Chapter 7

Holistic Development of eHealth Technology

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Introduction

Many eHealth technologies are already being used in different kinds of settings, for example in public, somatic, consumer and mental health. As was already explained in Chapter 1, the technology should fit the specific culture, processes and demands of these different kinds of health-related contexts, but in practice, this often doesn't happen. Many technologies stop being used because they are, for example, hard to understand for the user, require too much effort or time to use, or are simply too expensive. An explanation for these errors can be found in faulty development processes that didn't pay enough attention to the interrelationships between the people, the context and the technology. Such a holistic vision of eHealth is required during the entire development process. The importance of this an approach has been acknowledged by multiple researchers (Coiera, 2004; Feldman, Schooley, & Bhavsar, 2014; Glasgow, Phillips, & Sanchez, 2014; Nielsen & Mathiassen, 2013; Beerlage-De Jong, 2016; Wentzel, 2015; Van Limburg, 2015; Van der Vaart, 2013; Nijhof, 2013). Even though more research is necessary, findings point into the direction that a holistic development process increases the chances of a successful adoption and sustained use of eHealth technology, thus increasing the likelihood of achieving the desired effects on health and healthcare (Kushniruk, Bates, Bainbridge, Househ, & Borycki, 2013).

The CeHRes Roadmap, which was introduced in Chapter 1, is a framework that provides guidelines for a *holistic development approach* of eHealth technology. This chapter starts with an explanation of what a holistic approach towards eHealth development entails. After this introduction, the phases of the CeHRes Roadmap are separately described, their main objectives are given, a theoretical background is provided, and outcomes of the phases are discussed. To clarify the phases, they are illustrated with possible research methods and cases from practice. After completing this chapter, you will be able to:

- explain the need for a holistic, iterative and multidisciplinary development approach for eHealth technology
- describe and define the five phases of the CeHRes Roadmap, state their main objectives, and explain the rationale behind each phase.
- list several suitable methods for eHealth development, implementation and evaluation and explain the added value of a multi-method approach for each phase.
- explain how the phases of the CeHRes Roadmap are interrelated and connect this to an iterative, agile development approach.
- explain the relationships between formative evaluation, holistic development, and the involvement of stakeholders in eHealth development, implementation, and evaluation.

The need for a holistic approach

During development, potential issues must be accounted for and are expected to be avoided (Kushniruk et al., 2013). Despite this, most existing frameworks were found to take a rather

conceptual approach instead of practical guidelines, and lacked the stakeholder-driven approach that is required in eHealth development (Van Gemert-Pijnen et al., 2011).

Holism is a central construct with regard to eHealth development. It means that constructs as technology, people and context are all interrelated and interdependent, and are all part of one whole instead of separate elements (Van Gemert-Pijnen et al., 2011). A development process that creates a good fit between these technological, human and contextual factors will increase the chances of an intervention reaching its goals. This means that developers should see eHealth as more than a thing or a tool: it also entails creating an infrastructure for supporting health, organizing care, disseminating knowledge and communication via technology. Existing approaches, such as *participatory development*, *human centred design*, *business modelling* and *persuasive technology*, can be combined into a framework that supports the development of such an eHealth technology. The *CeHRes Roadmap* combines these approaches and thus provides a framework to develop a technology that fits the human and contextual perspective. The Roadmap is underpinned by five pillars of eHealth development (see Chapter 1), which are based on existing frameworks, insights from practice and empirical research (Van Gemert-Pijnen, Peters, & Ossebaard, 2013; Van Gemert-Pijnen et al., 2011):

- eHealth development is a participatory development process
- eHealth development creates new infrastructures for improving healthcare, health, and wellbeing
- eHealth development is intertwined with implementation
- eHealth development is coupled with Persuasive Design
- eHealth development requires continuous evaluation cycles

The CeHRes Roadmap

The CeHRes Roadmap (Figure 1) serves as a guideline for eHealth development, implementation and evaluation. Existing evidence-based activities, models, frameworks and methods derived from *persuasive design*, *participatory development*, *human centred design* and *business modelling* serve as the theoretical background of the Roadmap. All of this is translated into five intertwined phases and connecting cycles. These phases are the *contextual inquiry*, *value specification*, *design*, *operationalization* and *summative evaluation*. The connecting cycles represent the *formative evaluation* cycles, which ensure that activities during a phase are related to the stakeholder perspective, the context, and outcomes of previous phases. The CeHRes Roadmap assists the development team in planning, coordinating and executing the *development process* of eHealth technologies (Van Gemert-Pijnen et al., 2011). This can refer 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 process.

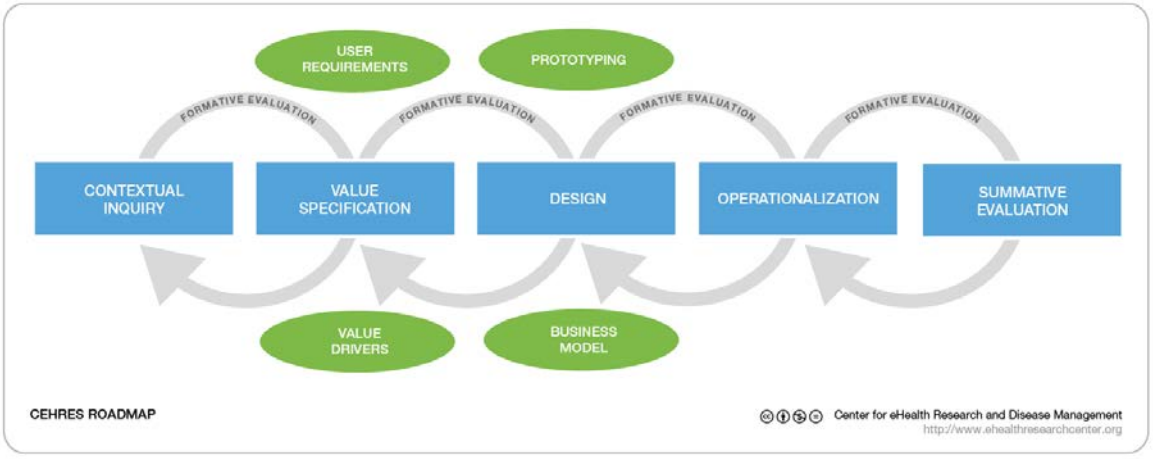

Figure 1. The CeHRes Roadmap (Van Gemert-Pijnen et al., 2011)

eHealth development is flexible and iterative

While the Roadmap consists of separate blocks, it definitely does not represent a sequential development process in which one phase has to be finished before moving on to the next. On the contrary, the Roadmap answers the call for more flexible and *agile* intervention development approaches (Glasgow et al., 2014; Patrick et al., 2016). Many classical evidence-based development practices in behavioural sciences are based on a four-phase biomedical model, which is seen as sequential. However, these kinds of models are being questioned more and more, since they do not seem to fit the complexity of behaviour change that has to be achieved by eHealth technology. Many sequential models reduce the complexity of a problem by studying behaviour out of context and only acknowledging the feasibility and context at the end of the process during a unique evaluation stage (Patrick et al., 2016). This approach does not take into account that behaviour is influenced at multiple levels, such as genetic, biological, social or environmental, and that these influences are reciprocal, dynamic, and temporally based (Carver & Scheier, 2001).

This complexity of behaviour requires *iterative*, evidence-based strategies that acknowledge these interrelations, and focus on an optimized fit between individuals, context and interventions (Chambers, Glasgow, & Stange, 2013). To achieve this, the use of methods from the software engineering community are promoted. *Agile science* in particular is considered as very promising and fitting to the field of eHealth. Especially since in agile science development and evaluation occur in parallel and iteratively, until the eHealth technology has been optimized to fit the complex context in which behaviour occurs (Patrick et al., 2016). Therefore, agile science enables rapid iteration and improvement of systems before they are widely implemented. Such an approach considers the interrelationship between *context*, people and technology better than a rigid, sequential approach. The CeHRes Roadmap provides a framework to guide a multidisciplinary development team through this process.

eHealth development requires multidisciplinary development teams

In eHealth development, a multidisciplinary *development team* has to operationalize these iterative phases to direct and manage the development process (Feldman et al., 2014; Nielsen & Mathiassen, 2013; Pagliari, 2007). As it will be explained further in this chapter, the team has to establish a thoughtful set of objectives and methods to accomplish them. Because of

this, this team has to be multidisciplinary, since it ensures more diversity in expertise, skills and perspectives, and prevents tunnel vision. Ideally, a development team must consist of two kinds of people:

- Professionals focused on the development, implementation, and evaluation of the technology, such as designers, technicians, business experts, project managers and researchers. Enrolling them in the development team ensures that the required multidisciplinary knowledge and skills are included.
- People whose involvement ensures that the technology fits with the target population and its context, such as patients or healthcare professionals that will use the technology to improve their health or to make their tasks more efficient. Including them ensures that the user perspectives are present in the development team.

All members of the development team are known as *stakeholders*, defined as those who affect or are affected by the technology. Moreover, stakeholders who aren't part of the main development team should be involved in the development process as well according to their relevance for certain phases. The development team is responsible for planning how, when and with what purpose other stakeholders will participate in the process.

Multidisciplinary project management is essential, since it facilitates the cooperation between all the parties involved (e.g., designers, users, researchers), it assists in avoiding a 'design-build-run-and-see-what-happens approach', and it ensures that the project is planned and managed in time and space (Van Gemert-Pijnen et al., 2011). The composition of the development team is not fixed from the beginning and might change along the way. For example, because a new phase requires new expertise (e.g., programming), or because of practical issues (e.g., lack of time).

Organization of the chapter

The remainder of this chapter focuses on the five phases and formative evaluation cycles. 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.
- Outcomes
  This section explains what kind of outcomes a phase should have, and how these outcomes are related to previous and following phases.
- Case

When necessary, cases are presented at the end of a phase to further illustrate it. These cases are derived from practice and based on research of the Centre for eHealth and Wellbeing Research.

How to read this chapter?

The methods presented in this chapter are not a complete list, other methods might also be used, provided they are relevant to the goal of the phase. Consequently, this chapter's main goal is to provide the reader with insight into the main objectives of several phases of the development process. This means that creating clear, specific research questions for every phase is essential for good eHealth development. The development team should have a clear vision on what they want to achieve in a specific phase, and why this is the case, and choose their research methods accordingly. This chapter assists in such matters, but by itself it should not be seen as a unique recipe or a concrete action plan for eHealth development.

To get a wider and more detailed view on the development process outlined by the roadmap, this book provides chapters that elaborate on (some of the) methods and principles of the phases introduced here. Each chapter will go into more depth and will provide cases from practice, as opposed to the present chapter, which mainly provides general objectives, illustrative methods and outcomes. The relationship between phases and chapters is shown in Table 1.

Table 1
Roadmap phases and chapters covering them

Phase	**Chapter**
Contextual Inquiry	8 – The contextual inquiry
Value Specification	9 – Value proposition design and business modelling
Design	10 – Human centred design 11 – Persuasive health technology
Operationalization	12 – The complexity of eHealth Implementation: A theoretical and practical perspective
Summative Evaluation	13 – User engagement 14 – eHealth Evaluation

Contextual Inquiry

What is the contextual inquiry?

The first step in any eHealth development project is a thorough investigation of the *context*. In order for an eHealth technology to be successful, it should provide a solution for relevant issues, it should be accepted by *stakeholders* such as the users, funders and policy makers, and it should fit the physical, social and cultural environment in which it will be used (Coiera, 2004; Glasgow et al., 2014). These requirements should be accounted for during the entire development process. This is necessary because the development team has to be aware of the daily lives of the users, other involved stakeholders, their environments, and any practical constraints such as rules and regulations (Sjöström, von Essen, & Grönqvist, 2014). The contextual inquiry helps the development team to get a grasp of the intended context through

the of using multiple methods. The outcomes of the contextual inquiry serve as a basis for the rest of the development process. It assists in keeping a focus on the people and their environment (Holtzblatt & Jones, 1993; Wentzel et al., 2014) . More in-depth information on the contextual inquiry can be found in Chapter 8.

Objectives of the contextual inquiry

The contextual inquiry has several main objectives.

1. The relevant stakeholders – anyone who affects or is affected by a potential eHealth technology – have to be identified.
2. The identified stakeholders have to be analysed: it should be clear what the tasks and roles of the stakeholders are in order to identify the key stakeholders.
3. The current situation and its weak and strong points have to be described in order to find out if and in what way an eHealth technology can contribute to the current situation.

Concepts, methods and activities in the contextual inquiry

1. Relevant stakeholders have to be identified.

During every phase of eHealth development, *stakeholders* should be 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, or designers. To make sure every stakeholder is identified, multiple methods can be used and combined (Bryson, 2004; Van Limburg, Wentzel, Sanderman, & van Gemert-Pijnen, 2015; Van Woezik, Braakman-Jansen, Kulyk, Siemons, & van Gemert-Pijnen, 2016). Some of the most common methods are:

- Literature scan/review. Stakeholders can be identified by reviewing literature, for example about stakeholder theories or 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 these already involved stakeholders to supplement the list. Stakeholders are good sources for identifying which stakeholders are missing.

After the stakeholders are identified, it might be necessary to narrow down and select the *key stakeholders*, which can be done by the project team (that should include stakeholders), or by letting a group of stakeholders who are not part of the team decide on who are the key stakeholders. This selection has to be made because not every stakeholder will be equally important to the development and implementation of an eHealth technology. It also takes too much time and resources to interact with every single stakeholder, so this activity facilitates a focus of the development efforts while considering the available resources.

2. The identified stakeholders have to be analysed

During the contextual inquiry, it should be clear what the roles and tasks of stakeholders are, in order to make sure who the key stakeholders are. These key stakeholders should be actively involved in the development process. 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. This can be done by both the project team and other stakeholders.

Often, stakeholders are visualized in a stakeholder map. These can be made by hand or with specialized software. Figure 2 shows an example of key stakeholders of a teledermatology project. As can be seen, not every stakeholder is of equal importance. For example, since the role of the General Practitioner (GP) appeared to be limited, they only scored 1 out of 5 points. Because of their important role for design and implementation, patients and dermatologists score 5 out of 5 (Van Gemert-Pijnen et al., 2013).

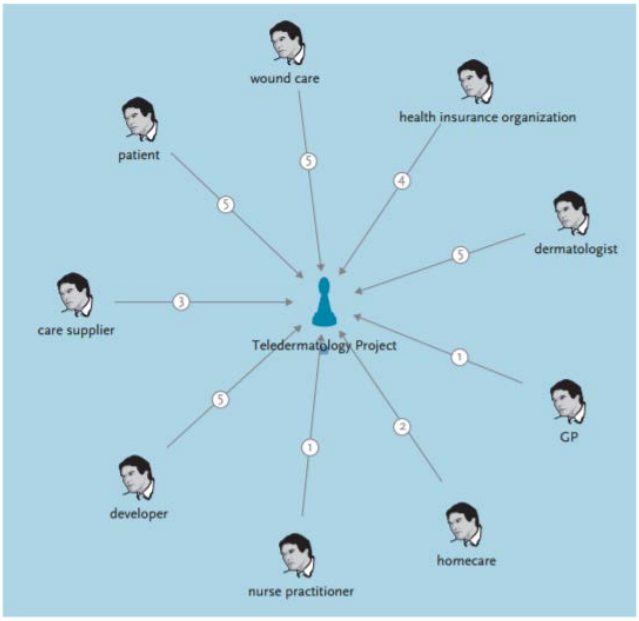

Figure 2. The visualization of a stakeholder analysis of a teledermatology project (Van Gemert-Pijnen et al., 2013)

3. The current situation and its weak and strong points have to be described

Throughout this book, it has been mentioned often that an eHealth technology should fit the context and the people. That is why, during the contextual inquiry the development team should aim to get a thorough understanding of the context. The exact definition and determination of the scope of the context is part of the contextual inquiry as well. Besides the perspectives and opinions of the stakeholders on the current situation, the context can be represented as the rules, regulations, ethical issues and other important matters that have to be considered during the development (Sjöström et al., 2014).

Many methods can be used to achieve this, and ideally methods should be combined to lead to an extensive, in-depth description and understanding of the context. Some examples of frequently used methods are provided below (Beerlage-de Jong, Eikelenboom-Boskamp, Voss, Sanderman, & van Gemert-Pijnen, 2014; Holtzblatt & Jones, 1993; van Gemert-Pijnen, Karreman, Vonderhorst, Verhoeven, & Wentzel, 2011; Van Woezik et al., 2016):

- *Desk research.* Its goal is to study already existing documents about relevant topics, like a specific subject, situation, regulations, or technology.

- Systematic literature review. A systematic search of scientific literature can be conducted to find out about the literature on a specific topic.
- *Focus groups.* In the contextual inquiry, focus groups are group discussions with stakeholders to, among other things, describe and identify problems in the current situation.
- *Interviews.* Interviews can be conducted with stakeholders to identify their individual perspectives on a certain situation, for example about possibilities of technology.
- *Observation.* Observing daily practice within a context can reveal abundant information about the designated end-users of the eHealth technology and their daily tasks, issues, and preferences.

Outcomes of the contextual inquiry

During the contextual inquiry, issues for which technology can be of added value should be identified by means of using stakeholders, as well as reviewing scientific and non-scientific literature. The identified issues can be related to, for example, *efficiency*, *effectiveness*, timely delivery of care, and safety of healthcare. The main outcomes of the contextual inquiry should be an overview of: the current situation; the rules, regulations, and ethical issues of the context; and possibilities and conditions for the use of technology.

The choices that are made in the contextual inquiry about the issues that can be addressed via technology will be elaborated on, and made more concrete in following phases. The possibilities of technology that have been identified need to be further specified in order to design an actual technology. During the following phases, the information of the contextual inquiry should constantly be used to make sure that the relation between the technology, context, and user is ensured. When there is a good match, the chances of it being adopted by stakeholders that will eventually use or finance the technology are increased. If there is indeed a good fit, these stakeholders are more likely to adopt the technology. This is an example of the pillar on implementation: it is intertwined with development.

Contextual Inquiry: Case

A Contextual Inquiry for Virtual Reality in Forensic Psychiatry

Forensic psychiatry is a sub-specialty of psychiatry that is at the intersection between law and psychiatry. A forensic psychiatrist focuses on the assessment, treatment and rehabilitation of mentally disordered offenders in prisons, other secure settings and communities. In the Netherlands, the use of eHealth in this sector lags behind, so a project which focuses on the development of Virtual Reality (VR) in a forensic psychiatry organization has recently started. The first phase of this project was a thorough contextual inquiry, coordinated by the *project team*. During this phase, the project team consisted of two patients, two therapists, two researchers, a policy maker, and a student of health sciences. The following research activities were undertaken:

- *Stakeholder identification* via desk research and snowball sampling with stakeholders. Examples of identified stakeholders are therapists, patients, VR developers, management, and other forensic psychiatric organizations.
- A *scoping review* on scientific studies about Virtual Reality in forensic psychiatry. It appeared that very few studies about this topic were published.
- *Desk research* (websites, existing documents, books) and unstructured interviews

about several topics:
    - The types of patients and treatments within the organization
    - Other VR projects that were going on in forensic psychiatry
- Two *focus groups*, called 'inspiration sessions', in which patients and therapists participated by, among other things, experiencing VR themselves.. The main goal was to introduce the project and to find out if the idea of using VR appealed to these intended end-users. It appeared that both patients and therapists were very enthusiastic.
- *Interviews* with therapists. The main goal of these interviews was to determine points of improvements of the current treatment. Therapists provided scenarios to illustrate these opportunities. Furthermore, the aforementioned categories on the possibilities that VR could address were presented and therapists were asked if and in what way they could be relevant in their treatments, again by providing scenarios.
- *Focus groups* with treatment coordinators and team managers. The main results of the interviews were discussed with them to reach a consensus on several useful goals, as well as identify points in the treatment where VR could be of added value.

The main outcome was a set of possible, broadly formulated VR scenarios that addressed the issues and possibilities identified in this contextual inquiry. These scenarios were presented to therapists, patients and other key stakeholders in the value specification to further specify what the exact needs and preferences are with respect to the use of VR in forensic treatment.

Value Specification

What is the value specification?

The *value specification* phase elaborates on the issues (problems or points for improvement) that were identified in the contextual inquiry. The outcomes of the contextual inquiry provide a general idea on the added values that a certain technology should have (e.g., users want to be able to use it whenever they want or need). However, these outcomes are not concrete enough to specify what is needed from an actual technology, so the value specification narrows down these identified issues. This is done by focusing on the exact added value of a technology, specifying the demands from the implementation context, and finding out what is required from the design of the technology by the identified key stakeholders (e.g., provide easy access via an online platform). A proper value specification assists in finding out what kind of goals the technology should reach according to stakeholders, and what should be done to reach these goals. Also, the value specification forces the development team to be precise, which helps them to deal with many implementation-related issues like adoption, financing, and use on the short and long term in time (Van Gemert-Pijnen et al., 2011).

To achieve this fit between the demands from the context and the technology, it first has to be determined what added value a technology should bring to the current situation. In other words: what exactly should be improved or supported by means of an eHealth technology? What should its main goals be, according to the involved stakeholders? These so-called *values* can differ per key stakeholder, so it is up to the development team and stakeholders to prioritize them, and make decisions on how to cope with conflicting values. Based on this, a value map is created (Van Velsen, Wentzel & van Gemert-Pijnen, 2013), this can be represented on a table which links every value with potential ways eHealth could serve it.

The value map is a subpart of another overarching activity that is relevant for the entire design process and which starts in the value specification phase: business modelling. A *business model* describes how the organization involved in the eHealth development creates, delivers and captures values. To put it simply: it describes how an organization conducts its business concerning the eHealth technology. A business model can be used to deliberate, plan, and operationalize the implementation of eHealth, by means of discussing the added value of an eHealth technology and what resources are required for the actualization of these values in practice. Therefore, business modelling, should already start in this phase of eHealth development, in which these values are being identified (Van Limburg et al., 2011).

The identified values serve as input for the more specific *requirements* of the design of a technology, which state what exactly is required from the technology with respect to matters like software, hardware, content and design/presentation. Requirements prescribe design details like what a technology should do, what content it should display, what kind of data is used, and what kind of user experience it should provide in order to achieve the values. They serve as the blueprint for the to-be-developed technology (Van Velsen, Wentzel & van Gemert-Pijnen, 2013).

The value specification phase is 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. The entire development team should have a thorough understanding of what is required from a technology, to prevent mismatches between the context in which it will be used, the wishes of the stakeholders, and the technology. Chapter 9 elaborates on value proposition design and business modelling.

Objectives of the value specification

The value specification has several main objectives.

1. The values from all involved key stakeholders have to be identified, and it should be clear what – according to them – the added value should be.
2. All identified values have to be prioritized and categorized into a value map.
3. A business model for the eHealth technology has to be created.
4. The values have to be translated into specific technology requirements that state what is required from the technology.

Concepts, methods and activities of the value specification

1. The values from all involved stakeholders have to be identified

The values should be related to the issues that were identified in the contextual inquiry. Values should logically arise from the contextual inquiry, since they elaborate on the issue that was identified by stating what is needed to improve that issue, partly by involving the already identified stakeholders. Because eHealth development is an *iterative process*, stakeholders can still be added or removed from the list at this point. The values of the involved key stakeholders can be discovered through several methods (Van Velsen et al., 2013; Van Woezik et al., 2016; Wentzel et al., 2014):

- *Interviews.* Interviews can be conducted with stakeholders to uncover their opinions, motivations, and wishes about the technology that will be developed.

- *Focus groups.* In focus groups, several stakeholders come together in a group to, for example, discuss their needs and wishes regarding the technologies.
- *Observations.* Observations of activities conducted by end-users can assist the development team in identifying concrete ways in which a technology could contribute to the current situation, and what it should entail.

Values can be related to economic, social, behavioural or healthcare issues. They can, for instance, focus on an improvement of people's mental health or better social functioning. Values can also have a more cognitive nature, for example, influencing attitude or knowledge about a health topic or increasing motivation to change a health-related behaviour. Other kinds of values can be increased access to healthcare, adherence to protocols and guidelines, and improved decision support.

2. All identified values have to be prioritized and categorized

During the value specification, many different kinds of values will be identified, since many different kinds of stakeholders are involved. Once these values have been identified, a hierarchical analysis of values is required since some values might be more important than others. These so-called critical values have to be addressed by the eHealth technology in any case. The development team has to decide what these critical values are, possibly in collaboration with stakeholders. This can be done by methods like focus groups with the development team and/or other stakeholders, and/or via techniques like Analytic Hierarchy Process (AHP; Saaty, 1988) that can assist in complex decision making. Software can be used to rank values from the involved stakeholders into a value map.

Often, conflicting values arise, for example when the values from an insurance company differ rigorously from those of an end-user. In those cases, the development team has to decide on how to cope with these conflicting values, for example by discussing this with involved key stakeholders. The importance of the stakeholders as was identified in the contextual inquiry should be kept in mind: the values from the most important stakeholders might be more relevant in in most – but not all – cases. All of the prioritized values are visualized in a value map.

3. A business model for the eHealth technology has to be created.

The value map that was developed is part of a *business model*. A business model can be defined as 'the rationale of how an organization creates, delivers, and captures value' (Osterwalder & Pigneur, 2010). It is essential during the entire eHealth development process since it guides the implementation processes and clarifies the costs and benefits (values) for stakeholders. Because the development team has to account for implementation from the start, the creation of the business model should also start at the beginning of the development process, and not merely during the implementation itself. The early development of a business model enables the development team to identify matters that might come up during implementation before the actual implementation in practice has started. In this way, information from the model can be used to account for possible pitfalls. A frequently used method to create a business model is the business model canvas (Osterwalder & Pigneur, 2010), which consists of several building blocks. A filled in, simplified example of a business model can be seen in Figure 3. This example is based on a business model that was co-created with stakeholders during the development process of an eHealth technology to ensure

adequate administration and use of antibiotics in hospitals (Van Limburg et al., 2015). Business models are further explained in Chapter 9.

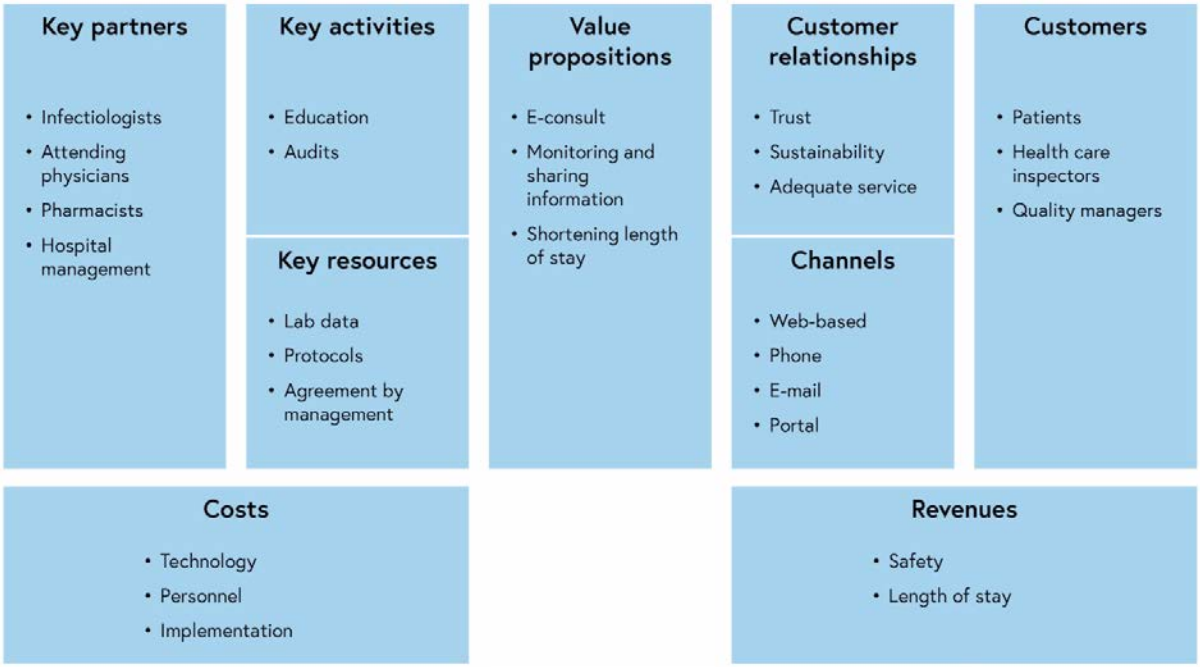

Figure 3. Example of a simplified, filled in business model, derived from www.futurelearn.com/courses/ehealth, based on (Van Limburg et al., 2015)

The creation of a business model is an iterative research process, so open-ended ideas can gradually become more substantiated during the development process. Also, ideas can be discarded or rigorously changed along the way. Multiple methods should be used to create the business model, and information from the contextual inquiry and value specification is used to make sure that the business model matches the entire development process, the context, and its stakeholders. Since a business model is more of a generic overview instead of a set of predetermined methods, the way it is filled in depends on the skills and preferences of the development team. But independent of the methods being used, it is always essential to carefully describe and document the process and rationale behind the filled in business model (Van Limburg et al., 2015).

4. The values have to be translated into specific requirements

The value map itself is not yet concrete enough to use for the actual design of the eHealth technology. Therefore, values are translated into specific *requirements* for the new technology. The elicitation of requirements is part of the value specification since requirements state what is required of the technology for it to achieve the added value (Van Velsen et al., 2013). A broad categorization of possible types of requirements is:

- Content requirements. They state what information the technology should present to the user, e.g. information on the symptoms of a minor depressive disorder.
- Usability and user experience requirements. These requirements concern the user perspective and specify the interface and interaction design of the technology. Think of requirements on the size of symbols and the clarity of the navigation.

- Functional and modality requirements. These requirements specify technical features and prescribe the kind of technology and operating systems. They are mainly focused on the programmer's point-of-view. These might be requirements that state that an eHealth intervention should run on both Apple and Android systems.
- Service requirements. These requirements state the best way to organize the services that support the technology. They are mainly relevant for managers who make decisions on matters like marketing or user support. This might refer to issues such as a 24-hour helpdesk in case of problems with a technology.
- Organizational requirements. These requirements concern the integration of the technology into the organizational structure and working routines. Again, they are mainly aimed at managers. An example is requirements on scheduling time in nurses' schedules to answer questions in an eHealth intervention.

Requirements can be elicited from multiple sources, like stakeholders, literature, legal documents or technical constraints. There are multiple methods that can be used to elicit or specify requirements (Beerlage-de Jong et al., 2014; Van Velsen et al., 2013). Some examples are:

- *Interviews*. Interviews with individual stakeholders can be held to ask them about matters, such as what a technology should look like and what it should be able to do. Existing or potential examples of technology might be used to support these interviews, since in many cases it is easier for participants to state what they need based on concrete examples, instead of coming up with it out of thin air.
- *Focus groups.* Requirements can be gathered via focus groups as well. Just like in interviews, examples of a technology might be presented to the group of stakeholders. In focus groups, stakeholders can elaborate on each other's ideas and opinions in order to find consensus.
- Requirement templates. A requirement documentation template, which is based upon Volere templates (Robertson & Robertson, 2006), can be used to document requirements. This makes it easier to enable programmers and designers to understand what the technology needs to entail and why (Van Velsen et al., 2013). In this template, values are ideals or interests of stakeholders; attributes are a summary of the need or wish that the stakeholder expressed, and requirements are technical, concrete translations of the attributes and values. It becomes apparent that all three are interrelated and based on each other.

Requirement #: 3	**Requirement type:** functional
Value: easy access	**Attribute:** one stop portal for information
Description: The system provides access to all (types of) information via one interface.	
Rationale: Nurses spend a lot of time gathering information from different (types of) sources while performing their antibiotic-related tasks. When all information can be accessed from one interface, one starting point, searching for information is facilitated.	
Source: Focus group 1 & 2, fragment 1,2,3,10,13	
Fit criteria **1. Acceptance testing:** not applicable **2. Usability testing:** The application allows participants to find the desired information within one minute. Note: time frame to be adjusted upon inspection of the high-fidelity prototype. **3. Summative evaluation:** Participants feel they have to spend less time on searching information via the app. Searching for information via the app results in an increase in success and a decrease in time, in comparison with searching for information in the traditional way.	
Priority: High	**Conflicts:** possible conflict with mobility and real time access and synchronization requirements because access to these databases at all places via the interface may be impossible due to limitations in wireless connections and security options.
History: Created on March 9 2012, adjusted on May 8 2012	

Figure 4. A requirement template for the development of a bedside technology for nurses (Van Velsen et al., 2013).

Outcomes of the value specification

The value specification has two main outcomes, the first of which is a value map that contains the values that the technology should address. If a technology focuses on these identified values, it has a higher chance of being used, since it actually has added value for the current context and stakeholders. The second outcome is a list of requirements. These requirements will be used to develop the actual technology and serve as concrete tools to make sure that the wishes of the stakeholders and context are incorporated in the technology. Again, this increases the chances of the technology being used, since it fits the intended users.

The values and requirements should logically arise from the *contextual inquiry*. This ensures that the issues identified there are addressed, and that the context and stakeholders are constantly being kept in mind. If the value specification is conducted in a proper way, it assists in creating a good fit between the technology, context and stakeholders. As said before, this contributes to a successful implementation by delivering actual added value to practice, which, in its turn, increases the chances of reaching the intended goals.

Value Specification: Case

eHealth to Prevent Lyme Disease: From Interviews to Values to Requirements

Ticks can potentially spread diseases, and Lyme disease is the most common. It is, therefore, important to check for ticks and to know how to remove them. To provide information on ticks and how to remove them in order to prevent Lyme disease, Velsen, Beaujean, Wentzel, Van Steenbergen and Van Gemert-Pijnen (2015) developed an online intervention. In order to achieve this, interviews with prospective users were conducted. Fragments from these interviews were used to formulate values and identify accompanying user requirements for an online intervention to prevent Lyme disease. To illustrate this process, an example is provided below.

Table 2
Example of quotes from interviews with prospective users

'Videos, yes, I would show things. What does such a bug look like? What happens? How do you remove it?'
'As a mother, I would say: Start with how to remove it. Because when are you going to look for that information? Especially when your child has one. Then you think aaaaah. And then the first thing you need to know is: How do I remove it? Very briefly, with pictures.'
'A video would be nice, perhaps on the removal. I think that causes problems for a lot of people. That the head sticks.'
'Texts and images, that will appeal. Perhaps videos, combinations. Then you can see how a tick is removed.'
'But this picture [points to a picture of an infected tick bite] is what you should pay attention to. So if it says, well, what are the symptoms? That there is a picture of it.'
'Those short videos of a couple of minutes. So you can see how someone removes it. Or a couple of people checking each other. Or something on where the ticks are often found. That you show that in text and video. That seems convenient, yes.'

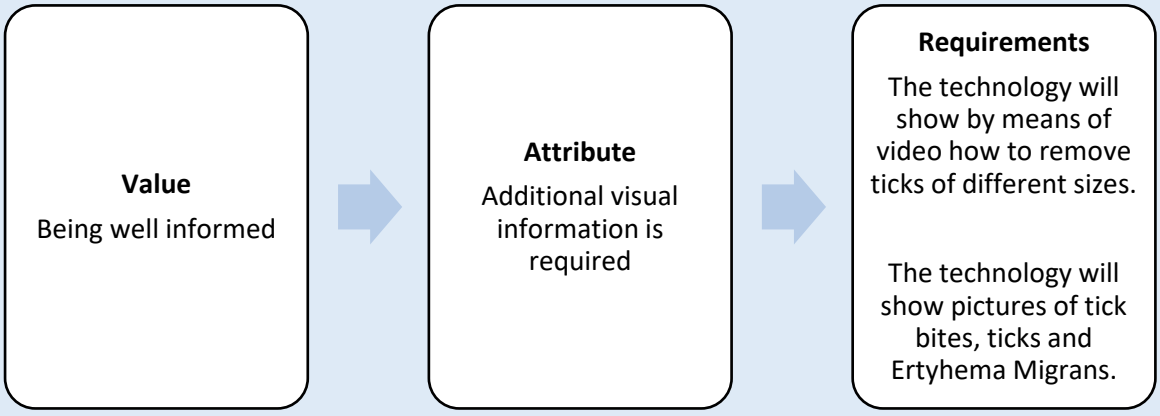

Figure 5. Example of transformation of value, into attribute, into requirements

Design

What is the design phase?

The output of the contextual inquiry and the value specification serves as the blueprint for the actual eHealth technology, which is developed in the *design phase*. A good design is also closely related to implementation, since a technology that fits the wishes and needs from the stakeholders will – in most cases – be used more and longer than a technology that doesn't.

That is why, during the design phase, the development team constantly has to keep the contextual inquiry and value specification in mind.

It is important that the final technology should not be developed at once, since chances are that, if that happens, a lot of important issues can be missed and arise just after its been implemented in practice. That is why multiple *prototypes* of the technology have to be developed to visualize and elaborate on initial ideas. A prototype is a visual representation of an idea about the eHealth technology, a simplified version of a final end-product. To make sure that issues are identified and that a technology fits with the needs and preferences of the users and other stakeholders, the prototypes have to be tested with them. This enables the development team to remove any critical issues and to add elements that are missed by the target group, and adapt the design accordingly. This is an iterative process, since constant changes to the idea and prototype of the technology can and should be made (Beerlage-de Jong et al., 2014; Wentzel et al., 2014). More information on this so-called Human Centred Design approach can be found in Chapter 10.

Besides ensuring that the design and content of a technology appeal to the user, the development team should also ensure that the technology influences cognitions or behaviours of users that should be adapted in order to reach the value of the technology. This can be achieved by using theory to add elements to the technology, for example from the *Persuasive System Design (PSD)* model, and by using *Behaviour Change Techniques (BCTs)*. This ensures that a technology is persuasive: it is compelling without being coercive (Fogg, 2009), and consequently increases adherence and behaviour change. Chapter 11 focuses on the PSD model, and BCTs are elaborated on in Chapter 2.

The design phase is an extremely dynamic, iterative and collaborative phase, during which the development team actively collaborates with stakeholders like designers, psychologists, users, content experts and funders. Not just by testing and perhaps even developing the prototypes, but also by ideating, creating, and discussing ideas together.

Objectives of the design phase

The design phase has several main objectives.

1. Both low-fidelity (lo-fi) and high-fidelity (hi-f) prototypes of the technology have to be developed.
2. Usability tests of the prototypes have to be conducted with end-users, experts and possibly other stakeholders
3. Persuasive elements and/or Behaviour Change Techniques have to be added to the design.

Concepts, methods and activities of the design phase

1. Both lo-fi and hi-fi prototypes of the technology have to be developed

When developing prototypes, it is especially important for every member of the development team to have a good grasp of the end-user. Insight into the end-users wishes, needs, and characteristics, facilitates the process of specifically designing for the target group. *Personas* can assist in this, defined as representative demographic and fictional profiles of target groups or end-users written like a story about a specific person (Grudin & Pruitt, 2002). The main

method to draw up a persona is by using interviews with end-users, and using the information from this interview to fill in templates such as a LeRouge table. This template can be used to create one or multiple personas (LeRouge, Ma, Sneha, & Tolle, 2013).

In some cases, the development team should also know which kind of information should be provided, and how this has to be structured. A card sorting study can be conducted among end users to obtain more information on the desired information structure of the technology. Participants are invited to cluster cards with information in whatever way they consider it to be logical. By analysing 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).

After a multidisciplinary project team has come up with the initial ideas about a technology by means of ideation, the first prototypes can be developed. A distinction can be made between low-fidelity (lo-fi) and high-fidelity (hi-fi) prototyping. The design process usually starts with lo-fi prototypes: prototypes that not have to resemble the final technology, as long as the most important features and the goal can be communicated clearly. They can be 'built' by people with little technical skills, using the following kinds of methods (Holtzblatt, Wendell, & Wood, 2004; Maguire, 2001; Signer & Norrie, 2007; Snyder, 2003):

- *Storyboarding.* Storyboards are sequences of images that clarify how the system interacts with the user by showing the relationship between user inputs and system outputs.
- *Paper-based prototyping*. Paper prototypes can be created with different kinds of materials such as pencils, paper, paint, sticky notes, cards or paint.
- Digital prototyping. Computer programs like PowerPoint or Balsamiq can be used. These programs can be used to make clickable, interactive lo-fi prototypes. See Figure 6 for two examples based on the previously described case on tick removal.
- 3D prototyping. This method uses materials such as cardboard, foam, wood, plastic, clay and building blocks.

Hi-fi prototypes have a higher resemblance to the final version of the eHealth technology 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.

Figure 6. An example of a prototype for a tick app based on two previously elicited requirements

2. Usability tests of the prototypes have to be conducted

Prototypes have to be tested with people to identify flaws, gather overall opinions or collect recommendations. This is called *usability testing*. Usability tests can be used for several purposes, for example, to observe how an end-user interacts with the system, to test the ease of use and user-friendliness of the technology, or to assess whether user requirements are correctly translated into the design. Information on these kinds of topics can be used to improve the technology. Broadly speaking, there are two ways of testing usability: expert-based and user-based.

- Expert-based usability testing. In this kind of usability testing, experts on design or the subject the technology is designed for are conducting the usability evaluation. They use their own knowledge about good design, the target group or the subject.
- User-based usability testing. Here, the test is performed with potential *end-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):

- *Heuristic evaluation.* Experts assess the usability of the system using a set of recognized usability principles, called the heuristics. There are several types of heuristics such as those of Nielsen (Nielsen, 1994). In heuristic evaluation, the experts are free to explore the system as they wish to discover major usability issues.
- *Cognitive walkthrough.* Here, experts are also involved, but in a very structured way. The researcher specifies the tasks that a user would want to perform with the system, after which an expert will perform these tasks to identify usability issues specifically related to the technology (Wharton, Rieman, Lewis, & Polson, 1994).
- *Think-aloud method.* This is a user-based method. Simply put, members of the target group use the prototype to complete scenarios that are usually a chain of tasks prepared by the researcher. This is called scenario-based testing. While completing these tasks, the user is asked to 'think aloud', in other words to verbalize his or her thoughts about using the system. Before and after the think-aloud method, an interview can be conducted with the user to find out about expectations and general impressions (Carroll, Rosson, Chin, & Koenemann, 1998; Jaspers, Steen, Van Den Bos, & Geenen, 2004).

3. Persuasive elements and or Behaviour Change Techniques have to be added to the design.

Persuasive technology is technology that is designed to change attitudes or behaviour (Fogg, 2009). To achieve this, persuasive elements should be added to the prototype during the design phase. The *Persuasive System Design (PSD) model* is a useful, widely used model that can assist in making technologies more persuasive (Oinas-Kukkonen & Harjumaa, 2009). The model, which is more thoroughly explained in Chapter 11, consists of four categories that all contain several persuasive features:

- Primary task support. Technology can support the primary goal of an intervention. Features of this category aim to assist the user in reaching this primary goal, like increasing exercising behaviour.
- Dialogue support. A technology can interact with its users in order to change their attitude or behaviour. This category's features are added to support and improve this user-technology interaction.

- Credibility support. Users should perceive a persuasive eHealth technology as highly credible. Features of this category can improve the trust people have in a technology.
- Social support. Technology can play a role in providing social support, which influences behaviour change. The use of features from this category can replace or add to users' social support from actual persons.

Most eHealth technologies aim to influence specific behaviours or cognitions. Consequently, *Behaviour Change Techniques (BCTs)* can be added to the design as well, especially since research has shown that more extensive use of theory in technology results in increased effects (Webb, Joseph, Yardley, & Michie, 2010). 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. Some examples of BCTs are reinforcement, goal setting, active learning, fear appeal, and social comparison (Michie et al., 2013). The BCTs and their relationship to eHealth are more elaborately discussed in Chapter 2.

BCTs 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 intervention to influence behaviour. Input from the PSD model and behaviour change techniques can be combined when designing eHealth, as they complement each other. In both approaches, the development team has to determine in what way the abstract theoretical principles should be translated into the prototypes, since there are no concrete guidelines for this. In any case, thorough knowledge on the models is required. The process can be facilitated by using literature that provides practical examples of the application of BCTs or persuasive features, which can serve as inspiration for the development team.

Outcomes of the design phase

The main outcome of the design phase is the first version of the eHealth technology that will actually be used in practice by the stakeholders. Consequently, the output of the contextual inquiry and value specification has to be used in the design to make sure that there still is a fit between context, technology and people: the technology has to address the issue identified in the contextual inquiry, it has to incorporate the requirements and aim to reach the values that were identified in the value specification. Furthermore, the constant usability testing and the adding of persuasive elements assists in ensuring that the user will actually start and keep on using the technology. It is important to note that a design is never really finished: in most cases, adaptations or improvements are required.

Design: Case

Applying Persuasive Design to a Web-Based Registration System for Infections in Nursing Homes

In nursing homes, annual prevalence measurements for healthcare-associated infections have to be conducted on a large scale. This requires elderly care physicians to once a year register all relevant data about residents that live in their nursing homes. They have to identify risk factors such as the use of antibiotics or catheters, or staying in a room with multiple other clients. A registration system consisting of an online questionnaire was already being used, but a contextual inquiry showed that many problems arose with this. For instance, physicians indicated that they sometimes debated with their colleagues about

how to interpret and answer a certain question (Beerlage-de Jong et al., 2014). It became clear that a new and improved version of this system was required. During the value specification, the team decided to create an app. An example of a value that arose was that users wanted the new system to work faster and easier. Based on this information, persuasive features to support this were translated into concrete requirements and added to the prototype. To address the aforementioned complexity of the questions, the principle of reduction, part of the category primary task support of the PSD model, was applied. The aim of reduction is to 'reduce complex behaviour into simple tasks, to help users perform the target behaviour'. The team actualized this by translating long and complex questions into multiple shorter and easy to answer questions, with a routing structure between them. This is visualized in the prototype shown below. Several rounds of usability tests of this prototype were conducted with experts and users. It became clear that the clarity of wording and sequence of questions could be improved, so based on these results, the prototype was further adapted and developed into a final system (Beerlage-de Jong et al., 2014).

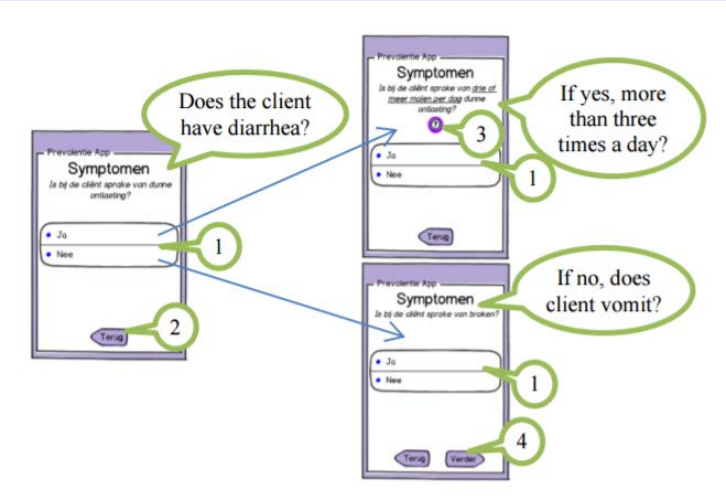

Figure 7. Prototype of visualization and 'reduced' interface of a registration system for infections in nursing homes

Operationalization

What is the operationalization phase?

Operationalization refers to the planning and actions for 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. A concrete plan is made to achieve this *implementation* of eHealth in context.

During the previous development phases, there has been a constant check with the context and stakeholders to ensure a good fit between technology and context. The better this fit, the higher the chances of a smooth operationalization. For example, because stakeholders have been involved from the start, they often feel more involved with the technology and thus start using, implementing or recommending it to their peers. Because of their knowledge of the context, they should be involved in developing a plan for operationalization as well. Furthermore, a *business model* that accounts for the stakeholders and context was created during the previous development phases as well (see Chapter 9). In the operationalization

phase, this business model is finished and practical strategies for its execution are developed (Van Gemert-Pijnen et al., 2011).

Besides using information from the context, stakeholders, and the business model, theory can be used during the operationalization phase as well. Implementation theories like the *Diffusion of Innovation theory* (Berwick, 2003; Cain & Mittman, 2002; Rogers, 2010) can be of added value when planning for the implementation of a new eHealth technology in practice. These kinds of theories can be used to bring the development team's attention to factors that are known to facilitate implementation. These factors can be accounted for and addressed by the team to ensure a smoother operationalization process.

Based on the business model, the gathered knowledge of the context and the input of its stakeholders, as well as a framework from an implementation theory, a realistic and comprehensive action plan for operationalization should be created (Van Limburg et al., 2015). This action plan prescribes how to roll out and implement the technology in the context that was described in the contextual inquiry. The plan consists of activities and resources for training, education, and financing the operationalization to enable the use of the eHealth technology. When the technology is operationalized in the most optimal way, it will be used in the most optimal way as well. This ensures that the users will be reached, that they use the technology as intended, and that the determined added value is achieved. A good operationalization also contributes to positive effects on the long term because it takes matters related to responsibility of technical support and financing into account. Chapter 13 focuses on implementation and further illustrates some of these concepts and theories.

Objectives of the operationalization phase

The operationalization phase has two main objectives.

1. Using the business model, input of the stakeholders, and implementation theory to create a plan to make sure that the technology is introduced and used in practice on the long term.
2. Determining concrete activities to implement the eHealth technology in practice.

Concepts, methods and activities of the operationalization phase

1. Create a plan to make sure that the technology is introduced and used in practice

As mentioned before, the information collected in the previous development phases is relevant for the operationalization phase, since it contributes to the plan for the operationalization.

First, the development team and stakeholders started developing the *business model* by filling in the business model canvas in the value specification. Consequently, the model was further specified alongside the development process, and is finalized and implemented in the operationalization phase. Concrete plans on how to deal with the nine blocks of the business model canvas have to be created in close cooperation with stakeholders. By means of methods like desk research, focus groups or interviews with stakeholders, the plan to implement the business model should be drawn up. Documented information from scientific or non-scientific literature on comparable operationalization processes might be used as well. Again, there are no concrete guidelines since the way to do this depends on the context,

technology, and the preferences and competences of the team. This implies that the development team has to make deliberate, well-substantiated decisions, and constantly cooperate with stakeholders.

Implementation theory can also be used to guide the development of an operationalization plan. According to the *Diffusion of Innovation theory*, the attributes of the technology itself strongly contribute to whether or not *implementation* will be successful. If the prior development process was good, the following attributes of the technology will be present and should be emphasized (Berwick, 2003; Cain & Mittman, 2002; Rogers, 2010):

- Relative advantage. The development team should make clear that the advantages of a new technology outweigh the advantages of an existing approach.
- Complexity. Generally, simple technologies spread faster than complicated ones, so it should be clear to users that they won't encounter a high level of difficulty.
- Compatibility. The development team has to make clear how the new technology should fit into the needs, values and routines of the user or organization.
- Trialability. Diffusion research has shown that it is beneficial for implementation when users can easily try out a technology without having to fully commit to it, so this has to be facilitated by the development team.
- Observability. The development team should make sure that potential users can see how an eHealth technology works by observing somebody else use it.

Furthermore, implementing an eHealth technology, it is important to account for the types of people that will be adopting and using it, since people differ in their willingness to use new technology. A useful way to do this is by accounting for how quickly they tend to adopt a new technology. The Diffusion of Innovation theory provides a categorization based on the innovativeness of adopters, which contains innovators (the quickest to adopt), early adopters, early majority, late majority and laggards. Figure 8 graphically represents this. The blue line stands for the percentage of people who adopt the new technology per category. The yellow line stands for the market share of the technology, which will eventually when it is adopted by all categories, reach the saturation level. Developers should always keep this in mind while implementing eHealth.

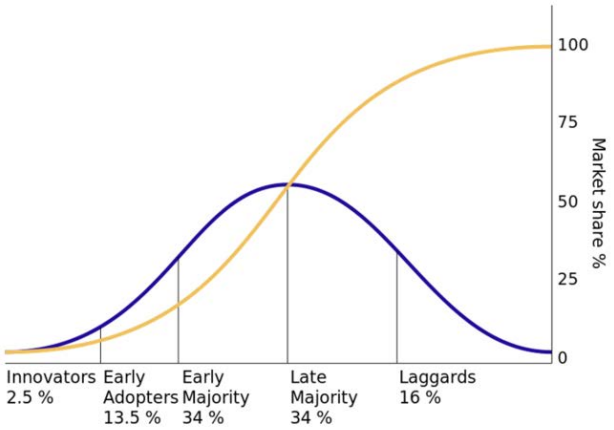

Figure 8. Categorization based on the innovativeness of adopters

2. Determining concrete activities to implement the eHealth technology in practice

The plan to operationalize eHealth should contain concrete methods. These methods can have different goals, for example, making potential users aware of the existence of the technology, persuading them to use it, and supporting them in continuing to use it. Some possibilities are:

- Pilot programs. A part of an organization starts using the eHealth technology. One aim of this is to make the entire organization aware of the existence and to show potential benefits of the technology.
- Advocates of the technology. During operationalization, it can be beneficial to have advocates of the technology who make their peers aware of and enthusiastic about the eHealth technology. Involving stakeholders in the development and implementation process are often committed to the technology and have much knowledge of it, which makes them good advocates.
- Presentations. The final eHealth technology can be introduced to the entire organization by means of presentations that provide potential users with information and the possibility to ask questions.

These methods are just some examples, but finding out the right implementation method requires some creativity and input from stakeholders who are acquainted with the context. Inspiration can also be gained from comparable projects, which can be found in literature, via desk research, or by contacting persons with relevant experience.

Outcomes of the operationalization phase

The main outcome of the operationalization phase is the introduction, dissemination, adoption, and incorporation or internalization of the technology in practice. This is guided by a plan that is developed in close cooperation with stakeholders to make sure it fits the context. Previous activities like business modelling and the contextual inquiry are used as input for the plan and methods to execute the plan.

An important issue to keep in mind during the operationalization phase is that, once technology is used in practice, it doesn't mean that the development process is finished. Changes to the content and form of technology can still be made, for example based on experience of stakeholders, changing practical demands, or evaluation outcomes. Technology is not fixed and can – and perhaps should – constantly be adapted to answer to the changing demands and possibilities of practice. Also, practical matters like financing and technical support of the technology keep on being relevant once it is implemented: constant attention has to be paid to these kinds of issues.

Summative Evaluation

What is summative evaluation?

Chapter 1 already explained that a holistic vision on eHealth is essential: technology, context and stakeholders are intertwined. Consequently, it makes sense to conduct an evaluation that involves all of these concepts. Among other things, it is important to determine if the added value that was identified in the value specification was achieved, and if and what kind of influence the eHealth technology had on the broad issue described in the contextual inquiry. The role that the technology played in changing these kinds of matters has to be determined as well, and the perspective of the stakeholders should again be taken into account. *Evaluation* of an eHealth technology should focus on the actual effects on health, the

influence on healthcare or related processes, the role and use of technology, and the perspectives of stakeholders.

Thus, *summative eHealth evaluation* should not just focus on its *impact* on health, healthcare and people, but also on the *uptake* of the technology (Van Gemert-Pijnen et al., 2011). The evaluation of the impact of an eHealth technology focuses on the values that were determined in the value specification phase. It aims to measure whether the intended effects in clinical (e.g., health status is improved), organizational (e.g., the hospital saves costs), and behavioural terms (e.g., due to an improved medication prescription protocol, MRSA is reduced) have been reached at a given point in time. Besides impact, summative evaluation also looks at the uptake of an eHealth technology in practice, which refers to the evaluation of how people and organizations have been using the technology. Was the technology used as was determined in the design phase, and was it implemented and used as described in the operationalization phase? Chapter 14 provides more in-depth information on the what, why and how of eHealth evaluation.

Objectives of the summative evaluation

The summative evaluation has two main objectives.

1. Determining the impact of the technology on the context and stakeholders, based on the predetermined values.
2. Analysing the uptake of an eHealth technology in terms of adoption or use of the technology by predetermined users and implementation, and use within the intended context.

Concepts, methods and activities of the summative evaluation

Multiple methods should be used to evaluate impact and uptake. This is needed because the development team has to collect different kinds of information from multiple perspectives to paint a broad, comprehensive picture of the influence that the technology has on the context and stakeholders. The choice for the evaluation method depends on the goal of the evaluation. These goals differ per context, technology, and overall aim of the technology. To further illustrate this, several possible research questions are provided. Also, several examples of much used methods that might be used in eHealth evaluation are presented.

1. Determining the impact of the technology

Several examples of research topics that determine the impact of eHealth technology are:

What impact does the eHealth technology have on patient or consumer health and wellbeing?

- Improved clinical values.
- Improved quality of life, social functioning, or general and mental health and wellbeing.
- Improved lifestyle, self-care and self-monitoring.
- Improved attitude and increased knowledge, behavioural intention and actual behaviour.
- Improved compliance with advice or treatment adherence.

What is the impact of the eHealth technology on healthcare delivery?

- Increased availability of healthcare, independent of place and time.

- Increased efficiency: reduced utilization of (unnecessary) healthcare services, time savings.
- Increased safety by the reduction errors by healthcare professionals.
- Improved interaction between caregivers and patients, among caregivers or among patients.

2. Analysing the uptake of an eHealth technology

Several examples of research questions that can determine the uptake of eHealth technology are:

How is the eHealth technology being used over a sustained period of time?
- How are the system's features and functions used in terms of frequency?
- How are the system's features and functions used in terms of usage patterns?

Who is motivated and capable of using the eHealth technology?
- Who are the 'hardcore' users?
- Who are the 'drop-outs'?

What factors explain the usage behaviour?
- What are reasons for hardcore (sustained) use, or dropout? How do the features and functions of the technology support the use of the technology and the satisfaction with it?
- What elements of the technology contributed to the effects that were found?
- Did the users notice the technology's persuasive elements? And did these persuasive elements work?

As mentioned before, multiple methods can be used, depending on the goal of the evaluation. Sometimes, the same method is used for both impact and uptake purposes. That is why the list below provides several methods, of which most can be used for both impact and uptake. Some of these methods are elaborated on in Chapter 14.

- *Randomized controlled trials (RCTs).* RCTs can be used to evaluate the results of an eHealth technology, for instance whether it had an effect on the health status of a patient or any health-related matters before and after the eHealth technology was used (Kelders, Van Gemert-Pijnen, Werkman, Nijland, & Seydel, 2011; Köhle et al., 2015).
- *Fractional factorial designs.* In a fractional factorial design, different users use different variations of an intervention. 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 (Kelders, Bohlmeijer, Pots, & van Gemert-Pijnen, 2015).
- *Interviews.* Interviews 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 (Maguire, 2001).
- *Log data analysis.* Log data is often used to register the actual use of the technology features and content. Examples of log data are the number of website visitors, or the frequency of use of the functionalities used. It provides insight into how the technology is being used by who. This method is especially suited for uptake purposes (Sieverink et al., 2017).

- *Ecological momentary assessment (EMA*). This method can be used to collect data on, for example, technology use or health behaviour during the day. It can provide insight into the use of the technology (uptake), or changes in health-related behaviours (impact) (Shiffman, Stone, & Hufford, 2008).
- *N=1 study.* In this type of study, data of single participants are analysed. Data collection can be intensive and complex and time consuming methods can be used (Lillie et al., 2011).
- *Time series analysis.* In time series analyses, data is collected over time and analysed to identify patterns (Velicer & Fava, 2003).
- *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 (Turchetti, Spadoni, & Geisler, 2010).

Outcomes of the summative evaluation

Because of the use of multiple methods and perspectives, eHealth evaluation can be seen as a contextual inquiry of the new situation that includes the technology. Its main purpose is determining whether the intended values have been achieved, if other unexpected effects arose, and what could be further improved. The exact nature of the outcomes of the summative evaluation depends on the research questions and accompanying methods. However, one should always look at both the impact and uptake of the technology in a holistic manner, involving health, behavioural, and organization in the evaluation. In the contextual inquiry, the development team should already identify the desired impact and uptake.

The results of the evaluation methods can be used for several purposes. First of all, claims can be made about the effects of an eHealth technology. If the added value of a technology is apparent and objective, it will be easier to implement it on a larger scale. Also, results can be used to make changes to the technology itself. If it becomes apparent that some features of the technology aren't used at all, or if users are dissatisfied with a specific element of the technology, this should be adapted. eHealth development is never finished. Furthermore, evaluation results can be used to form theory about eHealth, for example about the added value of persuasive features, or predictors of dropout. Finally, evaluation can also provide the development team with insight into their process: it might very well be that after evaluating, it becomes clear that certain activities should have been conducted in an earlier or later stage, that a suboptimal decision was made along the way, or that important information was overlooked. The development team can learn from these lessons. To conclude, evaluation is an essential part of eHealth development and should, just as the other phases, focus on the technology, stakeholders, and context.

Formative Evaluation

What is formative evaluation?

Formative evaluation is not a separate development phase, but a principle that is intertwined throughout the eHealth development process. It's very important to note that its place in 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. The eHealth development process is not

linear, but iterative and dynamic, and a formative evaluation represents this. In this, all development activities are interrelated and outcomes and decisions can constantly be adapted.

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 development 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. Using input gathered by different methods to improve the development and design process is the key.

To achieve this, formative evaluation is twofold. On the one hand, it can be used between development phases. At the end of a phase, the development team has to check whether the outcomes of a previous phase have been accounted for and haven't been forgotten along the way. For example, in the design phase, the development team has to make sure that the designed technology incorporates the requirements and addresses the values. Besides this, the development team also has to decide on whether changes in the outcomes of previous phase are required. This might be the case when new information arises during the value specification which has implications on, for example, the issue or target group that was specified in the contextual inquiry. This is part of the iterative nature of eHealth development.

The other use of formative evaluation is within a development phase. This refers to activities that support the development team in ensuring that there is a fit between their activities or output and the perspective of the stakeholders and context. An example of this is the constant involvement of stakeholders in decision-making, or interviewing potential end-users to elicit requirements instead of the development team autocratically coming up with them. These kinds of activities should be conducted in every phase of eHealth development.

Objectives of the formative evaluation

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

1. Checking whether the outcomes of previous phases have been accounted for in the current phase, and that the outcomes of all phases are related to each other.
2. Using methods to gather information from the stakeholders and context to continuously include their perspectives in the activities and outcomes of the development, implementation and evaluation.

Concepts, methods and activities of the formative evaluation

1. Checking whether the outcomes of previous phases have been accounted for

This aspect of the formative evaluation mainly focuses on ensuring that there is a clear relationship between the content and output of the separate phases. The responsibility for this lies with the development team. No concrete methods are prescribed for this, it depends on the nature of the project and the preferences of the project team. However, it is essential that every member of the development team is aware of the decisions that are being made. Another requirement is that in every eHealth development project, a thorough, transparent documentation of the activities and outcomes of each phase should be created for a proper formative evaluation. 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 methods like focus groups or meetings with the development team and/or stakeholders.

2. Including stakeholders' perspectives in the eHealth process and design

The formative evaluation does not have separate methods since it is an overarching term that refers to principles behind the methods used during development. However, to illustrate and further clarify this, some practical examples of methods that convey the principles from formative evaluation 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 assists the team in ensuring that the requirements they elicited from focus groups and interviews are still relevant and make sense to the stakeholders.
- In the *design phase* of the technology, a straightforward example of formative evaluation is *usability testing* among users via the think-aloud method. This method aims to make sure the technology fits the user's opinion.
- During the *operationalization* phase, the involvement of stakeholders in finishing up the *business model* and making a plan on how to implement the model is an example of formative evaluation. Involving stakeholders in the implementation increases the chances of the implementation strategies fitting the context.

Outcomes of the formative evaluation

The formative evaluation of eHealth is iterative and is the backbone of the development of eHealth technology. Formative evaluation aims to monitor whether a project is still on track, detect problems as early as possible, solve these problems as soon as possible, and to make sure that the relationship between the technology, stakeholders and context is guaranteed. In this way, formative evaluation can be used to identify potential implementation problems and to tackle them in early phases of development. Because of this broad scope, there are no concrete outcomes, since formative evaluation has no fixed endpoint and is part of the development, implementation and evaluation of eHealth.

Summary

This chapter has briefly introduced the *CeHRes Roadmap*, its underlying principles, the separate phases, their main goals, and possible methods to achieve these goals. More elaborate information on mentioned frameworks, approaches and theories can be found in the following chapters.

It cannot be emphasized enough that the choice for methods depends on the research questions and goals of each individual project, and that the list of methods provided in this chapter is far from exhaustive. New methods and frameworks for development, implementation and evaluation are constantly arising, meaning that the CeHRes Roadmap is continuously evolving as well. It is not a prescriptive theory or approach in itself, but mostly provides a framework in which different types of methods and approaches can be used.

eHealth developers should thus be flexible to deal with or make changes in process and content, they should be able to transcend their own discipline to collaborate with people with very different backgrounds, and they should have an eye for recent developments in research methods and technology. This flexibility combined with an eye for the context, people and technology should result in a thorough development process that can contribute to reaching eHealth's potential. The following take home messages summarize the essence of this chapter:

- eHealth development should be an iterative, agile, flexible, and formative process which reflects the complexity of behaviour change.
- During each development phase, multiple methods can be used. The nature of these methods should depend on the research question that was posed by the development team. Consequently, developers should have a clear idea of the main goals of each phase.
- During eHealth development, attention should constantly be paid to the interrelationship between the stakeholders, the healthcare context, and the technology. This is in line with the holistic view on eHealth.
- eHealth development is interdisciplinary and draws from evidence-based methods from different disciplines and approaches, such as participatory development, persuasive technology, business modelling and human centred design.
- eHealth technologies are never finished and require constant adaptation and improvements, based on demands from the people and context.

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