

Ondernemerschap

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# Abstract

The scientific literature consists of over 10,000 papers on eHealth, i.e. the application of information and communication technology (ICT) in the healthcare domain. An enormous amount of different applications are reported. However, remarkably few applications are consistently being used in the healthcare domain. In fact, progress from a test or pilot phase to full scale deployment is reportedly quite rare. Numerous reasons for this lack of progression have been noted, one of these being the objection of medical professionals to the introduction of interventions that are supposedly lacking evidence of their effectiveness. A study of existing literature and, especially, literature reviews confirms that there does not yet exist scientific evidence of the effectiveness of eHealth. But, this study also comes across insights in the reasons why scientific evidence is hard to come by and possible future directions for healthcare organisations how to take advantage of eHealth despite the current lack of interventions that are truly evidence-based and for eHealth researchers to build collectively a stronger evidence-based case for eHealth interventions.

# eHealth Effectiveness

# Does scientific literature provide evidence of the effectiveness of eHealth and what does that mean?

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#### Abstract

The scientific literature consists of over 10,000 papers on eHealth, i.e. the application of information and communication technology (ICT) in the healthcare domain. An enormous amount of different applications are reported. However, remarkably few applications are consistently being used in the healthcare domain. In fact, progress from a test or pilot phase to full scale deployment is reportedly quite rare. Numerous reasons for this lack of progression have been noted, one of these being the objection of medical professionals to the introduction of interventions that are supposedly lacking evidence of their effectiveness. A study of existing literature and, especially, literature reviews confirms that there does not yet exist scientific evidence of the effectiveness of eHealth. But, this study also comes across insights in the reasons why scientific evidence is hard to come by and possible future directions for healthcare organisations how to take advantage of eHealth despite the current lack of interventions that are truly evidence-based and for eHealth researchers to build collectively a stronger evidence-based case for eHealth interventions.

#### Introduction

The Hanze University of Applied Sciences has been involved in a number of eHealth projects over the last few years. The most extensive one of these was the IM-LVG project (Intelligent Monitoring of Mentally Handicapped People; running from mid-2009 till end of 2011)<sup>1</sup>. The aim of the project was to create a monitoring system that would be able to diminish dependence on human intervention in the day-to-day support of mentally handicapped people living in extramural housing settings. The rationale for this project is the expected future shortage of healthcare workers due to demographic change. The project used a multidisciplinary approach to developing a system that would satisfy the requirements of clients, healthcare workers, management, and other stakeholders. The project looked at aspects such as user acceptance, legal and ethical issues, technology, long-term financing, medical intervention, etc. In the end the development of the system taught the participants a lot about all the big and small issues that need to be addressed creating a successful, sustainable application of technology in a healthcare environment, but it did not yet lead to a system established as a dependable substitute of day-to-day human intervention. Other healthcare organizations report on similar experiences where eHealth projects have difficulties to move beyond (successful) pilots.

<sup>&</sup>lt;sup>1</sup> The IM-LVG project was a collaboration between healthcare organisation NOVO, IT system integrator AVICS and the Hanze University and sponsored by the IAG programme.

Despite the fact that the system has not achieved full operational status, the project partners still believe that the proposed solution for the future employee shortage is the right one, but the partners are also aware that this is still a belief not supported by evidence and that the costs involved in developing the solution to a level where it can dependably substitute human support are substantial. The involved costs and the need for confidence in the expected benefits of an eHealth approach have led management of the healthcare organisation to ask if evidence does exist that eHealth technology in general and telemonitoring more specifically can deliver on their promise. This has led to the following question:

"Is there scientific evidence in the literature supporting the assumption that eHealth and telemonitoring are effective?"

This paper aims to answer that question, as well as the question how to implement an eHealth intervention when the evidence for that particular intervention is still lacking.

#### Methodology and terminology

The scientific literature shows an enormous amount of papers on eHealth (based on the encountered reviews, these number in the thousands). However, quite a few related terms are used, sometimes interchangeably: Telemedicine, Telehealth, Telecare, eHealth, Medical Technology, Ambient Assisted Living. Definitions of these terms are available (e.g., Wikipedia), but not used consistently throughout the literature. Telemedicine is the generally taken as use of telecommunication technology to bridge distances in and to improve access to cure services, Telehealth is seen as a broader topic also supporting prevention and care. eHealth is a broader term still in the sense that it is about any use of information and/or communication technology (ICT) in the health domain. Medical Technology usually is about technology applying other than ICT: mechanical engineering, electrical engineering, life sciences, etc. Ambient Assisted Living is about the application of technology (typically

sensors and ICT) in a home environment, not necessarily including telecommunication.

The predominant terms in literature until several years ago were Telemedicine, Telecare and – encompassing both – Telehealth. In turn, these terms stood for a host of other – often medical specialisation-related – subfields: Home telecare, Telemonitoring, Telecardiology, Telepsychiatry, Tele-diabetes care, Teledermatology, Teleneurology, Teleoncology, Tele-Emergency and trauma, Telerehabilitation.

These terms have all been used when looking for relevant literature, but in this paper the term eHealth is preferred to denote the whole field of applying ICT to healthcare and wellbeing and excluding other technology domains.<sup>2</sup>

One other term came up that is relevant for the question this document tries to answer: Health Technology Assessment (HTA). HTA is about providing policy makers with tools for evaluating new interventions in healthcare. HTA is about technology in the broadest sense of the word, which implies that the application of ICT is just a subfield, but it does generate research relevant for this document's starting question.<sup>3</sup>

#### Findings

#### Effectiveness in the literature

The eHealth literature includes a plethora of so called "systematic reviews": analyses of existing literature to answer how a certain issue is addressed within the state-of-the-art. Quite a few are on the effectiveness of

<sup>&</sup>lt;sup>2</sup> ICT is different from most other technical disciplines because of its usual impact on existing working processes and organisations which creates additional challenges, e.g. in the area of change management.

<sup>&</sup>lt;sup>3</sup> In many countries, an agency exists assigned with the task of health technology assessment. In The Netherlands this agency is CVZ (College van Zorgverzekeringen). European HTA agencies are collaborating in EUnetHTA, internationally, HTA agencies are collaborating in the INAHTA organization.

eHealth: Ekeland et al. cites 50 such systematic reviews (2011). The advantage of such systematic reviews is that it provides an answer to our question without having to go through all the thousands of underlying papers.

One of the first things that becomes apparent from these systematic reviews is that "effectiveness" is not a singularly defined term. Effectiveness can refer to different aspects: economic benefit (Dávalos et al., 2009) and cost-effectiveness (Hailey, 2005; Peeters et al., 2011; Polisena et al., 2009; Rojas & Gagnon, 2008; Rumberger & Dansky, 2006; Whitten et al., 2002), study quality and research methodology (Hailey et al., 2004; Whitten et al., 2007), clinical outcomes (Hersh et al., 2001; Hersh et al., 2006), and patient satisfaction (Mair & Whitten, 2000).

This illustrates that eHealth applications usually involve multiple stakeholders, that success means different things for these stakeholders, and. therefore, that "effectiveness" also has different perspectives. Typically, a medical professional might focus on clinical outcome and ease of use; a patient on clinical outcome and service aspects such as user-friendliness, availability and access; a on cost-effectiveness manager and organisational impact; and a technical professional on operational performance. We will come back to this aspect of multiple stakeholders and their differing perspectives on effectiveness later in this document.

Regardless of the variation in perspectives on effectiveness, all the systematic reviews are remarkably consistent in their assessment of the existing literature. From Bashshur (2005): "We may draw the general conclusion, therefore, that with few exceptions the research in this field has yet to produce an adequate body of empirical findings that rises to the level of conclusive evidence as traditionally defined." And: "Nevertheless, the bulk of the research evidence to date has demonstrated the feasibility of telemedicine in almost all clinical and diagnostic applications."

Even though one might become curious after the "few exceptions", the conclusion is that –

to date - there doesn't exist scientific proof that eHealth is effective. But at the same time, there isn't proof that eHealth is a waste of time and effort either. With all that has been going on, the general belief is still that eHealth can be beneficial, provided it is being developed and applied well. Basically, the field suffers from a lack of scientific rigour.

#### Lack of scientific rigour

The lack of scientific rigour has been analysed and explained, e.g. by Bashshur et al. (2005) and by Grigsby & Bennett (2006). We mention a few here:

- Costs of technology interventions may be high, frustrating the potential for sufficient participants to experimental and control groups.
- Lack of subjects within the target group for satisfying statistical constraints.
- The presence or absence of the eHealth intervention may be obvious, making the selection not blind.
- There might be a bias in participants signing up, or being signed up, to get sufficient participants on board or to secure buy in from participants and/or healthcare workers.
- The pace of change in technology and solutions is so fast that specific solutions will have become obsolete once the verdict is in.
- Solutions are being adopted according to feedback during the trial to adjust to smaller or bigger observed shortcomings, thus preventing evaluation of a stable intervention.
- Information of the situation before or without – the intervention may be lacking due to a lack of a information systems present in the control situation.
- Solutions often involve different interventions at the same time, having implications for different different stakeholders. This makes it hard, if not impossible, to define and run conclusive experiments that determine the effectiveness of a specific intervention. At the same time such a situation involves so many variables that generalization of results would be dubious.

Costs of technology as an excuse for not doing a more rigorous study is – in a way – a remarkable excuse: the costs of getting a new medicine developed and approved runs in the billions of Euros these days. Therefore, healthcare as a market place is used to huge investments to develop new interventions. Apparently, it is not costs, but rather uncertainty regarding the expected revenues that prevents investing in rigorous testing and getting evidence-based results. Which in turn lets the uncertainty persist.

eHealth covers a wide range of possible solutions, ranging from very specific, contained interventions (e.g., making an appointment with a medical specialist via an on-line tool) to broad interventions that have a profound impact on an organisation, the established ways of working and the delivered care (e.g., telemonitoring for inpatient care in a nursing home). A broad intervention often has many stakeholders (see, e.g., Shea, 2006), such as the patients or clients, their family and carers, the healthcare workers, managers and administrators, technical support, and insurance companies and policy makers. The intervention may mean different things to different stakeholders. A manager may see the intervention as a tool for offering a more competitive service or lowering costs, a medical professional may see the intervention as a tool to improve the quality of the care given, and a technical professional may see the intervention as an interesting proof of concept. Each perspective leads to different standards with respect to the proof required to accept an intervention as a success.

Medical professionals are trained to accept new interventions only when they are evidence-based. Managers and administrators are trained to base decisions on incomplete information and may accept an intervention even though rigorous evidence is absent. Technical professionals are trained to build an intervention and to verify that the intervention satisfies the specification, not to validate that the intervention has the intended impact on processes, costs, and/or clinical outcome. Consequently, the validation and, thus, the generation of evidence hasn't received the level of attention from managers, administrators, and technical professionals it should have according to medical professionals. From a scientific methodology point of view, validation is supported more by medical science and by business science and economics than by technical science, putting it outside the scope of most technical professionals.

#### Addressing the lack of evidence

Having found repeatedly that the field is lacking scientific rigour, there are essentially two directions for going forward: either accept that scientific rigour is infeasible and try to work around this (a pragmatic approach), or step up the effort and find ways to improve the scientific evidence (a scientific approach). The *pragmatic* approach caters mainly to managers and administrators and requires validation from a business or economics perspective. The scientific approach would appeal more to medical professionals and requires validation from a medical perspective. Policy makers might prefer the scientific approach, but have to accept a pragmatic approach when a decision needs to be made while scientific evidence is still lacking. Health Technology Assessment (HTA) includes both approaches (Hailey, 2009).

## Pragmatic approaches

This approach takes a business view of innovation. In this approach, eHealth solutions do not necessarily fall within the domain of healthcare and wellbeing defined by health insurers, policy makers and medical professionals, but rather in a more free market domain.

An eHealth solution may be more a systemic change, being so much more than just one particular medical intervention that improves – or at least offers comparable – medical care, by achieving cost benefits, creating better access to health care, addressing labor shortages, etc.). Therefore, the usual requirement of RCTs does not necessarily cover the real benefit of an eHealth solution. Two main streams appear in the literature. The first analyzes successes and failures of technical innovations in healthcare and devises models and checklists that address the key success factors, e.g., (Barlow et al., 2006; Broens et al., 2007; Esser & Goossens, 2008; van Gemert-Pijnen et al., 2011; Hailey & Crowe, 2003; Kidholm et al., 2012; Postema et al., 2012; van 't Riet et al., 2010; Visser et al., 2011; Whitten et al., 2010). Typically, these papers note that success is dependent on adequate attention to aspects related to users, technology, organisation, finance, rules & regulation, etc. Quite a few different models and checklists have emerged recently, with at least based on a not too scrupulous investigation - only minor differences between them. One would do well to use at least one of these when starting with the development of a new eHealth project. From a Dutch and Dutch language perspective, it is interesting to follow the researchers of Windesheim and their eHix<sup>4</sup> model (Visser et al., 2011). On a European level, it is interesting to follow the development of MAST (Kidholm et al., 2012), as it is supported by the European Network for Health Technology Assessment (EunetHTA) and currently being evaluated within the context of the European project Renewing Health.

A next step from this could be the development of a maturity model to assess how well a certain eHealth solution addresses the issues from a checklist, an first example of which is found in (van Dyk & Schutte, 2012).

The second stream takes a customer-oriented view and starts from a needs analysis to develop adequate products and services, e.g., (van Hoof et al., 2011; Nijland, 2011). Here customer satisfaction is key and products and services are developed often via interactive design methods such as agile development (Baljé et al., 2012) and co-creation (Prahalad & Ramaswamy, 2004).

It is unlikely that eHealth interventions developed this way will become likely subjects for rigorous scientific analysis. Co-creation leads to continuous improvement of solutions and the creation of a solution that satisfies the needs of the stakeholders. A priori set up of an evaluation project for the end-product is impractical, because the end-product has not been fully specified yet, while a posteriori evaluation seems superfluous, because the created end-product already satisfies the needs (assuming that there is an end-product and the product is not constantly updated and augmented up to the end of the funding cycle as is quite common with technological solutions).

## Scientific approaches

The generally accepted golden standard for scientific rigour and evidence-based research is the Randomized Controlled Trial (RCT). Characteristics of an RCT are an experimental group and a control group (whose members are not subjected to the intervention), randomised allocation to experimental group and control group, blind (the subjects do not know to which group they belong), large enough numbers of subjects to reach statistically meaningful conclusions, long enough time to study the persistence of effects, and collection of sufficient "before and after" data. Few eHealth experiments satisfy all of these criteria.

The literature shows several directions to create better evidence and to overcome some of the challenges that exist in the field (Ekeland et al., 2011). One direction is to use more advanced statistical methods to adjust for sample size and bias or to expand on the available scientific theories and corresponding methodologies to achieve well-accepted results (Chumbler et al., 2008; Gammon et al., 2008; Grigsby & Bennett, 2006; Yellowlees & Harry, 2006).

A second direction is to use standardisation of populations and/or interventions and/or outcomes to make results from different studies more comparable and available for meaningful analysis of a combined data set. This direction requires standard definitions of target groups and interventions (Ekeland et al., 2011). As an example, Currell et al. (2010) did a systematic review of the effectiveness of

<sup>4</sup> www.ehix.nl

the specific intervention of substituting faceto-face contact between practitioner and patient by telecommunication-supported contact. When more studies become available of this type of intervention with standardized evaluation parameters (e.g. costs, frequency, duration, therapy loyalty) and both variation and replication of populations subjected to the study, a more thorough analysis can be made of the effectiveness of this type of intervention for potential target groups.

Regretfully, standardization is still far off (Schwarzer & Siebert, 2009; Yellowlees & Harry, 2006). Schwarzer and Siebert also show how far apart HTA agencies in different European countries are in assessing eHealth interventions in scope, ways of working, and conclusions.

Researchers at Windesheim University of Applied Sciences are working on a project trying to bridge the gap between pragmatic (business oriented) approaches and scientific (evidence-based approaches) in the SIA RAAK project "Succesvol ondernemen met eHealth: ontwikkelen van een aanpak voor evidence based eHealth".<sup>5</sup>

#### Areas of specific interest

With thousands of papers published in the domain of eHealth, there is bound to exist a few on any imaginable application of ICT to healthcare and wellbeing. No new project should start without an examination of existing literature.

The literature reviewed for this document focused on effectiveness of eHealth. Incidentally some relevant papers were encountered that appear to be of particular interest to ongoing projects of the Hanze University of Applied Sciences.

Several of these projects are dealing with Telehomecare (intramural and extramural, care and wellbeing, elderly and mentally handicapped, patients with dementia and other chronic diseases). Relevant literature on the effectiveness of Telehomecare was found in (Rumberger & Dansky, 2006; Postema et al., 2012; Rojas & Gagnon, 2008; Polisena et al., 2009). Polisena et al. report a lack of rigour in the contributions they analysed like other systematic reviews, but conclude also that the 20-odd papers studied do report relevant economic and functional benefits of the described Telehomecare solutions.

Telehomecare benefits from a large amount of interest due to its support for improving the lives of patients suffering from the major chronic diseases, i.e. congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), and diabetes.

In another application domain, Grady et al. (2011) provide guidelines for developing telemental health applications developed from evidence-based research results. These guidelines are adopted by the American Telemedicine Association (ATA) as "Telemental Health Standards and Guidelines". These are – based on the current literature review – the only existing standards and guidelines in the eHealth domain.

#### **Concluding remarks**

This document tried to answer the question:

"Is there scientific evidence in the literature supporting the assumption that eHealth and telemonitoring are effective?"

The answer to this question is – regrettably – "No". There is, however, an overwhelming amount of literature on eHealth, which – through sheer volume and the absence of proof of the contrary – suggests that eHealth, i.e., the application of information and communication technology in the area of healthcare and wellbeing, has benefits.

The literature also shows that it is not easy to achieve benefits through eHealth over a sustained period of time. The good news is that the research community is starting to converge on guidelines that help developing successful, beneficial eHealth solutions, but circumvent the absence of scientific evidence.

<sup>5</sup> 

http://www.windesheim.nl/onderzoek/onderzo eksthemas/gezondheid-en-welzijn/ictinnovaties-in-de-zorg/succesvol-ondernemenmet-ehealth/

The research community is also acutely aware of a lack of scientific rigidity and the need to come up with ways to provide scientific evidence for the effectiveness of eHealth. Some papers show sound, evidence-based results. These cover, almost by definition, very specialized cases of intervention/population combinations. A coordinated effort necessary to create a significant coverage of relevant intervention/population combinations – does not appear to exist. The policy "Evidence-based practice for Telemental Health" published by the American Telemedicine Association (ATA) provides a promising first exception.

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Ondernemerschap

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