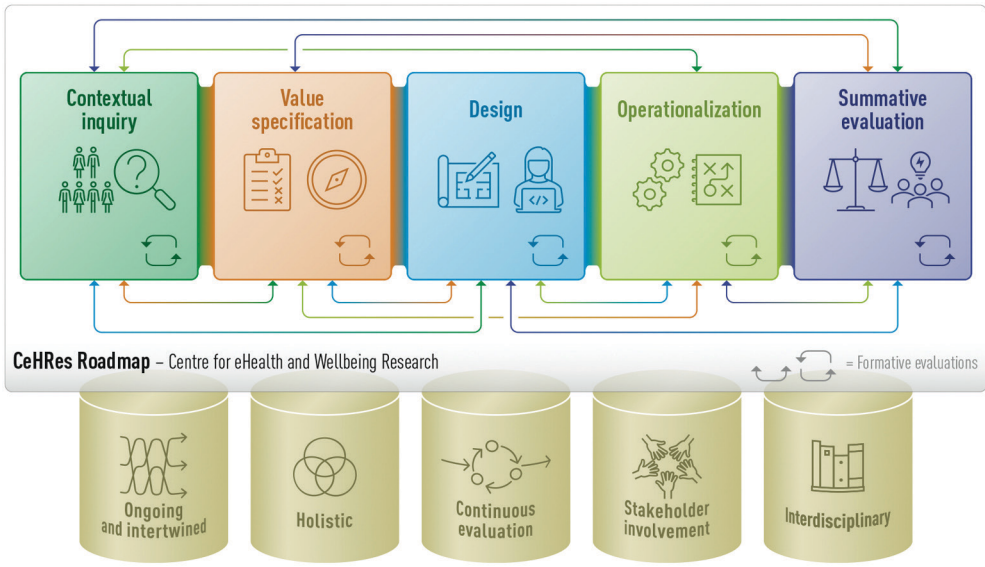

Figure 7.4 The CeHRes Roadmap.

- eHealth development, implementation, and evaluation are never finished: There is always a need for improvements of or additions to the technology, new or improved implementation strategies, and further evaluation.

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