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# Developing an evaluation framework for eHealth interventions

## An exploratory approach

*Master of Science Thesis*
*in the Quality and Operations Management Programme*

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# Abstract

Numerous efforts are being taken continually to understand the scope of eHealth in improving the current healthcare system. It is believed that eHealth, i.e. the use of information and communication technology in healthcare, is a promising contributor in alleviating the issues such as fragmented healthcare system, rapid escalation of diseases related to aging and other chronic diseases. However, when it comes to the empirical evidence, eHealth does not offer as much success as it promises. Such discrepancy is attributed to the fact that eHealth interventions are immensely complex; hence accumulating reliable evidence of success through evaluation is very challenging.

The purpose of the thesis is to explore how a framework can be developed to evaluate eHealth intervention. The understanding of how the eHealth interventions are evaluated was crucial for this study; hence various types of evaluation in eHealth intervention were analyzed in the preliminary stage. The study was conducted as a participatory action research within a multinational eHealth intervention project. It was a single case study and data was collected using qualitative methods. In addition to the case, with which we were involved throughout the research period, literature played an important role as a source of information in this study.

Several observations were made throughout the thesis. These resulted in some key findings. eHealth intervention can be organized in six phases titled as design, pre-testing, pilot study, pragmatic trial, evaluation, and post-intervention. There are several aspects to evaluate within an eHealth intervention and the aspects are categorized as clinical, human/social, organizational, technical, cost, ethical and legal, and transferability. A model has been proposed to exhibit how the evidence of efficacy and efficiency can be built along the phases of eHealth intervention through evaluating different aspects in different phases. Lastly, a roadmap consisting of seven phases for developing a framework for evaluating eHealth intervention is provided.

**Keywords:** evaluation, eHealth interventions, challenges in evaluation, evaluation frameworks, multinational case.

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# 1. Introduction

The chapter is divided into three sections. To initiate, background information of the main topic is provided. Then, the purpose and the research questions are presented to emphasize the importance of the study.

## 1.1. Background

The world population is aging faster than ever because of two global trends: increasing life expectancy and declining fertility (Muenz, 2007). According to United Nation's (UN) report titled *World Population Ageing 2015*, 25 percent of the population in Europe are expected to be elderly persons by 2030 and the growth rate of the number of older people is higher than any other age group. One of the corollaries of the aging phenomenon is the growing challenge for the physical and mental well being for elderly people (Bisschop et al., 2004). There is a lack of awareness regarding mental health, compared to physical health in society. Nonetheless, the mental health issues such as, mild cognitive impairment, dementia, Alzheimer's, depression have insidious social and economic effect.

With a view to mitigate the complications that arise with the mental health of elderly people, healthcare providers are devising different strategies as a part of the treatment along with the medication. Although there are a good number of initiatives taken worldwide, they vary depending on the existing healthcare system of the country or region. Nonetheless, integrated care model is one of the healthcare trends that is drawing noticeable attention in North America, Europe and elsewhere as an important framework that provides better and cost effective healthcare service (Kodner and Spreeuwenberg, 2002). Integrated care has been promoted as a mean to improve access, quality and continuity of services in a cost effective way especially for the patients with complex needs (Valentijn et al., 2013). Hence, integrated care has a great prospect for elderly people with mental health issue, although the underlying implications of the term vary to an extent depending on the context and logic (Kodner and Spreeuwenberg, 2002).

Information and communication technology (ICT) has a great potential to contribute to the improvement of the healthcare services all over the world. There are many different arenas within the healthcare process where ICT can play a significant role; e.g. assistive technology, mobile and web-based applications, online educational and disease support programs, electronic health record (EHR)/electronic medical record (EMR). ICT is considered as a change agent in organizing healthcare according to individual patient's need since it assists in coordinating care across different care providers (Winthereik and Vikkelsø, 2005). ICT applications are implemented by conducting intervention projects in healthcare referred commonly as eHealth. Although best practice research that determined the success factors for eHealth application in healthcare services, most of them still fail (Kaplan and Harris-Salamone, 2009). An evaluation framework is required to identify whether an eHealth intervention has caused the intended outcome or not as well as if it has caused any unforeseen consequence. It is also important to note that the design of evaluation is as important as the design of intervention as a badly designed evaluation framework can project erroneous conclusion regarding an intervention.

The majority of evaluation research on the eHealth interventions is done with an aim to assess the clinical outcome of the patient group, which is undoubtedly the most important aspect of a healthcare intervention. However, an evaluation framework needs to be enough comprehensive to take multiple aspects of the eHealth intervention into account; these aspects include but not limited to regulatory and policy requirement, communication, work environment, workflow, complexity of the ICT application (Kaplan et al., 2009). Usability and acceptance of the technology, the dimensions that are unique to eHealth intervention must be assessed by the evaluation framework. Nevertheless, there is a growing awareness that the critical issues in the healthcare project are related mostly to sociological, cultural and financial context (Kaplan et al., 2009). Thus, along with the technological functionality and clinical outcome, organizational affairs are required to be assessed during evaluation. The organizational context plays a significant role for the implementation of an intervention project. An eHealth intervention, proven to have excellent clinical outcome may not last longer if the organizational actors' roles are not aligned with the objectives of the intervention. Another important aspect of evaluating eHealth intervention is data collection and analysis. The quantitative method of data collection is prevalent in the most of the eHealth intervention studies since this method is highly structured and offers unambiguous data in comparison with qualitative method (Bryman and Bell, 2015). Qualitative method of data collection has its own merits, i.e. provide deeper insight of the intervention, and thus facilitate the knowledge creation for future use. It seems a fine balance in using both data collection methods in evaluating eHealth intervention is beneficial.

Hence, it can be argued that though eHealth intervention for elderly people with mental disease is not a novel concept, there is an opportunity of developing an evaluation approach that is more comprehensive as well as advantageous for future learning. It is also relevant to explore the research approaches for evaluating an eHealth intervention that is multifaceted.

### 1.2. Purpose

The study aims to explore how a framework for evaluating eHealth interventions can be developed. Understanding how the evaluation is carried out in eHealth interventions is also a purpose of the study since it is important for the development of evaluation framework.

### 1.3. Research Questions

Healthcare evaluations often entail only an impact assessment of the overall intervention, with little focus on the processes involved or the context of the participants (Parry et al., 2013). Most of the evidence-based healthcare procedures could not translate into practice, partly due to the research methods used to evaluate interventions that fail to consider the external validity and to provide information to the policymaker (Glasgow, 2007). The research methods used to evaluate an eHealth intervention vary in several dimensions, i.e. epistemological orientation, ontological orientation, data collection method, evaluators' position in the intervention. There are researches that advocate for the scientific method as the epistemological position for the evaluation of healthcare intervention (Bates and Wright, 2009; Catwell and Sheikh, 2009; Lilford et al., 2009). On the other hand, some researchers consider evaluation of healthcare intervention as a social practice in lieu of scientific method (Pawson et al. 2005; Greenhalgh and Russell, 2010). Similarly, as ontological position, some research on the intervention of the healthcare pursue objective evaluation of the actors involved in the intervention and some focus on the context of it along with the actors (McCormack et al., 2002).

The orientation of the researcher is another important element that can be defined by the background of the researcher and his/her position within the intervention project. For instance, the researcher(s) can be from a medical background and directly involved in taking actions in the intervention (Reid et al., 2009) or can be hired from a research organization(s) as evaluation expert (Mitseva et al., 2010). The later way of conducting evaluation is defined as participatory evaluation which is more preferred way according to some of the researchers (Greenwood and Levin, 2007). The research method to evaluate an intervention can also be divided into formative and summative assessment, where the former provides the feedback to the actors of the intervention to make adjusts in the intervention in real time and the latter provides the accumulation of the knowledge from the intervention that can be used in the future (Lilford et al., 2009).
The research method can differ in many ways and it is quite possible that the suitability of the methodology of evaluation in healthcare depends on the type of intervention. Therefore, it is important to explore the various ways of evaluation in eHealth interventions. Hence, the first research question is formulated as:

*RQ1: How do the evaluations vary in eHealth interventions?*

Furthermore, it seems significant to have a guided way of developing a framework for evaluating eHealth interventions, so that the evaluation can be proper and the evidence gathered from the intervention through the evaluation can be reused. The eHealth interventions are often more complicated and multifaceted compared to other healthcare interventions (Pingree et al., 2010). A complex intervention has various interconnecting knowledge domains (Campbell et al., 2000; Craig et al., 2008) and usually these domains have different vocabulary and policy for deploying the intervention. Developing an evaluation framework for such intervention can be quite challenging since eHealth interventions involve interdisciplinary collaboration (Pagliari, 2007). The evaluation framework varies in eHealth interventions due to these unique complexities attached to the intervention. Under this circumstance, it would be beneficial to have a standard way of developing an evaluation framework to assist people in developing a new one or adopt from an existing one, suitable for their own eHealth intervention. No such guide for developing an evaluation framework has been found in literature till date. The purpose of this study is to explore the development process of a framework for evaluating an eHealth intervention. Thereby, the second question is defined as:

> *RQ2: How can a framework for evaluating an eHealth intervention be developed?*

# 2. Theory

In order to address the research questions several healthcare-related concepts will be analyzed. In this section, a brief description of the key areas is presented, along with the correlation with the concepts and the central topic.

## 2.1. Healthcare

According to the World Health Organization (WHO), healthcare services are defined as "all services dealing with diagnosis and treatment of disease, or the promotion, maintenance and restoration of health". In any healthcare system, health services are considered the most perceptible function to the users (Tan, Wen and Awad, 2005). This fact is supported by the guide named *Key components of a well functioning health system* (2010), which states that a healthcare system is only as effective as the services it provides. In the publication, the service delivery characteristics required to cope with the health needs of the population are defined. First, close-to-patients primary care (i.e. well-organized health districts networks with specialists and hospital services that respond to the full range of current health problems of the local area population, and adapt to evolving needs) is crucial. Second, standards and protocols are required to meet the essential dimensions of quality (i.e. patient safety, service effectiveness, integration, continuity of care, and patient-centered services). Third, mechanisms are needed to hold health providers accountable for access and quality, and to ensure that the consumers' voice is used as an input for any healthcare provision process.

Healthcare service provision is an interaction of different components (i.e. leadership and governance, health information systems, health finance, human resource for health, and essential medical products and technologies), which make healthcare and service delivery systems large and complex (Tan et al., 2005). These systems are often complicated due to different factors that can be described by three levels: (1) Human, (2) Organization, and (3) System (Tan et al., 2005; World Health Organization, 2014).
To address the first level, healthcare-service delivery is a human-based system. The level refers to the intricacies of the human body and the corresponding available multiple healthcare professionals. A notion of complexity is added in the first level by understanding that a large amount of knowledge and skills are required to keep the human body functional, or to take it back to their original state of health. Hence, both diseases and medical specialists characterized the variation within the system (Wennberg, 2002; Tan et al., 2005). In relation to the second level, *Organization*, the provision of healthcare services relies on effective leadership and management. Managed care aims to improve the health status in humans by scaling up the quantity and quality of health services. For instance, healthcare service is moving towards integrated care systems created by a robust financing mechanism, well-trained medical professionals, reliable information to base decisions on, well-maintained facilities, and strategies to deliver medicine and technologies. (Büyüközkan, Çifçi and Güleryüz, 2011; World Health Organization, 2014)

Lastly, the third point refers to policies of the community, region or country shaping the particular system. The configuration of the healthcare services is designed to fulfill the policies of a particular setting. Delimitations could be generated by differences in cultural, social, and economic contexts. Intricacy in this macro level corresponds to the aim of achieving specific healthcare goals within a society and its related restrictions (i.e. differences of health needs of target populations, difference in occurrence of epidemic diseases, the availability of resources and wealth of the affected community). (Tan et al., 2005; World Health Organization, 2014)

## 2.2. Mental Healthcare

Mental health disease is an important source of burden on healthcare worldwide. In WHO's latest global estimates for 2010, neuropsychiatric disorders are the third leading cause of global disability-adjusted life years (DALYs)[1]; the category includes mental and behavioral disorders (7.4% of total global DALYs), and Neurological disorders (3% of total global DALYs) (Mathers and Loncar, 2006; World Health Organization, 2016). Likewise, due to physical illnesses and other mental disorders, the life expectancy of people with mental health problems is 20 years lower than of those without them. Therefore, in order to reduce the mental health impact, in terms of both diminishing quality of life and reducing life expectancy, the provision of high-quality mental healthcare is enforced (Thornicroft et al., 2011).

WHO suggested that mental health problems treatment should be based in primary care. To address the suggestion, the organization launched the project *Mental Health Atlas* to map mental health resources in the world. Project Atlas aimed to assess the current situation, and to later provide accurate information to develop plans regionally and globally for mental health treatment. In *Mental Health Atlas-2005*, mental health in primary care is defined as "the provision of basic preventive and curative mental health at the first level of the healthcare system" (World Health Organization, 2005). The inclusion of mental healthcare in primary care is supported by Bower and Gilbody (2005). The authors proposed a five-level model to access mental healthcare. The model's objective is to highlight two points: (1) the importance of the primary care clinician, and (2) the necessity of a mental healthcare to cope with the typology of mental disorders. First, the model encourages the idea that care is provided by a non-specialist who can refer cases to a specialized mental health professional according to the complexity of the case. Second, the model differs between severe and long-term mental health disorders, and common mental health disorders.

A complementary approach is given by Thornicroft et al., (2011); the balance care model presents strong evidence that a comprehensive mental health service with community-based and hospital-based care is beneficial for the treatment of mental health disorders. Generally, the fundamental principles of the model are that the services

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[1] Units to measure the burden of disability associated with a disease or disorder (World Health Organization, 2016).

should be close to home, provide interventions for disabilities and symptoms, be specific to the person’s needs, and include mobile and static services. Specifically, the community-oriented approach aims to address the value of the community and rights of people with mental disorders as persons and citizens by treating patients in a way that the connection with their families, friends, work, and community is not affected. Furthermore, the care model pursues to improve the active participation of the patient and the involvement of the decisions related to the treatment. Finally, the importance of the relationship with family or any key relationship is highlighted; the support and participation in the processes of assessment, treatment planning, and follow-up are considered a factor in assuring the success of the model. (Thornicroft et al., 2011)

In addition to the models, different guidelines have been developed to suggest a standardized behavior for professionals who perform evaluations of mental disorders. The American Psychological Association (APA) published the *Guidelines for the Evaluation of Dementia and Age-Related Cognitive Change* in 2012. The document conforms with other mental health-related documents previously published by the organization, and emphasizes the fact that guidelines are not intended to be mandatory and may not be applicable to every professional situation (American Psychological Association, 2012). Likewise, the American Psychiatric Association (APA) provided a guide to clinical practice titled *Diagnostic and Statistical Manual of Mental Disorders (DSM-5$^{TM}$).* Apart from its clinical purpose, the documents intend to improve the collection of information available on the topic for educational and research purposes (American Psychiatric Association, 2013). To frame this research, the two following sections define the mental clinical conditions undergone by the patients included in the study.

### *2.2.1. Mild Cognitive Impairment (MCI)*

Many attempts have been made to define the mental clinical condition of declining cognitive abilities associated with aging. Gauthier et al. (2006) defined mild cognitive impairment as a syndrome that causes “cognitive decline greater than the expected for an individual’s age and education but that does not interfere notably with activities of daily life” (p. 1262). Petersen (2011) defined the condition as an intermediate state of cognitive function between the changes associated with typical aging and the gradual cognitive decline associated with dementia and Alzheimer’s disease. The author also emphasized that the decline is often recognized by those experiencing it and by those around them.

### *2.2.2. Mild Dementia (MD)*

As defined in the *Diagnostic and Statistical Manual of Mental Disorders* (2013), dementia is characterized by the development of multiple cognitive deficits that include impairment in memory, and at least one of the cognitive disturbances described below:

- *Aphasia*: deterioration of language function;
- *Apraxia*: impaired ability to execute motor activities;

- *Agnosia*: failure to recognize or identify objects despite intact sensory function; or
- *Disturbance in executive functioning*: involves the ability to think abstractly and to plan, initiate, sequence, monitor, and stop the complex behavior.

Also, to consider a mild state, the cognitive deficits must cause minor impairment in occupational or social functioning, and must represent a decline from a previously higher level of functioning.

## 2.3. eHealth

According to the study *What is eHealth (3): a systematic review of published definitions* (2005), the term “eHealth” or “e-health” or “electronic health” was introduced during the 1990s and became an accepted neologism despite the lack of agreement upon the definition. Up to the year 2005, the authors found 51 unique published definitions that include the concepts health, technology, and commerce in different degrees of emphasis (Oh et al., 2005). In a more recent publication *Evaluating eHealth interventions: the need for continuous systemic evaluation* (2009); the authors support the fact that there is still no universal agreement on the meaning. However, it is stated that the term eHealth is commonly used to refer to the full spectrum of technology deployments in healthcare (Catwell and Sheikh, 2009).

Unlike past publications, in the article *eHealth literacy 2.0: problems and opportunities with an evolving concept*, Norman (2011) provides a single definition of eHealth: “the use of information and communication technologies (ICT) for health” (p. 1); which is also the definition currently used by the World Health Organization (2016). On the other hand, the use of alternative terms has been found in publications that do not focus on defining eHealth. The article *The impact of eHealth on the quality and safety of health care: a systematic overview* describes technology interventions in healthcare as eHealth technologies; and within this group the authors categorize any technology that fulfill three main functions: (1) enable storage, retrieval and transfer of data, (2) support medical decision making, and (3) facilitate remote care (Black et al., 2011).

While defining eHealth, the definitions include the term health in relation to health delivery services (e.g. health care, health system, health sector, or health industry). Additionally, the term technology is always referred either explicitly or implicitly in the definitions (Oh et al., 2005).

### *2.3.1. eHealth intervention*

Information and communication technologies are advancing in the healthcare sector more rapidly than ever before. eHealth solutions refer to any technological tool that delivers health-related content and clinical care, and enables patient connectivity and monitoring (Wilson and Lankton, 2004); the tools include electronic health records (EHR), patient-provider e-mail messaging, mobile health apps, and personal monitoring devices (Ricciardi et al., 2013). As the adoption of information technologies in healthcare increases, the prioritization of mechanisms to reduce costs and improve the quality and efficiency of healthcare services becomes crucial (Mair et al., 2012). One important priority is the exchange of information among hospitals, other healthcare providers, and patients. By sharing information between healthcare providers and patients, eHealth solutions are frequently used to provide safer, higher quality, and patient-centered care to people (Mostashari, 2014). Aligned to these criteria, interoperability[2], standardization and security of information are emphasized. For instance, every effective system would have capabilities to send and receive documents, using the same set of standards, and considering privacy as the key principle of the patient-physician relationship (Appari and Johnson, 2010; Mostashari, 2014).

Another noteworthy point is the progress towards a new standard in which patients can easily access and own their health information. eHealth solution providers have detected an increase in the level of patient involvement. Indeed, patients have changed their interest from sites with general health content to advanced applications with personalized content and self-management tools. Patients use eHealth to gain information regarding health conditions or diseases. Although eHealth solutions increase the availability of information, most of the patients do not want to make all the decisions concerning their own healthcare. Thus, patients consider medical technologies as a complement of the information received from a healthcare provider. (Wilson et al., 2004)

Beyond patient-centered care, eHealth represents a critical element by engaging patients, caregivers and family members to play an active role as direct consumers (i.e. anyone involved regardless of health status, whether or not is actively receiving healthcare services). Giving access to the health information and technological tools to use that information, consumers can participate more fully in the healthcare delivery service process by self-managing the disease, coordinating care across different healthcare providers, and improving communication among care teams. (Ricciardi et al., 2013) Lastly, access to health records enables the evolution of eHealth interventions towards the reduction of the time that patients spend receiving care. Once patients own their data, they can receive care through other means besides visits to primary care physicians or specialists. (Mostashari, 2013; Wilson et al., 2004)

eHealth research often focuses on the design and implementation process of technologies, but the acceptance of the solution by end users to already implemented technologies is often overlooked (Holden and Karsh, 2010). As any other technology, eHealth solutions require an efficient technology acceptance model to close the gap between the range of services that healthcare providers offer and the services that patients demand. Human-centered design issues enable medical technologies to meet

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[2] Ability of different information technology (IT) systems or software applications to communicate, to exchange data accurately, effectively, and consistently, and to use the information that has been exchanged (Balka et al., 2012).

the needs of different types of patients in different situations along the care delivery process (Wilson et al., 2004). In order to predict and explain the end-user reaction and increase the acceptance of eHealth, several methodologies have been implemented. However, the main principle of any acceptance model is to ask the potential users about the future intentions to use the technology, and use the factors to promote acceptance, and thus increase the technology use (Holden et al., 2010).

User-oriented assessment in the field of health informatics also includes usability, the term also known as user experience, refers to the users' perception and responses resulting from the use of the technology (Viitanen et al., 2011). Usability is associated to the human-technology interaction; as defined by the ISO 9441-210 "includes all the users emotions, beliefs, preferences, perceptions, physical and psychological responses, behaviors and accomplishments that occur before, during and after use" (Viitanen et al., 2011, p. 711)

## 2.4. Evaluation in eHealth

Evaluation is one of the regular activities of human life in both personal and professional sphere. According to the *SAGE Handbook of Evaluation*, systematic, formal evaluation is able to identify the evidence and criteria on which the evaluative judgment is based and to diminish the sources of biases (Mark, Greene, and Shaw, 2006). Evaluation is an indispensable procedure for expanding the utilization of technology in healthcare (Chamberlain, 1996). Evaluation process in eHealth interventions provides crucial information about the efficiency and effectiveness of the technology-enabled care, how the technology fits among users in different context, various constraints and the specifications of the technology that overcome such constraints (Kreps, 2002). Evaluations of eHealth interventions are supposed to deliver minutiae of technical, clinical, economic, organizational, ethical and legal issues (Hailey, Ohinmaa, and Roine, 2003). Evaluation of eHealth interventions can be carried out by formative and/or summative evaluation. Formative evaluation administers real-time feedback, directions for improving the implementation of the system to the people who are involved in current intervention and summative evaluation administers the overall impact and outcome of the intervention that is more general and address to the decision makers for future use (Kreps, 2002; Lilford, Foster, and Pringle, 2009). The authors also agree that summative and formative evaluations are not two distinct types of evaluation but often overlap each other. Moreover, the utilization of both types in different phases of the intervention enriches the overall evaluation.

It is relevant to discuss health technology assessment (HTA) while discussing evaluation of eHealth interventions. These two paradigms have some similarities as well as some dissimilarities. According to Health Technology Assessment International, "HTA is a field of scientific research to inform policy and clinical decision making around the introduction and diffusion of health technologies. HTA is a multidisciplinary field that addresses the health impacts of technology, considering its specific healthcare context as well as available alternatives. Contextual factors addressed by HTA include economic, organizational, social, and ethical impacts. The scope and methods of HTA may be adapted to respond to the policy needs of a particular health system." Gagnon and Scott (2005) provide a set of contrasts between HTA and evaluation of eHealth that says, evaluation in HTA is steadier and depends on a group of authenticated measurements, not biased by political activities and creates agreed knowledge about effectiveness. The evaluation of eHealth interventions is more unstable and the impact of the technologies in healthcare is proven in a fragmented manner. While the HTA completely relies on randomized control trials (RCTs)[3], evaluation of eHealth interventions cannot always be limited to RCTs, since the latter is more complex and considers socio-political interaction in the evaluation.

As long as the distinction between this two is understood well, one can be helped by the other. In this study, some of the evaluation frameworks of HTA have been mentioned and used for analysis of the evaluation of eHealth interventions. However, these frameworks are relevant to the evaluation of eHealth interventions as much as they are to HTA.

## 2.5. Challenges in Evaluation

Challenges faced in evaluating healthcare interventions are manifold. The difficulties in evaluating complex interventions arise both in practical and methodological aspect (Craig et al., 2008). It is necessary to take the multidimensional characteristics of the various components of an eHealth intervention into account while evaluating it. If the evaluation framework aims to contribute in future eHealth interventions which is expected in order to share information and to close the knowledge gap, it faces another new set of challenges could be named as transferability from a broad perspective. The goals and the evidence of achieving those goals in healthcare interventions are dynamic and can be interpreted in numerous ways depending on the context of the implementation.

One of the most critical issues in an eHealth intervention is to break the narrowly scoped research design (Glasgow, 2007). Whereas the majority of the evaluation frameworks are designed to assess the clinical performance and cost efficiency, eHealth interventions are needed to provide more answers in order to be sustainable. The importance of addressing the sociotechnical system context in which the eHealth will be embedded is underestimated in most of the cases (Sanderson, 2007). It is usually conceived that only the criteria that measure the endpoints[4] of the interventions are adequate for an evaluation framework but in reality, it is very important to measure the outcomes that will assist the policy makers in decision making irrespective of the fact whether those are endpoints or not (Tunis, Stryer, and Clancy, 2003). Moreover, emphasizing only on clinically significant outcome even though addresses efficacy of

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[3] A study in which subjects are randomly assigned to two groups: (1) The experimental group, receiving the intervention that is being tested, and (2) The comparison group or control group, receiving no intervention (Ireland, 2010).

[4] Specified health outcomes (Goodman, 2004).

care but fails to imply how the large-scale implementation would work in the regular set-up of the healthcare system (Glasgow, 1999). WHO stresses this issue saying that evidence from interventions needs thorough analysis not only of clinical dimensions but also of indicators relating to successful deployment in normal care: change management, human resources, organizational interfaces, financing requirements, technology integration and ethics for everyday practice (Stroetmann et al., 2010). Therefore, it is important to motivate the current research trend to be more open and to realize the gravity of considering factors that may not be directly connected to the endpoints but relevant to the success of the intervention.

Another challenge quite related to the previous one is to optimize the comprehensiveness of the evaluation framework with respect to the respondent burden (Glasgow, 2007). This aspect becomes even more crucial when the eHealth intervention is designed for elderly people with mental disease. An evaluation process designed with an aim to be exhaustive can be turned into a huge framework that imposes excessive burden on the participants by asking for lots of information through long survey questions. This also may lead to poor survey response rate and poor quality of data. Hence it is necessary to be able to create a framework that is capable of providing a complete picture, yet feasible to be carried out without the extensive commitment from the participants' side.

eHealth interventions demand an interdisciplinary collaboration that brings its own set of challenges. According to Glasgow (2007), the author of the article titled *Design and Evaluation in eHealth: Challenges and Implications for an Interdisciplinary Field*, along with the growing involvement of academics from social, economic, and legal science in the medical intervention, the boundaries among scientific, policy, and commercial areas of research and development are becoming grayer; this phenomenon has many benefits as well as several barriers. The barriers can be described as the difference in languages, culture, motives, and the operational constraints in different fields (Pagliari, 2007). Besides the presence of the multidisciplinary researchers, the intervention framework also needs to deal with the multilayered structure of the healthcare system, e.g. individual including patient and care provider, organization, policymaker (Evans, 2003).

Finally, standardization and transferability of the evaluation framework are quite challenging. Until now the research on the design of evaluation framework for eHealth interventions has been conducted in a localized manner due to the fact that every intervention has some novelty in technology and its own set of constraints. Furthermore, interoperability of the technology used in the interventions has not been accentuated by the evaluators thus far which is one of the reasons of weaker transferability of the frameworks. But the healthcare systems are so widely diverse in different countries that it is yet to decide how far the evaluation framework for the eHealth intervention can be standardized (Bates and Wright, 2009). Still, there is no way of denying that implementation of an eHealth intervention in isolation could add little to the research effort in this burgeoning field, hence this is a challenge worth conquering.

# 3. Methodology

This section describes the methods that were used to conduct the research. It includes research strategy, research process, the description of the case selected for the research, quality criteria, and the ethical consideration for the research. At the end of the chapter, specific methodology used for research questions 1 and 2 are elaborated.

## 3.1. Research Strategy

An inductive approach was considered since the nature of the research is open-ended and explorative. An exploratory study aims to examine existing relationships and dissimilarities among entities in order to recognize the processes at work, mainly where a problem is not well identified in initial stages of the research (Duignan, 2016). Instead of proving a set of theory, the study intended to dig into the context to discover useful lessons for learning. The epistemological position of the research can be characterized as interpretivist as the aim was to understand the phenomena as the outcome of the combination of the contexts and the participants functioning within the context. The research was designed as a single case study. The case discussed later in the section was the primary source of data, which is qualitative in nature.

## 3.2. Case Description

A case study means the thorough and concentrated analysis of a case where the case can be a single organization, a single location, a person or an event (Bryman et al., 2015). The aim of this study was to explore the development process of an evaluation framework for an eHealth intervention. Hence it was a prerequisite to include a case to have a real context for the research and to apply the result of the research for empirical evidence. A brief description of the project that was considered as the case of the research work is given below. The information used in this section was taken from the different documents of the project.

*Digital Environment for Cognitive Impairment (DECI)*

The objective of the DECI project is to define an innovative business model to provide assistive service to the elderly people with MCI or MD at their own home. It is expected that the services enabled with ICT, will positively affect the quality of life and independent living of the patients along with the improvement of the medical condition. Besides patients well being, DECI aims to analyze whether utilization of the technology at the home environment of this patient group reduce the burden of the caregiver’s life or not.  This European Union (EU) project consists of four clinical partners from four countries, i.e. Italy, Sweden, Spain, and Israel. The participants of DECI are not only multinational but also multifunctional. Table 1 represents the list of the organization involved in DECI.

**Table 1.** The participant organization of the DECI project

| Name of the organization | Participation Domain | Country |
|---|---|---|
| Fondazione Politecnico di Milano (FPM) | Coordinator and Research Partner | Italy |

| | | |
|---|---|---|
| Fondazione Don Carlo Gnocchi ONLUS (FDG) | Clinical Partner | Italy |
| Consoft Sistemi Spa (CS) | Technical Partner | Italy |
| Centre for Healthcare Improvement - Chalmers University of Technology (CHI) | Research Partner | Sweden |
| Skaraborg Hospital Group (SHG) | Clinical Partner | Sweden |
| Hospital Universitario de Getafe - Servicio de Geriatría (HUG) | Clinical Partner | Spain |
| Maccabi Healthcare Services (Maccabi) | Clinical and Technical Partner | Israel |
| Roessingh Research and Development (RRD) | Technical Partner | The Netherlands |

There are three technological services in total designed by three technical partners that will be introduced in the four pilot countries. These technologies are named as: (1) integrated care platform, (2) user activity and monitoring system, and (3) user coaching and training system. The *integrated care platform* will enable the communication among the different care providers, patients and informal caregivers through information sharing. This platform also includes the cognitive exercise module, which is expected to help the patients to improve their cognitive functioning. The *user activity and monitoring system* will record the patient's daily movement inside and outside of the house within a particular range. This technology will not interact with patients but monitor them and provide signals to the informal caregivers including falls alert. The third technology, *user coaching and training system*, provides a set of exercising videos that will help patients to be physically active. However, these technologies will be combined into a single platform and the combination of all the technology-enabled services will be mentioned as DECI solution in this study. A dedicated care team led by the case manager will be responsible for conducting the whole care service including the technologies in each pilot site.

The four hospitals from four countries participating in DECI have significant difference in their healthcare system as well as in their cultural norms. Nevertheless, there are some commonalities within the healthcare systems of these four countries and also of the most countries in EU. In these countries, the healthcare system is funded from the general taxation as the Government acts as the main responsible for providing the citizens with healthcare. There is no doubt that the healthcare system of these countries are well conditioned compared to the most of the countries in the world but when it comes to meeting the special needs of the elderly patients with MCI or MD, there are spaces for improvement. The healthcare system is clearly separated from the social care support in terms of delivering, legislation, and funding. Furthermore, the primary care and the specialized care are not always well coordinated. But the MCI and MD patients need to access the primary care; the specialized care and the community care very frequently. Due to the divergence between healthcare provider and community service and the lack of collaboration between the primary care and specialized care need for the dementia, patients suffer to a great extent. Hence, DECI aims to offer a solution with the help of the advancement of the technology that not only improve the care given to the patients but also improve the communication among the different actors within the system.

### 3.3. Research Process

It is important at this stage, to elaborate our research position in the case and in the whole research process. Being aware of the research position is imperative as it is connected with research validity and ethics (Herr and Anderson, 2005). However, identifying the research position can be a confounding task since the role of the researchers can vary to an extent along with the period of research. This research was conducted for the master's thesis under Quality and Operation Management Program in the department of Technology Management and Economics. Center for Healthcare Improvement (CHI) is a research and education center based at the same department. As mentioned in the description of the case study, CHI is one of the participants of the DECI project and we collaborated with CHI in order to study the DECI project.

Due to the nature of the collaboration that took place in the study, it is worth discussing whether it is an action research (AR). AR is the combination of three elements: namely action, research, and participation; the presence of all the elements in a research process is essential to call it an AR (Greenwood and Levin, 2007). Although, we participated in the discussions, created and shared knowledge with DECI, we were not involved in taking operating actions. Hence the research process could not be defined as the pure form of action research. On the other hand, the research process can be seen as a continuum where applied research is at one end and action research is at the other (Herr and Anderson, 2005). According to the book titled *The Action Research Dissertation*, the continuum includes several gradations depending on the relation between the researcher and the case under study. The researcher is the insider in action research and an outsider for the applied research. Within the continuum, there is a position named outsiders (researchers) in collaboration with insiders (people inside the case) that suites our study accurately since we were not part of DECI explicitly but we participated and cooperated with the research by being a part of CHI. Hence the thesis was conducted as the participatory action research (PAR), where we had the access into the inside i.e. the project DECI to a great extent but the space for taking action was limited. The purpose was to explore the project from an outsider's perspective while having the inside knowledge to the best possible level. The research was carried out in an iterative cycle of different stages starting from a general research query. Initially the research question was how to evaluate an eHealth intervention. A thorough literature review in relevant fields has helped to redefine the research questions of the study. Literature review and understanding the DECI project were the next stage of the research which were followed by data collection in terms of scanning the project documents, review of similar projects, meetings, and interviews. As the research was inductive in nature and aimed to conceive relevant insights for the evaluation of an eHealth intervention, we moved back and forth between literature review and the project. The idea of the study was not to prescribe some instructions regarding the evaluation framework for an eHealth intervention but to explore a relevant context and relate it to academic findings. Nonetheless, at the end of the study the concluding remarks by the researchers are presented. Following Figure 1 shows the schematic diagram of the research process:

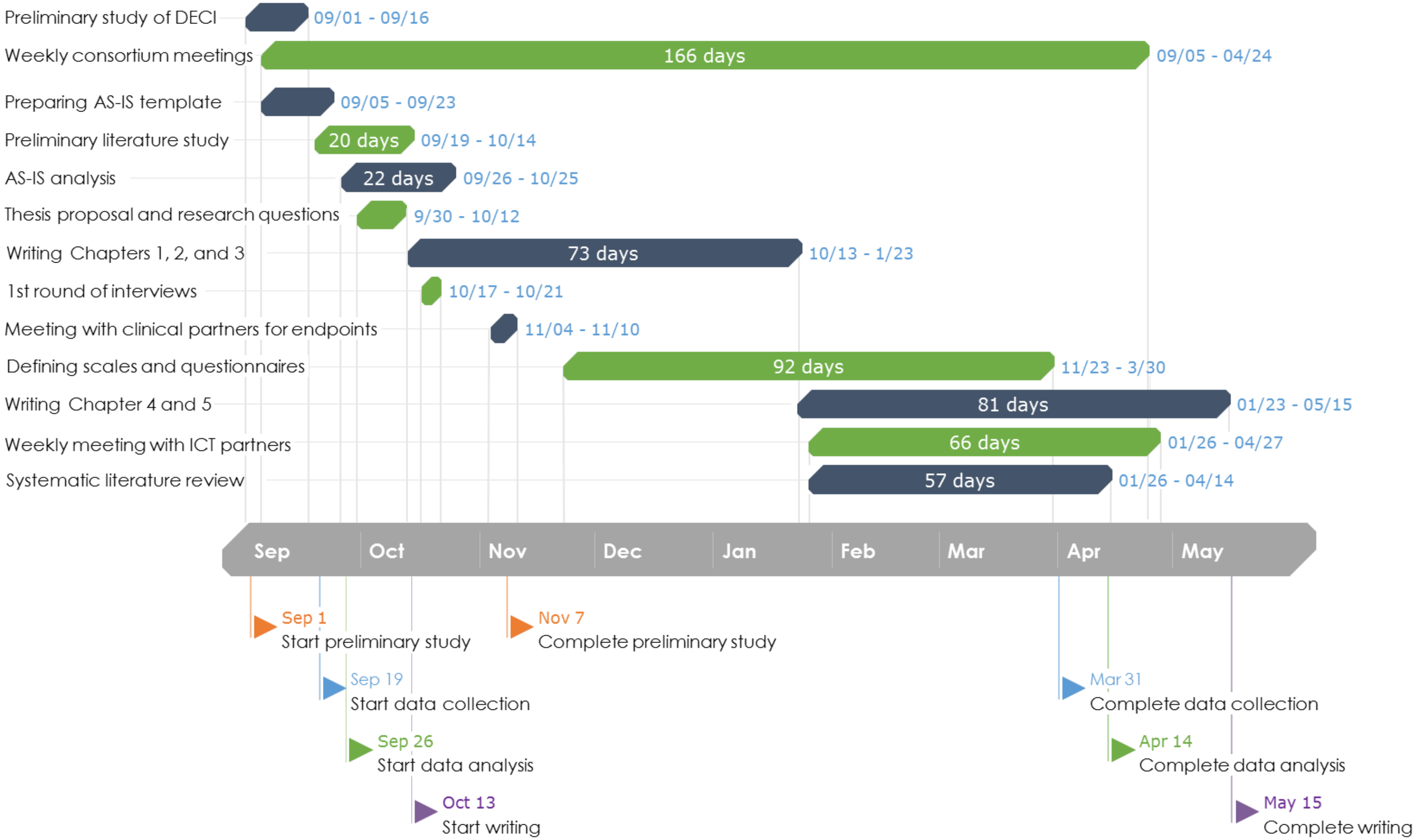

**Figure 1.** Research process.

### 3.4. Quality criteria of the research

The quality of the research can be categorized as internal validity (i.e. the true value of the inquiry or the evaluation), external validity (i.e. the applicability and transferability of the research), reliability (i.e. consistency and replicability of the work), and objectivity (i.e. neutrality of the work) (Schwandt, Lincoln and Guba, 2007; Bryman et al., 2015). Triangulation method was considered to strengthen the internal validity. Different sources of data collection e.g. documents, interviews, observation in meetings were used to verify the facts. Respondents’ validation was also achieved to some extent as the propositions of the study were communicated with some of the participants such as the clinical partners and several alterations were regarded complying their feedback. With the help of the communication and having feedback, the objectivity of the research was also maintained.

The literature review and the evidence found in similar types of interventions were utilized rigorously in order to ensure the reliability of the study. All the theories and ideas used in the research were scrutinized by academic viewpoint. External validity or transferability is highly important for research in evaluation for healthcare interventions as policy making and learning are two important purposes of evaluation that heavily rely on the transferability of the research method (Long, 2006). External validity enquires for the ability of the findings of a research to be applied beyond the context where the research has taken place (Bryman et al., 2015). The strength of the current study is that it has a rich context as the case selected for the study consists of four different healthcare systems. The design of the evaluation was done in a way that fits the four countries as well as conscious efforts were made to accumulate the learnings from the study, thus they can be reused in future research and in practice within slightly different contexts.

### 3.5. Ethical consideration

Ethical issues were treated with utmost importance throughout the research. As stated in the book titled *Business Research Method,* ethical issues can be broadly divided into four categories, i.e. harm to participation, lack of informed consent, invasion of privacy, and deception (Bryman et al., 2015). As advised by Miles and Huberman (1994), awareness, anticipations, documentation, and reflections have been part of our research work since the beginning of the study. In every area of data collection such as interviewing, observing, using documents of the DECI Project, proper permission was taken. While using the data for analysis and writing the report, the information was used carefully so that privacy and safety of the participants remain intact. Moreover, all the clinical scales and questionnaires selected and prepared for using in DECI pilots were scrutinized by the respective ethical committee of the four pilot countries of DECI project.

### 3.6. Literature Review: narrative and systematic

Literature review is a fundamental step for any research work. Literature review is the systematic analysis of the existing knowledge in the fields that are related to the research topic. The aim of the literature study is to understand the topic in terms of underlying theories and concepts, prevailing research methods, presence of disputations and evidence, and the key contributors to research and collect the existing information about it (Bryman et al., 2015). Thorough literature review is crucial for the study since the actors in healthcare are engulfed with the enormous amount of information, including evidence for healthcare research (Green et al., 2008). In this study, we used both narrative review, i.e. perform a comprehensive assessment and critical reading of the available literature to obtain an overview of the field of study (Bryman et al., 2015), and systematic review, i.e. exhaustive literature analysis that seeks to generate unbiased and comprehensive description of the literature (Bryman et al., 2015). The narrative review was used for the preliminary understanding of the relevant fields encompassed by the study and the systematic review was used to answer the research questions. This section discusses the narrative review whereas the systematic review is discussed in Section 3.7.

This study encompassed several number of fields of research, e.g. Healthcare intervention, mental health issues such as MCI and MD, interface between ICT and healthcare. Hence, it was important to conduct a comprehensive literature study in selected topics with pre-defined group of words. Initially, the research questions were analyzed to identify the topics for which the review of the literature was carried out. The literature review includes academic articles, books, guidelines in related fields, and project reports. Table 2 presents the topics and related group of words used for narrative literature review:

**Table 2.** Identified areas and keywords used for finding relevant literature

| **Identified area** | **Used keywords** |
|---|---|
| eHealth and ICT in healthcare | eHealth, e-Health, eHealth + ICT in healthcare, eHealth vs ICT in healthcare |
| eHealth intervention | eHealth intervention + healthcare, healthcare intervention, eHealth intervention, intervention + dementia, eHealth intervention + dementia |
| Evaluation framework for eHealth intervention | framework + intervention, program theory in healthcare, realistic evaluation, challenges + eHealth intervention |
| Acceptance of ICT | technology acceptance model, acceptance of technology in elderly people, usability satisfaction |
| Mental healthcare | mental health, mental healthcare, mental illness, mild dementia, mild cognitive impairment |

### 3.7. Methodology for addressing Research Question 1 (RQ1)

Our first research question intends to analyze the field of evaluation in eHealth interventions. To address this question, a systematic literature review was conducted, since a comprehensive, refined literature review is the base and motivation for notable and effective research (Boote and Beile, 2005). The aim of the systematic review was to find out the existing knowledge regarding the evaluation of eHealth interventions. The methodology used for the systematic review of the published articles in the relevant fields is explained in this section.

Initially, several number of groups of words were identified to use them as search strings, i.e. “research methods” + “healthcare interventions”, “research methods” + “eHealth interventions”, “research methods” + “eHealth interventions”, “study design”+ eHealth interventions”, “research strategy” + “eHealth interventions”, “evaluation methods” + “eHealth interventions”. Google Scholar and Scopus are two largest open-source databases for scientific journals and other literature, hence were used for searching articles using the mentioned strings. Depending on the number of results found in those databases, three of the strings selected for the final search were *“research methods” + “eHealth interventions”, “study design” + eHealth interventions”, “evaluation methods” + “eHealth interventions”*. The other strings were not considered due to the extreme number of search result, for example, “research methods” + healthcare interventions” resulted in 2250 articles in Google Scholar; it was not possible to handle this enormous number of articles.

With the selected strings, a total number of 1,313 and 227 results were found from Google Scholar and Scopus respectively. The timeline considered for the search was 1990 to 2016. As the term eHealth evolved during the 1990s (Oh et al., 2005), it was deemed appropriate to take into account the articles that have been published since then. The articles were screened in three steps. The first two steps were based on the titles of the manuscripts and the last step was based on abstract and the methodology of the articles. For the first layer of screening, the exclusion criteria were book, patent, citation, literature review, meta-analysis, publications solely on behavior change theory, ergonomics, drugs, sedentary issues, or physical activity intervention. The exclusion criteria were chosen to narrow down the variety of the articles keeping the scope of this thesis in mind, that is eHealth intervention for elderly people with MCI or MD. However, the literature reviews and meta-analyses were excluded from this systematic literature review in order to avoid overlapping of articles, i.e. using the same articles from different literature reviews or meta-analyses. At the end of the first elimination process, 640 and 140 articles were selected from Google Scholar and Scopus respectively. At this stage, all the articles were listed together in order to remove duplicates, i.e. the articles that were resulted from both databases. After removing the duplicates, the total number of articles was 697. Another round of screening was conducted by reading the titles of the articles and this time the selection only included articles which contain either conceptual discussion on eHealth intervention, and/or discussion of eHealth interventions in healthcare focused on adult patients and caregiver, and/or eHealth intervention focused on mental disease, which is the scope of the thesis. At the end of the elimination process, a total number of 261 articles were found and the abstracts of all the articles were read. We read each abstract individually and decided if the article follows the exclusion and inclusion criteria. In some cases, the abstracts were not enough informative to make the right judgment. In those cases, the methodology section of the articles was considered. We later presented our opinion regarding 261 articles and the articles that were selected by at least one of us were included for the literature review. At the end of the process, 90 articles were selected for final reading.

While reading the 90 articles, we realized that although all the articles are within the field of eHealth intervention, the objectives and outcomes of these articles vary in several fields categorized as: (1) Barriers and risks of evaluation of eHealth intervention (7 articles), (2) Guidelines and frameworks for evaluation of eHealth intervention (40 articles), (3) Cases of eHealth interventions (32 articles), (4) RCT designs (7 articles), (4) Cost evaluation of eHealth intervention (3 articles), and (5) Case management in eHealth intervention (1 article). Since our research question enquires the various ways of evaluation in eHealth interventions, the articles categorized under the first three fields were finally summarized and used for further study. Figure 2 presents the article selection process in brief.

In order to extract useful information from the articles found through systematic search, a predefined structure, referred as code book is essential and can be in a form of spreadsheet where the extracted data will be stored (Randolph, 2009). We designed the criteria of the summarization (presented in Table 3) of the articles with the help of the protocol for Cochrane review (Green and Higgins, 2008). Categories such as learning points, background of authors were added by us. Initially, the background of authors seemed to be an interesting aspect, as we wanted to investigate if the clinician-authors have different perspective for evaluation compared to the authors who mostly conduct research on eHealth intervention. Eventually, it has been found out that the majority of the articles have authors from both backgrounds. Similarly, the criteria related to the types of participants in the intervention did not vary that much as almost all of them had patients as type of participants. Hence, these two criteria were eliminated from the final summary spreadsheet.

In later stage, few other articles have been added to the literature review. These articles are cited by the authors of the articles that were primarily selected for literature review and very relevant to the research question under discussion. In total 8 articles are added to the literature review in this manner. The summary of all 87 articles (79 articles through systematic search and 8 articles added later) is presented by category in Appendix B, C and D.

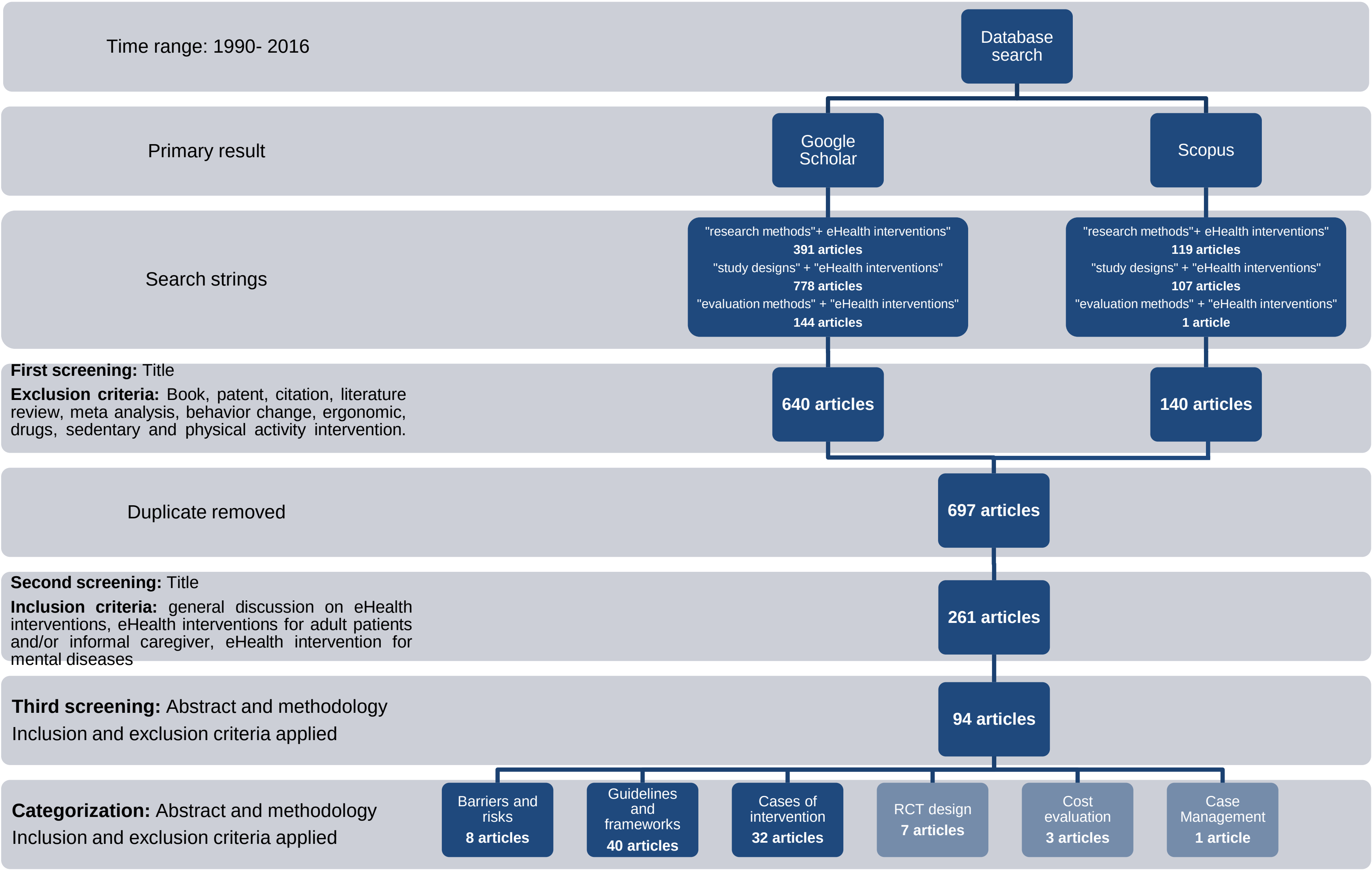

**Figure 2.** Process of article screening for the systematic literature review.

**Table 3.** Criteria for summarizing the articles found in the systematic literature review.

| **Summarizing criteria** | |
|---|---|
| **1. Objective** | In this section, the basic idea of the article is discussed focusing on the aim of the research. The main issues discussed in the article are noted here in a concise manner. |
| **2. Method** | With an aim to summarize the research methodology of the article, method section is categorized in following sections. |
| **2.1. Types of studies** | In this section, we noted whether the article is entirely conceptual, i.e. has not been connected to any empirical study of intervention, or based on any eHealth intervention. |
| **2.2. Background of the authors** | Whether the authors of the article are healthcare practitioners, researchers, or a combination of both. |
| **2.3. Types of participants** | This section records the types of participants taken part in intervention, i.e. patient, informal caregiver, formal caregiver, healthcare administrator; or the types of the people involved for the research purpose in conceptual articles; i.e. experts in related field. |
| **2.4. Types of outcome measures** | The ultimate outcome of the article was recorded in this section in terms of framework, model, guidelines, and evidence of efficiency, discussion, learning points. |
| **2.5. Data collection method and data analysis** | One of the objectives of this section was to record the data collection methods either prescribed by the authors in conceptual articles or used in the interventions, or used for writing the article. Another objective was to record the analysis method that has used to analysis the quantitative and qualitative data.<br>We classified the data collection method in three segments:<br>• Clinical (Cl), i.e. data collection through medical tests;<br>• Quantitative (Qn), i.e. data collected by using questionnaires that result in numerical scores;<br>• Qualitative (Ql), i.e. data collected through interviews and observations. |
| **3. Learning points** | This section was used to record the unique aspect of the article. We noted the points that seemed to be new and interesting in the article while reading it. |

## 3.8. Methodology for addressing Research Question 2 (RQ2)

The case of DECI has been used to design a development process of evaluation framework for eHealth interventions, which is the aim of RQ2. In order to address RQ2, we meticulously followed and participated in the development process of the evaluation framework for DECI. To gather relevant information, several qualitative data collection methods were used. This section offers a brief description of those methods including how the data collection was performed, and how the analysis of the data was conducted.

### *3.8.1. Observation*

Participant observation is one of the best-known qualitative data collection methods; it is usually applied in business and management research. Observation involves a prolonged immersion of the researcher in order to observe the behavior of members in a defined setting (e.g. group, organization, community) and participant observers decide to what extent they participate in the social setting (Bryman et al., 2015). In this study, observation was used to record and analyze the interaction between different members of the project, since DECI involves four countries and people from clinical and non-clinical backgrounds, a particular focus was directed to the communication process within the project. Also, based in the challenges that may appear associated to the multicultural nature of the project, culture was considered as a variable that might influence organizational behavior. For the means of this particular study, we participated in various settings (i.e. face-to-face and online) along with CHI. Additionally, the quarterly DECI-Consortium meetings, in which the progress of the Project was presented and points of common interest are analyzed and discussed, were monitored using Skype video calls.

#### *3.8.1.1. Data collection and analysis*

The methodology to analyze the data was designed to cope with the large amount of information generated during our participation in the project. As suggested by Bryman et al., (2015) full field notes were made as promptly and detailed as possible. The notes were taken individually and summarized in a file stored online with three fields: date, participants, and activity. The objective of the template was to summarize the key points of each observation and to maintain a record of the project activities. Using real-time online document collaboration allowed us to easily store, organize, and update the data, and avoid the duplication of information.

### *3.8.2. Meetings*

During this study, meetings were used as a source for collecting qualitative data. Due to the multi-country nature of the project, the meetings with partners outside Sweden were handled in Skype. We had access to different types of meetings in order to collect relevant information. The discussion points were sent to all the participants beforehand, Table 4 provides a brief description of each online meeting:

**Table 4.** Description of meetings conducted during the study.

| | | |
|---|---|---|
| **Type of meeting** | DECI-Consortium calls | |
| **Objective of the meeting** | The aim of the meeting was to discuss general topics defined beforehand, and to provide an update of the progress of the project by each partner. | |
| **Meeting frequency** | Usually two meetings per month. | |
| **Participants** | Project manager, clinical partners, technical partners, evaluators (CHI) | |
| **Number of meetings attended** | 11 meetings | |
| **Dates** | **2016** | **2017** |
| | September 22nd | January 30th |
| | October 5th | February 13th |
| | October 21st | February 27th |
| | November 14th | March 20th |
| | November 30th | April 3rd |
| | | April 20th |
| **Type of meeting** | Clinical calls | |
| **Objective of the meeting** | The meeting aimed to clarify and discuss clinical matters regarding the evaluation framework of the four-pilot intervention. The schedule and agenda were fixed by CHI. | |
| **Meeting frequency** | Irregular, depending on the situation in project | |

| | | |
|---|---|---|
| **Participants** | Clinical partners and CHI | |
| **Number of meetings attended** | 10 meetings | |
| **Dates** | **2016** | **2017** |
| | October 13th | January 25th |
| | November 4th (Sweden) | March 14th |
| | November 9th (Italy) | March 21st |
| | November 10th (Spain) | March 28th |
| | | April 4th |
| | | April 18th |

| | | |
|---|---|---|
| **Type of meeting** | Technical calls | |
| **Objective of the meeting** | The meeting aimed to discuss technical matters regarding the data management (i.e. storage, accessibility, processing, and reporting) of the information related to the evaluation of the pilots. | |
| **Meeting frequency** | Irregular, depending on the situation in project | |
| **Participants** | Technical partners participated regularly, and CHI participated depending on the topic of discussion. | |
| **Number of meetings attended** | 5 meetings | |
| **Dates** | **2016** | **2017** |
| | | January 18th |
| | | January 26th |
| | | February 9th |
| | | March 2nd |
| | | March 16th |

| | | |
|---|---|---|
| **Type of meeting** | Meetings with Swedish clinical partner | |
| **Objective of the meeting** | The meetings were conducted to gain deeper understanding of the clinical perspective regarding the project. | |
| **Meeting frequency** | Irregular, depending on the situation in project | |
| **Participants** | Skaraborg Hospital Group (SHG) and CHI. | |
| **Number of meetings attended** | 4 meetings | |
| **Dates** | **2016** | **2017** |
| | September 6th | |
| | October 4th | |
| | November 4th | |
| | November 24th | |

#### *3.8.2.1. Data collection and analysis*

During the meetings full field notes were taken individually, to record the information a standardized format was agreed beforehand. The form includes the fields: type of meeting, participants, and date of the meeting. After each meeting we presented our individual notes regarding the issues discussed by the participants. Afterward, based on the comparative analysis of the field notes, the key points of the meeting were included in the shared online file. Finally, when available, the *Meeting Report and Minutes* were used as support information.

### *3.8.3. Interviews*

The method was conducted as structured interview. As stated by Bryman et al., (2015) this technique aims to administer a standardized set of questions by the interviewer to ensure that the interviewees' responses can be aggregated. To assure the reliability of the technique, the questions must be asked in the same order to all the participants. In this study, the schedule for the interview was selected by each interviewee (i.e. project manager, clinical partner, technical partner, evaluation researcher) from a timetable proposed by CHI. The main purpose of the interviews was to gather general perception regarding the project, and the individual's expectations from DECI. Open questions were defined and sent to the interviewees via e-mail before the Skype call.

#### *3.8.3.1. Data collection and analysis*

The interview was led by a member of CHI and we took field notes. The interviews took place through Skype between October 18th and 21st, and the duration varied from 40 minutes to 1 hour. The data analysis followed a similar pattern as the one used for meetings. First, full field notes were taken individually in a standardized format. Second, a discussion was held to present our individual perception and highlight the relevant issues. In this particular way of data collection method, we seek for recurrent topics regarding the discussed points. Third, the key points were summarized and recorded in the shared online file.

### *3.8.4. Documents*

Organizational documents are considered a very heterogeneous source of data; the vast type and quantity of available documents may provide valuable information to business and management research (Bryman et al., 2015). As established by Bryman et al. (2015), documents are non-reactive because they were created with a purpose other than research, and that could compromise the validity of the data. However, all the documents used during this study were evaluated according to the four criteria suggested by Scott (1990): authenticity, credibility, representativeness, and meaning to assure the validity of the information. Documents generated during the different phases of the DECI project were used as qualitative organizational data source. The main purpose was to extract background information about the project, clinical partners, and other organizations involved (see section 3.2).

#### *3.8.4.1. Data collection and analysis*

Deliverables that contain information related to the evaluation of the DECI project were scrutinized; a list of the documents analyzed during the study is presented in Table 5.

**Table 5.** List of documents from DECI Project analyzed

| Work Package | Document |
|---|---|
| - | Project Proposal Part B Section 1-3. |
| - | Project Proposal Part B Section 4-5. |
| WP1 | D1.1 Analysis of the state-of-art and best practices for the clinical management of elderly patients with cognitive impairment. |
| | D1.4 Identification of key indicator for performance evaluation on the side of clinical management. |
| WP2 | D2.2 Business model of the digital solutions used for assisting elderly people with cognitive impairments. |
| | D2.3 Change management and introduction processes of the digital solutions used for assisting elderly people with cognitive impairments. |
| WP3 | D3.3 Definition of requirements and design of ICT infrastructure and application. |
| | D3.4 Design of different implementation settings. |
| - | Scientific Advisory Board (SAB) Meeting Report. |

Before analyzing the data, we crosschecked the information among different documents. The methodology to analyze the data was designed taking into account that the information on DECI documents was usually country-specific. A comparative analysis of information among countries was conducted; we developed matrixes that allowed both, cross-country comparison and an overall overview of the specific topic.

### *3.8.5. Feedback and e-mails correspondence*

E-mail correspondence was used as a channel of communication among partners. Besides having discussions through e-mail, we used this media to conduct surveys. An email survey is a form of online social surveys and contains elements of two methods: structured interviews, in which all the interviewees receive a set of specific open questions (i.e. the respondent can write as much as he/she wants) and closed questions (i.e. fixed range of answers); and self-competition questionnaires, in which the respondents answer questions by completing the questionnaires themselves. (Bryman et al., 2015) In order to collect specific data, questionnaires were sent to the clinical and technological partners of DECI. Two methods were used, embedded questionnaires (i.e. the questions are in the body of the e-mail) and attached e-mail surveys (i.e. the questionnaire arrives as an attachment to an e-mail); in both cases the purpose, directions and deadline to answer were stated in the e-mail. Moreover, respondents were asked to return the answers by replying e-mail.

#### *3.8.5.1. Data collection and analysis*

For questionnaires, the data was collected in different files, one for each country. The methodology for analyzing the data was the same as the one used for documents. By developing aggregated matrixes, a comparative analysis among countries was conducted. Additionally, since the aim of the questionnaires was to reach agreement among partners, color-coding was used to highlight the frequency of similar answers by different partners.

# 4. Empirical findings and analysis

In this chapter the findings of RQ1 and RQ2 are presented and analyzed in section 4.1 and 4.2 respectively.

## 4.1. Evaluations in eHealth interventions

A thorough analysis of all the articles revealed that the evaluation of eHealth interventions is discussed differently in the conceptual articles, (i.e. the articles that discuss guidelines and frameworks and barriers and risks) and in the articles that report specific eHealth interventions. In the first type of articles, the discussion revolves around what should be done in evaluation, how to do it, and why to do it; whereas in the later type, the discussion hugely focuses on the result of evaluation. In this study, we first analyzed the conceptual articles and later we compared these articles with the second type of articles that report specific interventions. While analyzing the conceptual articles, it was discovered that a few number of articles predominantly discuss the development of the technology used in eHealth interventions (Van Velsen, Wentzel, Van Gemert-Pijnen, 2013; Chung et al., 2015; Horvath et al., 2015; Kassam-Adams et al., 2015; Steele Gray et al., 2016). There are articles that discuss on the various types of study design of the eHealth intervention (Baker t al, 2010; March et al., 2010; Dallery, Cassidy, and Raiff, 2013; Law and Wason, 2014). Some of the articles discuss individual issue of eHealth interventions such as implementation science of intervention (Glasgow, Phillips, and Sanchez, 2014), reducing the time-period of intervention (Baker, Gustafson, and Shah, 2014). Although all these aspects are relevant to the eHealth intervention but not quite congruent with the research question asked here. Hence for further analysis, we combined the articles that explicitly discuss evaluation of eHealth intervention and provide a structure or a pattern in which evaluation is supposed to be carried out in eHealth interventions. Most of these articles referred their outcomes as frameworks; hence in the following part the word framework is designated to present these outcomes. In total 18 articles were found that have contributed in frameworks for evaluation in eHealth intervention.

At the beginning these frameworks were mapped to examine the similarities among them. It was observed that there are two distinctive patterns: (1) frameworks that examine the phases for designing an eHealth intervention, and (2) frameworks that examine the areas to evaluate an eHealth intervention. It is to note that the first branch of the frameworks includes evaluation as one of the phases whereas the second branch provides detailed framework on the evaluation of the intervention. The following sections (4.1.1. and 4.1.2.) elaborate on the both branches of the framework, followed by a comparative discussion among these frameworks and the evaluation approaches taken in the articles that report on specific eHealth interventions.

### *4.1.1. Frameworks for designing an eHealth intervention*

The result of the systematic literature review has shown a number of frameworks to design eHealth interventions (see Table 6). As an outcome of the analysis, it was determined that different frameworks include different phases depending on the type of eHealth intervention they have been developed for, and the starting point of the eHealth intervention. Based on the literature, we created the full spectrum of the phases for designing an eHealth intervention. A categorization of six phases is possible: (1) Design, (2) Pre-testing, (3) Pilot study, (4) Pragmatic trial, (5) Evaluation, and (6) Post-intervention (see Figure 3). One end of the spectrum is occupied by the *Design* phase (Lilford, Foster and Pringle, 2009; Proudfoot, 2011; Whittaker et al., 2012, Van Gemert-Pijnen et al., 2012; Van Velsen, Wentzel and Van Gemert-Pijnen, 2013; Lyon et al., 2016). It is of utmost importance to mention that the frameworks that do not initiate in this phase have already selected a technology, which seems to have been pre-tested and fulfill the requirements of the intervention. At the other end of the spectrum, the *Post-intervention* phase is found (Nguyen, 2007). However, only one framework has recognized the importance of the follow-up process of the technology. The following sections provide a general description of each phase as a discussion of how each of the founded frameworks addresses them.

### *Design phase*

The first phase entails the design and development of the technology. The starting point is gathering theoretical foundations and evidence to have an overall understanding of problems of the current provision of care, and identify the possible solutions (Proudfoot et al., 2011; Whittaker et al., 2012; Van Gemert-Pijnen et al., 2012; Lyon et al., 2016). To achieve the general aim of the stage, it is important to assemble a multidisciplinary team including experts in the field of health-related technologies design and business model, medical experts, technical experts (Van Velsen et al., 2013; Lyon et al., 2016), and marketing experts (Whittaker et al., 2012). Furthermore, the definition of the overall goals of the to-be-developed technology and the legal and technological constraints related to the development (Van Velsen et al., 2013; Proudfoot et al., 2011).

Another area of focus is the identification of end-users and stakeholders, and the analysis of their context (Whittaker et al., 2012; Van Gemert-Pijnen et al., 2012; Van Velsen et al., 2013; Proudfoot et al., 2011; Lyon et al., 2016). Van Velsen et al. (2013) define end-users as the people who will directly use the technology and stakeholders as the persons or organizations indirectly affected by the intervention (e.g. purchasers, marketing staff, user support department). A person or organization can be both end-user and stakeholder, thus understanding what characteristics and needs the technology must fulfill is crucial (Lilford et al., 2009; Van Gemert-Pijnen et al., 2012). Regarding the context analysis, the aim is to determine how the health-related program could be integrated within the context of the target population (Whittaker et al., 2012). By profiling the end-user and map the context of use of the technology, it is possible to have preliminary information on the technology functions and how it should be implemented (Van Velsen et al., 2013).

**Table 6.** Frameworks for designing an eHealth intervention – List of articles found in the systematic literature review that contain frameworks for designing and eHealth intervention.

| No. | Reference | Design | Pre-testing | Pilot Study | Pragmatic Trial | Evaluation | Post-intervention |
|---|---|---|---|---|---|---|---|
| 1 | Dansky et al., 2006 | | | - Design and methodology<br>- Technology issues<br>- Environmental constraints<br>- Logistics challenges | | | |
| 2 | Nguyen et al., 2007 | - Pretesting of design to determine feasibility, usability and early evidence of efficacy | - RCT trial to determine efficacy | - Pragmatic trial | | | - Post marketing and surveillance study |
| 3 | Lilford et al., 2009 | - Specification of need<br>- Systems engineering and software development | - Pre-implementation testing | - Early implementation | - Later implementation | - Formative assessment<br>- Summative assessment<br>- Internal assessment<br>- External assessment | |
| 4 | Nykanen et al., 2011 | | | - Preliminary outline<br>- Study design<br>- Operationalization of methods<br>- Project Planning<br>- Execution of evaluation study<br>- Completion of evaluation study | | | |
| 5 | Proudfoot et al., 2011 | - Focus and target population<br>- Authorship details<br>- Model of change | | - Type and dose of intervention<br>- Ethical issues<br>- Professional and other support<br>- Program interactivity<br>- Multimedia channel of delivery<br>- Degree of synchronicity | | - Audience reach<br>- Program evaluation | |
| 6 | Van Gemert-Pijnen et al., 2012 | - Contextual Inquiry<br>- Value specification<br>- Design | | | - Operationalization | - Evaluation cycle | |
| 7 | Whittaker et al., 2012 | - Conceptualization<br>- Formative Research | - Pre-testing | - Pilot study | - Pragmatic trial | - Qualitative research<br>- Evaluation of implementation impact | |
| 8 | Van Velsen et al., 2013 | - Preparation<br>- End user and stakeholder identification<br>- Requirements elicitation<br>- Requirement analysis<br>- Communicating requirements | | | | | |
| 9 | Lyon et al., 2016 | - Compilation and coding academic and commercial materials to identify capabilities and characteristics<br>- Conducting system developer or | - Experimental testing of HIT capabilities and mechanisms. | | | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | purveyor interviews to gather more detailed information about development and implementation processes<br>- A process of putative implementation mechanisms are linked to HIT capabilities | | | | | |

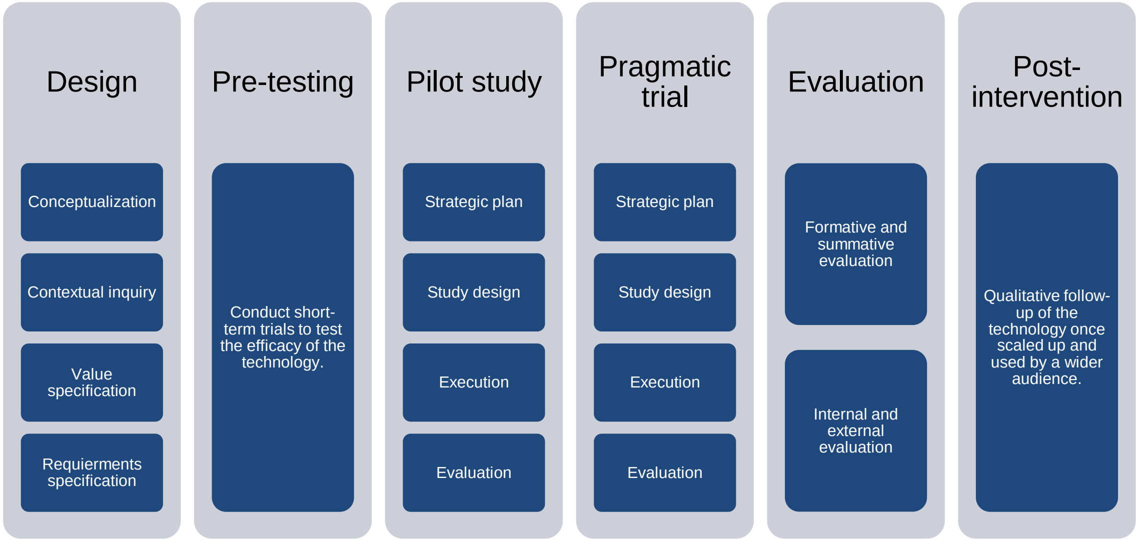

**Figure 3.** Identified phases to design ICT interventions in healthcare.

The next stage included in this phase is the value specification. This stage seeks to prioritize the critical values (e.g. socio-economic, cultural, clinical) using the stakeholders' needs and problems as an input (Van Gemert-Pijnen et al., 2012). The outcomes of this stage is used to the later translation of the values into functional and technical requirements that frame the final design and the technology development (Lilford et al., 2009; Van Gemert-Pijnen et al., 2012; Van Velsen et al., 2013; Lyon et al., 2016).

### *Pre-testing phase*

Conducting a series of micro-trials (i.e. short-term tests of the effects of the technology) provide preliminary evidence of efficacy for the implementation trials of the technology (Nguyen et al., 2007; Lyon et al., 2016). Lilford et al. (2009) describe this phase as "the use of analytic procedures to predict the failure rate of a system still in the design phase" (p. 1). Depending on the type of intervention, other factors such as optimal intensity, timing, safety, feasibility, usability, intervention content, and logistic issues are discovered in this phase (Nguyen et al., 2007; Whittaker et al., 2012). The phase aims to evaluate the connection between the technology capabilities and the requirements identified in the design phase (Lyon et al., 2016). The outcomes of the phase attempt to adjust the technology to the context of the study design (Whittaker et al., 2012), and to create more pragmatic technologies (Lyon et al., 2016).

### *Pilot Study phase*

The objective of conducting pilot studies with optimal testing conditions is to obtain feedback from the end-users and stakeholders on the intervention to further and final adjustments before the main trial (Nguyen et al., 2007; Whittaker et al., 2012). The first stage is to develop the strategic planning of the study; the preliminary outline presents the general purpose of the pilot, identification of payers, draft budget, preliminary timeline of the study, the overall description of the organizational context where the study will be conducted (Nykanen et al., 2011), identification of the multidisciplinary team members and their roles and responsibilities (Dansky, Thompson and Sanner, 2006), and the ethical and legal issues (Dansky et al., 2006; Nykanen et al., 2011; Proudfoot et al., 2011).

The core stage of this phase is the development of the study design. To begin with, the authors suggest determining the study type, duration, and participants (Nguyen et al., 2007; Nykanen et al., 2011; Proudfoot et al., 2011). The second area of focus is the selection of appropriate methods to address the objectives of the pilot (Nykanen et al., 2011). In regard to the data collection methods, Dansky et al., (2006) propose that an exploratory design that uses both qualitative and quantitative data might be suitable for eHealth interventions research. The combined approach enables to foster a holistic study to understand the social phenomena, which characterized this type of research. A third stage is the design of the recruitment process. During the recruitment of participants, the aim is to conform to statistical validity (Dansky et al., 2006) and to minimize the selection bias (Dansky et al., 2006; Nykanen et al., 2011) by selecting the adequate sample size and randomization of subjects (Nykanen et al., 2011).

Identifying outcome measures and evaluation criteria are highlighted by several authors (Dansky et al., 2006; Lilford et al., 2009; Nykanen et al., 2011; Proudfoot et al., 2011). In this stage, the focus is to identify specific methods for data collection (e.g. interviews, questionnaires, observations, surveys, log file analysis, document analysis), and success and failure levels for evaluation to fulfill the objectives of the study (Nykanen et al., 2011). In *A framework for evaluating eHealth research* Dansky et al., (2006) discuss the relevance of evaluating simultaneously the technology and its impact. To cope with the challenge, the evaluation must differentiate the issues related to the technology itself from those that are generated by the technology deployment. The fact is supported by Proudfoot et al. (2011), whose guideline outlines the importance of identifying technical support professionals and channels.

Once the settings are defined, the study can be executed. During the execution formative internal assessment (i.e. measures that provide timely feedback) is needed to identify events and conditions that may require the redefinition of the study design Finally, after the completion of the pilot study a summative assessment (i.e. provision of generalizable knowledge and benefits of the intervention) is suggested to inform decision makers and potential users the benefits of conducting similar studies and using similar systems. (Lilford et al., 2009; Nykanen et al., 2011)

### *Pragmatic Trial phase*

Once the evidence of effectiveness is shown with objective measurements of key outcomes; funders, decision makers, and providers can decide if the intervention is immediately available for scaling (i.e. use in broader audiences) (Van Gemert-Pijnen, et al., 2012; Whittaker et al., 2012), and to be subjected to practical or pragmatic trials (Nguyen et al., 2007). Although these studies are also randomized and controlled, the intervention is administered to a larger group of participants with fewer eligibility restrictions, thus the usefulness and generalizability issues can be properly addressed (Nguyen et al., 2007). Regarding evaluation, Lilford et al. (2009) in *Evaluating eHealth: how to make evaluation more methodologically robust*, propose the same evaluation scheme as the one suggested for pilot studies, formative and summative assessment of the implementation. Additionally, the author suggested including external assessment to measure outcomes where special expertise is required. Since external evaluation is conducted independently from the implementation team, the results are usually trustworthy to a broader audience.

### *Evaluation phase*

Specific issues regarding the evaluation process of pilot studies and pragmatic trials were already discussed independently in each section. However, some general viewpoints on evaluation are discussed in this section. As introduced by Whittaker et al. (2012), evaluation process in eHealth interventions is iterative in nature, since the findings from each step are used to inform subsequent steps. The authors outline the three main objectives of this phase: (1) improve the intervention, (2) identify intervention issues and methods, and (3) determine the effect of the intervention once scaled up. Likewise, Lilford et al. (2009) and Van Gemert-Pijnen et al. (2012) propose formative and summative evaluations cycles to test two main expected results: (1) whether the technology fits with the need and contexts, and (2) what are the clinical, behavioral and organizational effects of the implementation. Aligned to these objectives, Proudfoot et al. (2011) include a program evaluation stage in their guideline, in which the authors suggest to assess outcome measures (e.g. symptom and/or behavior change, user functioning, quality of life, health service usage), process measures (e.g. web usage, dropout), user acceptance, and cost-effectiveness. Finally, Lilford et al. (2009) discuss the necessity of internal and external evaluation. While internal evaluation must be intrinsic to ICT implementations and conducted by the implementation team, external evaluation can provide expertise where is needed and minimize the bias of in-house evaluators.

#### *Post-intervention phase*

Nguyen et al. (2007) in *Methodological considerations in evaluating eHealth interventions* include a final phase labeled post-marketing or surveillance studies. The authors explain that compared to other interventions in healthcare (e.g. new drug introductions), ICT tools are not regulated and do not need formal approval process before the diffusion into practice. Thus observational studies follow the same study design of comparing groups and random assignment as discussed in sections *Pilot study* and *Pragmatic trial*. The main objective is the follow-up of the technology once scaled up and used by a wider audience.

### *4.1.2. Frameworks for evaluating an eHealth intervention*

The frameworks analyzed in this section elaborate the evaluation phase of the eHealth intervention. While mapping these frameworks, it was found the frameworks basically elaborate on the different spheres that need to be evaluated in eHealth intervention. We have classified these spheres into seven aspects: (1) organizational aspect, (2) technological aspect, (3) human/social aspect, (4) clinical aspect, (5) cost and economic aspect, and (6) ethical and legal aspect. The frameworks have variety in their own categorizations and not every framework consists all of the areas mentioned above. The frameworks analyzed are shown in Table 7, and will be now discussed on the basis of the aspects below.

**Table 7.** Aspects of evaluation of an eHealth intervention – List of articles found in the systematic literature review that contain frameworks for designing and eHealth intervention.

| No. | Reference | Organizational aspect | Technological aspect | Human/ social aspect | Clinical aspect | Cost and economic aspect | Ethical and legal aspect | - Transferability aspect |
|---|---|---|---|---|---|---|---|---|
| 1 | Glasgow et al., 1999 | - Adoption (of the setting)<br>- Implementation<br>- Maintenance | | | - Efficacy | | | - Reach<br>- Representativeness<br>- Robustness<br>- Replicability |
| 2 | Ohinmaa et al., 2001 | - | - Technical assessment | - User assessment of the technology | - Effectiveness | - Cost of telemedicine | | - |
| 2 | Yusof et al., 2008 | **Organization:**<br>- Structure<br>- Environment | **Technology:**<br>- System Quality<br>- Information Quality<br>- Service Quality | **Human:**<br>- System use<br>- User satisfaction | | | | |
| 3 | Lampe et al., 2009 | - Organizational aspects | | - Patients perspectives<br>Socio-cultural aspects | - Health problem and characteristics of the application<br>- Safety<br>- Clinical effectiveness | - Economic | Ethical and legal aspects | |
| 4 | Lovejoy et al., 2009 | | - Relative advantage<br>- Compatibility<br>- Complexity<br>- Triability<br>- Observability | | | | | |
| 5 | Kidholm et al., 2012 | **Multidisciplinary Assessment:**<br>Organizational aspects | **Preceding consideration** | **Multidisciplinary Assessment:**<br>- Patients perspectives<br>- Socio-cultural aspects | **Multidisciplinary Assessment:**<br>- Health problem and characteristics of the application<br>- Safety<br>- Clinical effectiveness | **Multidisciplinary Assessment:**<br>- Economic | **Multidisciplinary Assessment:**<br>- Ethical and legal aspects | **Transferability assessment:**<br>- Cross-border<br>- Scalability<br>- Generalizability |
| 6 | Leon et al., 2012 | **Government stewardship:**<br>- Strategic leadership<br>- Learning environment<br>**Organizational:**<br>- Culture of information use<br>- Capacity for implementation | **Technological**<br>- Use-ability<br>- Interoperability<br>- Privacy and security | | | **Financial**<br>- Sustainable funding<br>- Cost-effectiveness | | |
| 7 | Lo et al., 2012 | - Logistics evaluation | Technical evaluation | Usability evaluation | | | | |
| 8 | Takian et al., 2012 | - The Health Care System | - System Functions | Human Perspectives | | | | |
| 9 | Cresswell et al., 2014 | **Social context:**<br>- Organizational context<br>- Professional roles<br>- Use by healthcare professionals | **Technology:**<br>- Usability<br>Design | **Social Context:**<br>- Wider environment | **Quality and safety of care** | | | |

### *Organizational aspect*

The organizational aspect deals with the structure of the institutions where the intervention is taking place. In eHealth interventions, the institution can be the healthcare center(s), the region, and the country depending on the scale of the intervention. The *Human/social aspect* and the *organizational aspect* have some commonality since the organization is a collective form of the human actors. The fact that differentiates the latter from the former is, the organizations are governed by specific rules and infrastructure. The technology cannot be evaluated just on the basis of clinical efficacy or on the capability of functioning under an experimental set-up but must be evaluated in the context of the relative advantage it provides to the host organizations (Cornford, Doukidis, Forster, 1994). Due to its importance as an area of assessment, the organizational aspect is added in a good number of frameworks for evaluation in healthcare.

Most of the evaluation frameworks agree that the change occurred inside the organization due the intervention is needed to be captured (Cornford et al., 1994; Liberati et al., 1997; Glasgow et al., 1999; Kidholm et al., 2012; Leon, Schneider and Daviaud, 2012; Takian et al., 2012; Cresswell and Sheikh, 2014). Cornford et al. (1994), Liberati et al. (1997), Takian et al. (2012), and Cresswell and Sheikh (2014) aim to evaluate if the intervention will change the balance between the functions of healthcare provider, how the demand for resource and skill will change, and the impact of the intervention on the current roles of professionals in the organization. In order to answer these questions, Glasgow et al. (1999) use the term *adoption*, which is one of the five dimensions of the RE-AIM framework. Adoption measures the representativeness of the organization and participation rate of the professional during the intervention program. The more involvement of the real organization and the healthcare professional the better the evaluation of the organizational aspect.

The capability of the organization to implement the intervention is another part of organizational aspect. The capacity of implementation mainly targets the management of the healthcare system. The MAST framework (Kidholm et al., 2012), and the HTA Core Model (Lampe et al., 2009) include management as one of the features of the element of assessment while the HOT-fit framework elaborates this feature in terms of autonomy, communication, leadership, top-management support, teamwork, medical sponsorship. The capability of implementation also depends on eReadiness, a functional ICT environment, effective mechanism for supporting and monitoring evaluation (Leon et al., 2012; Lo et al., 2012).

The RE-AIM model defines the implementation of an intervention as the “extent to which the program is delivered as intended” (Glasgow et al., 1999, p. 1323). The authors also indicate that a program implemented in the real setting with real actors instead of research staff is more likely to be effective. Another facet of implementation is the congruence between the intervention program and policy of the organization, e.g.

healthcare center, region, country (Cornford et al., 1994; Leon et al., 2012). This part is more related to the ethical and legal aspect, hence will be elaborated later.

Sustainability is the last feature of the organizational aspect that shed lights on the long-term implementation of the eHealth intervention. The question for assessing this feature is as simple as could such a technology be sustained and functioned in the organizational context and enhance the value of the care delivery? (Cornford et al., 1994; Takian et al., 2012). Glasgow et al. (1999) use the term *maintenance* to address sustainability and define it as the degree to which the technology becomes accustomed in the daily practice of an organization.

### *Technological aspect*

From a general perspective, some key challenges to overcome for eHealth interventions are ensuring trust (Lo et al., 2012), effectiveness, and contribution of quality of care (Kidholm et al., 2012) of the technology implemented. Accordingly, evaluation frameworks often include technology assessment as an independent category (Lovejoy et al., 2009), or from a comprehensive viewpoint, the interplay among technology, human perspective, (Yusof et al., 2008, Kidholm et al., 2012, Lo, 2012; Cresswell and Sheikh, 2014), and organizational perspective (Leon, Schneider, and Daviaud, 2012; Cornford et al., 1994). More specifically, while a great number of frameworks are designed to evaluate existing technologies (Cornford et al., 1994; Yusof et al., 2008; Leon et al., 2012; Lo et al., 2012), two frameworks evaluate systems that are in early stages of design and development (Lovejoy et al., 2009; Kidholm et al., 2012). Therefore, the technology category is usually divided into subcategories suitable for the evaluation design.

Although each of the analyzed frameworks has identified different categories to address the technological aspect of the evaluation, some common categories are acknowledged. First, the assessment of *system quality* is highlighted in several empirical and conceptual studies. The measure is focused on assessing the system performance by determining if the system meets the users' needs, if it is convenient and easy to use, and if it fits the work patterns of the healthcare system' professionals (Yusof et al., 2008). Other aspects, such as the hardware and software requirements, and the correct functioning of the system components are included in this category (Cornford et al., 1994; Lo et al., 2012). Another prevailing measure is *usability* of the system. Cornford et al. (1994) include the measure in the *process* aspect of the *system functions* category. It measures if the technology is pleasant to use. In this area, the evaluator assesses whether the data is correct and valid, and the interface of the system. Leon et al. (2012) defined this area as *use-ability*, since it measures the ease to use, flexibility, durability and the general experience of the users with the system. Aligned with these criteria, Cresswell and Sheikh (2014) propose two subcategories, *design* and *usability* of the system, which are used not only to understand how the technologies change the social processes, but how technologies change over time as a result of new user and organizational requirements. A third prevalent aspect found was *privacy and security*, which can be addressed from different viewpoints. While Cornford et al., (1994) focus in measuring whether the technology is safe and reliable, Leon et al., (2012) and Lo et al. (2012) focus in ensuring the security of the data managed in the technology.

Besides the common categories, different frameworks include different spheres of assessment within technological aspect. Ohinmaa et al., (2001) propose the assessment of *technical accuracy*, which measures the quality of the transfer of data by assessing two criteria: (1) whether the data transfer process is feasible and corresponds to the technical quality requirements, and (2) the quality of the data after the transfer. Additionally, the authors outline the importance of technical evaluation and resolution of any identified issue before the assessment of clinical effectiveness.

Yusof et al. (2008) propose the Human, Organization and Technology-fit factors (HOT-fit) evaluation framework, which is a multidimensional information systems (IS) success model, where the variables have a causal and temporal relationship. Aside from system quality, the framework measures information quality and service quality. *Information Quality* relates to the information produced by the system (e.g. patients records, reports, images, and prescriptions), and depends on the users' subjectivity. The subcategory can be measured by information completeness, accuracy, legibility, timeliness, availability, relevancy, consistency, and reliability. *Service Quality* measures the support and follow-up service delivered by the technology provider. It can be measured through technical support, quick responsiveness, assurance, empathy and follow up service.

Lovejoy et al. (2009) present the Rogers' Diffusion of Innovations model, in which the aim is to assess the acceptance of the innovation by the members of a social system. The objective is achieved by the assessment of the users' perception of five innovation characteristics. *Relative advantage* refers to the cost-benefit analysis of the innovation; *compatibility* is related to the accordance between the innovation and the existing users' values, need and experiences with other systems; *complexity* assesses the ease to use measured by the potential users; *triability* is the ability of the innovation to be tested on a small scale before the final implementation; and *observability* measures the positive outcomes from the innovation use.

The Model for Assessment of Telemedicine Applications (MAST) developed by Kidholm et al. (2012) includes the category *preceding consideration* to assess the system and determine the effectiveness and the contribution to the quality of care. Although, the aspect is defined by four areas: legislation, reimbursement, maturity and number of patients; only the two last areas are discussed in the Technological Aspect section. *Legislation* is presented in section Ethical and Legal Aspects, and *reimbursement* is discussed in Cost and Economic Aspects. The area *maturity* refers to the system maturity, and as explained by the author, it develops over time. Therefore it is important to measure whether the system is mature (i.e. whether the system has been used on a sufficient number of patients to address all the technical problems).

Implementation of telemedicine applications often requires investment on equipment, integration with other systems, and training of clinical staff. Thus, the *number of patients* must be relevant to justify the significant fixed costs associated with the application.

The technological system category proposed by Leon et al., (2012) intends to provide insights regarding the usability, privacy and security, and interoperability of the chosen technology for the healthcare intervention. While the first two aspects were already discussed in the common areas of measurement, *interoperability* measures the communication between the technology and the pre-existing systems, the fit between the technology and the existing work practices.

### *Human/social aspect*

The human/social perspective deals with the interaction between the social actors and the technology that includes the perception of individuals regarding technology, the context under which the technology is implemented. In total, six evaluation frameworks found under the systematic literature review include human/social perspective as an area to evaluate. Although there are few dissimilarities in the way of defining this area, all of the frameworks agree to measure the acceptance and usability satisfaction of the technology used in the intervention (Liberati, Sheldon, and Banta, 1997; Ohinmaa et al., 2001; Yusof et al., 2008; Kidholm et al., 2012; Lo et al. 2012; Cresswell and Sheikh, 2014). Some articles include the context as an integral part of human/social perspective (Kidholm et al., 2012; Cresswell and Sheikh, 2014). However, usability satisfaction is regarded as an area of technological evaluation in some of the frameworks as mentioned in the Technological Aspect. Following is a brief description on how individual framework delineates this area in its own way.

The framework designed by the International Network of Agencies for Health Technology Assessment INAHTA) named this as *user assessment of the technology*, where the user can be physicians, nurses and other staffs, and patients depending on the type of the participants in the intervention. According to INAHTA, the measurement topics under this area are quality, usability, and satisfaction related to technology (Ohinmaa et al., 2001). The HOT-fit framework includes *human* as one of its three areas of evaluation (Yusof et al., 2008). This area has further been divided into two criteria, i.e. system use and user satisfaction. System use is concerned with the issues such as the volume of use, who is using, purpose of use, and motivation to use the technology. User satisfaction relates to the perceived usefulness, enjoyment, decision-making satisfaction, and overall satisfaction for the technology. The HTA core model (Lampe et al., 2009) considers social aspect as a domain for health technology assessment. According to this model a domain "represents an angle from which to view the use, consequences, and implications of any technology" (Lampe et al., 2009, p. 11). This definition is an interesting addition to the model as it defines the domains more like a perspective than an area for evaluation. The domains for HTA core model are defined in the EUR-ASSESS project and the social aspect is originally defined as social and psychological aspect (Liberati et al., 1997). According to Liberati et al. (1997), the psychological aspect refers to the satisfaction, wellbeing, and other psychological variables, whereas the social aspect refers to the accessibility to the technology, the social relationships evolving over the transmission of care or activities of the patients under the intervention.

MAST identifies patient perspective and socio-cultural aspect as two different areas of assessment (Kidholm et al., 2012). According to the MAST model (2012), the patient perspective relates to the perception and level of acceptance of the patients and their relatives regarding the eHealth intervention that encompasses confidence in treatment, understanding of information, ability to use the application, empowerment, accessibility, and self-efficacy. The socio-cultural aspect refers to the circumstance, where the patients live and acts while using the technology. Whereas MAST recognizes only the circumstance of the patients and their relatives, the framework proposed by Lo et al. (2012) acknowledges a broader spectrum named public perspective. The authors of the article *Technical evaluation of an e-health platfor*m (2012) aim to evaluate the perspective of all the end-users, i.e. patients, doctors, and nurse regarding the usability of the e-Health platform. The goal of the usability evaluation is to identify whether the technology is able to overcome the challenges of public trust. In the article titled *Undertaking sociotechnical evaluations of health information technologies*, the authors emphasize on exploring the use of technology by individuals and also the extended environment where the intervention happens (Cresswell and Sheikh, 2014).

### *Clinical aspect*

The RE-AIM framework suggested by Glasgow et al. (1999) emphasizes the importance of clinical assessment of eHealth interventions. In order to measure the efficacy of interventions, both *positive and negative outcomes* (i.e. benefits and unanticipated negative effects) must be addressed. Also, the model highlights the importance of *biologic outcomes* in healthcare interventions, including disease risk factors. The third type of outcome is presented, *behavioral outcomes* of the participants, the staff who deliver the intervention, and the sponsors of the intervention. Finally, a participant-centered *quality of life outcome* should be measured to evaluate the participants' functioning, mental health, and satisfaction with the intervention.

As a part of the assessment framework developed by INAHTA, Ohinmaa et al. (2001) included the assessment of effectiveness. The focus is on measuring the diagnostic and therapeutic effectiveness rather than the effects on the health status. It is stated that the effects of a telemedicine often continues beyond the pilot project, thus an ongoing monitoring of the patient may be necessary. Additionally, limited availability of data, minor differences between the telemedicine and conventional options of care, and the relatively short-term interventions are the main challenges while measuring the effectiveness of telemedicine applications. Consequently, long-term measurements of outcomes (e.g. quality of life) may assess time-related aspects (e.g. differences in waiting times) rather than health effects.

The HTA Core Model introduced by Lampe et al. (2009) includes a *multidisciplinary assessment* category, which comprises seven multidisciplinary assessment domains. However, this section discusses three domains related to clinical outcomes. The evaluation of *clinical effectiveness* and *safety* aspects are assessed using the PICO structure i.e. the aspects are described in detail from the perspective of the population (P), intervention (I), comparators (C), and Outcomes (O). While the first three perspectives may have overlapping information, the outcomes are domain-specific. This framework is usually used for a comprehensive and multidisciplinary assessment. However, the authors propose a more liberal selection and use of the domains based on the needs and interests of the evaluator. The model for assessment of telemedicine applications (MAST) presented by Kidholm et al. (2012) includes the *multidisciplinary assessment* category of the HTA Model and HTA Core Model. First, *health problem and description of the application* refers to the description of the health problem of the patients expected to use the application, and an exhaustive description of the application itself (e.g. technical characteristics, current use of the application). Second, *safety* involves the identification and assessment of harms related to the telemedicine application. The domain includes the clinical safety of patients and staff, and the technical reliability of the application. Third, *clinical effectiveness* assesses the effects of the telemedicine application on the patient's health (e.g. effects on mortality, effects on morbidity, effects on health-related quality of life (HRQL)).

The sociotechnical evaluation of technological systems in healthcare authored by Cresswell and Sheikh (2014) emphasizes the importance of understanding the correlation between the implementation of eHealth solutions and the improvement of safety, quality of care, and health outcomes. The *quality and safety of care* assessment must be achieved by identifying the key quantifiable benefits of the technology. Such outcomes must have an impact on the quality and/or safety of care and are most likely to be influenced by the technology.

### *Cost and economic aspect*

All of the frameworks found through the systematic literature review admit that cost assessment is mandatory for an eHealth intervention since this sort of assessment plays a significant role in future decision making. Nonetheless, only a few frameworks show any direction for conducting an economic evaluation of the eHealth intervention. The INAHTA (Ohinmaa et al., 2001), HTA Core Model (Lampe et al., 2009), and the MAST model (Kidholm et al., 2012) have cost and economic evaluation as a specific area of assessment. Among these, INAHTA provides the most comprehensive description of the cost analysis and the economic evaluation method. In this framework, Ohinmaa et al. (2001) break down the cost of the intervention in investment cost, monthly user charge of equipment, costs of used communication line, wages of doctor and other staff, education of the technology, costs of patients and their close relatives. In INAHTA framework, different cost analysis methods such as cost minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), cost-utility analysis (CUA) have been proposed and CMA has been described as the most frequently used method for economic evaluation. The cost analysis methods mentioned in INAHTA model are similar to the ones described in the health technology assessment (HTA) (Liberati et al., 1997). Moreover, in HTA, it is emphasized to have a well-defined research question that will clarify the scope of the cost analysis. Liberati et al. (1997) indicate that the cost analysis can be conducted from several perspectives such as societal, third-party payers, healthcare providers, or patient and should involve the people who will use the result of the assessment in future in identifying the suitable analysis method. The HTA core model (Lampe et al., 2009) adopts the cost assessment from the HTA model; hence conform to the same evaluation structure.

*Reimbursement* is one of the issues identified as one of the *preceding considerations* in MAST. *Reimbursement* is the principle by which the payers (e.g. health authorities, insurance body) pay for the healthcare services. Telemedicine applications may have an impact on the tariff of the service, thus the inclusion of this data is highly recommended for the economic analysis of this type of implementation. *Economic evaluation* and *business case* are two sub-criteria for assessing the economic aspect in the MAST model. The model recommends the societal *economic evaluation* as the cost analysis method and it aims to compare the intervention with relevant alternatives in terms of costs and consequences. The *business case* analyzes the expenditure and revenue for the healthcare organization adopting the technology. (Kidholm et al., 2012).

Although RE-AIM framework does not include cost assessment as one of its dimension, it advocates for cost-effectiveness and cost-benefit analysis as these analyses reveal the resource utilization and opportunity cost of the eHealth intervention (Glasgow et al., 1999). The framework proposed and used in the assessment of mHealth[5] in South Africa includes cost-effectiveness and sustainable funding as sub-criteria of financial analysis (Leon et al., 2012). But the goal of the financial analysis is to determine whether the enough financial provision is available for medium to long-term use of mHealth, which is not exactly the economic evaluation of the eHealth intervention.

The economic evaluation is a critical part of the assessment of the whole intervention. The cost analysis and the economic evaluation is conducted at the end of the evaluation cycle but the related research question and the appropriate evaluation method need to be selected beforehand.

### *Ethical and Legal aspect*

*Socio-cultural, ethical and legal aspects* is the seventh domain included in the *multidisciplinary Assessment* category of the HTA Core Model developed by Lampe et al. (2009), and in MAST introduced by Kidholm et al., (2012). In regard to the domain, the assessment is performed by addressing the effects of these aspects on the patients and on the intervention. Both the HTA Core Model and MAST address this aspect focusing on three independent areas. However, the socio-cultural area was already

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[5] Sub-section of eHealth that refers to the utilization of mobile communications and network technologies in healthcare system (Istepanian et al., 2006)

included in the Human/Social Aspect section. The second area, ethical analysis, addresses ethical concerns of the application itself and its implementation (Kidholm et al., 2012). It includes all the stakeholders' viewpoints on using the technology and the key ethical principles associated with the context in which the intervention is conducted (Lampe et al., 2009). Finally, the legal aspect identifies and analyzes the legislative documents and legal obligations that may exist in each context involved in the intervention.

Besides the *socio-cultural, ethical and legal aspects,* MAST includes the category *preceding considerations*, which is divided into four subcategories, three of them have been already included in the analysis of the Social/Human Aspect and Cost and Economic Aspect. The final subcategory, *legislation*, is created to assess whether the telemedicine application meets the national and regional legislation regarding regulations of medical care provision. The assessment of this area enables to ensure the applications' effectiveness and the contribution to the quality of care (Kidholm et al., 2012).

### *Transferability aspect*

The RE-AIM framework proposed by Glasgow et al. (1999) includes an individual-level measure of participation; the category is denominated *reach*. The category measures the participation and representativeness of the intervention. While *participation* refers to the percentage of persons who receive or are affected by the program; *representativeness* concerns the characteristics of participants and nonparticipants to investigate the extent in which participants are representative and what population group should be a priority for future research.

The MAST model presented by Kidholm et al. (2012) includes an *assessment of transferability* category. The authors highlight the importance of the transferability of results from studies of eHealth from one setting to another. The inclusion of information on organizational issues presented during the implementation of the application, or the cost per patient and its calculation could provide relevant information regarding transferability of the results to other settings. The importance of the assessment of validity and reliability of the study is also emphasized. Finally, the authors suggest the use of meta-analysis as a statistical method to combine results from different interventions.

### *4.1.3. Evaluation reported in empirical studies of eHealth interventions*

Apart from the frameworks discussed in previous chapters, there are numerous articles that report on individual intervention in healthcare. The focus of these articles is to describe how the intervention has been carried out and the result of the intervention. Most of this literature exhibits a minimum emphasis on the evaluation framework or on the design of the intervention in terms of underlying theory, hypothesis, and reasons behind the areas chosen for evaluation. Among the 32 articles of this sort, only two have used a pre-defined structure for evaluation and hence included in the previous section

(Leon et al., 2012; Takian et al., 2012). The rest of the articles vary to a great extent in various aspects. Several of them conduct either randomized control trial (RCT) or naturalistic study and present the result of the intervention in a quantitative manner with the help of statistical analysis (Meglic et al., 2010; Klein et al., 2011; Glozier et al., 2013; Mohr et al., 2013; Ali et al., 2014; Ebert et al., 2014; Kleiboer et al., 2015; Zimmer et al., 2015; Burton et al., 2015). The number of participants and the duration of the interventions vary respectively from 7 patients (Holländare et al., 2015) to 241 patients (Ali et al., 2014) and from 12 weeks (Klein et al., 2011) to more than 4 years (Zimmer et al., 2015).

Along with the quantitative data analysis approach, a good number of interventions have considered qualitative data collection in the form of interviews, observations, thematic analysis of text messages exchanged between patient and doctor (Frangou et al., 2005; Robertson et al., 2010; Burns et al., 2011; Harrison et al., 2011; Bergmo et al., 2013; Bouamrane and Mair, 2014; Cristancho-Lacroix et al., 2014; Muhammad and Wickramasinghe, 2014; de Wit et al., 2015; Salisbury et al., 2015; Schaller et al., 2015; Aschbrenner et al., 2016; Langrial and Lappalainen, 2016; Pham et al., 2016; Skidmore et al., 2016). It can be said from the systematic review that the use of qualitative data in the eHealth interventions is on rising. The importance of qualitative information to explain the quantitative results has been discussed in many conceptual articles (Ahern, Kreslake, and Phalen, 2006; Glasgow, 2007; Lilford et al., 2009; Chung et al., 2015; Cresswell and Sheikh, 2014; Kassam-Adams et al., 2015) and with time, the use of both quantitative and qualitative data collection and analysis in actual intervention is escalating.

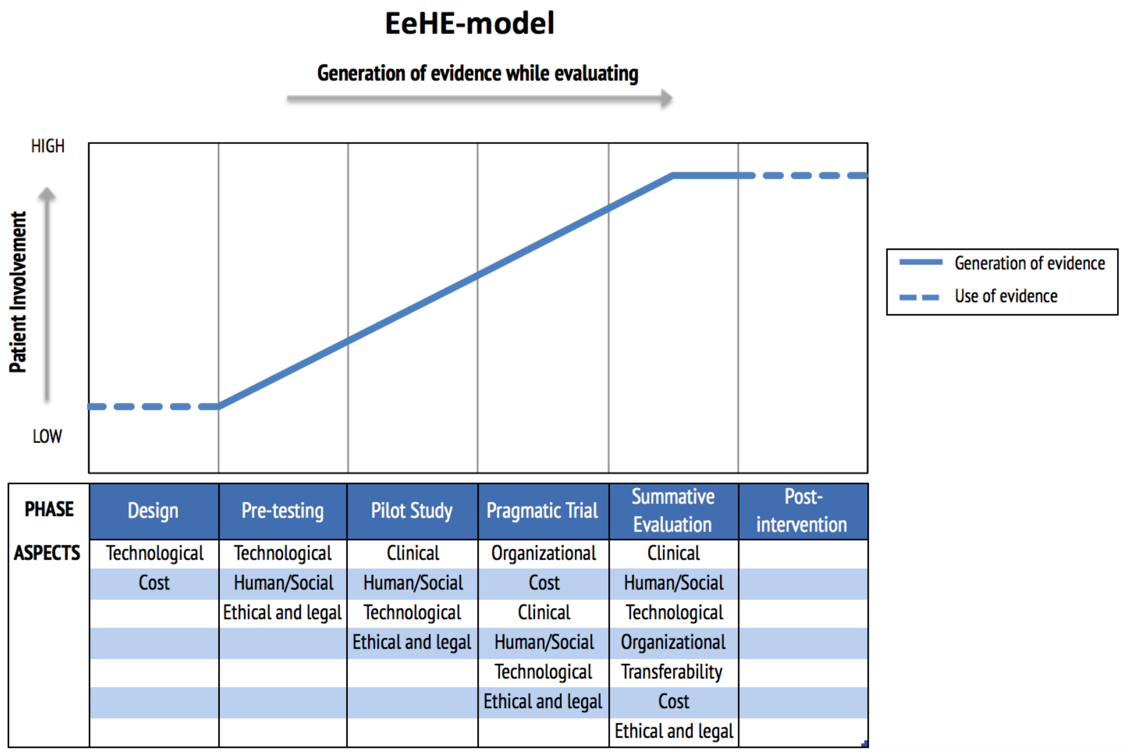
The systematic review reveals that there is a substantial gap between the conceptual intervention and evaluation frameworks and the way the actual interventions and evaluations take place in healthcare. In spite of the fact that the conceptual frameworks vary within a spectrum as presented in section 4.1.1 and 4.1.2 they emphasize on a specific set of inquiry such as the context of the intervention, importance of stakeholders, evaluation approach, importance of evaluating the user's perception of technology along with clinical efficacy and cost evaluation. Unfortunately, the majority of the actual eHealth interventions disregards these issues holistically and targets a niche area of evaluation. These niches such as adherence, quality of life, depression, and anxiety are, perhaps the most important areas to be evaluated in healthcare interventions, but scattered evaluation of this area fails to depict the complex scenario of an eHealth intervention. Rather, an evaluation that not only measures clinical efficacy but also looks for the evidence of why and how certain technology increases or does not increase clinical efficacy and other indicators such as satisfaction, the usability of the technology, represent the complete scenario of the intervention.

Another interesting observation from the systematic review is that very few articles convey the importance of developing a suitable technology for healthcare. Most of them emphasize on evaluating the impact of the available technologies in healthcare but do not discuss the origin of the technology or do not even provide a rich description of their functionality. Thus, it becomes quite challenging to discern the usefulness and appropriateness of the technology for future use. Almost no real interventions found in the literature review provide any description on how the technology enabled care fits into the current organizational and social practice; e.g. how the job of the healthcare provider, informal caregiver changes due to the new model of care, how the interaction between patient and healthcare provider changes. Unlike the conceptual intervention and evaluation frameworks, the articles describing specific interventions neglect cost evaluation in most cases. It seems that these issues are mainly responsible for the lack transferability and interoperability of the eHealth intervention.

### *4.1.4. Evaluation of an ideal eHealth intervention*

In this section the Evidence in eHealth Evaluation (EeHE) model (see Figure 4) explaining the evaluation in an ideal eHealth intervention is presented. The EeHE-model is based on the findings of the systematic review. As a summary of the findings of the systematic literature review, it can be said that, due to the complexity of the subject, evaluations in eHealth interventions are conducted in numerous ways. The full spectrum of eHealth intervention consists six phases: *design, pre-testing, pilot study, pragmatic trial, evaluation*, and *post-intervention* (section 4.1.1). Depending on the type of intervention, i.e. how many of these phases are included in an intervention, the evaluation can be performed in the phases such as design, pre-testing, pilot study, pragmatic trial, and mostly in the evaluation. Moreover, the evaluation is supposed to cover multiple aspects of eHealth intervention, i.e. *organizational aspect, technological aspect, human/social aspect, clinical aspect, cost aspect, ethical and legal aspect*, and *transferability aspect* (section 4.1.2). Nonetheless, when it comes to the empirical studies of eHealth intervention, none includes all six phases and most cover *pilot study* and few cover *pragmatic trial*; and none evaluates all the aspects but most evaluate the *clinical aspect* and few evaluate *technical aspect* as well.

Under this circumstance, our endeavor was to present a model that shows how the evidence can be created through evaluation in an ideal case of eHealth intervention. By an ideal case of eHealth intervention, we refer to an intervention that covers the full spectrum, i.e. includes all the six phases. As seen in the Figure 4, the model shows that in an ideal case *design* phase starts with the information collected from previous interventions and use those to build a new technology-enabled care or to improve an existing one. The development process of such technology should preliminarily focus on the technological aspect and cost of the development, although the formal evaluation begins in the next phase, i.e. pre-testing phase. From the *pre-testing* phase, the evidence of the efficacy and effective started to grow by means of evaluation in a gradual manner. Eventually, the evidence reaches the zenith in the phase named *summative evaluation*. In the *post-intervention* phase, the gathered evidence is used to commercialize the technology-enabled care. The model also presents how the aspects evaluated in each phase vary while an eHealth intervention passes through all the phases. The evaluation in the *pre-testing* phase focuses on the *technological*, *human/social*, and *cost aspects*. Whereas, during the *pilot study* phase, the *clinical aspect* is the prime focus for evaluation, followed by *human/social*, *technological*, and *ethical and legal*. Once the evidence of clinical efficacy is gathered, the *pragmatic trial* phase is carried out and substantially focuses on the evaluation of *organizational* and *cost aspect*. Evaluation of all the other aspects are also carried out with great importance but the main aim of the pragmatic trial is to gather evidence on whether the new technology enabled care can be implemented for a bigger audience under the realistic set-up of the organization. In the *summative evaluation* phase, all the aspects are evaluated including *transferability* in order to provide the evidence that is crucial for future decision-making. This evidence is used in the *post-intervention* phase. Lastly, the model shows that the involvement of the patients increases gradually from the design phase to pragmatic trial escalating the complexity in the intervention.



| PHASE | Design | Pre-testing | Pilot Study | Pragmatic Trial | Summative Evaluation | Post-intervention |
|---|---|---|---|---|---|---|
| ASPECTS | Technological | Technological | Clinical | Organizational | Clinical | |
| | Cost | Human/Social | Human/Social | Cost | Human/Social | |
| | | Ethical and legal | Technological | Clinical | Technological | |
| | | | Ethical and legal | Human/Social | Organizational | |
| | | | | Technological | Transferability | |
| | | | | Ethical and legal | Cost | |
| | | | | | Ethical and legal | |

**Figure 4.** Evidence in eHealth Evaluation (EeHE) model.

We propose this model to explain the fact that it would be beneficial to target specific phases to gather specific evidence in an eHealth intervention. The common practice is to target the pilot study or sometimes the pragmatic trial to evaluate all aspects at the same time. This leads to ambiguous results and leaves the decision maker bewildered. Instead of evaluating in this manner, the evaluation should focus different aspects in different phases, e.g. technical aspect in pre-testing phase, clinical aspect in pilot phase, organizational aspect in pragmatic trial. We are aware of the fact that the completion of the full spectrum of the phases is time and resource consuming but this process would make a trustworthy evaluation of eHealth intervention.

## 4.2. Developing an evaluation framework in eHealth intervention

From the findings of the systematic review, it can be said that the evaluation of eHealth intervention is not standardized. Due to the wide variety in the type of the interventions and the fact that healthcare intervention is being studied by researchers from various fields such as doctors, social scientists, the frameworks are diversified in many dimensions. We believe that it is not pragmatic to offer a framework that would be suitable for all eHealth interventions, but it is reasonable and beneficial to have a roadmap on how to develop a framework for the evaluation. From the systematic literature review done in the previous section, it is noticeable that such roadmap does not exist. Hence this chapter presents the phases to develop a framework to evaluate an eHealth intervention.

### *4.2.1. Procedure for developing the phases*

The phases of developing a framework for evaluation have been evolved from the experience of the researchers in the DECI project. By being a part of CHI in DECI project, we were actively involved in the development process of the evaluation framework that will be employed in the four-pilot intervention. The phases are the outcome of an explorative process through which the DECI evaluation framework is designed. It is worthwhile to mention that these phases also comply with academic evidence. The process of identifying the phases of developing the framework to evaluate the eHealth intervention is discussed in the following section.

Initially, with an aim to understand the current measurement practices of the four hospitals a survey titled *As-Is Analysis* has been conducted during September to October 2016. The content of the survey is stemmed from the goals of the project, which are translated into the key areas whose performance are to be measured as the part of the evaluation, e.g. patient's cognitive performance, quality of life. The *As-Is template* (see Appendix A) was sent to the clinical sites in order to investigate if the current healthcare systems of the hospitals measure these key areas and if they do so, then at which frequency and by which method. Besides this, another objective of the survey was to create a common vocabulary base among the involved partners of DECI, which is essential for meaningful communication throughout the project. Apart from the survey, various project documents namely D1.1, D1.4, D2.3 have been used to collect information about the clinical sites and the healthcare system of the regions and the countries they belong to.

With the help of the *As-Is Analysis,* it becomes quite apparent that there is a lack of consensus about what to measure and most importantly why to measure, among the partners of DECI. This finding leads the researcher to the stakeholder analysis. Understanding the roles and the expectations of every stakeholder involved in DECI seems to be the stepping-stone of the evaluation framework. DECI has various types of stakeholders such as MCI and MD patients, relatives of the patients in the role of informal caregiver (IFG), hospital management, clinicians, ICT providers, policymakers, researchers. During the stakeholder analysis, several thorough meeting were held over Skype with the hospital management representatives including clinicians and ICT providers to determine their expectations during November 2016. It is worth mentioning that the patients are the ultimate stakeholder of DECI and during the stakeholder analysis phase, their expectations are identified through the clinicians. One of the outcomes of the stakeholder analysis is to realize the need of establishing the research method of the evaluation e.g. qualitative and quantitative method, whether data will be collected longitudinally, i.e. in different points of time during the pilot or in cross-section method, i.e. in a single point of time during the pilot.

The stakeholder analysis also revealed the necessity of prioritizing the objectives of DECI which in later phases are identified as primary and secondary endpoints. Identification of endpoints assists to the categorization of the key areas that will be evaluated during the intervention. However, the research method proposed by the evaluators (CHI) and agreed by other partners guide the data collection method of the key areas. Eventually, the detailed planning for the operationalization of the evaluation is made. At the end, it is important to reflect upon the previous phases and make adjustments if needed; as eHealth intervention is a very dynamic process. The phases (Figure 5) are described below.

### *4.2.2. Phases for developing an evaluation framework for eHealth interventions*

In this section, the phases for developing an evaluation framework for eHealth interventions are discussed. Each phase is approached from a conceptual and an empirical perspective.

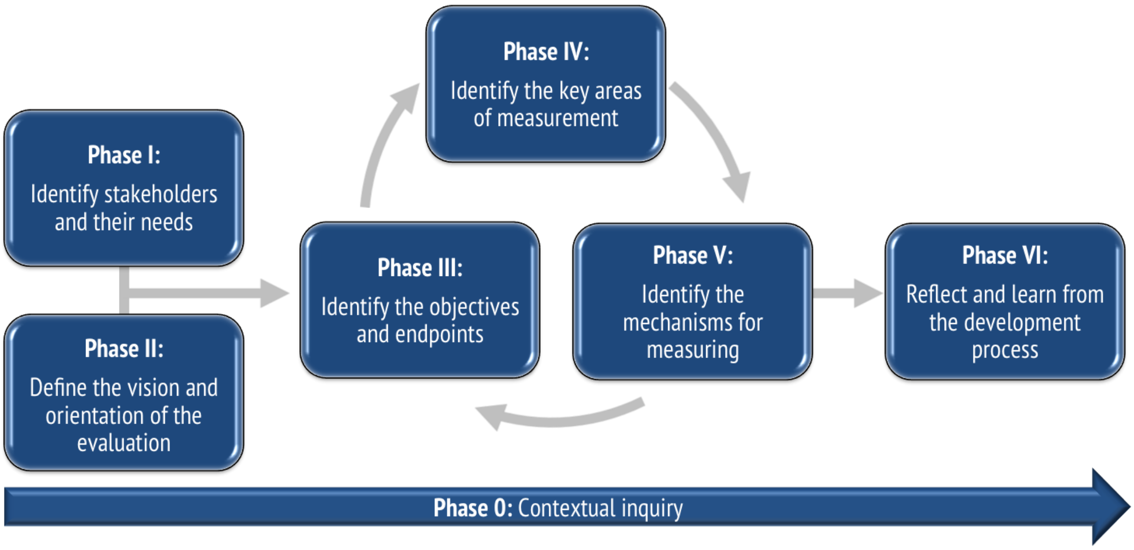


**Figure 5.** Phases for developing an evaluation framework

## Phase 0: Contextual inquiry

In the field of healthcare, context means the setting in which the healthcare practice occurs (McCormack et al., 2002). In order to cope with the complexity of disease management, eHealth interventions differ in aims and target groups. Accordingly, the interventions may vary in the context of use and the value they bring to the different participants involved (Catwell et al., 2009).

The contextual considerations are also highlighted by Greenhalgh and Russell (2010) in the article *Why do evaluations of eHealth programs fail? An alternative set of guiding principles.* eHealth interventions have individual, social, political, and ideological components hence the outcomes may change over time and across contexts. Aligned to this notion, two levels of context are introduced and proposed to evaluate ICT solutions *macro-level of context* (e.g. economic, political, demographic, technological), and *meso-level of context* (e.g. organizations, professional groups, networks) (Greenhalgh and Russell, 2010). A similar approach is described by Boddy et al. (2009) in *The influence of context and process when implementing e-health*. According to the authors, context aims to frame the designing and implementation of eHealth interventions. In this case, context is also divided into two dimensions: internal and external. Even though the terminology differs, the external dimension encompasses the similar aspects as macro-level of context, and the internal dimension refers to the same features as the meso-level.

### *Phase 0 in DECI*

In a more pragmatic way, the context of the healthcare intervention can be explained by micro, meso, and macro levels (Greenhalgh and Russell, 2010; Muhammad and Wickramasinghe, 2014). Figure 6 presents the levels of the context-hierarchy and the actors within each level. Although the development process of the framework has considered mostly the micro and partially the meso-level of the context, it is noteworthy that this is a multinational project and even within the micro level, the evaluation process of DECI intervention needs to deal with four different countries.

The first step of the contextual inquiry (Phase 0) is the awareness of the circumstance where the intervention is taking place. For the multinational project as DECI, one additional step is to identify the difference among different pilots. In this regard, DECI has contemplated the Hofstede study (Hofstede, 1984) to recognize the similarities and dissimilarities among the pilot countries along the six dimensions, i.e. power distance, individualism, masculinity, uncertainty avoidance, long-term orientation, and indulgence.

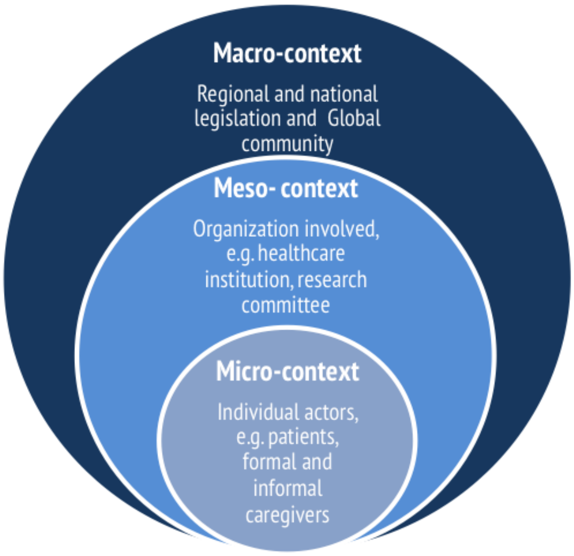


**Figure 6.** The context-hierarchy diagram

The current care model of each pilot is also an important condition to evaluate since each clinical site is shifting from their respective current position to the DECI platform for the pilot study. Even if the intervention components are the same, the transition during the pilot is unique for every country. For instance, one pilot is already using an electronic platform to store and communicate the patient record, whereas other pilots still use the paper-system or discrete electronic system for the patient record. Consequently, in terms of changes in the system, the first pilot has less to do compared to others. As a part of the contextual inquiry, it has been found out that there are differences in the availability of Internet provider services (IPSs) in the pilots; some countries are more advanced in the use of Internet than the others. Another finding of the contextual inquiry is that due to distinctive sociocultural structure, the relationship between patient and informal caregiver varies in a continuum, starting from the majority of the patients live with informal caregivers to the majority of the patients live alone or with another elderly person. During the intervention, one pilot will provide all the care service at patient's home i.e. all the tests and evaluation will be performed at patient's home, whereas other pilots will provide the care service at respective healthcare institutions.

The target population of DECI project, i.e. the elderly people with MD or MCI poses a unique context for us. Due to their limited capability of remembering incidents in daily life, the evaluation faces a set of challenges. One part of this challenge is to ask the patient group as few questions as possible to minimize the burden on them. The other challenges include reliability; to what extent the answers provided by such patient can be relied as evidence of evaluation. We needed to consider these constraints during the development process of the evaluation framework and chose the data collection method wisely so that these do not limit the evaluation.

These findings will be considered while developing the evaluation framework as they shed light on the feasibility of using certain methodology and tools in the evaluation.

Furthermore, the contextual awareness is potentially helpful while comparing the results of the pilots at the end of the evaluation. Every eHealth intervention is unique greatly for the context where it takes place. Only the thick description of the context while describing the case can enhance the generalizability and interoperability of an intervention study (McCormack, 2002; Bryman et al., 2015).

### Phase I: Identify Stakeholders and their needs

To reduce the risk of failure eHealth interventions, a “fit to purpose” approach is suggested by Catwell and Sheikh (2009). To achieve that, besides the context considerations, van Limburg et al. (2010) stress the importance of the social system surrounding the technology, and how it must be the central focus for the socio-technical design of the eHealth intervention. The authors also emphasize that the direct involvement of the stakeholders maximizes the likelihood of implementation and adoption of eHealth interventions. According to the literature, there are two main purposes to include the stakeholders’ perspective. First, as stated by Catwell and Sheikh (2009) in *Evaluating eHealth interventions: the need for continuous systemic evaluation,* stakeholders must reflect critically on the vision and objectives of the intervention to determine if the project is appropriate and feasible. Second, Greenhalgh and Russell (2010) propose to engage the stakeholders in exchanging information about ideas, values, and priorities. The authors encourage researchers to map the expectations of the intervention and the evaluation. This is supported by Boddy et al. (2009), where it is stated that the eHealth intervention design and implementation are decided by the interests of the healthcare system’s stakeholders.

A related pitfall detected in the literature is that healthcare interventions usually have multiple stakeholders, and the power is unevenly distributed among them. A method to reduce the impact of the issue is performing a stakeholders’ analysis. Different models have been developed and applied to identify the stakeholders and map out their expectations of different phases of the intervention. (Greenhalgh and Russell, 2010) Following are discussed some of the proposed methods used to develop a generalized stakeholders’ analysis for eHealth interventions.

Glouberman and Mintzberg (1996) acknowledge that healthcare systems are considered as complex organizations. By using an integrative framework, the *4C model* aims to combine the different elements in the healthcare organizational context into a connected managerial network. As shown in Figure 7, a four-quadrant scheme is created by differentiating how the service is managed with respect to the healthcare institution. *Cure*, all the doctors and physicians fall into this category because they are involved in the clinical operations, but not report into the healthcare institution’s hierarchy. *Care*, the nurses and specialists who provide basic care belong to this category; they are directly involved in the treatment of the patient and follow the line management hierarchy. *Control* that is the conventional administration or those who are responsible for the institution. *Community*, those who are neither involved in the clinical operations nor follow the internal line of management.

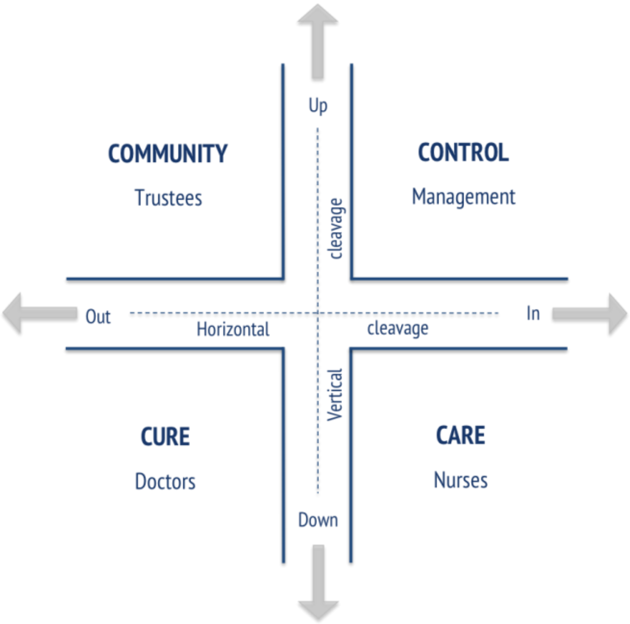


**Figure 7.** 4C model (adopted from Glouberman and Mintzberg, 2001)

A more recent publication *Designing and evaluating healthcare ICT innovation: a cognitive engineering view* by Sanderson (2007) proposed the *patients to politicians* model to explain the multiple pressures from the various stakeholders towards the healthcare system. The model, shown in Figure 8, is presented as a relationship between six stakeholders and a complex sociotechnical system as the author describes the healthcare system, while implementing a healthcare ICT innovation. *Patients* and *medical practitioners* are placed in the base of the model; it is here where the changing pathologies and the need for new skill sets and tools are generated. The third and fourth stakeholders are the *hospital and clinical management* and *healthcare organizations*, who are responsible for providing the resources to meet the demands of knowledge, skills, and have access to diagnostic technologies and treatment. The last two positions of the model belong to *regulators and associations* and the *government*, this level sets and controls the standards that must be met.

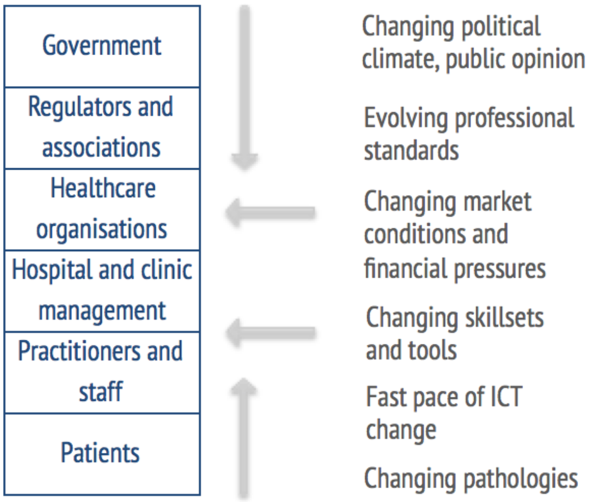


**Figure 8.** Patients to politicians model (adopted from Sanderson, 2007)

Omachonu and Einspruch (2010) define the process of innovation in the healthcare industry as complex and multi-dimensional, which makes it necessary to understand and identify the key stakeholders and their needs and expectations. According to the authors, the adoption of healthcare innovations has five key stakeholders: Physicians and other caregivers, patients, organizations, innovator companies, and regulatory agencies.

### *Phase I in DECI*

Based on the models discussed above, and on the empirical experience obtained from the case study; a stakeholders' analysis for eHealth interventions in healthcare is deployed in Figure 9. First, as stated by van Limburg et al. (2010), before any categorization or classification, the general overview of the stakeholders from the perspective of the project is needed; that is, identifying the complete list of stakeholders. Second, it is relevant to identify the stakeholders' *types*, this concept is used to categorize each stakeholder and understand the reason for including or excluding stakeholders. Third, when the complete list is available, the validation of the stakeholders' analysis by experts or the stakeholders' perspective is required to finalize the stakeholder identification. (Limburg et al., 2010)

In this study, the identification of stakeholders is divided into internal and external in regard to the healthcare institution. To begin with, the most relevant stakeholder type is *users* or *service customers* (Limburg et al., 2010). It has been stated that the core of healthcare innovation is the needs of the patients', healthcare practitioners, and healthcare providers (Sanderson, 2007; Omachonu and Einspruch, 2010). To be more specific and aligned to the case study, technology-assisted care is shaped to adjust to care recipients' preferences and promote independence (Fondazione Politecnico di Milano, 2015), most likely increasing the level of involvement of informal caregivers (i.e. non-professional care providers such as partners and relatives) (Palm, 2013). Therefore, *Patients and patients' family members as informal caregivers (ICG)* are defined as the first out of six key stakeholders.

Overlapping with the concept of users or service customer, the 4C model allows defining the three internal stakeholders: *Doctors and physicians*, *Nurses and formal caregivers (FCG)*, *Healthcare Institution's Management*, and one external stakeholder: *Policymakers*. Finally, because DECI is an eHealth intervention, the model includes a sixth key stakeholder *Technology providers* that have not been included in any other stakeholders' model.

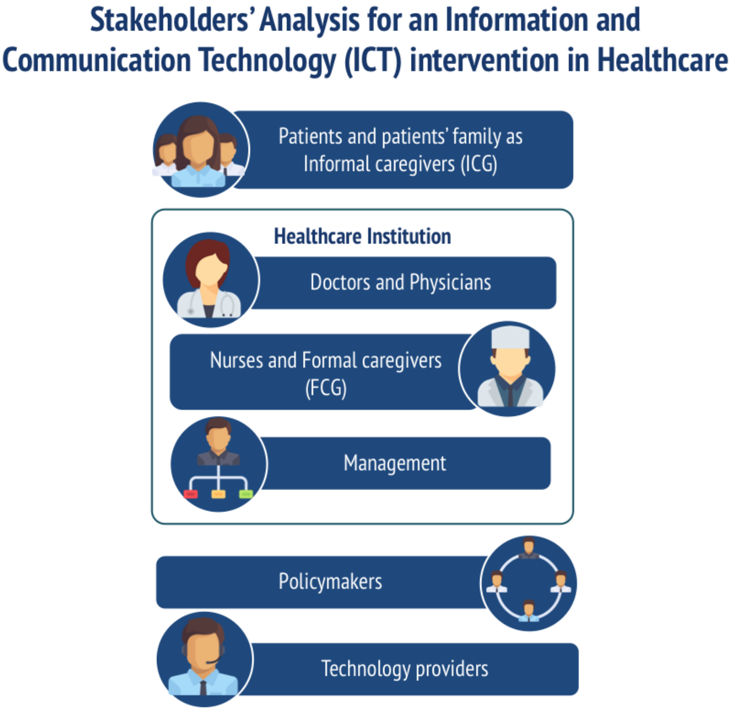


**Figure 9.** Stakeholders' analysis for an eHealth intervention.

Once the preliminary list of stakeholders is defined, the next step is to map out the needs for the evaluation of the eHealth intervention. For that, different research methods were selected and applied. Document *D2.2 Business model of the digital solutions used for assisting elderly people with cognitive impairments* is used as main input. In the deliverable, the elements of the Business Model (BM) of the ICT solution are described. Although the description is based on a four-domain framework (i.e. service, technology, organization, and finance), the document is scanned to extract information related to the stakeholders' needs and expectations. Additionally, a series of one on one interviews with technical partners were conducted by CHI with specific questions regarding the needs and expectations of the Project from a technological perspective. The empirical information is supported by Omachonu and Einspruch (2010) *Innovation in healthcare delivery systems: a conceptual framework* article, in which the key stakeholders and the needs, wants and expectations of the healthcare innovation process are listed. It is important to mention that all the information obtained from the literature regarding needs corresponds with DECI's ICT solution BM analysis.

A one on one interview with a representative of a clinical site and a Skype call with all clinical partners were scheduled to validate the information of the preliminary list of stakeholders and the needs inventory. During the meetings, some words were changed to make them more comprehensible and to adjust to the different contexts of the Project are implemented. The final list of stakeholders and their needs and expectations are described in Table 8.

**Table 8.** Stakeholders and their needs for an eHealth intervention

| Stakeholders | Needs |
|---|---|
| Patients and patients' family as Informal caregivers (ICG) | Improved physiological well-being.<br>Improved patients' clinical outcomes.<br>Improved satisfaction.<br>Reduce dependency.<br>Reduced waiting time.<br>Reduced delay.<br>Improved diagnosis and treatment.<br>Reduced risks and improved safety. |
| Formal caregivers (FCG) | Improved patients' clinical outcomes.<br>Improved diagnosis and treatment.<br>Improved physiological well-being<br>Reduced risks and improved patients' safety.<br>Improved FCG' satisfaction |
| Management | Improved patients' satisfaction.<br>Improved staffs' satisfaction.<br>Reduce dependency.<br>Reduced waiting time.<br>Reduced delay.<br>Reduced risks and improved patients' safety.<br>Enhanced efficiency of internal operations.<br>Improved communication among stakeholders.<br>Cost containment.<br>Increased data access.<br>Increased data sharing. |
| Policymakers | Improved communication among stakeholders.<br>Cost containment.<br>Profitability. |
| Technology providers | Potential commercialization.<br>Usability.<br>Acceptance of the technology<br>Opportunity to test technologies (solutions mainly developed for research). |

## Phase II: Define the vision and orientation of the evaluation

A good number of academic literature, including examples of eHealth interventions espouse the idea of having a theoretical base in the background of interventions (Kok et al., 2004; Rogers and Weiss, 2007; Nahm et al., 2009; Proudfoot et al., 2011; Baird, 2014; Muhammad and Wickramasinghe, 2014; Kassam-Adams et al., 2015). Evaluation of eHealth interventions can be either inductive or deductive depending on the role of the theory in the intervention. The deductive eHealth intervention usually aim to prove the theories such as technology acceptance model (TAM), theory of planned behavior (TPB), diffusion of innovation theory (DIT), activity theory network (ATN), patient activation measurement (PAM), whereas the inductive studies aim to explore certain context and provide description of the cases (Baird, 2014). As stated in the Declaration of Innsbruck, "evaluation of IT in health care only has a value when there is a purpose, i.e. there is a question to be answered, for example, improvement of knowledge and generation of insight from a scientific perspective, or making informed decisions about design, procurement, development or routine operation of a health information system" (cited in Nykanen et al., 2011, p. 818), some research questions or hypotheses are fundamental to any healthcare intervention.

eHealth interventions conducted on the basis of a well-defined program theory is considered to be most effective (Kassam-Adams et al., 2015). Using program theory to map the mechanism among the functions and the outcomes is certainly conducive to create knowledge from an intervention (Rogers and Weiss, 2007). But, the very definition of program theory evaluation (PTE) does not include the evaluations that are not explicitly driven by a theory(s), instead explicate a theory(s) from the evaluation (Rogers et al., 2000). Hence, it can be said that PTE is applicable for deductive interventions but not suitable for the inductive ones. The inductive intervention studies start with some hypotheses or research questions, which are supposed to be answered at the end of the intervention. In order to create such questions, the evaluators need to be familiar with the prior research and studies that have dealt similar topics as the one under evaluation (Nykanen et al., 2011). Experts in the relevant field of the intervention need to review the theories, existing evidence (Whittaker et al., 2012) and translate this information in a way to utilize them in current intervention. Defining the theories that will be proven through the intervention (deductive) or identifying the areas that will be explored through the intervention (inductive) adds value in the development process of the framework. Having a theoretical base is called by different names such as conceptualization (Whittaker et al., 2012), intervention mapping (Kok et al., 2004), mapping sentence (Proudfoot et al., 2011). Such process of utilizing theory precludes the evaluators from digression and helps them to delineate the scope of the intervention (Pingree et al., 2010).

### *Phase II in DECI*

DECI is not driven by any particular theory, rather primarily aims to observe how an integrated care model activated by a certain group of ICT tools influences the wellbeing of the elderly patients diagnosed with MD and MCI and their caregivers and also affect the organizational performance. As a theoretical base, DECI identifies itself as a sociotechnical intervention; where sociotechnical intervention means that organizational and human factors and information technology are interrelated parts of one system and are dependent on each other (Cresswell and Sheikh, 2014). So, along with the human facets, DECI considers organization changes and interaction between human and technology as important part of evaluation. Furthermore, as determined by the stakeholders’ analysis, a thorough evaluation of the ICT tools of DECI platforms are expected by the technical partners. To address this, technology acceptance model (TAM) is being considered. The theory of TAM will be used to understand the user's’ perception regarding the ICT tools. To address the organizational changes in each pilot, the routine care delivery processes are being thoroughly analyzed through the project documents and the control group of patients who will receive the routine care during the pilot study. Besides the sociotechnical evaluation, DECI evaluators use a realist point of view (by assessing what components of the intervention works, for whom and under which circumstance) (Pawson et al., 2005). How DECI have used these theories for developing/choosing the framework is discussed in following phases.

## Phase III: Identify the objectives and endpoints

Research on the topic relies on the fact that identifying the objectives is a key milestone while evaluating eHealth interventions. As explained by Baker et al., (2010) in *Relevance of CONSORT reporting criteria for research on eHealth interventions*, stating clearly the objectives facilitates to understand the context of the evaluation and the intended use of the ICT solution. Furthermore, the authors highlight the linkage between the ultimate objectives and the extent to which the defined outcome measures assess the relevant domains of the intervention.

eHealth interventions often have multiple goals (Greenhalgh and Russell, 2010). Literature provides foundations for linking eHealth interventions with multiple objectives. First, the introduction of ICT systems within healthcare combined with the necessary social (e.g. organizational and behavioral) changes develops eHealth interventions into complex or multifaceted interventions (Catwell et al., 2009). Second, as stated by Linford, Foster and Pringle (2009) in *Evaluating eHealth: how to make evaluation more methodologically robust*, although some ICT systems are analyzed at the level of individual patients, the primary unit of analysis is organizational or workgroup level. Accordingly, the intervention may impact on different levels of the organization (e.g. operational effects, social variables). Third, as stated on Phase 1: Identify stakeholders and their needs; eHealth interventions usually have multiple stakeholders, therefore the priorities and expectations of the intervention and the evaluation may differ (Greenhalgh et al., 2010). Hence it is required to establish different sets of objectives or endpoints (Lilford et al., 2009; Greenhalgh et al., 2010; Law and Wason, 2014), and to create a causal chain (i.e. find the cause-effect relationship between different variables) (Lilford et al., 2009).

### *Phase III in DECI*

Directly connected to phases I and II, the ultimate objectives and endpoints of the evaluation of the eHealth intervention are founded on the stakeholders' needs and the sociotechnical and realist orientation of the research. Aside from the information from past phases, the partners' overview of the issue and the Project's documents are used also as an input. During a Consortium call, the necessity of defining the objectives and endpoints are introduced. Several group interviews with clinical and technical partners are scheduled to define and agree on a preliminary list of objectives and endpoints, which is shown in Table 9. Other influential factors and the final list of objectives and endpoints are discussed in the following phases.

**Table 9.** Objectives and endpoints of Digital Environment for Cognitive Inclusion (DECI).

| Stakeholders | Needs | Objectives and endpoints |
|---|---|---|
| Patients, ICG, FCG | Improved physiological well-being. | Improve cognitive performance/ prevent cognitive deterioration. |
| | Improved patients’ clinical outcomes. | |
| | Improved diagnosis and treatment. | |
| | Improved physiological well-being. | Improve quality of life (QoL). |
| | Increased autonomy. | |
| | Reduced risks and improved safety. | |
| | Improved patients’ clinical outcomes. | |
| | Improved physiological well-being. | Improve adherence to physical activity/ improve adherence to cognitive stimulation |
| | Improved patients’ clinical outcomes. | |
| | Improved diagnosis and treatment. | |
| Patients, ICG, FCG, Management | Increased autonomy. | Improve autonomy |
| | Reduced risks and improved safety. | |
| | Improved patients’ satisfaction. | Improve satisfaction. |
| | Improved staffs’ satisfaction. | |
| | Improved physiological well-being. | |
| | Increased autonomy. | |
| | Reduced risks and improved safety. | |
| | Improved patients’ clinical outcomes. | |
| | Reduced waiting time. | |
| | Reduced delay. | |
| ICG | Reduced ICG's burden | Reduce caregivers' burden. |
| Management | Cost containment. | Verify economic feasibility |
| Policymakers | Profitability. | |
| Technology providers | Potential commercialization. | |
| Patients, Management and Policymakers | Reduced waiting time. | Improve operational efficiency |
| | Reduced delay. | |
| | Increased data access. | |
| | Increased data sharing. | |
| | Enhanced efficiency of internal operations. | |
| | Improved communication among stakeholders. | |
| Technology providers | Usability. | Assess system usability/ assess system acceptance. |
| | Acceptance of the technology | |
| | Opportunity to test technologies (solutions mainly developed for research). | |

## Phase IV: Identify the key areas of measurement

As an evolving topic, evaluation of eHealth interventions faces several challenges. One of these issues is related to the outcome measures and metrics (Eng, 2002). Ahern (2007) supports the fact by outlining the need for consensus and standardization of measures of evaluation to ensure comparable results, particularly measures of efficacy and effectiveness. In *eHealth Research and Evaluation: Challenges and Opportunities*, Eng (2002) explains that common metrics of success relies on process rather than outcome measures. Although process indicators provide information for the implementation, they do not necessarily reflect the application's effectiveness. Also, the author suggests that in order to define evaluation metrics, the outcomes must determine whether the application improves the users' health status, and show the health and social effects of the application on the population level. Likewise, the systematic literature review conducted in this study (section 4.1.2) revealed that the key areas of measurement vary to a great extent depending on the eHealth intervention. Consequently, as an outcome of the analysis, seven aspects were identified: organizational aspect, technological aspect, human/social aspect, clinical aspect, cost and economic aspect, and ethical and legal aspect.

Other authors have proposed specific areas of evaluation. Shaw (2002) introduced six areas for evaluating eHealth technologies: clinical, human and organizational, educational, administrative, technical, and social. Chaundry et al., (2006) review the evidence on the effect of eHealth in three different categories, e*ffects on quality* refers to the improvement in primary and secondary preventive care (e.g. adherence to guidelines, enhancing disease surveillance, decreasing medication errors), *effects on efficiency* is related to the utilization of care and care provider time, and e*ffects on cost*, where most of the data is linked to changes in cost in utilization services, and system implementation or maintenance of ICT. Glasgow (2007) makes recommendations for the types of measures needed for the integration of ICT programs into practice. First, the *clinical measures* to which the eHealth intervention intent to affect. Second, the author suggests a systematic collection of *cost and economic measures* to perform comprehensive economic analysis to determine outcomes such as cost-benefit or cost-offsets. Third, measuring *quality of life and potential adverse effects* allows detecting if the intervention generates adverse outcomes. Fourth, qualitative measures are required to understand contextual issues and quantitative results.

### *Phase IV in DECI*

Besides the general categorization discussed above, the preliminary selection of key areas of measurement is defined based on the objectives and endpoints assigned by each stakeholder involved in the eHealth intervention, and the key areas currently measured by each clinical partner. A review of similar projects is conducted in order to detect similarities and gather information on the different perspectives used while selecting the areas of measurement. For example, the *Intelligent system for independent living and self-care of seniors with cognitive problems or mild dementia (ISISEMD)* project is an evaluation framework for impact assessment of ICT pilot services for elderly with mild dementia who lives in the community and with their relatives. As DECI, the pilot is validated and tested in four-member state regions of the European Union (EU) (Mitseva et al., 2010). The *National Evaluation of the Department of Health's Integrated Care Pilots* is a two-year program that includes 16 healthcare institutions to explore different ways of delivering integrated care to drive improvements in care and wellbeing (Ernst & Young, 2012). However, the differences between DECI project and other eHealth interventions, and within the four clinical partners resulted in the identification of eleven key areas of measurement: (1) health outcomes, (2) adherence to physical activity, (3) adherence to cognitive stimulation, (4) patients' autonomy, (5) patients' satisfaction, (6) patients' quality of life (QoL), (7) FCG satisfaction, (8) ICG burden, (9) operational efficiency, (10) acceptance and usability satisfaction of technology, and (11) cost.

Since Phase III, IV and V are directly connected, the selection of parameters follows a cyclic process of continuous analysis and update (see Figure 5). Thus the validation of the seven key areas is achieved after completing the preliminary stage of Phase V: Identify the mechanisms for measuring.

### Phase V: Identify the mechanisms for measuring

In order to provide a measure of a key area of measurement, it is necessary to have a key performance indicator(s). Generally, there are four ways in which indicators can be formulated: (1) questions or series of questions as a part of a structured interview or self-competition questionnaire, (2) recording of individuals' behavior using structured observation, (3) official statistics, and (4) content analysis (i.e. technique to analyze documents and texts to quantify the content into predefined categories). There are also other aspects to consider while using quantitative methods for measurement. A single indicator may incorrectly classify many individuals into it or may capture only a portion or the underlying key area of measurement. Thus, a multiple-indicator measure (i.e. five-point or seven-point Likert scale) is recommended. (Bryman et al., 2015)

In addition to the ways mentioned above, clinical tests are used for measuring key areas related to health outcome in healthcare interventions. The systematic literature review (section 4.1) on healthcare intervention studies reveals that there are multiple combination of measurement or data collection process used in eHealth interventions, e.g. only clinical measurement (Kleiboer et al., 2015), clinical and quantitative measurements (self-completion questionnaire) (Klein et al., 2011), quantitative and qualitative measurements (semi-structured interviews) (Bergmo et al., 2013). The majority of the eHealth interventions are evaluated by clinical tests and quantitative study. Although the use of ethnography can be very insightful, it has limited use till date due to logistical issues such as the need of intensive human resource. Nonetheless, the intervention studies with shorter sample size use ethnography in order to evaluate the interaction between the technology and the human (e.g. Cristancho-Lacroix et al., 2014). Past project documents are also frequently used to assess the implementation of the project (e.g. Leon, Schneider and Daviaud, 2012). The use of qualitative measures is rising in the recent eHealth intervention studies (Leon, Schneider, and Daviaud, 2012; Muhammad and Wickramasinghe, 2014; Aschbrenner et al., 2016), since qualitative methods capture individuals' experiences and perceptions which are crucial for evaluating eHealth interventions (Steele et al., 2016).

### *Phase V in DECI*

DECI is a comparative, multi-center, longitudinal, and randomized study. While randomized experimental studies are the best-suited method to evaluate efficacy in healthcare (Nguyen, 2007), they are not suitable for taking the account of contextual considerations, which have an important role in the success of the eHealth intervention being studied (Catwell and Sheikh, 2009). Hence, DECI aims to use both quantitative and qualitative studies within the randomized experimental trial. The initial step is to identify the appropriate measurement tool or scale for the key areas mentioned in Phase IV. Table 10 presents the initial questionnaires selected for some of the key areas. These questionnaires are selected after an intensive literature study. The primary focus was to identify the questionnaires that are relevant under the DECI circumstance, for instance, the questionnaires that are designed for the elderly patient with mental impairment.

**Table 10.** The alternatives of questionnaires for some of the key areas

| Key areas of measurement | Alternative Questionnaires |
|---|---|
| Improved patients' quality of life (QoL) | EQ-5D-5L; SF-20; QOL-AD |
| Improved autonomy | PAM-13 |
| Improved patients' satisfaction | PSQ-18 |
| Reduced caregivers' burden | Zarit (ZIB) |
| Improved ICG quality of life (QoL) | SF-12; SQLC |
| System usability | SUS |

These questionnaires were presented to the clinical and technical partners to select the best available option out of those. The selection of questionnaires was an iterative process. As pointed out by Bates and Wright (2009) in *Evaluating eHealth: undertaking robust international cross-cultural eHealth research*, the translation of the questionnaires was a primary constraint during the selection of the questionnaires. It was more difficult to reach consensus regarding the questionnaires mentioned above in Table 10 than the scales of health outcomes presented in Table 11. Apart from translation validity issue, the capability of the elderly patient with MCI or MD to answer the questionnaires that include the Likert scale was a critical factor for selecting suitable questionnaires. Another pressing issue was the respondent burden as discussed by Glasgow (2007) in *eHealth evaluation and dissemination research*. After considering these facts, a decision was made to rely more on qualitative data in terms of semi-structured interviews and observations and to reduce the number of questionnaires.

**Table 11.** Scale for measuring the health outcome

| Key areas of measurement | Scales for measurement |
|---|---|
| Health outcome | Activities of daily living (ADL) |
| | Instrumental activity of daily living I-ADL |
| | Camberwell assessment of need for elderly- short form (CANE-S) |
| | Mini mental state examination (MMSE) |
| | Clock drawing test |
| | Clinical dementia rating scale (CDR) |

Cresswell and Sheikh (2014, p. 80) emphasize the importance of using qualitative measurement saying, “Qualitative data can help to shed light on social processes and perceived technical features such as individual attitudes and expectations (interviews and focus groups), planned organizational strategies and policies (documents), and use of technology in context (observations)”. Initially CHI, as the evaluators of DECI decided to use both semi-structured interviews and observation for assessing the key areas of measurement. Eventually carrying out observation seemed to be less applicable in DECI context since a considerable portion of the intervention will take place at patients’ home. However, the semi-structured interviews are going to be used to assess a good number of key areas including the usability satisfaction and the acceptance of the different functionalities of the DECI technology. The total number of patient in DECI intervention study is 610 ranging from 100 to 180 in each pilot. These patients will be randomly divided into three different study groups (one control group, intervention group 1 with integrated care platform, and intervention group 2 with integrated care platform and ICT devices) in each pilot.10 patients from each study group from each pilot will be interviewed. All the FCGs who will be actively involved in the pilot will be interviewed. The interviews will be taken at the end of the study whereas the questionnaires will be used twice; at the beginning and at the end of the pilot. The key areas such as adherence to physical and cognitive exercise will be assessed through the electronic data extracted from the ICT devices. Table 12 presents the final measurement process of the final key areas. This is the outcome of the cyclic movement within phase III, IV, and V. The contextual awareness and the continuous communication with the stakeholders lead to the final version of the key areas and their measurement mechanism.

**Table 12.** Final list of key areas of measurement and corresponding mechanism of measurement

| Key areas of measurement | Mechanism of measurement |
|---|---|
| Adherence to physical activity | Data extracted from ICT devices |
| Adherence to cognitive stimulation | Data extracted from ICT devices |
| Patients’ autonomy | Interpreted from ADL, I-ADL |
| Patients’ satisfaction | Questionnaire (PSQ-18) |
| Patients’ quality of life (QoL) | Questionnaire (EQ-5D-5L) |
| Formal caregiver satisfaction | Questionnaire made by CHI |
| Informal caregiver burden | Questionnaire (Zarit) |
| Operational efficiency | Semi-structured interview with patients and formal caregiver |
| Acceptance and usability satisfaction of technology | Semi-structured interview with patients and with formal caregiver |
| Cost | Project documents and cost-benefit analysis |

**Note:** The measurements related to health outcomes are not included in Table 12 as it remains the same as Table 11.

## Phase VI: Reflect and learn from the development process

The last phase of the development of an eHealth evaluation framework is reflection. This phase focuses on the formalization of learning through reflection. The authors of the book titled *Reflection: Turning experience into learning* define *reflection* as an active process of exploration within what have already been experienced (Boud, Keogh and Walker, 2013). The authors also underscore the fact that reflection is instinctive for human nature so much so that it is often overlooked in the formal learning process. From the action research point of view, reflection consists of three tasks: (1) reflect on the design and redesign during the project, (2) evaluate adherence to principles, and (3) analyze intervention results according to the stated goal (Sein et al., 2011). It is noteworthy that like most evaluations of healthcare intervention, evaluation of DECI falls inside the continuum of action research.

### *Phase VI in DECI*

In order to establish the learnings from the development process of the evaluation framework, it is important to assimilate the experiences from the early phases and reflect upon them. This phase will help to formalize the evaluation framework that will be used for DECI. Another important aspect of reflection phase is that it will facilitate the future research in eHealth intervention by providing the proper reasoning of the choices made in the previous phases. The evaluation framework of DECI is still under development phase but once it will be ready to implement, the standardization of the learnings will be conducted as the last phase of the framework development process. We believe that this sort of pursuit will help to share the knowledge and accelerate the growth of evaluation research in eHealth interventions.

# 5. Conclusion

To conclude this study, the following sections present the key findings, a discussion on the main observations, the limitations, and the scope for future research.

## 5.1. Findings

After addressing *RQ1: How do the evaluations vary in eHealth interventions?* it can be said that evaluation in eHealth interventions has not found a standardized procedure yet. This leads to a question of whether it is even possible to have a standardized procedure to carry out an evaluation of something that is so complex and context-dependent. However, it would be appropriate to evaluate an eHealth intervention in a way that provides an enriched description of the intervention and explains the reasoning of the actions taken during the evaluation. A brief summary of our findings from RQ1 are listed as following:

- eHealth intervention can be seen as a continuum of six phases; *design, pre-testing, pilot study, pragmatic trial, evaluation,* and *post-intervention.*
- The evaluation of eHealth intervention starts from the *pre-testing* phase and continues till the *evaluation* phase. However, when an intervention covers more than one phase, then the evaluation phase deals with the summative evaluation as the other phase(s) of the intervention covers the formative intervention. There are seven aspects of eHealth intervention that can be evaluated. They are clinical, human/social, organizational, technological, cost, ethical and legal, and transferability.
- It is important to go through all the phases of the eHealth intervention in order to make it credible and valuable for future. The EeHE-model (Figure 4) exhibits how the evidence of efficacy and effectiveness grows along the phases of the intervention and how the aspects of the evaluation vary along these phases. When different phases focus on evaluating different aspects for evaluation, the evidence is more observable and reliable.

In order to address *RQ2: How can a framework for evaluating an eHealth intervention be developed?* a roadmap for developing the evaluation framework is created (Figure 5). The phases included in the roadmap are *contextual inquiry, identify stakeholders and their needs, define the vision and orientation of the evaluation, identify the objectives and endpoints, identify the key areas of measurement, identify the mechanisms for measuring,* and *reflect and learn from the development process*. These phases guide to build an evaluation framework that will suit the unique aspects of an eHealth intervention. Although this roadmap was created by exploring the case of DECI but it could be applicable to other kind of eHealth interventions.

## 5.2. Discussion

In this section, we have reflected upon the observations that we made during the research process. These observations have primarily resulted from the experience we had in DECI project. However, since we had also been learning from the literature continuously, the observations discussed below are the reflection from both the experience in DECI and the literature.

In this study, we explored the diversified process of evaluating an eHealth intervention and articulated principles for developing a framework for evaluating eHealth interventions delineated by a multinational single case study. Accordingly, the results are framed in that context. In doing so, communication among a multinational, multidisciplinary team represented a challenge. While the setting of the project supports continuous communication and the use of several channels (e.g. Skype calls, email correspondence) achieving consensus on critical topics demanded a significant amount of time. The delay on the agreement was caused not only because of the characteristics of a multidisciplinary team but the differences of the healthcare system among countries. From an overall point of view, unanimity was more difficult to achieve in clinical-related subjects. First, the complexity linked to the treatment of elderly patients with MCI and MD influenced the parameters to develop the evaluation framework of the project (e.g. key areas of evaluation and mechanisms for measuring). Also, the particularities of each clinical site generated the inclusion and exclusion of scales to attain comparable results among countries. Second, eHealth interventions require the combined expertise of clinical and technical partners. However, the non-shared concepts and vocabulary ascribed to different disciplines may complicate the communication among partners. Based on the empirical case, both multidisciplinary meetings and single-discipline meetings (i.e. separated meetings only with clinical partners or only with technical partners) were fundamental to discuss issues regarding the project.

Ethical approval is one of the unique characteristics of research related to healthcare. Ethical approval from a legitimate board is an absolute prerequisite for conducting research that involves patients. All the steps of the pilot project in DECI including every question that will be asked to the patients and every clinical test that will be applied to the patient during the pilot have had been presented to this board in individual countries. The necessity of ethical approval makes the evaluation process rigid to some extent since any change needs to be approved and it is quite a time-consuming process. Moreover, in order to have ethical approval, the evaluation framework needed to be finalized quite earlier compared to the time the pilot will start. Another limitation caused by this is the limited use of formative evaluation. Formative evaluation provides real-time feedback so that the implementation of the intervention can be improved. But changing the plan that involves patient is not available, as the new plan needed to be approved by the ethical committee. The need for ethical approval may also pose some serious constraints to develop the technology for healthcare since it is quite time and resource consuming to include patients in the development process, who are one of the major users of such technologies. Although it is not the case for DECI since the development of the technology used in the pilot is out of the scope of DECI.

We have discussed the importance of understanding the context of the intervention several times in this study. The context plays a huge role in framing the evaluation.

Whether the framework for evaluation is adopted from an existing framework or designed by the project team, the ultimate evaluation is unique for each intervention. The decisions such as how many questions to be asked, whom to ask, what is the most reliable source of data (i.e. the system itself, the patients, the informal caregivers, or the formal caregivers), what is the appropriate data collection method (i.e. self-completed questionnaire, interviews, or observation depend on the specific intervention). As an example, observation could have been a suitable way to collect the data on how the patients are using the new system since self-reported views by elderly patients with MD or MCI are not reliable and the process can be burdensome to the patients. But the intervention is basically providing home-based care and patients will use the technology at their home so observation cannot be a method for data collection. An idea was to ask informal caregiver about this issue, but not in all countries (four pilot countries) patients live with adult caregivers. Eventually, the chosen method was short and semi-structured interview by the doctors. Similarly, every decision has had to consider the specific situation where the intervention is taking place.

Due to the fact that eHealth intervention is context specific, the generalizability and the transferability of the impact of such intervention are quite challenging. This can be one of the reasons behind the eHealth intervention being so fragmented (Ossebaard and Van Gemert-Pijnen, 2016). When some evidence have been collected under a very specific set-up, which is the case for interventions in healthcare, it is hard to establish a conclusion that is applicable for other set-ups. Presenting the intervention as a business model seems to be one way to deliver the created knowledge in a transferable format so that it can be applied in future projects. DECI has a plan to present a business model at the end of the pilot. But the business model is not within the scope of this thesis. From our experience, it can be said that detail explanation of the decisions that have been taken during the intervention and the evaluation and detail description of the context of the intervention may help future researchers to extract useful information.

We believe that the prime object of conducting research is to create knowledge that is reusable. Throughout this study, our endeavor was to bridge the gap between the formal theory and reality. To do so, we aimed to understand and identify the gap and offered the substance that seemed to be logical and beneficial to fill in the gap.

### 5.3. Limitations

This study has few limitations. Being part of DECI, which is a EU project with well-defined structure and methods of organizing tasks, we try to maintain an objective perspective to attain the research purpose. However, there might be some observations made and actions taken that were project specific and may not necessarily be relevant to other eHealth interventions. Another limitation is that the thesis ended before the evaluation framework that will be used in DECI is finalized. This has limited the discussion of the last phase (i.e. *reflect and learn from the development process)* of the development process of the evaluation framework to an extent.

### 5.4. Scope for future research

There is little evidence that suggests the long-term implementation of the technology in healthcare. Neither the literature nor the empirical studies imply the integration of the technology into the healthcare system after the pilot study. In regard to the project in which this study is based, one reason can be attributed to the necessity of results before considering long-term planning. However, from the intervention cases analyzed during the systematic literature review, it seems that few studies have not moved towards pragmatic trials despite achieving positive results from the pilot projects. This finding opens one of the several scopes of future research. We think it will be interesting and relevant to investigate why the most of the eHealth intervention do not proceed for long-term implementation. Besides, if any of the participant countries of DECI decides to use the DECI system or a part of it in their existing care model it will be a valuable project to follow. Another idea of the future research is to explore the development process of the technology such as the assistive or monitoring devices, the applications that are used for healthcare intervention. Undoubtedly there are myriads of such devices and applications but the efficacy of them are hardly proven. Such situation demands a thorough examination of the development process of these technologies.

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# Appendix

## Appendix A: As-Is Template

| Key areas | Categories | | Is the category currently measured in your organization? | | KPI Name in your organization | KPI Formula in your organization | Where is the data stored in your organization? | Frequency of the measurement | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | No | Yes | | | | | |
| 1. Health outcomes | 1.1 | Falls reporting (adopted from 1.4.) | | | | | | | |
| | 1.2. | Emergency calls (adopted from 1.4.) | | | | | | | |
| | 1.3. | Minimum dataset (adopted from 1.4.) | | | | | | | |
| | 1.3.1. | Mini-Mental State Examination (MMSE) | | | | | | | |
| | 1.3.2. | Clock drawing test | | | | | | | |
| | 1.3.3. | Clinical Dementia Rating Scale | | | | | | | |
| | 1.3.4. | Basic ADL | | | | | | | |
| | 1.3.5. | Instrumental ADL | | | | | | | |
| | 1.3.6. | Camberwell Assessment for the Elderly Short form (CANE-S) | | | | | | | |
| | 1.4. | Primary care visits (adopted from 1.4.) | | | | | | | |
| | 1.5. | Adherence to cognitive stimulation (adopted from 1.4.) | | | | | | | |
| | 1.6. | Adherence to physical activity (adopted from 1.4.) | | | | | | | |
| 2. Patients' empowerment | 2.1. | Confident to take actions that will prevent or minimize the symptoms or problems | | | | | | | |
| | 2.2. | Knowledge about disease | | | | | | | |
| | 2.3. | Knowledge about medicine | | | | | | | |
| | 2.4. | Ability to follow the instructed lifestyle | | | | | | | |
| | 2.5. | Right and responsibility to access own health information | | | | | | | |
| 3. Patients or relatives' satisfaction | 3.1. | Quality of care- Emotional aspect | | | | | | | |
| | 3.2. | Quality of care-Qualification of staff | | | | | | | |
| | 3.3. | Accessibility | | | | | | | |
| | 3.4. | Facilities | | | | | | | |
| | 3.5. | Availability | | | | | | | |
| | 3.6. | Continuity of care | | | | | | | |
| | 3.7. | Efficacy/Outcome of care | | | | | | | |
| | 3.8. | Affordability | | | | | | | |

| Key areas | Categories | | Is the category currently measured in your organization? | | KPI Name in your organization | KPI Formula in your organization | Where is the data stored in your organization? | Frequency of the measurement | Comments |
|---|---|---|---|---|---|---|---|---|---|
| | | | No | Yes | | | | | |
| 4. Patients' Quality of Life | 4.1. | Social engagement | | | | | | | |
| | 4.2. | Emotional functioning | | | | | | | |
| 5. Process efficiency | 5.1. | Service utilization | | | | | | | |
| | 5.2. | Waiting-time | | | | | | | |
| | 5.3. | Service time/ Cycle time | | | | | | | |
| | 5.4. | Distribution of time between administrative work and care delivery | | | | | | | |
| | 5.5. | Multidisciplinary team meetings/ Consultancy (adopted from 1.4.) | | | | | | | |
| 6. Staff/ caregivers' satisfaction | 6.1. | Burden of the caregiver (adopted from 1.4.) | | | | | | | |
| | 6.2. | Family involvement related measurement | | | | | | | |
| 7. Cost | 7.1. | Cost of service | | | | | | | |
| | 7.2. | Cost per patient | | | | | | | |
| | 7.3. | ICT related expenses | | | | | | | |

## Appendix B: Summary table of articles found in the category *Guidelines and frameworks for evaluation of eHealth intervention*.

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
| 1 | A development and evaluation process for mhealth interventions: Examples from New Zealand | Whittaker, R., Merry, S., Dorey, E. & Maddison, R. 2012, "A Development and Evaluation Process for mHealth Interventions: Examples From New Zealand", *Journal of Health Communication*, vol. 17, no. sup1, pp. 11-21. | Process of developing and testing mHealth intervention: conceptualization, formative research to infirm development, pretesting content (content of the technology), pilot study, pragmatic RCT, further qualitative research to inform improvement and evaluation of implementation impact. Strength: the steps involve theory and evidence together; focus on the implementation (large scale implementation after intervention).<br>Weakness: time consuming (3-4 years in these examples). | Framework | Clinical + Ql | - This framework and an example of intervention combine the theory and evidence in a good way. But in order to follow this framework, the evaluators need a long period of time, which is not feasible in most cases. |
| 2 | A framework for evaluating eHealth research | Dansky, K.H., Thompson, D. & Sanner, T. 2006, "A framework for evaluating eHealth research", *Evaluation and Program Planning*, vol. 29, no. 4, pp. 397-404. | The analysis of two eHealth projects challenges base on four dimensions: (1) design and methodology issues; (2) challenges related to the technology itself; (3) environmental issues that are not specific to eHealth but pose special problems for eHealth researchers; and (4) logistic or administrative concerns of the evaluation methodology selected. The four dimensions are used to create a holistic framework for eHealth design and implementation. | Framework to design and implement eHealth. | Project 1 & Project 2: RCT<br>Framework propose a Ql + Qn approach | - This framework and an example of intervention combine the theory and evidence in a good way. But in order to follow this framework, the evaluators need a long period of time, which is not feasible in most cases.<br>- Training must be provided prior to technology deployment and throughout the course of the project. |
| 3 | A holistic framework to improve the uptake and impact of eHealth technologies | Gemert-Pijnen, v., Julia E.W.C, Nijland, N., Limburg, v., Maarten, Ossebaard, H.C., Kelders, S.M., Eysenbach, G. & Seydel, E.R. 2011, "A holistic framework to improve the uptake and impact of eHealth technologies", *Journal of medical internet research*, vol. 13, no. 4, pp. e111. | To address the low rate of success of eHealth technologies in realizing sustainable innovations in healthcare, the paper analyzes the disregarded interdependence among technology, human characteristics, and the socioeconomic environment in the development of eHealth technologies. The article aims to improve the impact of eHealth technologies by using a holistic approach for the development and later implementation of the technology in the healthcare system. | Framework | Ql | - eHealth design requires to take into account the complexity of healthcare systems and the demands of patients and other stakeholders.<br>- In practice, time, policies, and financial considerations may hinder the use of the full framework.<br>- The framework is flexible and can be used for the development of the eHealth intervention (forward) or to perform summative evaluation (backward). |
| 4 | A model for assessment of telemedicine applications: MAST | Kidholm, K., Ekeland, A.G., Jensen, L.K., Rasmussen, J., Pedersen, C.D., Bowes, A., Flottorp, S.A. & Bech, M. 2012, "A model for assessment of telemedicine applications: mast", *International journal of technology assessment in* | This article presents the Model for Assessment of Telemedicine applications (MAST). The framework aims to assist decision makers with the selection of the most efficient and cost-effective telemedicine applications. | Framework | Ql | - The framework is based on the EUnetHTA Core HTA Model.<br>- MAST is composed by three elements: (1) Preceding considerations, (2) Multidisciplinary assessment, and (3) Transferability assessment.<br>- While assessing telemedicine applications, the main objective is to measure the |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
| | | *health care*, vol. 28, no. 1, pp. 44-51. | | | | effectiveness and the level of contribution to the quality of care of the telemedicine applications. |
| 5 | A new method for assessing content validity in model-based creation and iteration of eHealth interventions | Kassam-Adams, N., Marsac, M.L., Kohser, K.L., Kenardy, J.A., March, S. & Winston, F.K. 2015, "A new method for assessing content validity in model-based creation and iteration of 4eHealth interventions", *Journal of medical Internet research*, vol. 17, no. 4, pp. e95 | The paper provides a method of assessing the content validity of the eHealth interventions. The method is five steps as follow: identify objectives of the intervention, delineate activity-target pairing, using content validity survey tool (consists of: activity's relevance, likely effectiveness, appropriateness of the specific intended group) among experts outside of the intervention but with proper knowledge, rating of the intervention by the experts, and analyze result and refine the intervention. | A method that complements the evaluation of the intervention but it is not supplementary to the evaluation process. | Ql + Qn | - The paper advocates that an intervention that is design based on a theory or model (i.e. program theory) has larger effect.<br>- Qualitative data (reviewers' narrative comments) are helpful in understanding the gaps and strength of the intervention. |
| 6 | An evaluation framework for Health Information Systems: human, organization and technology-fit factors (HOT-fit) | Yusof, M.M., Kuljis, J., Papazafeiropoulou, A. & Stergioulas, L.K. 2008, "An evaluation framework for Health Information Systems: human, organization and technology-fit factors (HOT-fit)", *International Journal of Medical Informatics*, vol. 77, no. 6, pp. 386-398. | The article aims to analyze the current evaluation methods used to assess different aspects of Health Information Systems (HIS). The study proposes a new evaluation framework: Human, Organization and Technology-fit (HOT-fit) developed after the critical appraisal of existing HIS evaluation studies. | Framework | Ql (literature) + Ql (observation, interviews and documents' analysis) | - Health Information Systems (HIS) require comprehensive evaluation that addresses technology, human, and organization perspectives.<br>- HOT-fit is built base on existing models of HIS evaluation: (1) the Information System (IS) Success Model and (2) the IT-Organization Fit Model.<br>- Having the right user attitude and skills combined with good leadership, IT-friendly environment and effective communication have a positive impact on the system adoption. |
| 7 | Design of telehealth trials - Introducing adaptive approaches | Law, L.M. & Wason, J.M.S. 2014, "Design of telehealth trials--introducing adaptive approaches", *International journal of medical informatics*, vol. 83, no. 12, pp. 870-880. | Provides various adaptive approaches for designing the telehealth trials, which are applicable to general eHealth trials. Discuss about the challenges i.e. uncertain parameters, multiple endpoints, efficiency and ethics, compliance and usability, heterogeneity among response to telehealth and provides adaptive measures to minimize the effect of the challenges. | Several adaptive approaches for designing intervention | Ql (Literature) | - Adaptive design: new design can be made about the design or progress of trial, once the trial is already underway.<br>- Talks about the importance of evaluating compliance and usability of technology<br>- Talks about multiple endpoints<br>- Provides various adaptive approaches to design intervention. |
| 8 | Designing eHealth that matters via a multidisciplinary requirements development approach | Van Velsen, L., Wentzel, J. & Van Gemert-Pijnen, J.E. 2013, "Designing eHealth that Matters via a Multidisciplinary Requirements Development Approach", *Journal of Medical Internet Research*, vol. 15, no. 6. | It provides a method of identifying and communicating the requirements of an eHealth technology from a multidisciplinary team based on user-centered and business model approach. The method lies within the CeHRes Roadmap and consists of 5 phases: preparation, end-user and stakeholder identification, and requirement elicitation, communicating requirements. Strength: | A method for identifying requirements while designing the eHealth technology. | Ql | - Suggest evaluating eHealth on a feature-specific level in order to learn why a technology lives (or does not) up to the expectations.<br>The importance of considering context has been mentioned several times.<br>- Business model as a base for creating fit among technology, organizational |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
| | | | thorough, limitation: time consuming. | | | procedure and resources CeHRes roadmap consists both summative and formative evaluation. |
| 9 | Developing internet-based health interventions: A guide for public health researchers and practitioners | Horvath, K.J., Ecklund, A.M., Hunt, S.L., Nelson, T.F. & Toomey, T.L. 2015, "Developing Internet-based health interventions: a guide for public health researchers and practitioners", Journal of medical Internet research, vol. 17, no. 1, pp. e28. | A sample of six study coordinators and five principal investigators were interviewed about the process of developing online interventions to provide insights fore researchers and practitioners who are considering technology-based interventions (insights for the process of developing online applications) | Seven points to take into account while developing an web-based intervention project | Ql + Qn | - Hire a strong (or at least the right) research team.<br>- Take time to plan before beginning the design process.<br>- Recognize that vendors and researchers have differing values, objectives, and language.<br>- Develop a detailed contract.<br>- Document all decisions and development activities.<br>- Use a content management system.<br>- Allow extra time for testing and debugging your intervention. |
| 10 | EHealth and quality in health care: Implementation time | Ossebaard, H.C. & Van Gemert-Pijnen, L. 2016, "eHealth and quality in health care: implementation time", *International journal for quality in health care: journal of the International Society for Quality in Health Care / ISQua*, vol. 28, no. 3, pp. 415-419. | It discusses about the importance of proper implementation process of eHealth. It discusses findings on quality in healthcare, eHealth, and implementation. Though it does not provide any framework but advocates for CeHRes roadmap. Last but not the least the paper heavily focus on the human aspect of the technological intervention and describe the importance of acceptance, adoption and adherence. | Discussion on how to implement and evaluate eHealth intervention to get the maximum benefit out of it. | Ql (Literature) | - Outcome indicators measuring patients' experience outweigh the so-called process indicators as later do not always correspond to clinical outcome hence quality of care.<br>- 6 components of quality in healthcare: safety, effectiveness, patient-centeredness, timeliness, efficacy and equity.<br>- EHealth intervention is fragmented, short of breath, lacking in vision and strategy.<br>- Conventional controlled or randomized study designs are less appropriate for evaluation of eHealth as it is characterized by complex and sociotechnical dynamics. |
| 11 | EHealth evaluation and dissemination research | Glasgow, R.E. 2007, "eHealth Evaluation and Dissemination Research", *American Journal of Preventive Medicine*, vol. 32, no. 5, pp. S119-S126. | It focuses on the gap between research and clinical practice. Discusses the challenges such as respondent burden, time required to assess behavior changes. It mentions several frameworks including author's own RE-AIM (another article). It recommends for making the intervention representative, replicable and robust. | Discussion on RE-AIM regarding the challenges in eHealth intervention and overcoming them. | Ql | - Both quantitative and qualitative data.<br>- Understanding the context. Thorough assessment is not costly, feasible if the project records are kept systematically (Evaluation process). |
| 12 | EHealth wiki-platform to increase the uptake and impact of eHealth technologies | Van Gemert-Pijnen, J.E.W.C., Nijland, N., Van Limburg, A.H.M., Kelders, S.M., Van Velsen, L., Brandenburg, B. and Ossebaard, H.C. 2012, "eHealth wiki-platform to | The article provides a holistic roadmap on the development of the technology in order to improve the impact of eHealth. The roadmap has five steps, i.e. contextual inquiry, value specification, design, operationalization, and evaluation cycle, The evaluation cycle consists both summative and | Discussion | Ql (Literature) | - The article discusses the importance of context, stakeholders and both, the summative and formative evaluation. |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
| | | increase the uptake and impact of eHealth technologies", In Proceedings *4th International Conference on eHealth, Telemedicine, and Social Medicine eTELEMED*, p. 184. | formative evaluation and the later one takes place throughout the roadmap. | | | |
| 13 | ELEMENTS FOR ASSESSMENT OF TELEMEDICINE APPLICATIONS | Ohinmaa, A., Hailey, D. & Roine, R. 2001, "ELEMENTS FOR ASSESSMENT OF TELEMEDICINE APPLICATIONS", *International Journal of Technology Assessment in Health Care*, vol. 17, no. 2, pp. 190-202. | As an initiative of the International Network of Agencies for Health Technology Assessment, the study provides an approach to assess telemedicine applications, and to assist decisions makers who are considering the implementation of a telemedicine technology. | Framework | Ql (literature) | - The developed business case included population, services, personnel and consumers, delivery arrangements, specifications and costs.<br>- The study included three phases: (1) development of the business model, (2) evaluation of the telemedicine application, and (3) follow-up<br>- Evaluation and follow up included the domains of technical assessment, effectiveness, user assessment of the technology, costs of telemedicine, trials, economic evaluation methods, and sensitivity analysis.<br>- Decisions makers should take into consideration the relationship among the introduction of a new technology, its cost, and its feasibility.<br>- The evaluation should include the possibility of long-term sustainability and impact on the healthcare system<br>- Because of the local context related to the implementation of telemedicine applications, the results of effectiveness and efficiency may not be generalizable. |
| 14 | Ensuring Evidence-Based Safe and Effective mHealth Applications | Vallespin, B., Cornet, J. & Kotzeva, A. 2016, "Ensuring Evidence-Based Safe and Effective mHealth Applications", *Studies in health technology and informatics*, vol. 222, pp. 248 | It discusses on the several things such as promises of mHealth, category of mHealth technology, challenges of mHealth adoption and the evaluation of mHealth. It discusses three framework of evaluation (**Kidholm K et al., 2012; Catwell & Sheikh, 2009, Yusof et al., 2008**). It proposes regulatory framework, standardization and interoperability, and certification of application to overcome the challenges. | Discussion | Ql (Literature) | - Technologic turnover and strong influence of design and organizational context make eHealth evaluation challenging.<br>- Very little scientific success evidence found in mHealth. Evaluation approach should be iterative and involve the views of stakeholders.<br>- Lack of agreement for common research method for mHealth assessment hinders the generalization of reliable and comparable knowledge. |
| 15 | Establishing | Proudfoot, J., Klein, B., Barak, | Establishes a guideline to execute and report | Framework | Ql (Literature) | - The framework is very broad but useful. |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
|  | guidelines for executing and reporting internet intervention research | A., Carlbring, P., Cuijpers, P., Lange, A., Ritter band, L., Andersson, G. 2011, "Establishing Guidelines for Executing and Reporting Internet Intervention Research", *Cognitive Behaviour Therapy*, vol. 40, no. 2, pp. 82-97 | internet evaluation research. The framework has triple layer as follow: mapping sentence (3), core facets (12), and elements. The core facets are focus and target population, authorship detail, **model of change**, type and dose of intervention, **ethical issues,** professional support, other support, program interactivity, multimedia channel of delivery, degree of synchronicity, audience reach, **program evaluation.** Each facet has guidelines. |  |  | - Talks about outcomes i.e. clinical, QoL and also process outcome for evaluation to shed light on delivery mechanism.<br>- The guideline of program evaluation is efficacy, effectiveness, and readiness for mass dissemination.<br>- The heterogeneity among the studies limits the comparison among them and lead to confounding interpretation. |
| 16 | Estimating the success of e-health collaborative services: the THEMIS framework | Gortzis, L.G. 2011, "Estimating the success of e-health collaborative services: the THEMIS framework", *Informatics for Health and Social Care*, vol. 36, no. 2, pp. 89-99. | This study proposes a prototype framework (THEMIS) for estimating algebraically the success (S) of the electronic health collaborative services (e-HCS) and examines two hypotheses: (1) S estimation of an e-HCS, developed by a third-party vendor, demands a 'shrunk formative model' and (2) Causal relationships between the involved dimensions (Fitness for Purpose (FFP), Collaborators objections (CO), Costs (COSTS)) do exist, and their parameters affect the S – from weakly to strongly and vice-versa. | Framework that estimates algebraically the S of an e-HCS developed by a third-party vendor (pilot e-HCS) | Ql + Qn | - Success (S) should be estimated using a **socio-technical framework** and the same rigor as a treatment program.<br>- **Content** (what data are being used and why), **process** (who is evaluating and how) and the **context** (with what) must be considered simultaneously.<br>- Due to causality, there is an agreement that standalone data-extraction methods (i.e. questionnaires, concept briefings, etc.) have limited capabilities in the initial phase of the success estimation and success judgment process.<br>- The translation of the summative data into YES or NO answers might introduce some bias --> **analysis of the type of questions used.** |
| 17 | EUR-ASSESS Project Subgroup Report on Methodology: Methodological Guidance for the Conduct of Health Technology Assessment | Liberati, A., Sheldon, T.A. & Banta, H.D. 1997, "EUR-ASSESS Project Subgroup Report on Methodology: Methodological Guidance for the Conduct of Health Technology Assessment", *International Journal of Technology Assessment in Health Care*, vol. 13, no. 2, pp. 186-219. | The report aims to identify the key elements of health technology assessment. By having a standard set of principles and methods HTA provides a basis for collaboration and eases the identification of areas where the results cannot be generalized. Specifically, the report seeks to contribute to three aims: (1) To promote common elements in an assessment, (2) To promote common methods; and (3) To promote a common reporting structure. | Framework | Ql | - The quality of health care and health policy decisions may improve by the use of a framework for identifying and assessing health technologies.<br>- Health technology assessment (HTA) must be tailored to the needs of a particular situation (making process, political factors and influences, and cultural variability)<br>- There is not one process or method of HTA applicable to all circumstances. |
| 18 | Evaluating eHealth: how to make evaluation more methodologically robust | Lilford, R.J., Foster, J. & Pringle, M. 2009, "Evaluating eHealth: how to make evaluation more methodologically robust", *PLoS medicine*, vol. 6, no. 11, | Provide an approach of evaluation for IT systems introductions in healthcare based on the National Programme for Information Technology (NPFIT) while trying to move towards a single, centrally mandated electronic care record for patients and to connect general practitioners to | Learning points | Ql (Literature) | - Multiple methods research is the best way to evaluate eHealth is through **methodological pluralism** (undertaking combined quantitative and qualitative work when evaluating IT systems).<br>- Observations at Patient and |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
|---|---|---|---|---|---|---|
| | | pp. e1000186. | hospitals. | | | System Level. IT may impact at many levels in the organization and may have many effects (good or bad) at these different levels: **causal chain**.<br>- Both Formative and Summative Assessment.<br>- Both External and Internal Assessments |
| 19 | Evaluating eHealth interventions: the need for continuous systemic evaluation | Catwell, L. & Sheikh, A. 2009, "Evaluating eHealth interventions: the need for continuous systemic evaluation", *PLoS medicine*, vol. 6, no. 8, pp. e1000126. | This paper provides a novel approach for eHealth intervention evaluation- that is a continuous systemic evaluation through the life cycle of the intervention. The life cycle is identified as inception, requirements and analysis, design, develop and test, and implement and deploy. Each phase has own evaluation steps (pg. 4, fig.1). | Framework | Ql (Literature) | - Both summative and formative evaluation RCT is not enough to capture the effect of the complex intervention like eHealth. As this method fails to take contextual and sociotechnical influences into account.<br>- The potential benefit of eHealth still does not equate with empirical demonstrations. |
| 20 | Evaluating eHealth: undertaking robust international cross-cultural eHealth research | Bates, D.W. & Wright, A. 2009, "Evaluating eHealth: undertaking robust international cross-cultural eHealth research", *PLoS medicine*, vol. 6, no. 9, pp. e1000105. | This paper discusses on the cross-country effort on the research of eHealth interventions to make it more robust. the challenges of eHealth in global context include translation of content. tendency of deploying eHealth without evaluating it, variance in respect to ethics, very few cross-country collaboration. The ways of improving collaboration are, education about eHealth research, common definition and outcome measures, using common guidelines for reporting. | Discussion | Ql (Literature) | - Translation of the content issue. The potential benefit of eHealth still does not equate with empirical demonstrations. |
| 21 | Evaluating the Public Health Impact of Health Promotion Interventions: The RE-AIM Framework | Glasgow, R.E., Vogt, T.M. & Boles, S.M. 1999, "Evaluating the public health impact of health promotion interventions: the RE-AIM framework", *American Journal of Public Health*, vol. 89, no. 9, pp. 1322-1327. | The study proposes a model (RE-AIM model) for evaluating public health interventions. The model encompasses five dimensions: reach, efficacy, adoption, implementation, and maintenance. | Framework | Ql | - All the dimensions assessed occur in thee different levels: individual, clinic or organization, and community.<br>- The assessment of dimensions such as reach, adoption, and implementation are crucial to evaluate programs that are intended to become wide-scale implementations. |
| 22 | Experience with a structure, process and outcome framework for evaluating an information system. | Cornford, T., Doukidis, G. & Forster, D. 1994, "Experience with a structure, process and outcome framework for evaluating an information system", *Omega*, vol. 22, no. 5, pp. 491-504. | The study presents the structured evaluation of an information system, based on a case with medical decision-aid system in developing countries. The paper provides a framework for evaluating that combines the analysis of information systems and health policies. | Framework | Ql + Qn | - The framework covers three concepts: the information system's structure, the process that the system supports, and the outcome of the system use.<br>- The analysis is considered in three levels: (1) System's functioning, (2) Human and user perspectives and the overall impact of the system, and (3) The impact on the health care system.<br>- Ex post evaluation: evaluation as a part of the overall process of systems |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | | | | | development and not as a single activity undertaken in the initial stages of a development effort to justify an expenditure of resources.<br>- Ex ante evaluation: evaluation should not be seen as an activity to be undertaken at a late stage to validate the initial decision to go ahead with a development. |
| 23 | Guideline for good evaluation practice in health informatics (GEP-HI) | Nykanen, P., Brender, J., Talmon, J., Keizer, d., N, Rigby, M., Beuscart-Zephir, M.C. & Ammenwerth, E. 2011, "Guideline for good evaluation practice in health informatics (GEP-HI)", *International Journal of Medical Informatics*, vol. 80, no. 12, pp. 815-827. | This paper provides a set of guidelines for planning and executing evaluation studies. It is called Good Evaluation Practice for Health Informatics (GEP-HI). The phases of the guidelines are: preliminary outline, study design, operationalization of methods, project planning, and execution of the evaluation study, completion of the evaluation study. Each phase has several numbers of items. As agreed by the authors, it is very broad and generalized offering | Guidelines | Ql (Literature) | - Discussed about a good number of existing frameworks: HIT, MAST, AHRQ, CONSORT, EQUATOR network. |
| 24 | Heuristic evaluation of EHealth interventions: Establishing standards that relate to the therapeutic process perspective | Baumel, A. & Muench, F. 2016, "Heuristic Evaluation of EHealth Interventions: Establishing Standards That Relate to the Therapeutic Process Perspective", *JMIR mental health*, vol. 3, no. 1, pp. e5. | Discuss the relevant principles and concepts for evaluating interventions form the perspective of the minimum standards that eHealth interventions targeting behavioral and mental health should meet with regard to patients needs in the therapeutic process prior to empirical examination of a **product.** | Guideline for heuristic evaluation of eHealth interventions | Ql (Literature) | - Heuristic evaluation:<br>1. Particularly in terms of identifying problems with user interface usability.<br>2. Broad principles of product design that can be inspected by evaluators prior to empirical testing.<br>3. Implemented widely and transferred easily to new organizational contexts.<br>- Four main points:<br>1. The product should be as easy to use as products in similar settings.<br>2. The ehealth intervention should respond to the user’s needs with respect to the specific clinical setting.<br>3. The ehealth intervention should make it easier for users to engage in therapeutic activities by providing them with the relevant tools “in house”.<br>4. The ehealth interventions should provide a feasible therapeutic pathway to growth |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| 25 | How can research keep up with eHealth? Ten strategies for increasing the timeliness and usefulness of EHealth research | Baker, T.B., Gustafson, D.H. & Shah, D. 2014, "How can research keep up with eHealth? Ten strategies for increasing the timeliness and usefulness of eHealth research", *Journal of medical Internet research*, vol. 16, no. 2, pp. e36. | Strategies of improving the efficiency of eHealth research: think small, use efficient design, anticipate the next big thing, study universals, improve information delivery system, develop models including mediators and moderators. Strategies for improving the quality of eHealth interventions: continuous quality improvement, help consumers identify quality, reduce costs of care, and deeply understand users. | Guidelines/strategy | Ql (Literature) | - The shelf life of technology and publishing research on eHealth intervention.<br>- Due to the elongated time that an, eHealth intervention takes to be evaluated (from the development of the tech to show the proof of improvement), the technology may become less attractive. Sometimes the commercial tech intervention are used widely compare to the validated intervention.<br>- Talks mostly about RCTs, factorial study design, SMART. |
| 26 | How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research | Gaglio, B., Phillips, S.M., Heurtin-Roberts, S., Sanchez, M.A. & Glasgow, R.E. 2014, "How pragmatic is it? Lessons learned using PRECIS and RE-AIM for determining pragmatic characteristics of research", *Implementation science: IS*, vol. 9, no. 1, pp. 96 | The article applies two frameworks in three different interventions to determine how pragmatic the design of the interventions is. The frameworks are PRECIS (Pragmatic Explanatory continuum Indicator Summary) and RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance). Pragmatic trials are designed to evaluate the effectiveness in real world setting whereas explanatory trails evaluate whether the intervention works in optimal situation. | Learning points about the frameworks | Qn | - Analyzing the design of trial is crucial for evaluation as trials are frequently designed for explanatory trials but evaluated as pragmatic trials and lead to ineffective result.<br>- The characteristic of pragmatism is within a continuum so it is quite difficult to define a trail as explanatory or pragmatic. |
| 27 | Implementation science approaches for integrating eHealth research into practice and policy | Glasgow, R.E., Phillips, S.M. & Sanchez, M.A. 2014, "Implementation science approaches for integrating eHealth research into practice and policy", *International journal of medical informatics*, vol. 83, no. 7, pp. e1-e11. | The aim of the paper is to summarize key issues in the eHealth field from an implementation science (IS) perspective and to highlight illustrative processes, examples and key directions to help more rapidly integrate research, policy and practice. | Rapid and relevant research: IS methods for development and assessment of eHealth. | Ql (Literature) | - **Rapid and relevant research:** cycle of innovation and rapid testing, reduce the time between assessment and identification of exemplars and dissemination into practice (1-2 years) **Traditional research pipeline:** 7 + years.<br>- **IS models:** 60 frameworks (e.g. Evidence Integration Triangle, Expanded Chronic Care Model (CCM), Health Literate Care Model, RE-AIM) **key elements of IS methods:** assessment Evaluability/Health Technology, RE-AIM, cost and economic, contextual Dynamic systems models, N-of-1, A–B quasi experimental, multiphase optimization strategies (MOST), and sequential multiple assignment (SMART) to **answer the "what works?" question**<br>- **Data harmonization**: conduct systematic reviews, research syntheses, and |

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| | | | | | | comparisons across studies |
| 28 | Implementing and adopting electronic health record systems: How actor-network theory can support evaluation | Cresswell, K., Worth, A. & Sheikh, A. 2011, "Implementing and adopting electronic health record systems: How actor-network theory can support evaluation", *Clinical Governance: An International Journal*, vol. 16, no. 4, pp. 320-336. | Integrate actor-network theory (ANT) with other theoretical frameworks to study the implementation and adoption of information technology systems in healthcare by using a case study-based approach informed by multi-sited ethnography | Learning points | Ql | - Conceptual/methodological approaches used: Actor-network theory (ANT), Strong structuration theory (SST), Greenhalgh and Stones' model, Social shaping of technology, Social psychology, Theory of the diffusion of innovations.<br>- ANT: its most radical assumption is that things (such as technologies) are "actors" and as such have the potential to transform and mediate social relationships.<br>- ANT has limited theoretical and practical applicability, which has led some to suggest that it is most useful if combined with other theoretical lenses.<br>- ANT problems:<br>1. The role of wider social factors.<br>2. Going beyond description.<br>3. The positioning of human and non-human actors.<br>4. The problem of defining the network.<br>5. The role of the researcher |
| 29 | Improving Patient Experience and Primary Care Quality for Patients With Complex Chronic Disease Using the Electronic Patient-Reported Outcomes Tool: Adopting Qualitative Methods Into a User-Centered Design Approach | Steele Gray, C., Khan, A.I., Kuluski, K., McKillop, I., Sharpe, S., Bierman, A.S., Lyons, R.F. & Cott, C. 2016, "Improving Patient Experience and Primary Care Quality for Patients With Complex Chronic Disease Using the Electronic Patient-Reported Outcomes Tool: Adopting Qualitative Methods Into a User-Centered Design Approach", *JMIR research protocols*, vol. 5, no. 1, pp. e28. | The objective of this paper is to develop a user-centered qualitative method to design technology used in eHealth. The insights provided by the article both on the use of qualitative method and preferences of elderly people with chronic disease are helpful. The lessons are: developing tools for such patients requires balancing multiple needs, the purpose of the tools should be flexible in design phase attention should be given to organization barrier where tool will be adopted | Learning point | Ql | - User-centeredness while developing tools.<br>- Ql methods capture individual experiences & and perceptions Interpretive description, a method of Ql inquiry draws on data collected through in-depth interviews and focus group to capture human experiences. Detail description on number of interview, focus group is presented. |
| 30 | Making the case for leveraging the patient-centered e-health (PCEH) context to expand information systems theory | Baird, A. 2014, "Making the Case for Leveraging the Patient-Centered E-Health (PCEH) Context to Expand Information Systems Theory", *Communications of the* | This article presents some area for research in patient-centered eHealth context. The areas are platform and portfolio decision, locus of informational control, value appropriation, market structure, and value chain, capabilities and strategies, information system feature and feature | Discussion | Ql (Literature) | - The author divides the research on patients-centered eHealth on deductive and inductive approach.<br>- The first on is conducted on the basis of a theory such as TAM, whereas the latter is conducted with an exploratory view |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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|  |  | *Association for Information Systems*, vol. 34, no.1, p.18. | fatigue, policy, social norm, design science, agency theory and consumer empowerment, behavioral economics |  |  | without following a theory but rather describe the case.<br>- Deductive approach is more prevalent.<br>- A complete understanding of PCEH is possible by understanding pre-consumption (motivation, search, selection), consumption (usage, engagement and retention), and post consumption (satisfaction, loyalty, switching, repurchase). |
| 31 | Methodological considerations in evaluating eHealth interventions | Nguyen, H.Q., Cuenco, D., Wolpin, S., Benditt, J. & Carrieri-Kohlman, V. 2007, "Methodological Considerations in Evaluating eHealth Interventions", *CJNR (Canadian Journal of Nursing Research)*, vol. 39, no. 1, pp. 116-134. | The article reviews issues related to study design, treatment implementation, and outcome measurement in eHealth trial. For the discussion of these issues authors chose clinical trial framework of Phase I-IV. The issues discussed are: selection of comparison group (e.g. should control group be standard care or usual care), randomized or preference of patient (or both?), strengthening effect and minimizing crossover (increasing treatment fidelity while reducing random and unintended variability), measuring outcome relevant to the participants and decision makers. | Discussion | Cl + Qn | - The randomized experimental design provides the strongest evidence on the efficacy of eHealth intervention.<br>- The eHealth intervention with chronic disease should be conducted in the context of existing care-relationship.<br>- Computerized adaptive tests (CAT) for measuring outcomes promises to increase efficiency and measurement precision hence reduce the potential number of needed patients without sacrificing statistical power. |
| 32 | Online research in older adults: lessons learned from conducting an online randomized controlled trial | Nahm, E., Bausell, B., Resnick, B., Covington, B., Brennan, P.F., Mathews, R. & Park, J.H. 2011; 2009;, "Online research in older adults: lessons learned from conducting an online randomized controlled trial", *Applied nursing research* : ANR, vol. 24, no. 4, pp. 269-275 | This article talks about few challenges and strategies to overcome those in online intervention with older adults. The learning points are from a social cognitive theory (SCT) based intervention where recruiting to evaluation were done online. The challenges found out are representativeness (trust issue and recruitment method), informed consent, and retention of participants. The strategies implemented are having a toll-free telephone for inquiry, helpdesk, regular communication from the beginning, using trusted web-portal, having moderator on online discussion, using web tracking program. | Learning point | Not mentioned | - Most of the complaints about the technology were related the Internet service provider (ISP).<br>- For successful online survey implementation, collaboration between researcher and ICT designer is very important. |
| 33 | “Real-world” practical evaluation strategies: a review of telehealth evaluation | Agboola, S., Hale, T.M., Masters, C., Kvedar, J. & Jethwani, K. 2014, ""Real-world" practical evaluation | This paper discusses number of evaluation frameworks and provides strategies for real world evaluation. The evaluation should be conducted through the lifecycle of the intervention | Learning points | Cl + Ql + Qn | - Text boxes in pg. 6 & 8.<br>- Evaluate the whole lifecycle of the intervention.<br>- Involve stakeholder as much and as soon |

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| | | strategies: a review of telehealth evaluation", *JMIR research protocols*, vol. 3, no. 4, pp. e75. | divided as planning, implementation and impact assessment. The challenges with telehealth are: diversity of telehealth program, designs like RCTs might be impractical for these, programs are complex,<br>dynamic and evaluation framework cannot capture all process and outcome metrics satisfactorily. | | | as possible |
| 34 | Relevance of CONSORT reporting criteria for research on eHealth interventions | Baker, T.B., Gustafson, D.H., Shaw, B., Hawkins, R., Pingree, S., Roberts, L. & Strecher, V. 2010, "Relevance of CONSORT reporting criteria for research on eHealth interventions", *Patient education and counseling*, vol. 81 Suppl, pp. S77-S86. | In 1996, 2001, and 2010, the Consolidated Standards of Reporting Trials (CONSORT) group released criteria for reporting critical information about randomized clinical trials (RCT). These criteria were intended to improve the quality and completeness of reporting of RCTs in health care research. The paper focuses on topics such as: Background and objectives, Methods, Participants, Outcomes, Blinding. | Learning points divided by topics | Ql + Qn | - Well-designed and properly executed RCTs provide the best evidence on the efficacy of health care interventions.<br>- Global statements about efficacy will be possible only once an intervention has been compared with multiple control conditions.<br>- Outcomes besides clinical:<br>1. Peripheral dimensions: difficulties in gaining Internet access<br>2. Subjective ratings of factors: satisfaction<br>**Table with the selected criteria** |
| 35 | Single-case experimental designs to evaluate novel technology-based health interventions | Dallery, J., Cassidy, R.N. & Raiff, B.R. 2013, "Single-case experimental designs to evaluate novel technology-based health interventions", *Journal of medical Internet research*, vol. 15, no. 2, pp. e22. | This paper provides an introduction to single-case techniques and highlights advances in developing and evaluating single-case experiments, which help ensure that treatment outcomes are reliable, replicable, and generalizable. It also describes experimental designs that allow researchers to isolate the active elements in a treatment package and to assess the mechanisms of behavior change. | Learning points for different types of single-case designs | Ql (Literature) | - Single-case research requires frequent contact with the participant's behavior, which can be challenging in some research contexts but is more straightforward with technology.<br>- Single-case research is also well suited to demonstrate preliminary efficacy, which can be defined as "clinically significant patient improvement over the course of treatment".<br>- Experimental designs, such as group designs that take only a "snapshot" of behavior, fail to resolve this temporally dynamic feature of behavior.<br>- Single-case research → Component analysis → Determining the active elements may be important to increase dissemination potential and decrease cost.<br>- Some might assume that the issue of generality can be accommodated by inferential statistical testing |
| 36 | Smart designs for smart technologies: | Clough, B.A. & Casey, L.M. 2015, "Smart designs for smart | Base on the fact that traditional research designs, such as the randomized controlled trial (RCT), are | Learning points | Ql (Literature) | - **Single-Case Research**<br>SCR and N-of-1: these designs should be |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | Research challenges and emerging solutions for scientist-practitioners within e-Mental health | technologies: research challenges and emerging solutions for scientist-practitioners within e-mental health", *Professional Psychology, Research and Practice*, vol. 46, no. 6, pp. 429-436. | limited in their capacity to match the pace of development and evolving nature of e-mental health. The paper uses a research example of a Smartphone application (PsychAssist is a smartphone app we designed to assist in the treatment of anxiety in adults) aimed at the treatment of anxiety disorders to illustrate the procedure, value, and clinical applications of each of the emerging research designs. | | | given greater consideration within the e-mental, rapidly implemented and provide results more consistent with the person-centered approach to treatment.<br>Combine data from a series of SCRs can permit sufficient evidence of generalizability, reducing the need for a larger trial.<br>- **SMART**<br>Based on a sequence of decision rules that specify "whether, how, when (timing), and based on which measures, to alter the dosage (duration, frequency or amount), type, or delivery of treatment(s) at decision stages in the course of care. Understand the best sequencing of intervention components. Elements: decision stages, treatment options, tailoring variables, decision rules.<br>- **Multiphase Optimization Strategy (MOST)**<br>Determining the most effective version of an e-mental health intervention. Creating optimal versions of multicomponent interventions (4 steps)<br>- **Continuous Evaluation of Evolving Intervention Technologies CEEBIT** multiple versions of web-based or mobile interventions to be deployed simultaneously |
| 37 | Supporting HITECH implementation and assessing lessons for the future: The role of program evaluation | Jones, E.B., Swain, M.J., Patel, V. & Furukawa, M.F. 2014, "Supporting HITECH implementation and assessing lessons for the future: The role of program evaluation", *Healthcare (Amsterdam, Netherlands)*, vol. 2, no. 1, pp. 4-8. | Present the HITECH logical model: importance of tailoring evaluation activities to each phase of implementation, flexible mixed methods, and continuous formative evaluation. | HITECH logical model | Ql (Literature) | - The framework of the HITECH programs specifically includes evaluation as a continuous activity, to not only ensure the programs promote the meaningful use of health IT, but that health IT supports delivery system transformation.<br>- Challenges:<br>Context sensitivity: Use a variety of data sources to maintain situational awareness of contextual factors.<br>Complex interventions: Timely, flexible evaluation techniques employ mixed |

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| | | | | | | methods.<br>Delivery innovation: Original data sources, theory-building, and effective dissemination<br>**HITECH evaluation logic model** |
| 38 | Technical evaluation of an e-health platform | Lo, O., Fan, L., Buchanan, W.J. and Thuemmler, C., 2012. Technical evaluation of an e-health platform. *IADIS E-Health*, pp.21-28. | The paper proposes an e-Health evaluation framework that aims to provide a concise methodology for the evaluation of e-Health platforms under three main categories: usability evaluation, logistics evaluation and technical evaluation by assessing the key challenges of e-Health from an organizational, public and technical perspective rather than how well the technology works for specific healthcare services. | Framework to evaluate usability, logistics and technical evaluation. | Ql (Literature) | - Key challenges e-Health must overcome, from an organizational perspective, include governance, standardization and cost, whilst from a technical perspective we must consider the functionality, security and scalability of the technology.<br>- This evaluation framework is designed to evaluate already existing e-Health platforms rather than systems that are still in early stages of design.<br>- The experiments just covered technical evaluation with two experiments (see Data analysis in this table) |
| 39 | The application of technology acceptance and diffusion of innovation models in healthcare informatics | Ward, R., 2013. The application of technology acceptance and diffusion of innovation models in healthcare informatics. *Health Policy and Technology*, 2(4), pp.222-228. | This paper analyses the advantages of several relevant models (from the point of view of usability and ease to use) and explores their potential significance for the success or otherwise of health related Information Technology projects, highlighting their weaknesses in relation to the lack of differentiation between technological and human factors which limit their applicability in practice. | Learning points | Ql (Literature) | - “Person factors” play an important role at individual level and “organizational issues” are critical in influencing adoption and acceptance.<br>- Many of the models of innovation acceptance, adoption and diffusion are developed from a limited empirical evidence base and have only been tested by post hoc application.<br>- **Technology acceptance model (TAM):** measures Perceived usefulness and Perceived ease-of-use **Disadvantage:** it is difficult to distinguish if technology usage behavior is caused by the influence of outside factors on one′s intent or by one′s own attitude. Various studies have found that TAM does not fully explain acceptance of IT by health professionals, because of its positivistic approach, which does not fully take into account the qualitative, emotional and cultural components of decision-making in healthcare.<br>- **Proposed models:** Rogers’ diffusion of innovation theory and Greenhalgh′s |

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| | | | | | | model. |
| 40 | The eHealth enhanced chronic care model: a theory derivation approach | Gee, P.M., Greenwood, D.A., Paterniti, D.A., Ward, D. and Miller, L.M.S., 2015. The eHealth enhanced chronic care model: a theory derivation approach. *Journal of medical Internet research*, 17(4), p.e86. | The objective of the paper was to review research on eHealth tools that support self-management of chronic disease using the CCM. The second goal was to present a revised model, the eHealth Enhanced Chronic Care Model (eCCM), to show how eHealth tools can be used to increase efficiency of how patients manage their own chronic illnesses. | Framework Enhanced Chronic Care Model (eCCM)) | Ql | - The model includes six key interdependent components: community resources, health system support, self-management support, delivery system design, decision support, and clinical information systems.<br>- EHealth technology interventions must contain a closed or complete feedback loop (CFL) to have an impact on chronic illness outcomes.<br>- The CCM has two major components: Community and Health Systems, the notion of community should be expanded to include online community and health-related social networks, or eCommunity. |
| 41 | The HTA core model: A novel method for producing and reporting health technology assessments | Lampe, K., Mäkelä, M., Garrido, M.V., Anttila, H., Autti-Rämö, I., Hicks, N.J., Hofmann, B., Koivisto, J., Kunz, R., Kärki, P., Malmivaara, A., Meiesaar, K., Reiman-Möttönen, P., Norderhaug, I., Pasternack, I., Ruano-Ravina, A., Räsänen, P., Saalasti-Koskinen, U., Saarni, S.I., Walin, L., Kristensen, F.B. & European network for Health Technology Assessment (EUnetHTA) 2009, "The HTA Core Model: A novel method for producing and reporting health technology assessments", *International Journal of Technology Assessment in Health Care*, vol. 25, no. S2, pp. 9-20. | The study aims to develop and test a generic framework to standardize to enable international collaboration and to facilitate the production and transferability of results while performing Health Technology Assessment (HTA). | Framework | Ql + Qn | - The framework considers nine domains<br>- There are two applications of the HTA Core Model: (1) Medical and surgical interventions and (2) Diagnostic technologies.<br>- Online Handbook available for this framework. |
| 42 | The origin and impact of ideals in eHealth research: experiences from the U-CARE research environment | Sjöström, J., von Essen, L. and Grönqvist, H., 2014. The origin and impact of ideals in eHealth research: experiences from the U-CARE research environment. *JMIR research protocols*, 3(2), p.e28. | The objective of the study is to seek to make explicit contributions to the understanding of ideals in eHealth research, and illuminate their implications for establishing an effective research environment. The analysis draws from three years of experience in establishing an eHealth research environment, and the literature. | Learning points | Ql (Literature) | - The scrutinized ideals are accountability, innovation, rigor, relevance, and sustainability. Theoretical discussion and definitions, stakeholders and managerial implications.<br>- **Accountability:** concerns about privacy issues and avoiding misuse of patient |

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| | | | | | | information.<br>- **Innovation:** In health care research, innovation concerns the translation of evidence-based knowledge into everyday care. There is a need for innovative alternative methods to evaluate complex interventions, such as those developed and evaluated within the U-CARE.<br>- **Relevance:** Researchers should describe the context in which the intervention was developed, applied, and evaluated, so that readers can determine the relevance of the results to their own situation". Research should proactively adopt a stakeholder-centric design process, including a broad range of stakeholders.<br>- **Rigor:** Rigor concerns the effective use of knowledge, including both the theoretical foundations and the research methodology throughout the research process.<br>- **Sustainability:** adds complexity to organizing research, since it enhances the need for competences in social and ethical issues, IP rights, and the design of technology that benefits society outside the scope of the ongoing trials. |
| 43 | The quest for engaging AmI: Patient engagement and experience design tools to promote effective assisted living | Triberti, S. & Barello, S. 2016, "The quest for engaging AmI: Patient engagement and experience design tools to promote effective assisted living", *Journal of Biomedical Informatics*, vol. 63, pp. 150-156. | This paper discussed the current issues of building Ambient Intelligence (AmI) technologies for promoting effective assisted living interventions. (1) Theoretical framework to include patient engagement in the design of AmI technologies. (2) Assessment measures for patient engagement while developing and testing the effectiveness of AmI prototypes for healthcare. (3) Overview of the main issues emerging while implementing AmI technologies and suggests specific design solutions to address them. | Learning points | Ql (Literature) | - ‘‘Engaged” patients, or patients who actively participate in managing their own disease condition, are demonstrated to gain successful clinical outcomes more than patients who simply adhere to treatments in a passivizing logic.<br>- The term Ambient Intelligence refers to monitoring and assistive technologies embedded in the everyday objects, which already affect the everyday activities of the target users.<br>- User Centered Design (UCD) is a type of design whose goal consists in ensuring that no aspects of the user experience take place in the interaction without the designer’s knowledge → the first step is to identify all the different stakeholders |

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| 44 | The use of think-aloud to evaluate a navigation structure for a multimedia health and wellness application for older adults and their caregivers | Chung, J., Chaudhuri, S., Le, T., Chi, N., Thompson, H.J. & Demiris, G. 2015, "The Use of Think-Aloud to Evaluate a Navigation Structure for a Multimedia Health and Wellness Application for Older Adults and Their Caregivers", *Educational Gerontology*, vol. 41, no. 12, pp. 916-929. | Describes the value of the think-aloud usability approach as a simple and relatively inexpensive approach to assessing the usability of health IT systems for older adults and, more broadly, for individuals who take care of or work with older adults. | Learning points | Ql (Literature) | - The think-aloud approach is one of the usability testing methods in which users are asked to verbalize their internal thought process while interacting with a system.<br>1. Usability testing applies different methods towards evaluating a system.<br>1. On the empirical end of the spectrum are performance-based metrics such as task completion time, success rate, time on task, and number of errors.<br>2. Qualitative measures include descriptive lists of usability problems and perceptions related to ease and effectiveness of a system.<br>3. Testing may be used during the whole life cycle of the HIT system— either during the design and development process (formative evaluation) or once the system is implemented (summative evaluation)<br>**Checklist for Implementing Think-Aloud Protocol.** |
| 45 | Towards a shared service centre for telemedicine: Telemedicine in Denmark, and a possible way forward | Larsen, S.B., Sørensen, N.S., Petersen, M.G. & Kjeldsen, G.F. 2016, "Towards a shared service centre for telemedicine: Telemedicine in Denmark, and a possible way forward", *Health Informatics Journal*, vol. 22, no. 4, pp. 815-827. | This article presents results from a multi-stakeholder project that developed a new concept, a 'shared service centre' for telemedicine that is envisioned as working across different telemedical initiatives to support the implementation and wider adoption of telemedicine. | Learning points | Ql | - The purpose of the 'shared service centre SSC project was to design an organizational construct that could work across different telemedical setups, and leverage the adoption and practice of telemedicine.<br>- Four categories of services:<br>1. Technical support and logistics: The SSC must provide first-level technical support to healthcare professionals and patients, delivery and pickup of telemedical equipment, setup, installation and testing, system administration, cleaning and preparation of equipment for other patients, and educating users in its use. |

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|  |  |  |  |  |  | 2. Information and coordination: SSC must run a platform for data sharing.<br>3. Self-service and personal care coordinator: must provide the patient with access to calendars, contact data, monitoring data, reports, and communities of peers.<br>4. Knowledge and development centre: both clinically and organizationally, the SSC must facilitate a knowledge centre that collects experiences and resources related to various, certified telemedical solutions.<br>- The SSC project set out to identify a better way to integrate telemedicine into healthcare, not by inventing a new healthcare authority, but by pursuing a virtual organization combining the existing resources. |
| 46 | Undertaking sociotechnical evaluations of health information technologies | Cresswell, K.M. & Sheikh, A. 2014, "Undertaking sociotechnical evaluations of health information technologies", *Informatics in primary care*, vol. 21, no. 2, pp. 78-83. | Explains what sociotechnical evaluations are, consider the contexts in which these are most usefully undertaken, explain what they entail, reflect on the potential pitfalls associated with such research, and suggest possible ways to avoid these. | Learning points | Ql (Literature) | - Sociotechnical evaluations involve researching the way technical and social dimensions change and shape each other over time.<br>- The dimensions explored in an evaluation may encompass investigating how technologies change social processes and how technologies themselves can change over time as a result of user/organizational requirements.<br>- Sociotechnical evaluations should ideally be undertaken using a prospective design, as this can help to map and understand the interplay between the technology and the social context, and thereby identify important insights into how the technology is received and used.<br>- **Mixed-methods** sociotechnical evaluations are becoming more popular and are likely to represent an important expansion area for this research approach.<br>- Learning across implementations can be |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | | | | | promoted by identifying what mechanisms underlie observations and hypothesizing if/how these may be applicable to other contexts → **Realistic evaluation perspective**<br>- A lack of existing overall framework through which implementations can be examined<br>**BOX 2: existing approaches** |
| 47 | What have we learned about trial design from NIMH-funded pragmatic trials? | March, J., Kraemer, H.C., Trivedi, M., Csernansky, J., Davis, J., Ketter, T.A. & Glick, I.D. 2010, "What Have We Learned about Trial Design From NIMH-Funded Pragmatic Trials?", *Neuropsychopharmacology*, vol. 35, no. 13, pp. 2491-2501. | The objective of the paper is to answer the question 'what have we learned about the design of pragmatic clinical trials (PCTs) from the recent costly long-term, large-scale trials of psychiatric treatments?' | Learning points | Ql (Literature) | - 8 factors to ensure that a trial is fully pragmatic.<br>- All of the T-PCTs (not fully pragmatic) attempted to answer multiple research questions, not one straightforward clinically relevant question.<br>- In a PCT, extended follow-up is usually implemented using survey-research methodology or, better, via extracting clinical data from an electronic health record.<br>- PCTs must exclude only those patients whom they are ethically obliged to exclude (e.g. those who refuse informed consent).<br>- One of the persistent major problems in many PCTs is that of multiple outcomes → benefit–harm balance → using time to failure of a treatment, with failure defined as the time point when, from the point of view of the clinician and patient (both blinded as to which treatment was being used), the clinical harm outweighs the clinical benefit.<br>- In designing PCTs, potential moderators (age, gender) should be considered 'a priori ' and efforts made to assess them that are consistent with limited patient and investigator burden, e.g., single or a few questions rather than long questionnaires. |
| 48 | What is eHealth (6): perspectives on the evolution of eHealth research | Ahern, D.K., Kreslake, J.M. & Phalen, J.M. 2006, "What is eHealth (6): perspectives on the evolution of eHealth research", | · A series of interviews was conducted among opinion leaders (stakeholders) in eHealth in order to assess the existing strengths and challenges in eHealth evaluation research for health behavior | Learning points | Ql | - Consensus and Standardization: There was universal frustration with the lack of comparability and standardization within the domain of eHealth |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | *Journal of medical Internet research*, vol. 8, no. 1, pp. e4. | change and chronic disease management. | | | - Evaluation Methods and Challenges: **Randomized controlled trials were regarded as the "gold standard"** for evaluating application effectiveness, but stakeholders noted that eHealth presented unique challenges to this study design.<br>- Qualitative, self-report, and Likert scales were named as helpful in obtaining certain types of information, but objective evidence of behavior change was preferred over self-reported measures or patient satisfaction ratings. Stakeholders involved in research and development regarded the creation of an intervention and its evaluation to be a cyclical process.<br>- Quality, Value, and Future Potential: As a component of health care, it was unanimously held that these applications should be tested and ranked in terms of quality in a similar fashion as other treatment regimens.<br>- Health Disparities–eHealth as a Bridge or Another Hurdle?: Stakeholders with a macro- or policy-oriented perspective (developers, researchers, IT opinion leaders) were confident that technology has the ability to surmount factors (e.g., reading literacy, distance and time constraints, language fluency) that contribute to limited access to health care. |

## Appendix C: Summary table of articles found in the category *Barriers and risks of evaluation of eHealth intervention*

| **No.** | **Title** | **Reference** | **Objective** | **Outcome** | **Data collection method** | **Learning points** |
|---|---|---|---|---|---|---|
| 1 | Advancing the practice of online psychotherapy: an application of Rogers' diffusion of innovations theory | Lovejoy, T.I., Demireva, P.D., Grayson, J.L. & McNamara, J.R. 2009, "ADVANCING THE PRACTICE OF ONLINE PSYCHOTHERAPY: AN APPLICATION OF ROGERS' DIFFUSION OF INNOVATIONS THEORY", Psychotherapy: Theory, Research, Practice, Training, vol. 46, no. 1, pp. 112-124. | The articles discusses the challenges of online psychotherapy found in different literature and discuss them in light of the five-user perspective innovation characteristics of Roger's diffusion of innovation theory (DIT), i.e. relative advantage (the barriers: cost of service, infrastructure and training cost,). Compatibility (barriers: dehumanizing, the therapeutic environment, ethical guideline for standard care, privacy, confidentiality and safety, patient and clinician suitability). Complexity (barriers: licensure and jurisdiction concerns). Triability (barriers: ethical guideline for standard care). Observability (barriers: professional reputation and acceptance). | Learning points | N/A | - Roger (2003) diffusion of innovation theory can be a base for the evaluation framework for ICT intervention.<br>- The challenges/barriers presented in the summary are helpful and can be used in our thesis as text. |
| 2 | Challenges and opportunities of eHealth research | Ahern, D.K. 2007, "Challenges and Opportunities of eHealth Research", American Journal of Preventive Medicine, vol. 32, no. 5, pp. S75-S82. | The article describes the context of the eHealth research form the perspective of a project that grants resources on multiple number eHealth programs to understand the research challenges and opportunities.<br>The key challenges are: Stringent institutional review process, recruitment (considering that it takes place online), selected methodology and design challenges (what is control group-the gold standard or the current, randomization), treatment fidelity and attrition (adherence). | Learning points | Ql | - It is hard to compare the results of individual in ICT interventions since each individual may have a unique experience and exposure to technology.<br>- The stakeholders discussed regarding: the need for consensus and standardization of measures and approaches to evaluation in order to integrate the field and ensure comparable results; tension arising from the effort to balance the demands of technology development with those of evaluation, especially around the necessity for measures of efficacy and effectiveness; and given the nascent stage of the field, uncertainty about the future potential for eHealth to enhance quality and value within the healthcare system. |
| 3 | Barriers to Office-Based Mental Health Care and Interest in E-Communication With Providers: A Survey Study | Rai, M., Vigod, S.N. & Hensel, J.M. 2016, "Barriers to Office-Based Mental Health Care and Interest in E-Communication With Providers: A Survey Study", JMIR mental health, vol. 3, no. 3, pp. e35. | The article talks about the patients' interest and barriers to the eHealth applications by using internet and other devices such as mobile phones. The result of the survey shows that the patients who uses social media and has at least one barrier to visit hospital are strongly interested in using eHealth. The majority of the survey group was aged 25-44. Overall patient showed interest in using eHealth for mental health. However the | Learning points | Ql + Qn | - The result of the survey shows that the patients who uses social media and has at least one barrier to visit hospital are strongly interested in using eHealth. The majority of the survey group was aged 25-44. Overall patient showed interest in using eHealth for mental health. However the barriers were privacy issue, loosing in-person connection. |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | | barriers were privacy issue, loosing in-person connection. | | | |
| 4 | Critical Issues in eHealth Research | Atienza, A.A., Hesse, B.W., Baker, T.B., Abrams, D.B., Rimer, B.K., Croyle, R.T. & Volckmann, L.N. 2007, "Critical Issues in eHealth Research", American Journal of Preventive Medicine, vol. 32, no. 5, pp. S71-S74. | This article is an introductory paper of an issue of the journal and discusses about the papers published in that issue. | N/A | N/A | - Articles for the second layer of literature review:<br>1. Hesse BW, Shneiderman B. eHealth research from the user's perspective. Am J Prev Med 2007;32(5S):S97–S103.<br>2. Collins LM, Murphy SA, Strecher V. The Multiphase Optimization Strategy (MOST) and the Sequential Multiple Assignment Randomized Trial (SMART): new methods for more potent eHealth interventions. Am J Prev Med 2007; 32(5S): S112–S118.<br>3. Curry SJ. eHealth research and healthcare delivery: beyond intervention effectiveness. Am J Prev Med 2007; 32(5S): S127–S130. |
| 5 | Magnitude of ehealth technology risks largely unknown | Ossebaard, H., van Gemert-Pijnen, L., de Bruijn, A. and Geertsma, R., 2013. Magnitude of ehealth technology risks largely unknown. Int J Adv Syst Meas, 6, pp.57-71. | The present paper aims to assess the risks of eHealth technologies for both patient safety and quality of care. Identified risks were structured according to a multi-level approach covering risks dealing with either human factors (patient), technology factors or organizational factors, | Learning points | Ql (Literature) | - Risks concerning Human factors:<br>1. Some eHealth applications appear to be more beneficial for specific patient groups.<br>2. A positive association was found between educational level and ability to use the tele-monitoring system without assistance.<br>3. Higher time consumption, unintended adverse effects, and selective benefits differing for sex, education, age and other variables are the risks observed on the side of the human (end-user).<br>- Risks concerning Technology:<br>1. Usability problems among participants.<br>2. The technical problems decreased participants' engagement with the tools.<br>- Risks concerning Organization:<br>1. Increased time consumption, barriers for proper use and financial |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | | | | | issues are the risks observed at the organizational level. |
| 6 | Patients' reported reasons for non-use of an internet-based patient-provider communication service: qualitative interview study | Varsi, C., Gammon, D., Wibe, T. & Ruland, C.M. 2013, "Patients' Reported Reasons for Non-Use of an Internet-Based Patient-Provider Communication Service: Qualitative Interview Study", Journal of Medical Internet Research, vol. 15, no. 11, pp. e246. | The goal of our study was to investigate patients' views of an patient–provider communication services (IPPC) (WebChoice, which was designed to support cancer patients living at home between treatments and during rehabilitation), that they could use from home to pose questions to nurses and physicians at their treatment facility, and their reported reasons for non-use of the service. | Learning points | Ql | - Reasons for Non-Use of the IPPC<br>1. Had Sufficient Access to Information Elsewhere: patients did not have any questions, because they had long-term experience with their illness, some patients also reported having a close relationship with their physician, so that they could drop in if they had questions, lack of time or of motivation was also reported as reasons for non-use.<br>2. Preferred Other Types of Communication: patients preferred to talk to the health care providers, either by telephone or in person, and their experience of getting answers quickly enhanced this practice, the necessity of follow-up questions, and the information seemed more trustworthy when it was explained verbally, instead of written.<br>3. Prevented by Factors Associated With the IPPC: not all patients had understood what the IPPC was, how the service was organized, and what they could use it for., patients think that it would have been more appropriate to introduce the IPPC at an earlier point of time in the disease trajectory. |
| 7 | Which Frail Older Patients Use Online Health Communities and Why? A Mixed Methods Process Evaluation of Use of the Health and Welfare Portal | Makai, P., Perry, M., Robben, S.H.M., Schers, H.J., Heinen, M.M., Olde Rikkert, M.G.M. & Melis, R.J.F. 2014, "Which frail older patients use online health communities and why? A mixed methods process evaluation of use of the health and welfare portal", Journal of Medical Internet Research, vol. 16, no. 12, pp. e278. | The aim was to (1) evaluate differences in use of a personal online health community (POHC) for frail older people in relation to personal characteristics, and (2) explore barriers and facilitators for use as experienced by older people and their informal caregivers, using the case of the Health and Welfare Information Portal (ZWIP). | Learning points | Ql + Qn | - Barriers:<br>1. The physical barriers of working in different institutions located in different geographical locations.<br>2. Not having a timely overview of all professionals involved in the care of the patient.<br>3. Information that colleagues have on the patient.<br>4. How they treat the patient.<br>5. That multidisciplinary consultation |

| No. | Title | Reference | Objective | Outcome | Data collection method | Learning points |
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| | | | | | | can take place only if all professionals are available at the same time.<br>- Having an informal caregiver also contributed positively to ZWIP usage.<br>- All patients slightly decreased in their use of ZWIP over time. |

# Appendix D: Summary table of articles found in the category *Cases of eHealth interventions*

| No. | Title | Reference | Data collection | Frameworks used |
|---|---|---|---|---|
| 1 | A National Patient-Centered E-Health Solution – The Experience from Down Under To-Date with the Personally Controlled Electronic Health Record (PCEHR) | Muhammad, I. and Wickramasinghe, N. 2014, A National Patient-Centered E-Health Solution–The Experience from Down Under To-Date with the Personally Controlled Electronic Health Record (PCEHR). In *Twentieth Americas Conference on Information Systems, Savannah (2014)*. | Ql | - Actor-Network theory, considering social/organizational change and the competence for using technology |
| 2 | A qualitative study of client–clinician text exchanges in a mobile health intervention for individuals with psychotic disorders and substance use | Aschbrenner, K.A., Naslund, J.A., Gill, L.E., Bartels, S.J. & Ben-Zeev, D. 2016, "A Qualitative Study of Client-Clinician Text Exchanges in a Mobile Health Intervention for Individuals With Psychotic Disorders and Substance Use", *Journal of Dual Diagnosis*, vol. 12, no. 1, pp. 63-71. | Thematic analysis of client-clinician text message | No framework |
| 3 | A Randomized Controlled Trial Evaluating a Manualized TeleCoaching Protocol for Improving Adherence to a Web-Based Intervention for the Treatment of Depression | Mohr, D.C., Duffecy, J., Ho, J., Kwasny, M., Cai, X., Burns, M.N. & Begale, M. 2013, "A randomized controlled trial evaluating a manualized TeleCoaching protocol for improving adherence to a web-based intervention for the treatment of depression", *PloS one*, vol. 8, no. 8, pp. e70086. | Cl + Qn | No framework |
| 4 | A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety | Kleiboer, A., Donker, T., Seekles, W., van Straten, A., Riper, H. & Cuijpers, P. 2015, "A randomized controlled trial on the role of support in Internet-based problem solving therapy for depression and anxiety", *Behaviour research and therapy*, vol. 72, pp. 63-71. | Cl | No framework |
| 5 | A web-based program for informal caregivers of persons with Alzheimer's disease: an iterative user-centered design | Cristancho-Lacroix, V., Moulin, F., Wrobel, J., Batrancourt, B., Plichart, M., De Rotrou, J., Cantegreil-Kallen, I. & Rigaud, A. 2014, "A web-based program for informal caregivers of persons with Alzheimer's disease: an iterative user-centered design", *JMIR research protocols*, vol. 3, no. 3, pp. e46. | Qn + Ql | No framework |
| 6 | Actor-network theory and its role in understanding the implementation of information technology developments in healthcare | Cresswell, K.M., Worth, A. & Sheikh, A. 2010, "Actor-Network Theory and its role in understanding the implementation of information technology developments in healthcare", *BMC Medical Informatics and Decision Making*, vol. 10, no. 1, pp. 67-67. | N/A. this paper does not discuss any particular intervention, rather it is a conceptual paper on Activity Network Theory (ANT) | ATN |
| 7 | Anxiety online—a virtual clinic: preliminary outcomes following completion of five fully automated treatment programs for anxiety disorders and symptoms | Klein, B., Meyer, D., Austin, D.W. & Kyrios, M. 2011, "Anxiety online: a virtual clinic: preliminary outcomes following completion of five fully automated treatment programs for anxiety disorders and symptoms", *Journal of medical Internet research*, vol. 13, no. 4, pp. e89. | Cl + Qn | No framework |
| 8 | Applying a framework for assessing the health system challenges to scaling up mHealth in South Africa | Leon, N., Schneider, H. & Daviaud, E. 2012, "Applying a framework for assessing the health system challenges to scaling up mHealth in South Africa", *BMC Medical Informatics and Decision Making*, vol. 12, no. 1, pp. 123. | Ql | - Developed their own framework that has four dimensions: government stewardship, organizational systems, technological system and financial system. This framework is made for |

| No. | Title | Reference | Data collection | Frameworks used |
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| | | | | decision making about mHealth for community based health service (CBS) |
| 9 | Automated telehealth for managing psychiatric instability in people with serious mental illness | Pratt, S.I., Naslund, J.A., Wolfe, R.S., Santos, M. & Bartels, S.J. 2015, "Automated telehealth for managing psychiatric instability in people with serious mental illness", *Journal of mental health (Abingdon, England)*, vol. 24, no. 5, pp. 261-265. | Cl + Qn | - No framework |
| 10 | Building a house on shifting sand: Methodological considerations when evaluating the implementation and adoption of national electronic health record systems | Takian, A., Petrakaki, D., Cornford, T., Sheikh, A., Barber, N., Natl NHS Care Records Serv Evaluat & National NHS Care Records Service Evaluation Team 2012, "Building a house on shifting sand: Methodological considerations when evaluating the implementation and adoption of national electronic health record systems", *BMC Health Services Research*, vol. 12, no. 1, pp. 105-105. | Ql | - Realist and sociotechnical evaluation.<br>- The model has a matrix form where the rows are structure, process and outcome.<br>- The columns are system function, human perspective, and healthcare system. |
| 11 | Effectiveness of an Internet-based preparation for psychosomatic treatment: Results of a controlled observational study | Zimmer, B., Moessner, M., Wolf, M., Minarik, C., Kindermann, S. & Bauer, S. 2015, "Effectiveness of an Internet-based preparation for psychosomatic treatment: Results of a controlled observational study", Journal of psychosomatic research, vol. 79, no. 5, pp. 399-403. | Ql + Qn (no description given on the procedure) | - No framework |
| 12 | Effectiveness of web-based versus folder support interventions for young informal carers of persons with mental illness: A randomized controlled trial | Ali, L., Krevers, B., Sjöström, N., Skärsäter, I., Akademin för hälsa och välfärd, Centrum för forskning om välfärd, hälsa och idrott (CVHI), Hälsofrämjande processer & Högskolan i Halmstad 2014, "Effectiveness of web-based versus folder support interventions for young informal carers of persons with mental illness: a randomized controlled trial", Patient education and counseling, vol. 94, no. 3, pp. 362-371. | Qn | - No framework |
| 13 | Electronic Messaging to Improve Information Exchange in Primary Care | Bergmo, T.S., Ersdal, G., Rødseth, E. & Berntsen, G. 2013. *Electronic Messaging to Improve Information Exchange in Primary Care* [online]. [Accessed: 17 March, 2017]. | Ql + Qn (data from system, survey and interviews | - No framework but the evaluation was based on following criteria:<br>1. Logging of messages,<br>2. Time saving potentials<br>3. Quality of nursing service<br>- The implementation process |
| 14 | Feasibility and efficacy of an mHealth game for managing anxiety:"Flowy" randomized controlled pilot trial and design evaluation | Pham, Q., Khatib, Y., Stansfeld, S., Fox, S. & Green, T. 2016, "Feasibility and Efficacy of an mHealth Game for Managing Anxiety: "Flowy" Randomized Controlled Pilot Trial and Design Evaluation", Games for Health Journal, vol. 5, no. 1, pp. 5-67. | Ql + Qn | - No framework but the idea was to asses the clinical efficacy, and also the usability and design feasibility of the mobile app. |
| 15 | Feasibility of an eHealth service to support collaborative depression care: results of a pilot study | Meglic, M., Furlan, M., Kuzmanic, M., Kozel, D., Baraga, D., Kuhar, I., Kosir, B., Iljaz, R., Novak Sarotar, B., Dernovsek, M.Z., Marusic, A., Eysenbach, G. & Brodnik, A. 2010, "Feasibility of an eHealth service to support collaborative depression care: results of a pilot study", Journal of medical | Cl, Qn+Ql (in terms of patients' feedback | - No framework |

| No. | Title | Reference | Data collection | Frameworks used |
|---|---|---|---|---|
| | | Internet research, vol. 12, no. 5, pp. e63. | | |
| 16 | GET.ON Mood Enhancer: efficacy of Internet-based guided self-help compared to psychoeducation for depression: an investigator-blinded randomised controlled trial | Ebert, D.D., Lehr, D., Baumeister, H., BoB, L., Riper, H., Cuijpers, P., Reins, J.A., Buntrock, C. & Berking, M. 2014, "GET.ON Mood Enhancer: efficacy of Internet-based guided self-help compared to psychoeducation for depression: an investigator-blinded randomised controlled trial", Trials, vol. 15, no. 1, pp. 39-39. | Cl + Qn | - No framework |
| 17 | Guided training relative to direct skill training for individuals with cognitive impairments after stroke: a pilot randomized trial | Skidmore, E.R., Butters, M., Whyte, E., Grattan, E., Shen, J. and Terhorst, L. 2016, “Guided training relative to direct skill training for individuals with cognitive impairments after stroke: a pilot randomized trial”, *Archives of Physical Medicine and Rehabilitation*. vol. 98, no. 4, pp. 673-680. | Ql (interview) + Qn (performance-based assessment | No framework |
| 18 | Harnessing context sensing to develop a mobile intervention for depression | Burns, M.N., Begale, M., Duffecy, J., Gergle, D., Karr, C.J., Giangrande, E. & Mohr, D.C. 2011, "Harnessing context sensing to develop a mobile intervention for depression", *Journal of medical Internet research*, vol. 13, no. 3, pp. e55. | Ql + Qn | No framework |
| 19 | Health Information Technologies—Academic and Commercial Evaluation (HIT-ACE) methodology: Description and application to clinical feedback systems | Lyon, A.R., Lewis, C.C., Melvin, A., Boyd, M., Nicodimos, S., Liu, F.F. & Jungbluth, N. 2016, "Health Information Technologies-Academic and Commercial Evaluation (HIT-ACE) methodology: description and application to clinical feedback systems", *Implementation Science*, vol. 11. | Ql + Qn | - Health Information Technologies—Academic and Commercial Evaluation (HIT-ACE) methodology:<br>1. (Compilation and coding academic and commercial materials to identify capabilities and characteristics.<br>2. Conducting system developer or purveyor interviews to gather more detailed information about development and implementation processes.<br>3. A process in which putative implementation mechanisms are linked to HIT capabilities.<br>4. Experimental testing of HIT capabilities and mechanisms. |
| 20 | Implementation and adoption of nationwide electronic health records in secondary care in England: Qualitative analysis of interim results from a prospective national evaluation | Robertson, A., Cresswell, K., Takian, A., Petrakaki, D., Crowe, S., Cornford, T., Barber, N., Avery, A., Fernando, B., Jacklin, A., Prescott, R., Klecun, E., Paton, J., Lichtner, V., Quinn, C., Ali, M., Morrison, Z., Jani, Y., Waring, J., Marsden, K. & Sheikh, A. 2010, "Implementation and adoption of nationwide electronic health records in secondary care in England: qualitative analysis of interim results from a prospective national evaluation", BMJ: British Medical Journal, vol. 341, no. 7778, pp. 872-872. | Ql + Qn | No framework |
| 21 | Implementation of an integrated preoperative care pathway and regional electronic clinical portal for | Bouamrane, M. & Mair, F.S. 2014, "Implementation of an integrated preoperative care pathway and regional electronic | Ql | No framework |

| No. | Title | Reference | Data collection | Frameworks used |
|---|---|---|---|---|
|  | preoperative assessment | clinical portal for preoperative assessment", BMC Medical Informatics and Decision Making, vol. 14, no. 1, pp. 93-93. |  |  |
| 22 | Implementing multifactorial psychotherapy research in online virtual environments (IMPROVE-2): Study protocol for a phase III trial of the MOST randomized component selection method for internet cognitive-behavioural therapy for depression | Watkins, E., Newbold, A., Tester-Jones, M., Javaid, M., Cadman, J., Collins, L.M., Graham, J. & Mostazir, M. 2016, "Implementing multifactorial psychotherapy research in online virtual environments (IMPROVE-2): study protocol for a phase III trial of the MOST randomized component selection method for internet cognitive-behavioural therapy for depression", BMC Psychiatry, vol. 16, no. 1, pp. 1-13. | Ql + Qn | No framework |
| 23 | Information systems for improving mental health: six emerging themes of research information systems | Langrial, S.U. and Lappalainen, P., 2016.” Information systems for improving mental health: six emerging themes of research information systems”, *PACIS 2016 PROCEEDINGS.* | Ql + Qn | No framework |
| 24 | Internet-based cognitive behavioral therapy for residual symptoms in bipolar disorder type II: a single-subject design pilot study | Holländare, F., Eriksson, A., Lövgren, L., Humble, M.B. & Boersma, K. 2015, "Internet-Based Cognitive Behavioral Therapy for Residual Symptoms in Bipolar Disorder Type II: A Single-Subject Design Pilot Study", JMIR research protocols, vol. 4, no. 2, pp. e44. | Qn (several clinical outcomes + a single question related to satisfaction (5-point likert scale)) | No framework |
| 25 | Internet-Delivered Cognitive Behavioural Therapy for Adults with Mild to Moderate Depression and High Cardiovascular Disease Risks: A Randomised AttentionControlled Trial | Glozier, N., Christensen, H., Naismith, S., Cockayne, N., Donkin, L., Neal, B., Mackinnon, A. and Hickie, I., 2013. Internet-delivered cognitive behavioural therapy for adults with mild to moderate depression and high cardiovascular disease risks: a randomised attention-controlled trial. PLoS One, 8(3), p.e59139. | Cl | No framework |
| 26 | Mobile mental health: review of the emerging field and proof of concept study | Harrison, V., Proudfoot, J., Wee, P.P., Parker, G., Pavlovic, D.H. & Manicavasagar, V. 2011, "Mobile mental health: Review of the emerging field and proof of concept study", Journal of Mental Health, vol. 20, no. 6, pp. 509-524. | Cl+ Ql + Qn | No framework |
| 27 | Moderated online social therapy: Designing and evaluating technology for mental health | ederman, R., Wadley, G., Gleeson, J., Bendall, S. & Álvarez-Jiménez, M. 2014, "Moderated online social therapy: Designing and evaluating technology for mental health", ACM Transactions on Computer-Human Interaction (TOCHI), vol. 21, no. 1, pp. 1-26. | Ql (interviews) + Qn | - Framework for trials of complex interventions from the article: M. Campbell, et al. 2000. Framework for design and evaluation of complex interventions to improve health.<br>1. Sequential phases of developing randomized controlled trials of complex interventions.<br>2. Iterative view of development of randomized controlled trials of complex interventions |
| 28 | Pilot randomised controlled trial of Help4Mood, an embodied virtual agent-based system to support treatment of depression | Burton, C., Szentagotai Tatar, A., McKinstry, B., Matheson, C., Matu, S., Moldovan, R., Macnab, M., Farrow, E., David, D., Pagliari, C., Serrano Blanco, A., Wolters, M., Help4Mood Consortium & for the Help4Mood Consortium 2016, "Pilot randomised controlled trial of Help4Mood, an embodied | Cl + Qn | No framework |

| No. | Title | Reference | Data collection | Frameworks used |
|---|---|---|---|---|
| | | virtual agent-based system to support treatment of depression", Journal of Telemedicine and Telecare, vol. 22, no. 6, pp. 348-355. | | |
| 29 | Tailored e-Health services for the dementia care setting: a pilot study of 'eHealthMonitor' | Schaller, S., Marinova-Schmidt, V., Gobin, J., Criegee-Rieck, M., Griebel, L., Engel, S., Stein, V., Graessel, E. & Kolominsky-Rabas, P.L. 2015, "Tailored e-Health services for the dementia care setting: a pilot study of 'eHealthMonitor'", BMC Medical Informatics and Decision Making, vol. 15, no. 1, pp. 58. | Ql | No framework |
| 30 | TElehealth in CHronic disease: Mixed-methods study to develop the TECH conceptual model for intervention design and evaluation | Salisbury, C., Thomas, C., O'Cathain, A., Rogers, A., Pope, C., Yardley, L., Hollinghurst, S., Fahey, T., Lewis, G., Large, S., Edwards, L., Rowsell, A., Segar, J., Brownsell, S. & Montgomery, A.A. 2015, "TElehealth in CHronic disease: mixed-methods study to develop the TECH conceptual model for intervention design and evaluation", BMJ open, vol. 5, no. 2, pp. e006448. | Ql + Qn | - Proposed model for effective use of telehealth, the TElehealth in CHronic Disease (TECH):<br>1. Engagement of patients and health professionals.<br>2. Effective chronic disease management (including subcomponents of self-management, optimization of treatment, care coordination)<br>3. Partnership between providers.<br>4. Patient, social and health system context. |
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