Magnitude of eHealth Technology Risks Largely Unknown

An Exploratory Study into the Risks of Information and Communication Technologies in Healthcare

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***Abstract* – Many believe that eHealth technologies will contribute to the solution of global health issues and to the necessary innovation of healthcare systems. While this may be true, it is important for public administrations, care professionals, researchers, and the general public to be aware that new technologies are likely to present new or uncertain risks along with their great new opportunities. 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 as well as an analysis of web-based sources and databases. Outcomes were validated in a focus group setting against expert views of stakeholders from health care, patients' organizations, industry, academic research, and government. Risks at human, technological or organizational levels appear to be no subject of systematic research. However, they come into view as 'secondary' findings in the margin of these studies. Extensive anecdotal evidence of risks is reported at all three levels in web-based sources as well. Recent authoritative reports substantiate these outcomes. Members of the focus group generally recognized the findings and provided valuable, additional information. A realistic approach to the implementation of eHealth interventions is recommended, taking into account potential benefits as well as risks, and using existing risk management tools throughout the life cycle of the intervention.**

Keywords - risks; eHealth; health technology; patient safety; quality of care

I. INTRODUCTION

Trust in technology is of growing importance in view of the challenges for global healthcare [1]. Most countries face a serious increase in healthcare expenditures that corresponds to ageing, a growth in multi-morbid chronic illnesses, the enduring menace of infectious diseases, consumerism and other dynamics [2, 3]. eHealth technologies have frequently been hailed as a panacea for these challenges. We view eHealth as the use of information and communication technologies (ICTs) to support or improve health and healthcare. 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 [4-7]. However, 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, systematic evidence for the impact of eHealth technologies on healthcare outcomes so 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 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]. Common principles of evidence based medicine are apparently ignored regularly in this field, leading to fast introduction of promising eHealth interventions without carefully evaluating benefits versus risks.

Recently, we have reported on some drawbacks of eHealth technologies at another level and from a different perspective [17]. 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 shortcomings are closely related to risks. Eventually, 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/or the severity of that harm. These are exactly the two components used in the internationally accepted definition for risk that we are applying in our investigation, i.e., "risk is a combination of the probability of occurrence of harm and the severity of that harm" [18]. This definition is also used in the international standard for risk management of medical devices [19], which is the regulatory sector in which part of the eHealth technologies can be classified, as well as in other standards more specifically relevant to ICT applications in health care.

In the present study, we investigate the nature and occurrence of any risk to patients´ safety and quality of care that may be associated with eHealth applications. 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. In view of the diversity and dynamics of the field, we have chosen to use multiple approaches to gather our data and to verify our findings. As a first approach, we searched for risks as established in randomized controlled trials and reported in scientific literature (see Section II). This provides an inventory of documented risks that impact on quality of care and the patients' well-being. Additionally we have searched a selection of web-based sources related to (inter)national health organizations/government agencies, incident databases, expert centers, and opinion papers in the medical field (Section III). While we were analyzing our search results, three authoritative reports with scopes closely related to our own were published, and we decided to compare their findings with our own as a method of independent control. The outcomes were eventually validated in a focus group setting against expert views of stakeholders from health care, patients' organizations, industry, academic research and government (Section IV). In Section V we present the outcomes of these approaches, to draw conclusions in the next section and discuss the in the last.

II. LITERATURE SCAN

The literature scan was designed to exploratory assess only those risks that are reliably documented in systematic studies, i.e., randomized controlled trials (RCTs). The scan was restricted to scientific publications regarding risks that affect the quality of healthcare and patient safety while public health was excluded. Issues concerning security of data-transmission, storage, encryption, standardization, data-management and privacy were excluded as well to avoid overlap and redundancy in view of other studies [20]. The search was limited to RCTs. This type of studies represents the highest power of evidence in the absence of meta-analyses or systematic reviews and allows for comparisons with alternative approaches.

The bibliographic database SciVerse Scopus was searched because of its broad content coverage including all 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. 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, technological factors or organizational factors, referring to the framework for health information systems evaluation as proposed by Yusof et al. [21].

III. WEB-BASED SOURCES

To broaden our view we have included 'grey literature'. The 'Prague Definition'[1] of grey literature states that "Grey literature stands for manifold document types produced on all levels of government, academics, business, and industry in print and electronic formats that are protected by intellectual property rights, of sufficient quality to be collected and preserved by library holdings or institutional repositories, but not controlled by commercial publishers, i.e., where publishing is not the primary activity of the producing body." This material cannot be found and disclosed easily through the usual channels. It may include government research and non-profit reports, dissertations and expert assessments, conference proceedings and technical reports, institutional repositories, investigations, and other primary resource materials such as records, archives, observations, data, filed notes and 'new' sources such as pre-prints, web logs, online preliminary research results, open data, unpublished theses, project web sites, standards and specifications collections, online data archives or other types of documentation.

Given the plethora of different types of organizations publishing information on eHealth, we decided to start with explorative searches in sources of different status without using a systematic selection procedure. Firstly, we have visited a series of websites of international and national health organizations/government agencies to see if they mention risks associated with eHealth technology in any way. Secondly, we have searched databases, respectively of the U.S. Food and Drug Administration and the ECRI Institute. Thirdly, we have accessed websites of three expert centers on medical technology: the ECRI Institute, Prismant (Dutch) and ZonMw (id.). Finally, a major Dutch professional journal on health care matters was queried on risk factors concerning eHealth and telemedicine (see Appendix V). On each website we searched for information on the risks involved with eHealth and telemedicine. The search terms used were ehealth, telemedicine and tele*. Results involving the monitoring, programming or diagnosis of pacemakers and other implantable cardiologic devices were excluded because they are considered to represent ancillary functions to those devices, rather than eHealth applications in their own respect.

[1] 12th International Conference on Grey Literature (Prague, Dec. 2010); http://www.opengrey.eu/item/display/10068/700015 [accessed Jan 15, 2013]

IV. FOCUS GROUP

To test the findings from literature against the opinions of stakeholders we organized an `invited expert meeting'. We selected experts from industry, health care, government, patient organizations, insurers and universities from our networks and requested them to participate. In advance, they received a working draft version of the research report. A focus group (n=38) could be composed representing the respective stakeholders. Its main goal was to identify important sources of data that were not yet included at that time, and to further discuss and develop the preliminary conclusions and recommendations from the literature scan.

A professional talk-host led the meeting that opened with an introduction and a summary of the study outcomes by the authors. This was followed by a one-hour 'knowledge café' method, an informal but systematic way to exchange and map opinions and ideas of participants. After a break and a philosophical reflection on technologies and risk, a discussion panel took place wherein representatives of stakeholders actively participated. Outcomes were noted down, analyzed and summarized.

V. OUTCOMES

A. Literature scan

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.

Human, technological or organizational risks appear to be no primary subject of the randomized clinical trials identified in the search. However, they are reported as secondary effects or unintended outcomes of eHealth technology effectiveness studies. In most cases, the observed risks are related to a lack of effectiveness in all or part of the target groups due to either the design of the intervention, implementation factors or intrinsic characteristics of the target groups. Other types of unintended adverse effects leading to harm for patients, users or third persons were rarely mentioned.

Identified risks have been structured with regard to their primary occurrence at a human level, a technological level and an organizational level (Table III). Appendix III contains a detailed overview of risks, the level where they occur, their classification and their source in eHealth literature.

1) Risks concerning Human factors

Masa et al. [22] 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. [23] 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. [24] 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 15-20 years 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=0.06; 1.6 more drinks/week), at one month follow-up. Zimmerman et al. [25] 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. [26] 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. [27] 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. [28] 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. [29] 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. [30] 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. [31] 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 desired effect of an intervention.

2) Risks concerning Technology

Evaluating a tele-homecare application for monitoring diabetes Bujnowska-Fedak et al. [23] 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. [32] 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. [26] 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. [33] 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. [34] 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. [35] 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. [27] 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 has 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. [36] 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 [35]. 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. [37] 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. [38] 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. In addition, 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.

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 Table III, the identified risks have been summarized with regard to the various levels of their occurrence.

B. Web-based sources

From the mixed web-based sources it appears that the information on eHealth and telemedicine is overly positive. The risks, downsides or failures that are inevitably part of any project, are rarely mentioned - neither prominently nor implicitly. Nevertheless, a number of sources mention the imperative provisions that should be made to ensure that eHealth or telemedicine projects will be successful. It could be assumed that these are indicative of the risks they are often related to. These are grouped into three categories: the

human factor, technology and organization, summarized in Table IV.

TABLE IV. SUMMARY OF OBSERVED RISKS IN WEB-BASED SOURCES

RISK LEVEL	DESCRIPTION
Human level	Lack of physical, mental, social, cognitive skills (eHealth literacy)
	Substitution human contact, doctor-patient relationship
Technology level	Problems with resolution, interference, bandwidth, connections
	Incompatibility, sub optimal interoperability
	User-unfriendly technology
	Insufficient error handling, no emergency plans
Organizational level	Money, lack of training/instruction, data-management, hardware
	Home (unclear liability, accountability, insurance issues)
	Uncertain response speed of care organizations 24/7

1) The human factor

eHealth and telemedicine are not intended to substitute patient-physician contact. Use of technology may reduce the number of contacts, thus increasing the efficiency of health care. For patients it may be beneficial that the number of visits to the physician can be reduced, thus saving time and expenses. Nevertheless, periodic direct in-person contact should not be completely replaced. Any project should primarily be driven by needs and not by technology. Before a project starts, a needs-analysis should be performed and the added value should be proven. Scientific evidence of effectiveness in a large scale settings seems to be missing in many cases. Safe application of eHealth and telemedicine requires that patients are capable of self-management and are physically and mentally able to handle the technology and the tasks that come with an intervention. The patient should be motivated to use the technology correctly, follow instructions and procedures, be well-trained and function without cognitive or communication difficulties. The patient should be confident to use the technology, but at the same time not completely rely on it.

2) Technology

The early initiatives of eHealth and telemedicine suffered from technological shortcomings such as the limited resolution or the narrow band width for transmitting data. These limitations are largely overcome, but others appear. With more and more wireless applications that transmit digital signals, problems arise like interference and frequency overlap. Where eHealth or telemedicine depend on a continuous online connection, the risk of a failing connections should be taken into account. Equipment should be designed to match the skills of the user, ergo shall be self-explanatory, as simple as possible to operate and be 'layman proof'. The databases from the FDA and ECRI clearly show that medical technology is known to fail and may subsequently cause harm to the patient. Where there is a physical distance between the patient and the care provider it may occur that a device is not working properly, while this is not noticed by the patient or the care provider. Mechanisms should be implemented to detect and identify errors in transmission, equipment failure and software bugs. An emergency plan for alternative treatment or monitoring should be in place. Where medical devices and equipment from different manufacturers are used together or are connected to generate, store or process data, these shall be interoperable. The same applies for electronic patient records and health files, and where possible internationally.

3) Organization (incl. legal and financial issues)

All stakeholders should be identified and there shall be a common understanding of tasks and responsibilities of the stakeholders. Training of the users of the technology should be well organized and should include actions that need to be taken in case of emergencies, e.g., patient distress, or failing equipment. If the technology sends messages to the health care provider these should be followed up without delay. The health care organization should consider hiring dedicated personnel to handle the technical side of eHealth or telemedicine services, so that the physicians can focus on the medical aspects. Depending on the type of eHealth service or telemedicine it may be necessary to have a 24/7 care response service available. The staff that provides the response service should be adequately trained. The supply and management of equipment, including maintenance, response to malfunction and training of the patient shall be organized. To sum up, the management of the technology must be well embedded in the organization of the health care provider and not be an isolated entity. Legal issues include licenses and credentials (especially when patient and physician do not reside in the same country), liability, data confidentiality, data storage and patient privacy. eHealth and telemedicine projects may benefit from local electronic patient files and a national (or even international) health file. The tasks and responsibilities of all the parties involved in the implementation and use of the technology must be documented. Financial issues appear to be an important 'show stopper'. eHealth and telemedicine need to mature into accepted forms of health care that can operate without special funding. To convince policy makers and financers, every eHealth or telemedicine project needs to be evaluated to demonstrate the added value and that the project goals are met.

C. Authoritative reports published during data analysis

Near the end of our data analysis process, three reports were published that we considered particularly relevant to our own study. The first is the report 'National

Implementation Agenda eHealth' [39], a joint policy paper (Dec. 2011) of the Royal Dutch Medical Association (KNMG), the Dutch Federation of Patients and Consumer Organizations (NPCF) and the Dutch Health Care Insurers Association (Zorgverzekeraars Nederland). The second is the report 'Health IT and Patient Safety: Building Safer Systems for Better Care' (Nov. 2011) published by the U.S. Institute of Medicine [40]. The third is 'State of Health Care 2011. In health care, patient information exchange challenges is not resolved with ICT without the standardization of processes' (Oct. 2011) a report by the Dutch Healthcare Inspectorate [41]. These authoritative reports exemplify that eHealth technology will substantially change the health care system in the coming decade. They confirm that inconclusive evidence exists when it comes to risks for patient safety and quality of care. If risks are to be contained at an acceptable level, some serious hurdles have to be taken.

The policy paper of three main stakeholders in Dutch health care, which was also sent to the Parliament by the Ministry of Health, demonstrates the present political dynamics necessary to bring about such a change. However, the scientific back-up for their claims is not as strong as their political determination. For instance the statement that eHealth "contributes to affordable, accessible, high-quality health care and more direction for patients" is not supported by prevailing evidence as of yet. The National Implementation Agenda also neglects the considerable risks as outlined by the Institute of Medicine (IOM) and the Dutch Healthcare Inspectorate (IGZ). At the same time, it is true that reports are available of successful practices and promising outcomes in the whole range of health care services. These developments render a certain urgency to the issue of risk control and prevention, which until recently did not receive much attention.

IOM advances safety as an essential value in health care and favors an holistic approach to improve overall safety of the health care system. Transparency, education and collaboration of all stakeholders are the main components of the approach. IGZ emphasizes the importance of safe and secure information exchange as a vital to risk reduction. Both organizations provide a series of recommendations to improve patient safety.

D. Focus group

The preliminary conclusions of the draft report were generally accepted and supported by the experts. From their respective angles they advanced valuable additional subjects related to the present paper. We inferred the following cross-cutting themes from the discussion, that are vital for risk control in eHealth:

- Patient-centeredness;
- Interoperability and standardization;
- Risk management tools and regulations;
- Integrative approach of risk-management in eHealth;
- eHealth affects organization of care;
- Transparency in risk documentation;
- Education.

The integration of these themes in the implementation of eHealth is expected to considerably reduce the incidence of risks in healthcare.

VI. CONCLUSION AND FUTURE WORK

Randomized clinical trials and studies of the immediate risk of eHealth technology for patients' safety or quality of care have not been found. In the margin of studies aiming to evaluate the effectiveness of eHealth interventions risks are reported as unintended, secondary outcomes. The selected studies suggest 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. In some cases the causes of the risks were qualified as study (design) artifacts. In many instances the consequences have not been elaborated.

In the web-based sources we studied, a positive attitude towards eHealth prevails and risks or failures are rarely mentioned. A number of sources mention conditions for eHealth projects to succeed (Table IV). These may be used as input in risk analysis and should be reinforced through risk management and continuous surveillance.

The focus group outcomes demonstrate the significance of stakeholder involvement at all levels. Our findings from literature and web-based resources are reflected in the resulting themes. We conclude that while not much is known about the magnitude of risks associated with eHealth, a lot of non-systematic, anecdotal material indicates that risks happen at the level of human functioning, technology and organization.

We intend to further contribute to risk awareness in eHealth and conduct follow-up research in this field.

VII. DISCUSSION

Increasing use of eHealth technology is one of the major developments in today's healthcare [42]. The opportunities of web-based and mobile eHealth technologies should

therefore remain central to the global health discourse. At the same time, however, it is required to explore the risk potential of these technological advancements.

Risk is a complicated issue that refers to a lack of knowledge along subjective and objective dimensions. 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 higher level of risk awareness when it comes to new technologies. At present risks emerge in the margin of trials and interventions 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 to be disturbing at first glance, a wider search would almost certainly deliver a disquieting range and diversity of risks. Given the outcome of our study that none of the systematic studies 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 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. These are often viewed as avoidable or improvable intervention flaws, or explained as study (design) artifacts, but they should not be played down. Their presumed occurrence give rise to careful reconsideration when it comes to exploring the opportunities of web-based and mobile eHealth technologies for global healthcare innovation. eHealth is not an exotic domain in health care and should be treated as a such. The indications for risks found in the present study should play a role in keeping the health care community alert with regard to risk management. The participants of the focus group would certainly acknowledge this.

This implies the need for extensive research that explicitly focuses on establishing the volume and nature of such risks in order to prevent or minimize them. It also implies an improved way of monitoring to advance transparency in the reporting of risk occurrence and safety incidents. Finally, it implies a higher level of health care 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. Available tools and standards should preferably be used to achieve this.

The results of the present scan are in accordance with outcomes from the ceHRes study that covers over a decade of eHealth technological development [17]. The 'conceptual' risks (Table I) represent the same categories of risks that result from the literature scan. For instance expert-driven eHealth interventions that neglect the essential role of patients may lead to adherence issues as mentioned sub V-A.1). Or disregarding conditions for implementation may imply the underestimation of issues such as high time-consumption, mentioned sub V-A.3). To minimize and avoid such risks a 'Roadmap' has been developed to design, develop, implement and evaluate eHealth interventions (see Appendix IV). It applies concepts and techniques from business modeling and human centered design [43]. The roadmap serves as a guideline to collaboratively improve the impact and uptake of eHealth technologies. For this purpose it has been published as a wiki (ehealthresearchcenter.org/wiki/).

For now the ubiquitous trust in technology seems to be unjustified and it needs to be put in perspective. We have the instruments, in particular risk management approaches, and the knowledge to reconsider the implementation of eHealth to achieve this, so eHealth can become part of evidence based medicine.

VIII. LIMITATIONS

The inclusion criteria of the study, such as the requirement for RCTs in the review of scientific literature, were found to be limiting, since we are looking to novel technologies in tele-/eHealth. Moreover, RCTs in eHealth environments tend to mitigate the impact and uptake of interventions because of costs, timelines and limitations.

We have probably missed a number of British publications and websites because of the choice of the term 'eHealth', which appears to be not widely used in the United Kingdom, and generally is assumed to refer to electronic patient records and transmission of acute health information electronically. Furthermore, we may have missed important websites such as NHS networks (see: http://www.networks.nhs.uk/ because of the federal nature of the NHS as well as more regional online outlets.
Exploring the full spectrum of 'grey literature' would have delivered much more indications on the occurrence of risks though we expect it would not have helped in quantifying their magnitude.

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and Disease management (IGS - Institute for Governance and Innovation Studies, University of Twente).

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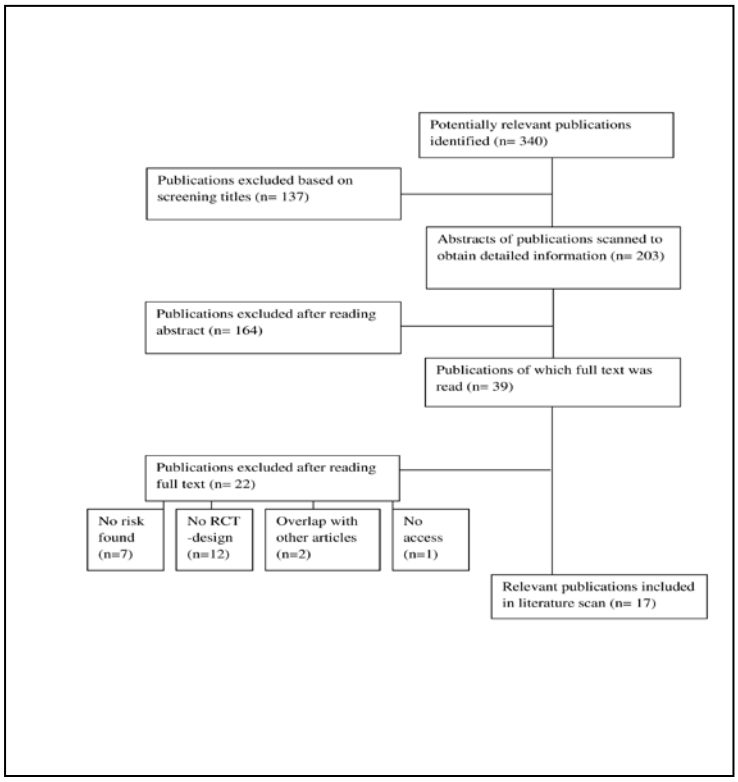
Appendix I

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



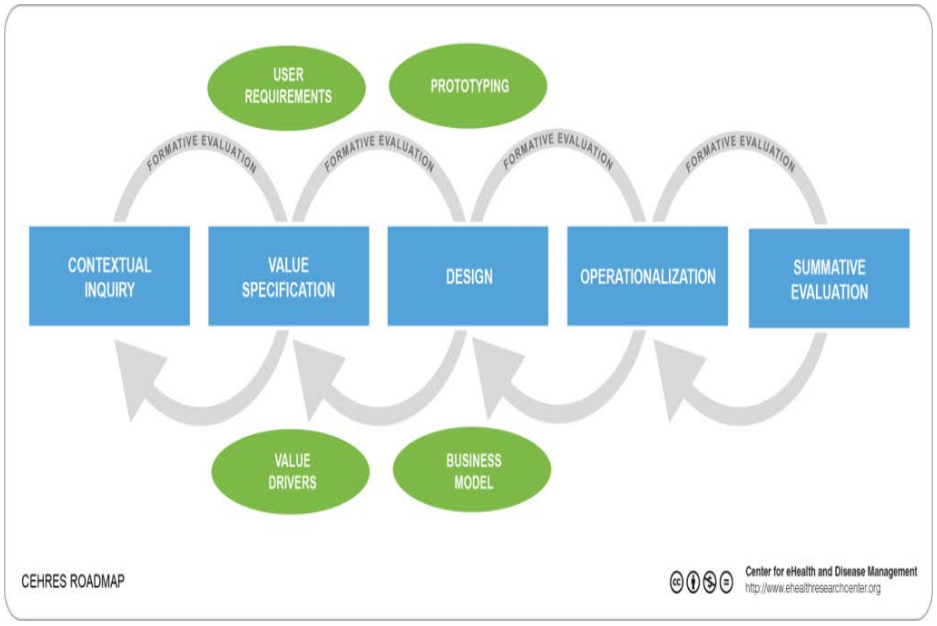
Appendix III

Classification of identified risks

Level	*Risk*	*eHealth application*	*Source*
Human (patient)	Time-consumption	Telecare	Masa et al. (2011)
	Selective benefit	Telecare	Bujnowska-Fedak et al. (2011)
	Selective benefits / negative effect	Web-based counseling	Spijkerman et al. (2010)
	Selective benefits	Telecare	Zimmerman et al. (2011)
	Low adherence	Web-based self-management	Cruz-Correia et al. (2007)
	Low adherence	Telecare	Willems et al. (2007)
	Low adherence / selective benefits	Web-based counseling	Verheijden et al. (2004)
	Low adherence/alliance	eTherapy	Morland et al. (2010)
	Drop-out	eTherapy	Postel et al. (2010)
	Pos. for 2 endpoints / Neg. for other	Tailored web-based counseling	Ruffin et al. (2011)
Technology	Usability	Telecare	Bujnowska-Fedak et al.(2011)
		Self-management via PDA	Nguyen et al. (2008)
	Technical problems	Self-management via PDA	Nguyen et al. (2008)
		Web-based self-management	Cruz-Correia et al. (2007)
		Telecare	Demaerschalk et al. (2010)
	Also time consumption as risk in this study	Telecare	Jansá et al. (2006)
		Telecare	Biermann et al. (2002)
	Technical / Logistical problems	Telecare	Willems et al. (2007)
Organization	Costs	Telecare	Copeland et al. (2010)
	Time-consumption	Telecare	Biermann et al. (2002)
		Telecare	Montori et al. (2006)
	Barriers using the application	PDA-based counseling tool	Strayer et al. (2010)

Appendix IV

ceHRes Roadmap to improve the impact of eHealth interventions



Appendix V

Web-based sources

Sources	urls
International and national health organizations /government agencies	❖ World Health Organization (WHO http://www.who.int/goe/en/); ❖ European Commission (EC http://ec.europa.eu/health/medical-devices/index_en.htm); ❖ UK Department of Health (http://www.dh.gov.uk/en/index.htm); ❖ MHRA (http://www.mhra.gov.uk/); ❖ Scottish Government (http://www.knowledge.scot.nhs.uk/telehealthcare.aspx); ❖ Irish Medicine Board (http://www.imb.ie/); ❖ Bfarm (http://www.bfarm.de/DE/Home/home_node.html); ❖ Australian Department of Health and Ageing (http://www.health.gov.au/internet/main/publishing.nsf/Content/eHealth); ❖ Swedish Medical Products Agency (http://www.lakemedelsverket.se/english/product/Medical-devices/)
Databases	❖ MAUDE (Manufacturer and User Facility Device Experience) database (U.S. Food and Drug Administration) http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM ❖ ECRI Health Devices Alerts (HAD) database https://members2.ecri.org/Components/Alerts/Pages/CPIssues/Issue.aspx?CH=1&ChName=Medical%20Devices&rid=0 ❖ ECRI Medical Device Safety Reports (MDSR) database http://www.mdsr.ecri.org/?pnk=healthdevices
Expert centers Medical technology	❖ ECRI Institute; https://www.ecri.org/Pages/default.aspx ❖ Prismant; www.kiwaprismant.nl/ ❖ ZonMw; www.zonmw.nl/
Dutch professional journal on health care	❖ Medisch Contact http://medischcontact.artsennet.nl/home.htm