

## Health Technology Trust: Undeserved or Justified?

A review of technological risks in eHealth

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**Abstract** - Challenges for global health care are considerable. Increasing healthcare expenditures, ageing, the rise of chronic diseases and the public health threat of infectious diseases give reason to worldwide concern. Many believe eHealth technologies to contribute to the solution of these issues and to the necessary innovation of healthcare systems. Is the widespread trust among public administrations, care professionals, researchers and the general public justified? The present paper aims to assess the risks of eHealth technologies for both patient safety and quality of care. A quick-scan of scientific literature was performed to collect publications on risks associated with the use of eHealth applications in cure and care. Only random clinical trials (RCTs) were included. Data-management issues were excluded. Of 340 identified publications, 17 met the inclusion criteria. Human, technological or organizational risks appear to be no subject of RCTs. But they come into view *en marge* implementations. As such, the selected studies suggest there is evidence for risks caused by the use of eHealth in healthcare which can negatively affect the quality of care and the safety of patients. A realistic reconsideration of the implementation of eHealth interventions is recommended. The ceHRes roadmap is an evidence-based guideline to systematically avoid or minimize these risks.

**Keywords** - risks; eHealth technology; patient safety; quality of care; trust

### I. INTRODUCTION

Challenges for global health care have been documented extensively. Most countries face a serious increase in healthcare expenditures that corresponds to ageing, a growth in multi-morbid chronic illnesses, the menace of infectious diseases, consumerism or other dynamics [1, 2]. eHealth technologies have frequently been hailed as a panacea for these challenges. These technologies have proven their potential to contribute to the increase of (cost-) effectiveness and efficiency of care, the improvement of the quality of care, the empowerment of consumers, system transparency, and eventually to the reduction of health care costs [3-7]. But expectations have recently been mitigated due to the publication of studies that emphasize the complex nature of innovation in healthcare and the lack of rigid evidence for

impact of eHealth technologies on health care outcomes thus far [8, 9]. Moreover, the application of eHealth technologies in healthcare may introduce risks for patient safety and quality of care [10-12]. Nonetheless, trust in information and communication technologies (ICT) seems to remain unaffected by these moderating results. This is remarkable against a backdrop of widespread declining trust in the legal system, in politics, finance, science and other public domains [13, 14]. Public administrations, care professionals, researchers and the general public are generally trustful and overly optimistic about the ‘a-political’ power of digital technology in virtually all public and personal domains [15, 16]. Investments in ICT are rarely withdrawn because of identified or alleged risks for patient safety or for the quality of care. Where interpersonal trust is an attitude towards others whom we hope will be trustworthy, institutional trust refers to institutions or systems (i.e. the government or the administration of justice) and their trustworthiness [17]. The value of institutional trust lies in its opportunities for cooperation, knowledge, autonomy and other ‘social goods’ that contribute to the foundations of society [18]. In the case of eHealth technology the question if trust is warranted is socially important as well. Is it plausible, justified and well-grounded to trust technologies that are designed to advance health, safety and care? Are these systems trustworthy themselves? Is adherence related to trust? Trust in and trustworthiness of eHealth interventions are obviously affected by (perceived) risks and lack of knowledge in the long run. Over the last decades studies of risk (and technology) have grown into a major interdisciplinary field of research. Risk researcher Hansson states “When there is a risk, there must be something that is unknown or has an unknown outcome. Therefore, knowledge about risk is knowledge about lack of knowledge. This combination of knowledge and lack thereof contributes to making issues of risk complicated from an epistemological point of view” [19]. Since epistemology is not our focus here we will apply an internationally accepted definition for risk i.e. “the combination of the probability of occurrence of harm and the severity of that harm” [20]. This definition is also used

in the international standard for risk management of medical devices [21] which is the regulatory sector in which part of the eHealth technologies can be classified.

In a recently published study we have reported on flaws and drawbacks of eHealth technologies [22]. This study was based on a comprehensive analysis of eventually sixteen frameworks regarding the development and implementation of eHealth interventions over the last decade (2000-2010). The reported drawbacks may legitimately be conceived as risks since they imply equivalent and immediate hazards for the patient’s safety or the quality of care. Therefore we think it relevant for the present study to provide a short summary of these findings. Table I shows a summary of these risks phrased in conceptual terms.

TABLE I. RISKS DERIVED FROM PREVIOUS RESEARCH\*

Conceptual risk	Description
eHealth technology development as an expert-driven process	If project management fails to arrange stakeholder participation in the full development process risks for rejection by (end-)users increase.
eHealth technology development ignores evaluation	If the development is viewed as a linear, fixed and static process instead of a iterative, longitudinal research activity risks of suboptimal outcomes increase.
Implementation of eHealth technology as a post-design activity	If conditions for implementation are not properly accounted for right from the start in all subsequent stages stakeholders may drop out.
eHt development does not affect organization of healthcare	If it is ignored that eHealth technologies intervene with traditional care characteristics and infrastructure unexpected effects cause stakeholders to abandon.
eH technologies as instrumental, determinist applications	If eH interventions ignore users’ needs for affective, persuasive communication and information technologies for motivation, self management and support, they drop-out..
eH research fails to integrate mixed-methods and data triangulation	If conventional research methods keep falling short of assessing the added value for healthcare in terms of process (usage, adherence) and outcome variables (behavioral, clinical outcomes; costs) societal and scientific refutation follows.

\* Van Gemert-Pijnen et al., 2011 [22]

Precisely the opposites of factors that improve the uptake and impact of eHealth technologies constitute risk for both patient safety and quality of care; they increase the probability of occurrence of harm and the severity of that harm. For further reading we refer to the abovementioned review.

In the present study we seek to validate these outcomes by assessing the nature and prevalence of any risk to patients’ safety and quality of care that may be associated with eHealth applications, as established in randomized controlled trials. These interventions include web-based and mobile applications for caregivers, patients and their relatives within a treatment relationship as well as technology regarding quality in healthcare. This provides an inventory of documented risks that impact on quality of care and the patients’ well-being. Increasing use of eHealth technology is one of the major developments in today’s healthcare [23]. The opportunities of web-based and mobile eHealth technologies should therefore remain central to the global health discourse. At the same time it is required to explore the risks of these technological advancements.

## II. LITERATURE SCAN

The present desk research involves a literature scan to exploratory assess only those risks that are reliably documented in the scientific literature. The scan is restricted to publications regarding risks that affect the quality of healthcare and the patients’ safety. The public health domain is excluded. Issues concerning security of data-transmission, storage, encryption, standardization, data-management and privacy are not included to avoid overlap and redundancy [24]. The search is limited to randomized controlled trials (RCT) to allow for comparisons. No systematic review was performed.

The bibliographic database SciVerse Scopus was searched because of its broad content coverage including 100% coverage of Medline titles and over 16.000 peer-reviewed academic journals. The used search query combined the topic ‘eHealth’ with search terms regarding risk, healthcare-setting and study design. The complete query can be found in Appendix I. One author reviewed the titles and abstracts of the identified publications to decide whether they should be examined in full detail. Inclusion criteria are: (1) the article deals with an eHealth application and/or (2) deals with risks for (3) quality of care in general and/or patients’ safety resulting from the use of the application. Articles describing such risks merely as unintended outcomes were included as long as these risks affect quality of care and/or patients’ safety. Articles whose titles contained outcome-measures or evaluation criteria of an eHealth program were included as well. If risks or limitations were explicitly mentioned in the abstract, the article was included. Furthermore (4) articles had to be RCTs published (5) between 2000-2011. Finally (6) only articles written in the German and English language were scanned. An overview of the inclusion criteria is presented in Table II. The study selection process is included in Appendix II.

TABLE II. INCLUSION CRITERIA FOR THE STUDY SELECTION PROCESS

Inclusion criteria
1. eHealth application
2a. in Title: outcome-measure and/or evaluation and/or risk
2b.in Abstract: risk and/or limitation found
3. Quality of care and/or patients' safety/well being
4. Design: Randomized controlled trial
5. Publication year: between 2000 – 2011
6. Language: German or English

Identified risks were structured according to a multi-level approach covering risks dealing with either human factors (patient), technology factors or organizational factors, referring to the framework for health information systems evaluation as proposed by Yusof et al. [25].

### III. OUTCOMES

#### A. Study characteristics

The search was performed in SciVerse Scopus in July 2011 delivering initially 340 potentially relevant publications. Of these, 17 were eventually included after the selection procedure described sub II.

#### B. Multi-level risks assessment

Human, technological or organizational risks appear to be no primary subject of the RCTs identified in the search. However they emerge as secondary effects or unintended outcomes of eHealth technology implementations. Identified risks have been structured with regard to their primary occurrence at a human level, a technological level and organizational level.

##### 1) Risks concerning Human factors

Masa et al. [26] compared conventional spirometry to online spirometry with regard to outcome measures like forced vital capacity, quality criteria (acceptability, repeatability) and the number of maneuvers and time spent on both of the two procedures. They found that the number of spirometric maneuvers needed to meet quality criteria was somewhat higher in the online mode as compared to conventional spirometry. Online spirometry also took more time for patients (mean differences of 0.5 additional maneuvers and 0.7 minutes more). Higher time-consumption may also negatively affect the remote technician instructing the patient while the latter uses the spirometer. The spirometric values achieved online were very similar to the values achieved by conventional spirometry.

Some eHealth applications appear to be more beneficial for specific patient groups. Bujnowska-Fedak et al. [27] tested a tele-homecare application for monitoring diabetes. Older and higher educated patients, spending a lot of the time at home and having acquired diabetes recently, benefited most from the application. A positive association was found between educational level and ability to use the tele-monitoring system without assistance. Spijkerman et al. [28]

evaluated a web-based alcohol-intervention without (group 1) and with (group 2) feedback compared to a control group in order to reduce drinking behavior in 15-20yrs. old Dutch binge-drinkers. They found that the intervention may be effective in reducing weekly alcohol use and may also encourage moderate drinking behavior in male participants over a period of 1-3 months. The intervention seemed mainly effective in males while for females a small adverse effect was found. Women following intervention group 1 were less likely to engage in moderate drinking and had increased weekly drinking a little, although significantly ( $p=.06$ ; 1.6 more drinks/week), at one month follow-up. Zimmerman et al. [29] performed a secondary analysis on data from an RCT on a symptom-management intervention for elderly patients during recovery after coronary artery bypass surgery. They found that the intervention had more impact on women than on men for symptoms such as fatigue, depression, sleeping problems and pain. Regarding measures of physical functioning no gender differences were found. Cruz-Correira et al. [30] tested adherence to a web-based asthma self-management tool in comparison to a paper-based diary. The tool was designed to collect and store patient data and provide feedback to both patient and doctor about the former's condition in order to support medical decision making. Patients' adherence to the web-based application was lower than in the control group. Willems et al. [31] tested a home monitor self-management program for patients with asthma where data such as spirometry results, medication use or symptoms were recorded. They found a low compliance of participants with the intervention protocol. Participants in the intervention group recorded in average less PEF tests (peak expiratory flow; lung function data): 1.5 per day versus the required number in the protocol of 2 tests per day. Verheijden et al [32] tested a web-based tool for nutrition counseling and social support for patients with increased cardiovascular risk in comparison to a control group receiving conventional care. The authors found that the uptake of the application in the intervention group was low (33%) with most participants using the tool only once during the 8 months study period. Patients properly using the intervention were significantly younger than those who did not. Morland et al. [33] compared an anger management group therapy for veterans delivered face-to-face versus via videoconferencing. Group therapy via videoconferencing teleconferencing seemed effective to treat anger symptoms in veterans. While no differences could be found between the two groups regarding attendance or homework completion, the control group reported a significant higher overall group therapeutic alliance than the intervention group. Postel et al. [34] evaluated an eTherapy program for problem drinkers, where therapist and patient communicated online to reach a reduction of alcohol use, as compared to a control group receiving regular information by email. While effective for complying participants, they found high drop-out rates in the eTherapy group though quitting the program

did not automatically mean that the participant had also relapsed or increased alcohol consumption. Ruffin et al. [35] tested a web-based application where participants received tailored health messages after giving information about family history of six common diseases. In the intervention group the authors found modest improvements in self-reported physical activity and fruit and vegetable intake. But participants also showed a decreased cholesterol-screening intention as compared to the control group who received standard health messaging.

In summary, 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. Frequently adherence (or compliance, drop-out, alliance, up-take) is mentioned and associated with a negative impact on the intended effect of an intervention.

### 2) Risks concerning Technology

Evaluating a tele-homecare application for monitoring diabetes Bujnowska-Fedak et al. [27] observe usability problems among participants; 41% of them (patients with type 2 diabetes) were unable to use the system for glucose-monitoring needing permanent assistance. Patients who could easily use the application derived a greater impact from its use. Nguyen et al. [36] evaluated an internet-based self-management program for COPD patients but discontinued before the sample target was reached due to technical and usability problems with the application. Participants stated at the exit interview that decreased accessibility, slow loading of the application, and security concerns prevented them from using the website more frequently. Participants reporting usability problems had to complete (too) many actions on a PDA-device before being able to submit an exercise or symptom entry. Other problems dealt with limited wireless coverage of the PDA. The technical problems decreased participants' engagement with the tools. Decreased engagement was associated with the number of web log-ins and the exercise and symptom entered via the website and/or the PDA. While evaluating a web-based asthma self-management tool Cruz-Correira et al. [30] found nine patients reporting problems (19 in total) related to the use of a web-based self-management tool. Most problems concerned the internet connection and the graphical user interface. Two of the patients could not even use the application because of technical problems. Demaerschalk et al. [37] tested the efficacy of a telemedicine application (vs. telephone-only consultation) for the quality of decision making regarding acute stroke. They found technical issues in 74% of telemedicine consultations versus none in telephone consultations. The observed technical problems did not prevent the determination of treatment decision but some did influence the time necessary to treatment decision-making. Jansà et al. [38] used a telecare-application for type 1 diabetes patients having poor metabolic control to send glycaemia values to

the diabetes team. They found that 30% of team-patient appointments were longer than expected (1h vs. 0.5h) due to technical problems with the application. Technical problems concerned the inability to send results of counseling caused by problems with the application itself, the server or internet-access. Using a telemanagement application for diabetes patients Biermann et al. [39] found that 15% of the participants had difficulties in handling the application, the consequences of which were not elaborated. In a study of an asthma self-management telemonitoring program by Willems et al. [31] 1/3 of participants experienced technical problems, mostly with malfunctioning devices. Practitioners had to contact patients e.g., regarding a missed data transfer leading to logistical problems.

In summary, a variety of issues have been reported at the technology level affecting patient safety or quality of care. They range from usability problems and security issues to problem with accessing the server or malfunctioning devices.

### 3) Risks concerning Organization

Copeland et al. [40] tested whether a telemedicine self-management intervention for congestive heart failure (CHF) patients could be effective in terms of improving physical and mental health-related quality of life and cost-effectiveness as compared to a control group receiving usual care. They could not find substantial differences between groups, but overall costs related to CHF were higher for the intervention group. The authors state that this might be related to the intervention encouraging medical service utilization by facilitating access to care.

One tele-management application for diabetics allows patients to measure their blood-glucose values and send it to their care provider [39]. Though time-saving for patients, use of the application lead to 20% more time investment (50 vs. 43 min. per month over a 4-month period, and 43 vs. 34 min. per month over an 8-month period) on the side of the care provider compared to conventional care. The higher time expenditure did not reflect time necessary to manage the application itself: it was due to more access to the provider, so that patients tended to call more often. Montori et al. [41] also found a comparable risk concerning time-consumption. They tested a telecare-application for data-transmission for type 1 diabetes patients. The nurses needed more time reviewing glucometer data (76 min. vs. 12 min.) and giving the patient feedback (68 minutes vs. 18 minutes) in the telecare condition as compared to the control group. The authors found more nurse feedback time to be significantly associated with more changes in insulin doses; more changes of doses thus appeared in the telecare group.

Strayer et al. [42] tested a personal digital assistant (PDA) as a tool for improving Smoking Cessation Counseling (SCC) against a paper-based reminder tool. In semi-structured interviews medical students providing SCC

reported that they felt barriers for using the PDA in practice such as a lack of time or a lack of training. Also they felt uncomfortable to use the PDA in the presence of patients. The PDA tool did not increase key SCC behaviors of the participants of the intervention group as compared with the paper-based reminder.

In summary, increased time consumption, barriers for proper use and financial issues are the risks observed at the organizational level.

#### IV. CONCLUSION

RCTs of the immediate risk of eHealth technology for patients' safety or quality of care have not been found. Risks emerge as unintended, secondary outcomes in the margin of studies aiming to evaluate the effectiveness of eHealth interventions. The selected studies suggest nonetheless evidence for risks at all three levels of the multi-level approach applied. Ten studies mention risks concerning the patient at the human level, especially where adherence issues lead to suboptimal use of an intervention and corresponding low effectiveness. But also adverse effects were reported, as well as the fact that not all patient groups can equally benefit from an eHealth intervention. Issues at a technological level were found in seven studies, revealing considerable rates of usability problems, limited access or other technical problems. Organizational issues were found with regard to higher use of resources (time, money, staff) affecting quality of care in two studies. Table III shows the level and nature of the risks observed in our study.

TABLE III. OBSERVED RISKS

Risk level	Description
Human level	Adherence (or compliance, drop-out, alliance, up-take)
	Unintended adverse effects
	Selective patient benefits (sex, education, age and other variables)
Technology level	Usability problems
	Access
	Security issues
	Malfunctioning devices
Organizational level	Higher time consumption
	Barriers for proper use
	Higher costs

In some cases the causes of the risks were qualified as study (design) artifacts. In many instances the consequences have not been elaborated.

#### V. DISCUSSION

Risk is a complicated epistemological issue that refers to a lack of knowledge along subjective and objective dimensions. Trust is an important social good. But trust is risky. The observed lack of academic interest for risk

assessment in eHealth technology should be a matter of concern. Patient safety and quality of care deserve a high level of risk awareness when it comes to new technologies. At present risks emerge in the margin of RCTs in eHealth. They are conceived as problems, issues, disadvantages, costs or other designations that one way or another affect human, technological or organizational functioning in a detrimental manner.

Though both quantity and quality of the reported issues do not seem disturbing at first glance, a wider search would almost certainly deliver a more disquieting range and diversity of risks. Given the outcome of our study that none of the RCTs were designed to study risks, we must conclude that they do in fact not represent the studies with the highest evidence level related to our research question. Therefore, a follow-up search, including review articles, controlled clinical trials, and perhaps also observational studies should be performed. Furthermore, in databases such as MAUDE (Manufacturer and User Facility Device) of the U.S. Food and Drug Administration, in grey literature, articles in professional magazines and other (online) sources of different organizational, consumer and academic nature a variety of incidents involving risks have been recorded<sup>1</sup>. While often viewed as avoidable or improvable intervention flaws or explained as study (design) artifacts they should not be played down. Their presumed prevalence and incidence give rise to reconsideration when it comes to exploring the opportunities of web-based and mobile eHealth technologies for global healthcare innovation.

This reconsideration implies the need for extensive research that explicitly focuses on establishing the volume and nature of such risks. It also implies an improved way of monitoring to advance transparency in the reporting of risk prevalence and safety incidents. Finally it implies a higher level of healthcare risk management, continuity of care and understanding of how risks affect patients through risk identification, operating ways to avoid or moderate risks and developing contingency plans when risks cannot be prevented or avoided.

The results of the present scan are in accordance with outcomes from the ceHRes study that covers over a decade of eHealth technological development [22]. The 'conceptual' risks (Table I) represent the same categories of risks that result from the literature study. For instance expert-driven eHealth interventions that neglect the essential role of patients lead to adherence issues mentioned sub B1). Or disregarding conditions for implementation imply underestimating issues such as time-consumption mentioned sub B3). To minimize and avoid such risks a 'Roadmap' has been developed to design, develop, implement and evaluate eHealth interventions (see Appendix III). It uses concepts and techniques from business modeling and human centered design [43]. The roadmap serves as a guideline to

<sup>1</sup> Risk analyses of these and other sources will be published in 2012.



collaboratively improve the impact and uptake of eHealth technologies. For this purpose it is published as a wiki ([ehealthresearchcenter.org/wiki/](http://ehealthresearchcenter.org/wiki/)).

For now the ubiquitous trust in technology seems unjustified and needs to be put in perspective to be deserved. We have the instruments and the knowledge to reconsider the implementation of eHealth to achieve this. Until then present stakeholders should be aware to minimize such risks ex ante. But at the end of the day it is the acceptability of a risk that determines the necessary course of action.

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## Appendix I

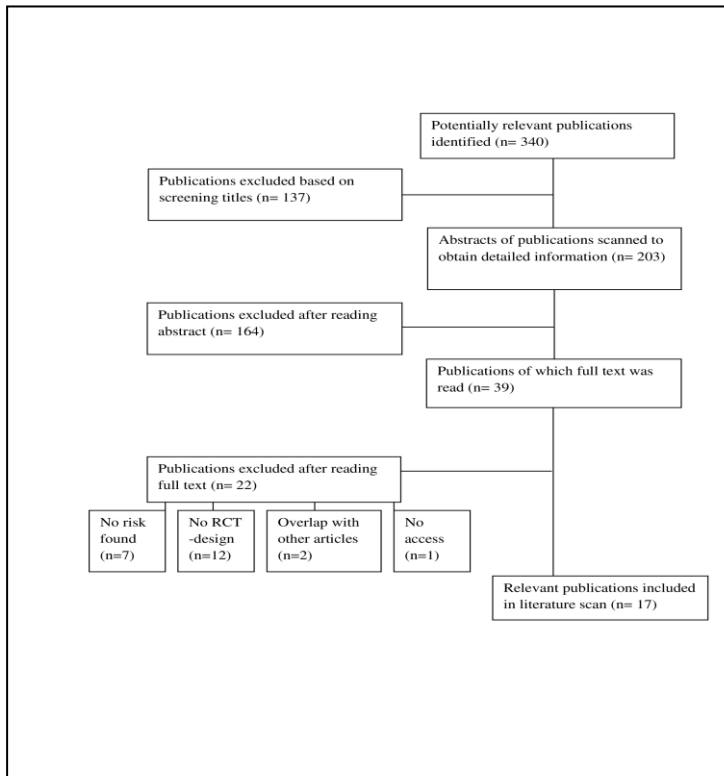
### Search query used in SciVerse Scopus

(TITLE-ABS-KEY(ehealth OR e-health OR "e health" OR etherapy OR e-therapy OR "e therapy" OR emental OR e-mental OR "e mental" OR telemedicine OR telecare OR teleconsult OR telemonitoring OR telehealth OR teleconference OR "health information technology" OR "web based") OR TITLE-ABS-KEY("internet based" OR "web application" OR domotica OR "personal digital assistant" OR "pda") AND TITLE-ABS-KEY(risk OR

risks OR danger\* OR threat OR threats OR limitation\* OR barrier\* OR problem\* OR concern\* OR challenge OR challenges OR "adverse effect\*" OR quality OR drawback OR drawbacks) AND TITLE-ABS-KEY(health OR care OR "healthcare" OR healthcare) AND TITLE-ABS-KEY("randomized clinical trial\*" OR "randomised clinical trial\*" OR "randomized controlled trial\*" OR "randomised controlled trial\*" OR rct OR "RCTs" OR experimental)) AND PUBYEAR AFT 1999 AND PUBYEAR BEF 2012 AND (LIMIT-TO(LANGUAGE, "English")) OR LIMIT-TO(LANGUAGE, "German"))

## Appendix II

### Study selection process





## Appendix III

### ceHRes Roadmap to improve the impact of eHealth interventions

