National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Risks related to the use of eHealth technologies

Risks related to the use of eHealth technologies

An exploratory study

National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Risks related to the use of eHealth technologies

An exploratory study

RIVM Report 360127001/2012

Colophon

H.C. Ossebaard[1,3]
A.C.P. de Bruijn[2]
J.E.W.C. van Gemert-Pijnen[3]
R.E. Geertsma[2]

Contact:
R.E. Geertsma
Center for Pharmaceutical Affairs and Medical Technology
robert.geertsma@rivm.nl

[1]Health portal kiesBeter.nl, National Institute for Public Health and the Environment, Bilthoven, The Netherlands

[2]Center for Pharmaceutical Affairs and Medical Technology, National Institute for Public Health and the Environment, Bilthoven, The Netherlands

[3]Institute for Governance and Innovation studies, Center for eHealth Research and Disease Management, University of Twente, Enschede, The Netherlands

This investigation has been performed by order and for the account of the Dutch Health care Inspectorate (IGZ), within the framework of project V/360127.

Abstract

Risks related to the use of eHealth technologies

An exploratory study

More awareness is needed about the risks of e-Health technology. While information regarding its potential is abundant, the risks associated with the use of information (including mobile) and communication technology in health care have scarcely been addressed. In order to implement e-Health technology successfully and safely, the evaluation of their benefits should be integrated into and complemented with systematic risk assessment. This is the main recommendation resulting from an exploratory literature study that was performed at the request of the Dutch Health Care Inspectorate.

A review of scientific literature identified no systematic studies *(randomized controlled trials)* that directly investigated the risks of e-Health technology. However, many unintended, 'secondary', outcomes have been reported that indicate risks for patient safety or quality of care at the level of the technology, the end-user (patient, professional) or the organization. They vary from high time consumption, adverse effects, usability problems, limited server access and malfunctioning devices due to improper use or financial issues. Similar outcomes were found through searching 'grey' sources accessed through the internet. From the combined scientific and grey sources, we found anecdotal evidence for a wide variety of risks in e-Health, of which the magnitude is largely unknown. Confirmation of these findings was obtained from several other recent, authoritative reports.

E-Health interventions are being increasingly used in Dutch health care. It is, therefore, important that tools currently used for risk management are applied to e-Health as well. A reliable system to report, identify, document and monitor risks would help to increase transparency in this field.

Keywords:

risk, e-Health, technology, patient safety, quality of care

Rapport in het kort

Risico's van het gebruik van eHealth-technologie.
Een verkennende studie.

Voor de risico's van eHealth-technologie is meer aandacht nodig. In de media, vakbladen, en wetenschappelijke tijdschriften is een overvloed aan informatie beschikbaar over de mogelijkheden van (mobiele) informatie- en communicatietechnologieën in de zorg. Voorbeelden zijn het 'op afstand' monitoren van diabetes in de thuiszorg, internethulp bij depressie, of digitale ondersteuning (PDA) bij stoppen met roken. Er is echter weinig bekend over de risico's van dergelijke technologieën. Als aanvulling op bestaande, veelal positieve, eHealth-evaluaties zouden de risico's daarom structureel en stelselmatig in kaart moeten worden gebracht. Dat is een voorwaarde om eHealth-technologie succesvol en veilig te kunnen gebruiken. Dit zijn de belangrijkste bevindingen van een verkennend literatuuronderzoek van het RIVM, uitgevoerd in opdracht van de Inspectie voor de Gezondheidszorg (IGZ).

Voorbeelden van risico's
In de wetenschappelijke literatuur zijn geen systematische studies *(randomized controlled trials)* gevonden die risico's van eHealth-technologie als hoofdonderwerp hebben. Wèl worden talloze, onbedoelde gevolgen van het gebruik van eHealth gemeld die raken aan de patiëntveiligheid of aan de kwaliteit van zorg. Risico's doen zich voor bij de gebruiker (patiënt), de technologie zelf en de organisatie die eHealth inzet. Voor de patiënt gaat het om gebruiksonvriendelijke technologie, onnadenkend gebruik ervan of beperkte toegang ertoe. Patiënten kunnen hierdoor vastlopen, gedemotiveerd raken of de therapie staken. Hierdoor kan de behandeling niet het beoogde effect hebben of de klacht zelfs verergeren. Bij de technologie komen de risico's vooral voort uit slecht functionerende apparaten. Op organisatieniveau ontstaan risico's wanneer eHealth onvoldoende is ingebed in het zorgproces.

De aangetroffen bewijzen voor de risico's zijn hoofdzakelijk anecdotisch van aard. Over de omvang ervan is weinig bekend. Zowel onderzoek van online 'grijze' bronnen, zoals databases en websites, als gezaghebbende publicaties laten deze uitkomsten zien.

Risicomanagement en meldsysteem
Omdat in Nederland steeds meer eHealth-technologie wordt gebruikt, is het belangrijk dat in de gezondheidszorg bestaande procedures voor risicomanagement ook voor eHealth worden ingezet. Een betrouwbaar systeem waar incidenten structureel kunnen worden gemeld, geïdentificeerd, gedocumenteerd en gemonitord zou daarbij helpen.

Trefwoorden: risico, eHealth, technologie, patiëntveiligheid, kwaliteit van zorg

Contents

Summary

Background

Under its 2011 Workplan the Dutch Health care Inspectorate (IGZ) requested the Dutch National Institute for Health and Environment (RIVM) to carry out an exploratory study of the risks associated with the use of eHealth technologies in health care.

Objective

The objective of this exploratory study is to give an overview of risks associated with the use of eHealth applications and technologies in health care based on outcomes as reported in scientific literature and in relevant web-based sources. Risk is viewed as the combination of the probability of occurrence of harm and the severity of that harm.

Methods

A quickscan of scientific literature was performed as well as an analysis of web-based sources. The bibliographic database SciVerse Scopus was searched to collect scientific publications (2000-2011) on risks resulting from the use of eHealth applications in health care. The search was restricted to studies regarding risks concerning the quality of health care and patient safety. Only randomized controlled trials (RCTs) were included. Security risks concerning data-management were excluded. We selectively included three recent, integrative reports with regard to patient safety and health technology that appeared during the time of study. To explore grey literature, a selection of websites was searched from health organizations of various types of institutions including (inter)national health organizations/government agencies, incident databases, expert centres and opinion papers. Outcomes were validated in a focus group setting against expert views of stakeholders from health care, patients' organization, industry, academic research and government.

Results

RCTs of the immediate risk of eHealth technology for patient safety or quality of care have not been found. Of 340 publications identified, 17 met the inclusion criteria. These report risks for patient safety and quality of care as a result of the use of eHealth technology, however, only as 'secondary' results. Higher time consumption, unintended adverse effects, and selective patient benefits differing for sex, education, age and other variables are the risks observed on the side of the human (end-)user. Adherence issues are frequently mentioned and associated with a negative impact on the intended effect of an intervention. Reported risks at the technology level range from usability problems and security issues to problems with accessing the server or malfunctioning devices. At the organizational level, observed risks concern increased time consumption, barriers for proper use and financial issues. A recent study reviewing sixteen eHealth frameworks confirms these risks at a conceptual level. Extensive anecdotal evidence of risks reported at all of these three levels in web-based sources as well as recent authoritative reports substantiate the outcomes of the literature scan. The expert focus group generally recognized the findings and provided valuable, additional information, e.g. recommending the proper use of existing regulations and tools for risk management.

Conclusion

The outcomes suggest that risks associated with eHealth interventions occur at all three levels of the multi-level approach applied, i.e. the human (end-) user,

technology and organization. The use of eHealth technology in health care brings along risks which can negatively affect patient safety and the quality of care. The magnitude of such risks is unclear. This finding is substantiated by other contemporary reports. A realistic reconsideration of the integration of eHealth in health care processes is needed to prevent or minimize such risks. To achieve this, four actions are recommended: 1) keep the health care community alerted with regard to the risk issue, 2) carry out more research on the risks of ICT in health care, 3) establish a system to report and document incidents (coherent with existing systems) and 4) apply risk management tools in all phases of the life cycle.

1 Introduction

The challenges for global health care have been documented extensively. Most countries face a serious increase in health care expenditures that corresponds to the ageing of the population, a growth in multi-morbid chronic illnesses, the enduring threat of infectious disease, consumerism and other dynamics (WHO, 2003; 2010). eHealth technologies have frequently been hailed as a panacea for these challenges. In background studies on the changing landscape of health care commissioned by the Council for Public Health and Health care the use of eHealth technologies (Health 2.0, telemedicine) is considered to be one of the major trends in today's health care (Duchatteau & Vink, 2011; Van der Klauw & Flim, 2011). 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 (WHO Resolution WHA58/28; Glasgow, 2007; Verhoeven et al., 2010; Kelders et al., 2011; Nijland et al., 2011; Van der Heijden et al., 2011). However, expectations have been mitigated due to the publication of studies that emphasize the lack of rigid evidence for impact of eHealth technologies on health care outcomes thus far (e.g. Atienza et al., 2007; Black et al., 2011). Moreover, the application of eHealth technologies in health care may introduce risks for patient safety and quality of care (Geertsma et al., 2007; IGZ, 2008; National Academy of Sciences, 2011). The Preface to a recent report published by the United States Institute of Medicine cites Sir Cyril Chantler of the Kings Fund, the leading UK health think tank, who hints to such risks:

> *'Medicine used to be simple, ineffective, and relatively safe. Now it is complex, effective, and potentially dangerous'*
> (National Academy of Sciences, Institute of Medicine, p. ix, Aug. 2011).

Nonetheless, trust in information and communication technologies (ICT) seems to remain rather unaffected by such moderating observations. This is remarkable against a backdrop of widespread declining trust in the legal system, in politics, finance, science and other societal domains (Dierkes & Von Grote, 2000; Barben, 2010). Public administrations, care professionals, researchers and the general public are generally trustful and optimistic about the 'a-political' power of digital technology in virtually all social and personal domains (WRR, 2011; Beeuwkes Buntin, 2011). Investments in ICT are rarely withdrawn because of alleged risks for patient safety or for the quality of care. The value of trust lies in the opportunities for cooperation, knowledge, autonomy and other 'social goods' that contribute to the foundations of society (Hardin, 2002; McLeod, 2011). 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 to eHealth interventions related to trust?

Trust in, and trustworthiness of, eHealth interventions are obviously affected by (perceived) risks. Over the last decades studies of risk and technology have grown into a major interdisciplinary field of research. Swedish risk researcher Hansson states that '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' (Hansson, 2011). 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' (ISO/IEC, 1999). This definition is also used in the international standard for risk management of medical devices EN ISO 14971 which is the regulatory sector wherein at least part of the eHealth technologies can be classified.

1.1 Objective

The present report is commissioned by the Dutch Health care Inspectorate in order to provide more insight into the nature and extent of risks to patient safety and quality of care that may be associated with eHealth applications.

The objective of this exploratory study is to give an overview of risks associated with the use of eHealth applications and technologies in health care based on outcomes as reported in scientific literature and documented in relevant web-based sources.

To avoid unsolved, academic issues of definition we simply consider eHealth technologies as digital information and communication technology used in care. This includes web-based and mobile applications for caregivers, patients and their relatives within a treatment relationship, as well as technologies aiming to improve quality in health care.

2 Methodology and structure of this report

This chapter provides a general overview of the design of the study and the structure of the report. A detailed description of the methodology used for the various parts of the study is included in each of the following chapters, which describe the separate components of the study.

This study uses the following sources of information:

- scientific literature
- grey literature and databases
- recent authoritative reports
- a focus group of stakeholders in the field of eHealth participating in an `invited expert meeting'.

For the scan of the scientific literature, we limited the search in the first instance to studies with the highest power of evidence, i.e. randomized controlled trials (RCTs). This could also serve possible comparisons between studies. The results of this search are described in Chapter 3. For grey literature, we mainly relied on web-based sources. After initial searches in the Google search engine, we selected specific websites and online databases of health organizations. A detailed description of the outcomes is included in Chapter 4.

During the course of the investigation, the need for reference information covering a broader set of scientific literature became clear. Firstly, we included a recently published review study (Van Gemert-Pijnen et al., 2011), in which we sought to improve the impact of eHealth technologies by advancing a 'holistic approach' towards their development and integration in the health care sector. This study was based on a comprehensive analysis of eventually sixteen eHealth frameworks over the last decade (2000-2010). The reported drawbacks can logically be transposed to risks at a conceptual level. We have therefore included a short summary of these findings in Chapter 5. Secondly we took account of three authoritative reports on the subject of patient safety and health technology that appeared at the time of study (National Implementation Agenda eHealth, 2011; National Academy of Sciences, 2011; IGZ, 2011). Chapter 6 contains a short summary of the most relevant findings of these reports.

Chapter 7 contains the results of guided focus group discussions among stakeholders from the field of eHealth during an `invited expert meeting' in November 2011 in Utrecht, The Netherlands (see also Appendix II and III).

Chapter 8 contains the discussion and recommendations based on the combined outcomes of the above data sources. Here we have also included comments from members of the Special Interest Group Telemedicine of the EC New and Emerging Technologies Working Group.

3 Literature scan[1]

3.1 Methodology

The present research involves a literature scan to exploratory assess risks that are reliably documented in the scientific literature. The scan is restricted to publications regarding risks that affect the quality of health care and patient safety. The public health domain is excluded. Issues concerning security of data-transmission, storage, encryption, standardization, data-management and privacy are not included in order to limit the investigation and to avoid overlap and redundancy with other studies (IGZ, 2011). The search is limited to randomized controlled trials (RCTs), representing the type of studies with the highest power of evidence in absence of meta-analyses or systematic reviews, and providing comparisons with alternative approaches.

The bibliographic database SciVerse Scopus was searched because of its broad content coverage including full coverage of Medline titles and over 16,000 peer-reviewed academic journals. The search query combined the topic 'eHealth' with search terms regarding risk, health care-setting and study design. The complete query is included 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 were: 1) the article deals with an eHealth application and/or 2) deals with risks for 3) quality of care in general and/or patient 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 patient safety. Articles whose titles contained outcome measures or evaluation criteria of eHealth programs were included as well. If risks or limitations where 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 in the German and English language were scanned. Table 3.1 summarizes the inclusion criteria.

Table 3.1 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 patient safety
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. (2008).

[1] Parts of this chapter have been presented as an original research paper at eTELEMED, the 4th International Conference on eHealth, Telemedicine, and Social Medicine (Ossebaard et al. 2012).

3.2 Study selection process

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 as depicted in the flow chart in Figure 3.1.

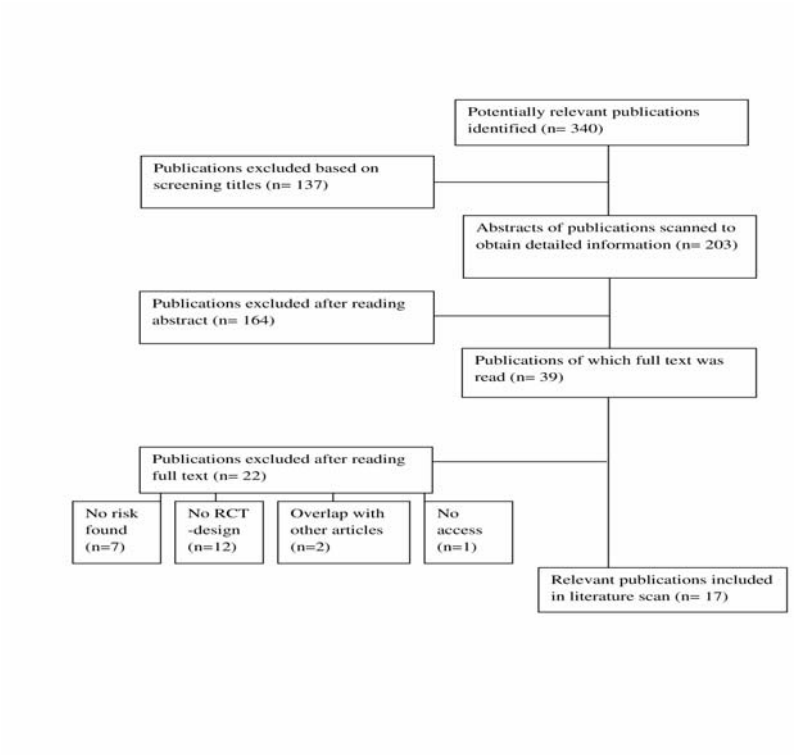


Figure 3.1 Flow chart showing the study selection process

3.2.1 Results

3.2.2 Multi-level risk categorization

Identified risks have been structured with regard to their primary occurrence at a human level, a technological level and organizational level. Human, technological or organizational risks appear to be no primary subject of the RCTs identified in the search. However, they are reported in these studies as secondary effects or unintended outcomes of eHealth technology implementations. 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 hardly mentioned. Table 3.2 provides an overview of identified risks in RCTs of eHealth Technologies. They are described in more detail in the subsequent paragraphs.

Table 3.2 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 counselling	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 counselling	Verheijden et al. (2004)
	Low adherence/alliance	eTherapy	Morland et al. (2010)
	Drop-out	eTherapy	Postel et al. (2010)
	Negative for intention variable	Tailored web-based counselling	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)
	Higher time-consumption	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 counselling tool	Strayer et al. (2010)

3.3 Risks concerning Human factors

Masa et al. (2011) compared conventional spirometry to online spirometry with regard to outcome measures like forced vital capacity, some quality criteria (acceptability, repeatability) and the number of manoeuvers and time spent on both of the two procedures. They found that the number of spirometric manoeuvres 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 manoeuvres 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. (2011) 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. (2010) evaluated a web-based alcohol-intervention without (group 1) and with (group 2) feedback compared to a control group in order to reduce drinking behaviour in 15 to 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 behaviour in male participants over a period of one to three 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. (2011) 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. (2007) 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. (2007) 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. (2004) tested a web-based tool for nutrition counselling 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 eight months' study period. Patients properly using the intervention were significantly younger than those who did not.

Morland et al. (2010) compared an anger management group therapy for veterans delivered in-person versus via videoconferencing. Group therapy via videoconferencing seemed equally 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 significantly higher overall group therapeutic alliance than the intervention group. Postel et al. (2010) 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 participants also relapsed or increased alcohol consumption.

Ruffin et al. (2011) 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.

3.3.1 Risks concerning Technology

Evaluating a tele-homecare application for monitoring diabetes Bujnowska-Fedak et al. (2011) 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. (2008) 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. (2007) 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. (2010) 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. (2006) 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 counselling caused by problems with the application itself, the server or internet-access. Using a tele-management application for diabetes patients Biermann et al. (2002) 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 tele-monitoring program by Willems et al. (2007) one third 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 problems with accessing the server or malfunctioning devices.

3.3.2 Risks concerning Organization

Copeland et al. (2010) 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 (Biermann et al. 2002). 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. (2004) 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 min. vs. 18 min.) 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. (2010) 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 behaviours 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.

3.3.3 Conclusions from the literature scan of RCTs

RCTs designed to identify risks of eHealth technology for patient 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 the occurrence of 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 equally benefit from an eHealth intervention, which implies that contra-indications for particular groups are indicated. 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 3.3 shows a summary of the level and nature of the risks observed in the present study.

Table 3.3 Summary of Observed Risks in RCTs of eHealth Technologies

Risk level	**Description**
Human level	Adherence (or compliance, drop-out, attrition, 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) artefacts. In many instances the (possible) consequences have not been elaborated.

4 Web-based sources

In order to broaden our view for this explorative study we have included 'grey literature'. The 'Prague Definition[2]' 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 body of materials cannot be found easily through conventional channels and includes government research, non-profit reports, dissertations, think tank assessments, conference proceedings, technical reports, institutional repositories, investigations, and other primary resource materials such as records, archives, observations, data, filed notes as well as 'new' sources e.g., pre-prints, blogs, preliminary research results (open files), unpublished theses, project web sites, standards and specifications, online data archives or other types of documentation. Because of limited resources our search in grey literature was restricted to a selection of websites of health organizations of different standing, including (inter)national health organizations/government agencies, incident databases (FDA), expert centres and opinion papers.

4.1 Methodology

Given the plethora of different types of organizations publishing information on eHealth, we decided to start with explorative searches in sources of different status. We did not use a systematic selection process to choose particular organizations within different categories. 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 accessed the websites of three expert centres on medical technology: the ECRI Institute, Prismant and ZonMw. Finally, one of the major Dutch professional journals on health care matters, Medisch Contact, was queried on risk factors concerned with eHealth and telemedicine.
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.

4.2 International Organizations

4.2.1 World Health Organization

The World Health Organization (WHO) is the directing and coordinating authority for health within the United Nations system. It is responsible for providing leadership on global health matters, shaping the health research agenda, setting

[2] 12th International Conference on Grey Literature (Prague, Dec. 2010); http://www.opengrey.eu/item/display/10068/700015 [accessed 1 May 2012]

norms and standards, articulating evidence-based policy options, providing technical support to countries and monitoring and assessing health trends.

In her report 'Telemedicine, opportunities and developments in Member States' (WHO, 2010), the WHO concludes that despite its promise, telemedicine applications have achieved varying levels of success. Challenges that need to be overcome (both in the industrialized and developing countries) are the following.

- The complex of human and cultural factors. Some patients and health care workers resist adopting service models that differ from traditional approaches or indigenous practices, while others lack ICT literacy to use telemedicine approaches effectively. Most challenging of all are linguistic and cultural differences between patients and service.
- Legal considerations. These include an absence of an international legal framework to allow health professionals to deliver services in different jurisdictions and countries, a lack of policies that govern patient privacy and confidentiality including data transfer, storage, and sharing between health professionals, health professional authentication, in particular in email applications and the risk of medical liability for the health professionals offering telemedicine services.
- Technological challenges. The systems being used are complex, and there is the potential for malfunction, which could trigger software or hardware failure. This could increase the morbidity or mortality of patients and the liability of health-care providers as well.
- The added value of telemedicine. The importance of evaluation within the field of telemedicine cannot be overstated: the field is in its infancy and while its promise is great, evaluation can ensure maximization of benefit. Indeed, the most frequently cited barrier to the implementation of telemedicine solutions globally is the perception that the cost of telemedicine is too high.
- Closely linked with cost is cost-effectiveness. There is a clear need for more information on the cost, the cost-effectiveness of telemedicine solutions, and the infrastructure necessary to implement telemedicine solutions.

These are conditions that correspond with a successful implementation. As such these challenges can also be interpreted as risks for patient safety and quality of care.

In her report 'mHealth: New horizons for health through mobile technologies' (WHO, 2011), WHO describes the outcome of a survey carried out in the member countries. The unprecedented spread of mobile technologies as well as advancements in their innovative application to address health priorities has evolved into a new field of eHealth, known as mHealth. mHealth or mobile health is a component of eHealth and could be defined as a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless, portable devices.
mHealth involves the use and capitalization on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including, mobile 'apps', general packet radio services (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and bluetooth technology. The barriers *casu quo* the risks with regard to mHealth implementation have been identified and

are more or less similar to the barriers that are encountered for the introduction of eHealth.

4.2.2 European Commission

The European Commission (EC) is the executive body of the European Union. It represents the general interest of the EU and is responsible for the general day-to-day running of the Union, for proposing legislation administering and implementing EU policies, enforcing EU law and negotiating in the international arena.

The EC has published online documents on the promotion of eHealth throughout Europe. In the 'Action plan for a European eHealth area' (EC, 2004) the EC states that eHealth offers European citizens important opportunities for improved access to better health systems. It could empower both patients and health care professionals. It could offer governments and tax payers a means - through substantial productivity gains - to cope with increasing demand on health care services. It could also help to reshape the future of health care delivery, making it more citizen-centred. Major challenges were identified:

- Commitment and leadership of health authorities, in particular related to financial and organisation issues, are essential elements for the successful deployment of e-Health;
- Interoperability of e-Health systems;
- User friendliness of e-Health systems and services;
- Lack of regulation and fragmentation of e-Health market in Europe. Most eHealth solutions in the Union have either been designed by small- and medium-sized businesses or are developed internally by specific health organisations;
- Confidentiality and security issues;
- Issues relating to the mobility of patients, including the cross border circulation of goods and services, among which eHealth services are of growing importance;
- Needs and interests of users. In general, the interests of the user communities (health professionals, patients, and citizens) should be better integrated into the development and promotion of eHealth;
- Access for all to eHealth;
- Common understanding and concerted efforts by all stakeholders. No single stakeholder can carry through implementation successfully on their own without the active co-operation of all the others.

These are conditions that correspond with a successful implementation of eHealth. As such these challenges can also be interpreted as risks for patient safety and quality of care.

In a Communication to the European Parliament on telemedicine for the benefit of patients, health care and society (EC, 2008) the EC mentions that despite the potential of telemedicine, its benefits and the technical maturity of the applications, the use of telemedicine services is still limited. Actions need to be taken by the Member States, the EC and the stakeholders on:

- Building confidence in and acceptance of telemedicine services by health professionals, patients and health authorities. Work has to be done to provide scientific evidence of effectiveness and cost-efficiency in a large scale setting;
- Bringing legal clarity, in particular with regard to licensing, accreditation and registration of telemedicine services and professionals, liability,

reimbursement, jurisdiction. Cross border provision of telemedicine services has to be taken into account;
- Solving technical issues and facilitating market development.

To establish the interoperability of the eHealth services throughout Europe two initiatives were started, Calliope (Calliope, 2011) and epSOS (epSOS, 2011). The joint project 'eHealth-INTEROP' addresses the requirements of the European Commission mandate (EC, 2007) to the European Standards Organisations (ESOs - CEN, CENELEC, and ETSI) on standardisation in the field of e-health. This mandate (M/403) aims to provide a consistent set of standards to address the needs of this rapidly evolving field for the benefit of future health care provision.

4.3 National health organizations

The websites of the UK Department of Health and MHRA, the Scottish Government, the Irish Medicine Board, the German Bfarm, the Australian Department of Health and Ageing and Swedish Medical Products Agency were searched for eHealth and telemedicine. Only the websites of the UK health department and the Swedish agency rendered results considered relevant to include in this report.

4.3.1 Department of Health (UK)

The website of the U.K. Department of Health contains two items on the evaluation of ETP (Electronic transmission of prescriptions) and nine items on telemedicine. Telemedicine is defined as telecare: a combination of equipment and monitoring that helps individuals to remain independent at home.
The policy document 'Building Telecare in England' (DoH, 2005) contains a section on implementation issues that clearly states that before advantage can be taken of telecare, infrastructures should be in place to deliver:
- staff training and development
- the supply and management of equipment
- the supply of relevant 24-hour/seven day contact services and
- the supply of 24-hour/seven day care response services.

4.3.2 Swedish Medical Products Agency (S)

The Medical Products Agency (MPA) is the Swedish government authority responsible for regulation and surveillance of the development, manufacturing and sale of drugs and other medicinal products. In 2008 the MPA invited stakeholders to form a working group to establish how digital patient information systems are affected by the medical device directives. The resulting report proposes guidelines for health care providers regarding the classification of software based information systems (MPA, 2010). These also serve as a prerequisite for ensuring that the safety requirements for medical information systems will have the intended effect. The report gives examples of telemedicine systems and concludes that the complexity of the devices and the accompanying risk vary (see Table 4.1). Reproduction of data can on some occasions be critical and it is a possible risk of maltreatment if the system fails. The authors imply that telemedicine systems shall be defined as medical devices.

Table 4.1. Complexity and risk matrix for telemedicine systems

	Telemedicine		
Factor / Severity	**1**	**2**	**3**
Fulfils the definition of a medical device in a broader sense	No	Possibly	**Yes**
Device complexity	Everything is visible. Like manual mode	**Hidden automatic function**	**Many hidden functions and processes**
Device overrules human responsibility	**Only presents basic data**	**Presents calculations**	**Provides suggestions and conclusions**
Risk for maltreatment / injury	No risk or little risk that always can be detected	**Risk is possible to detect to some extent**	**Risk can not be detected until it is to late**

4.4 Databases

4.4.1 Maude

The FDA manages the MAUDE (Manufacturer and User Facility Device Experience) database. Maude data represent reports of adverse events involving medical devices. The anecdotal, non-systematic data consists of voluntary reports to the FDA, user facility reports, distributor reports, and manufacturer reports since the 1990s. It includes the database of the Center for Devices and Radiological Health (CDRH), the FDA centre that is responsible for the premarket approval of all medical devices, as well as overseeing the manufacturing, performance and safety of these devices. The database contains information on medical devices which may have malfunctioned or caused a death or serious injury. MAUDE data is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices. Surprisingly, search terms 'telemedicine' or 'eHealth' gave almost no results, while related terms such as 'telemetry' gave thousands of entries, which reported mostly about problems in the data exchange between pacemakers and the programmer. Apparently, the broad concepts of eHealth and telemedicine have not been introduced in the database.

4.4.2 ECRI

The ECRI Institute is an independent non-profit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care. ECRI manages two databases, the ECRI Health Devices Alerts database and Medical Device Safety Reports database. The ECRI website was searched for position papers and incident reports.

ECRI Health Devices Alerts (HAD) database
The HAD provides recalls, hazards, product safety alerts, and reported device problems involving a broad range of medical devices and supplies since 1997. The database was queried for telemedicine, telehealth, telemetry, telepathology, teleradiology, and remote monitoring. Older information (before 2005) dealt with the limitations of bandwidth in telecommunication, the consequent low resolution of digital images, insufficient to be usable for diagnosis. This issue is solved with the availability of affordable broadband internet connection to almost every home.
Telemetry systems in hospitals that are used to remotely monitor the patient's condition are prone to software bugs, resulting in freezing displays, data mix up,

failing to alarm, and general interruption of monitoring. Also hardware issues are reported such as failing power supplies.
The growing number of wireless equipment that sends data frequency interference may arise, necessitating frequency management. Equipment may also experience interference from mobile phone networks and digital television broadcasting stations.
The reports in the ERCI HAD show that medical equipment that is used for telemedicine, like any other medical technology, may fail. The organisation that uses medical equipment for telemedicine should be vigilant for unexpected equipment failure.

Medical Device Safety Reports (MDSR) database
MDSR is a repository of medical device incident and hazard information independently investigated by ECRI Institute (ECRI). MDSR is not an alerting service, but a periodically updated review of the types of problems that have occurred with medical devices and lessons learned over the past three decades. It focuses on the steps that medical device users can take to prevent or reduce medical device risks to patient care and health care worker safety. The database contains a single relevant report on interference of telemetry equipment within a facility.

4.5 Expert centres

4.5.1 ECRI

Apart from incident reports in their databases (see 4.4.2), the ECRI website was also searched for position papers on eHealth and telemedicine.
The paper 'Telecommunications in Health care; a Primer' (ECRI, 1997) is a guidance article in six parts, providing an introduction to telecommunication technology. Part 4 is called Telemedicine and Videoconferencing. Apart from the benefits of telemedicine some limitations and problems involving telemedicine are briefly discussed. Despite the fact that this paper dates from 1997, several issues which can be interpreted as risks still may be relevant:

- Licensure and Credentialing
- Patient/Clinician Acceptance
- Data Confidentiality
- Costs of Telemedicine Services
- Compatibility Issues (proprietary systems versus standard systems).

The guidance article 'Telemedicine: An Overview' (ECRI, 1999) provides an overview of the issues surrounding telemedicine. Examples of successful telemedicine programs are given, along with guidance for facilities considering programs of their own, an outline of the barriers to successful implementation and ideas for evaluation of the effect of telemedicine on the delivery of health care. The following barriers identified in 1999 may be interpreted as risks and still be relevant:

- Insufficient justification for telemedicine. A needs analysis must be conducted, especially amongst patients and caregivers;
- Lack of planning for the implementation
- Choosing the wrong technology
- Lack of training in the use of the technology
- Legal issues, privacy and confidentiality.

The most recent paper by ECRI on the subject of telemedicine was published in 2007 by The Health Risk Control (HRC) section of ECRI (ECRI, 2007). The paper states that the Health care organisation providing telemedicine should:

- ensure that practitioners delivering telemedicine are properly credentialed, especially in the case that they are working in another country. Tasks and responsibilities should be accurately described and that liability insurance is concluded. It must be clear beyond doubt who participates in the patient/health care provider/practitioner(s) contract;
- monitor telemedicine-related laws and standards, and modify telemedicine activities accordingly;
- establish policies and procedures that outline the appropriate use of the technology and determine what regulations apply to the equipment and software used during telemedical procedures;
- implement a mechanism to identify errors in transmission, equipment failure and software bugs. A plan for alternative action should be established;
- ensure that the telemedicine system is secure enough to protect the confidentiality of patient records;
- have appropriate policies and procedures in place for retaining, accessing, and destroying telemedicine images;
- ensure that patients give informed consent when appropriate.
- ensure that patients that have to be actively involved in gathering and transmitting their health care data have the necessary technical and functional skills.

These are primarily conditions that correspond with a successful implementation of eHealth. As such these challenges can also be interpreted as risks for patient safety and quality of care.

ECRI also publishes health care product comparison reports. In 2009 a product comparison on 'Videoconferencing systems, Telemedicine' was published (ECRI, 2009). Telemedicine videoconferencing uses video and telecommunications technology to transmit medical information (audio, video and graphics) between two or more sites. These systems are used for diagnosis and prescription of medical treatment for patients at remote locations, for remote clinical consultations between medical professionals, for education and training of medical staff, and for administrative/business functions. The document identifies a number of problems associated with telemedicine, which can also be interpreted as risks:

- physician licensure and credentialing
- patient privacy, consent for videotaping the session, data security
- system design
- implementation
- high costs of telecommunication
- incompatibility of telemedicine systems because of the use on non-standardised architecture
- technical problems, equipment malfunction.

4.5.2 Prismant

Kiwa Prismant (known as Prismant until April 2010) is an expert centre for transparency in health care in the Netherlands. The work is performed on the bases of expertise, independence, reliability and integrity.

In her report of 2008, Prismant reports to IGZ about domotics and eHealth (Velde, 2008). For this category of ehealth, mostly applied in the context of home care, they have identified the following risks:

- patient and carers lack professional knowledge and skills, but should be able to act in case of emergencies and to take initiatives, and be aware of the larger responsibilities;
- home care providers have less knowledge and skills to operate the technology than hospital staff, and have little means for training, work in isolation without supervision and have limited means to consult colleagues or technicians;
- the technology may be too complicated and burdensome for the home user, and the instructions for use may not be adapted to the level of the home user;
- risk on user errors, which may go on unnoticed;
- in home care there is less professional observation;
- technology may fail and when needed professional intervention or technical support may take considerable time, alternative treatment/care must be available;
- the use of technology in the home situation may be hampered by unforeseen events;
- the organisation of home care involves many parties, potentially leading to miscommunication;
- technologies may be introduced without proof of efficacy (technology push); patient should not be forced into the use of ehealth;
- standard protocols for care are not developed as a result of small scale initiatives;
- replacing human care by technology may have a social context (increase of loneliness);
- privacy and confidentiality of health data may be at risk.

Prismant identified the following provisions that should be in place for successful ehealth in the home situation:

- technology should be simple to operate;
- the instructions for use must be clear for the home user;
- the home user, carer and health care providers must be trained in the use of the technology;
- where necessary the technology must be equipped with state-of-the-art alarms;
- the technology must be suitable for use at the patient's home;
- the maintenance and response to malfunction must be well organised by the homecare provider;
- tasks and responsibilities must be well documented;
- time and means must be reserved for frequent checks of the patient's condition.
-

4.5.3 ZonMW

Government departments, the Netherlands Organization for Scientific Research (NWO) and other organizations commission ZonMw to find solutions to certain problems or to boost work in the area of health care.
At www.veiligheidsdatabase.nl, ZonMw lists the descriptions of eHealth and Telemedicine projects that are developed in the Netherlands. Although these projects are developed in the context of patient safety, the project descriptions do not mention the risks involved with eHealth and telemedicine. In general, the

projects appear to aim primarily at improving the number of contacts between patients and care givers through ICT.

4.6 Unions of medical professionals

4.6.1 Royal Dutch Medical Association

The Royal Dutch Medical Association (KNMG) is the federation of medical practitioners' professional associations of The Netherlands. The main objectives are to improve the quality of medical care and health care in general and to promote the medical and associated sciences.

In the opening keynotes of a conference on eHealth that the association convened in February 2011, the convener clearly expressed that eHealth is no longer a hype but `is here to stay´. eHealth will prove to be an essential instrument to keep high quality health care available to all, at acceptable costs. The association published a book which gives 21 successful examples of eHealth projects that are implemented in the Netherlands (KNMG, 2011). However, no reflection is given on the risks involved.
A number of physicians were interviewed about their ehealth/telemedicine initiative. They were specifically asked about the practical issues that need to be resolved to make their initiative a greater success. The following issues were mentioned:

- Reimbursement. The reimbursement should be transparent and guaranteed for a prolonged period of time. eHealth can only mature when it is an accepted form of health care
- Quality control. Efficiency of new ehealth services should be proven before they enter the market, thus preventing loss of quality and ensuring a level playing field;
- The use of proven ehealth should be stimulated. Physicians need time to adapt to providing telemedicine and may be reluctant to do so;
- Telemedicine need to fit in the daily routine and easy to operate.

4.7 Opinion papers

4.7.1 Medisch Contact

Medisch Contact is a weekly published magazine for Dutch physicians. It is not a peer reviewed journal. Instead, it provides a quick platform for papers, interviews and opinions. It can be viewed as a source for signalling. Medisch Contact's website offers an archive of publications which was searched using simple search terms:

- 'eHealth': 86 hits
- telemedicine: 61 hits
- teleradiology: 6 hits
- telemonitoring: 38 hits.

The articles that were found in the queries on the publisher's website were screened for risks and requirements for implementation that may be interpreted as risks:

- the patient using eHealth must be committed to use the technology correctly and to follow the instructions for use and the procedures in which the use of the technology is embedded (Ikkersheim, 2006; Tokmetzis, 2007; Croonen, 2011);

- the eHealth program should be developed from the patients' perspective (bottom up), not the from the organisation (top down) (Tjalsma, 2007; Tjalsma, 2008; Croonen, 2011; Ploeg, 2011);
- systems that query the patient daily about their health should be programmed to ask the right questions. Conditions that are not queried will not be reported by the patient or their carers and will thus go unnoted by the health care provider (Ikkersheim, 2006; Tokmetzis, 2007);
- patients may become overconfident in trusting the technology. E.g. when a monitor device does not give an alarm people may interpret that all is well and ignore the signals their body is giving (Tokmetzis, 2007);
- the patient and carers should be well educated in the use of the technology (Seysener, 2001; Tjalsma, 2007; Tjalsma, 2008);
- the technology must be backed up by persons and shall be embedded in the organization of the health care provider (Tjalsma, 2008; Croonen, 2011).
    - The technology shall never be provided as an alternative for face to face contact but only as an addition (Tjalsma, 2007; Tokmetzis, 2007; Os, 2011).
    - Periodically, feedback must be given to the patient to confirm that all is well (Tjalsma, 2007; Tokmetzis, 2007).
    - The fact that a monitoring device sends emails to the health care provider implies that there must be somebody on the receiving end 24/7 to respond to these emails (Tokmetzis, 2007).
    - When eHealth is used on a large scale it may be necessary to hire dedicated personnel. eHealth may lead to extra work, not less (Ikkersheim, 2006).
    - GPs or community nurses need backup from technicians when they encounter problems with the technology that is used at the patients' home. GPs should deal with the medical aspects not the technology (Seysener, 2001).
- liability issues are not clear (Tjalsma, 2007; Nouwt, 2010). Who is responsible when something goes wrong (Tokmetzis, 2007)? Frank concludes however that eHealth is well covered by the Dutch legislation (in 2000). Certain aspects should be made crystal clear before eHealth commences such as the parties that are part in the contract, the qualification of the participating health care providers (especially when residing abroad) and the information that should be filed (Frank, 2000);
- financial issues are not clear (Tjalsma, 2007; Tjalsma, 2008; Hoencamp, 2010; Nouwt, 2010; Croonen, 2011);
- the technology may fail (Tjalsma, 2007; Croonen, 2011);
- security of patient's data (electronic medical record; lokaal EPD) is not clear (Tjalsma, 2007; Nouwt, 2010; Croonen, 2011);
- the preconditions for successful operation of eHealth are not established yet, e.g. the electronic health record, data security, authorization issues (Flim, 2006);
- the Rathenau Institute calls for a public discussion on issues involved with eHealth e.g. protocols for the accessibility of the patients' electronic health file, the development of medical regimes for administering medication via telecom, and the limits on the amount of care that could be transferred to the patients' home; how much can the patient and carers cope with (Tokmetzis, 2007)?;
- the fact that a monitoring technique is available doesn't mean that the technology is suitable for every patient or even the majority of patients

(Tjalsma, 2007; Venrooij, 2011). Selection criteria for patients should be developed (Ikkersheim, 2006);
- general practitioners have to deal with unknown consequences of eHealth such as the impact on day-to-day work, income and the necessary knowledge and skills (Flim, 2006). GPs fear that they have to deal with technology for a limited number of patients, insufficient to develop confidence in the use of such technology. The time investment to get acquainted with the technology may be too large, especially for those GPs that work alone (Seysener, 2001; Maassen, 2007);
- eHealth should be on the curriculum for students (Flim, 2006);
- evidence for the alleged benefits of eHealth (or even best practices) is missing (Tjalsma, 2008; Keijser, 2010; Venrooij, 2011).

4.8 Conclusions from grey literature

From the mixed web-based sources searched in this chapter 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 prominently or even implicitly. Nevertheless a number of sources mention the provisions that should be made to ensure that eHealth or telemedicine projects will be successful. It could be assumed that these provisions are indicative of the risks they are often related to. They should be used as input in risk analysis and should be mitigated through risk management and continuous surveillance. The provisions can be grouped into three categories: the human factor, technology and organization, summarized in Table 4.2.

Table 4.2. Summary of observed risks in grey literature on ehealth technologies

RISK LEVEL	**DESCRIPTION**
Human level	Physical, mental, social, cognitive skills (eHealth literacy)
	Substitution human contact, doctor-patient relationship
Technology level	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 (liability, accountability, insurance issues)
	Response speed care organization 24/7

The human factor
eHealth and telemedicine are not intended to replace direct patient - physician contact. With the aid of technology the number or frequency of direct contacts may be reduced, thus increasing the efficiency of health care. Also for the patient it may be beneficial that the number of visits to the physician can be reduced, thus saving time and expenses. The total number of contact moments could actually increase, which may be reassuring for patients. Nevertheless, periodic direct person-to-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 setting seems to 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 rely completely on it.

Technology
The early initiatives of eHealth and telemedicine suffered from technological shortcomings such as the limited resolution and colour depth of digital images and the narrow band width for transmitting data. These limitations are 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 connection should be taken into account. Equipment should be designed to fit to the possibilities of the user, ergo shall be self-explaining, 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 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 cross-border.

Organisation (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 of 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 it 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 licences 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.

5 CeHRes Roadmap[3]

The ceHRes Roadmap is one of the outcomes of a recently published study (Van Gemert-Pijnen et al., 2011) that aimed to improve the up-take and impact of eHealth technologies by advancing a 'holistic approach' towards their development and ultimate integration in the healthcare sector. 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). We have included this work because of its relevance for the objectives of our present investigation of risks in eHealth.

The proposed approach is deemed necessary since many eHealth technologies are not sufficiently successful in realizing sustainable innovations in health care practices. As a consequence, the potential health benefits of these innovations are not realized, and their adoption in practice is hampered. One of the reasons for the lack of impact appears to be that the current development of eHealth technology disregards the interdependencies between technology, human characteristics, and the socio-economical environment. The framework proposed in the study introduces six working principles for the development and implementation of eHealth technologies during their entire life cycle. Although the aim of the framework is primarily the realization of effective interventions with optimal uptake and impact, the management of risks for patient safety and quality of care is an integral part of this.

The drawbacks reported in the analysis of current practice may legitimately and logically be transposed to risks since they imply harm or hazardous situations that negatively impact patient safety or the quality of care. Therefore we think it is relevant for the present study to provide a short summary of these findings. Table 5.1 shows a summary of these risks phrased in conceptual terms.

Table 5.1 highlights those factors that threaten the eventual uptake and impact of eHealth technologies. Inversely they imply risk control measures for both patient safety and quality of care. For instance, if an eHealth intervention is developed while really taking into account the values of patients it is more likely to be used and accepted which can be a benefit for both the end-user and the organization.

In order to facilitate and support the effective development and implementation of eHealth interventions, Van Gemert-Pijnen et al. (2011) have proposed a 'Roadmap' (see Figure 5.1). It applies concepts and techniques from both business modelling and human-centred design (Van Limburg et al., 2011). The Roadmap serves as a guideline to collaboratively improve the impact and uptake of eHealth technologies. For this purpose it is published as a wiki (www.ehealthresearchcenter.org/wiki/).

[3] Parts of this chapter have been presented as an original research paper at eTELEMED, the 4th International Conference on eHealth, Telemedicine, and Social Medicine (Ossebaard et al., 2012).

TABLE 5.1 CONCEPTUAL RISKS DERIVED FROM VAN GEMERT-PIJNEN ET AL., 2011

Conceptual risk	Description
eHealth technology development as an expert-driven instead of participatory process	If project management fails to arrange stakeholder participation in the full development process, risks related to e.g. usability and patient safety increase, in the end potentially leading to rejection by (end-)users.
eHealth technology development ignores the need for continuous evaluation	If the development is viewed as a linear, fixed and static process instead of an iterative, longitudinal research activity, risks related to human, technological and organizational factors are not optimally managed.
Implementation of eHealth technology as a post-design activity	If conditions for implementation are not properly taken into account during the entire development process, introduction into healthcare practice will create risks for patient safety and quality of care.
The effect of eHealth technologies on the organization of health care is not taken into account	If it is ignored that eHealth technologies intervene with traditional care characteristics and infrastructure, unexpected factors may cause problems (e.g. the shift from hospital based care to home care requires new types of risks to be managed, along with user training, planning and reimbursement system issues).
Design of eHealth technologies without built-in modalities for interaction with users on multiple aspects they may need or expect.	If eHealth interventions ignore users' needs for affective, persuasive communication and information technologies for motivation, self management and support, they drop out.
eHealth technology development without integration of data from multiple sources, including qualitative and quantitative designs, and taken all factors of the complex use environment into account.	Conventional development methods keep falling short of assessing the combined added value for health care in terms of process (usage, adherence) and outcome variables (behavioral, clinical outcomes; costs), and the resulting risks from operating in a complex environment with different types of users, use environments and organizational characteristics.

Risk management also entails a repetitive, iterative process during the entire life cycle of technologies. It is a common tool in healthcare to control all processes of service delivery. See Figure 5.2 for a representation of the risk management process, as described in the international standard for risk management of medical devices NEN-EN-ISO 14971 (2007; corrected 2012).
We believe that if principles of risk management are explicitly integrated with the developmental process of the ceHRes Roadmap, the chances increase to balancing risks and benefits for innovative eHealth technologies.

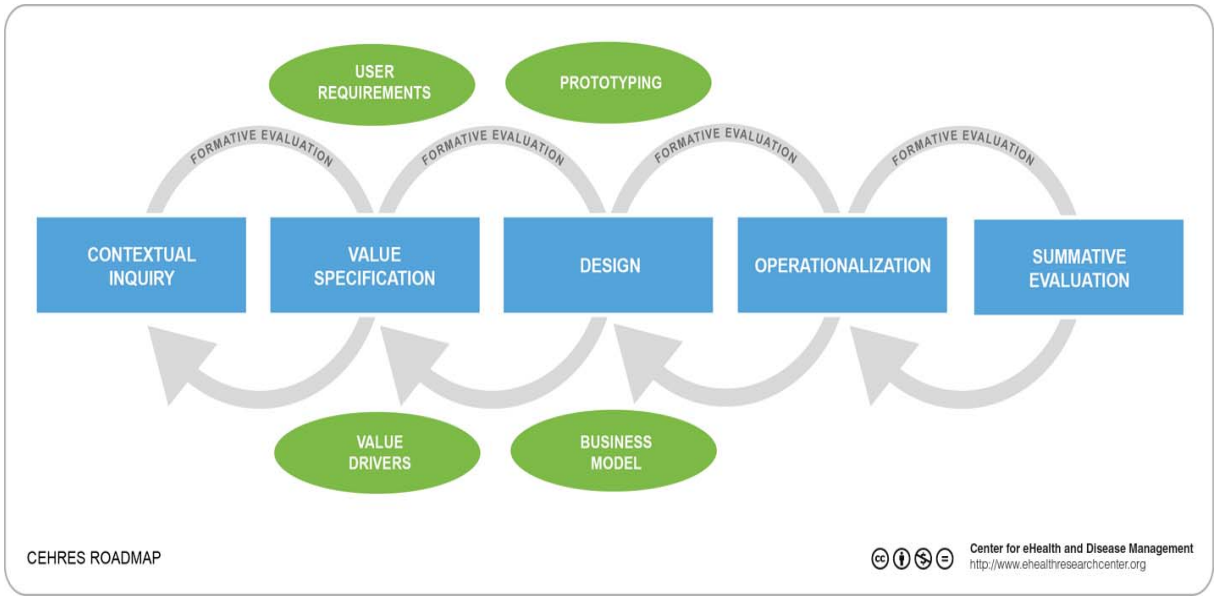


Figure 5.1 ceHRes Roadmap for the development of eHealth technologies

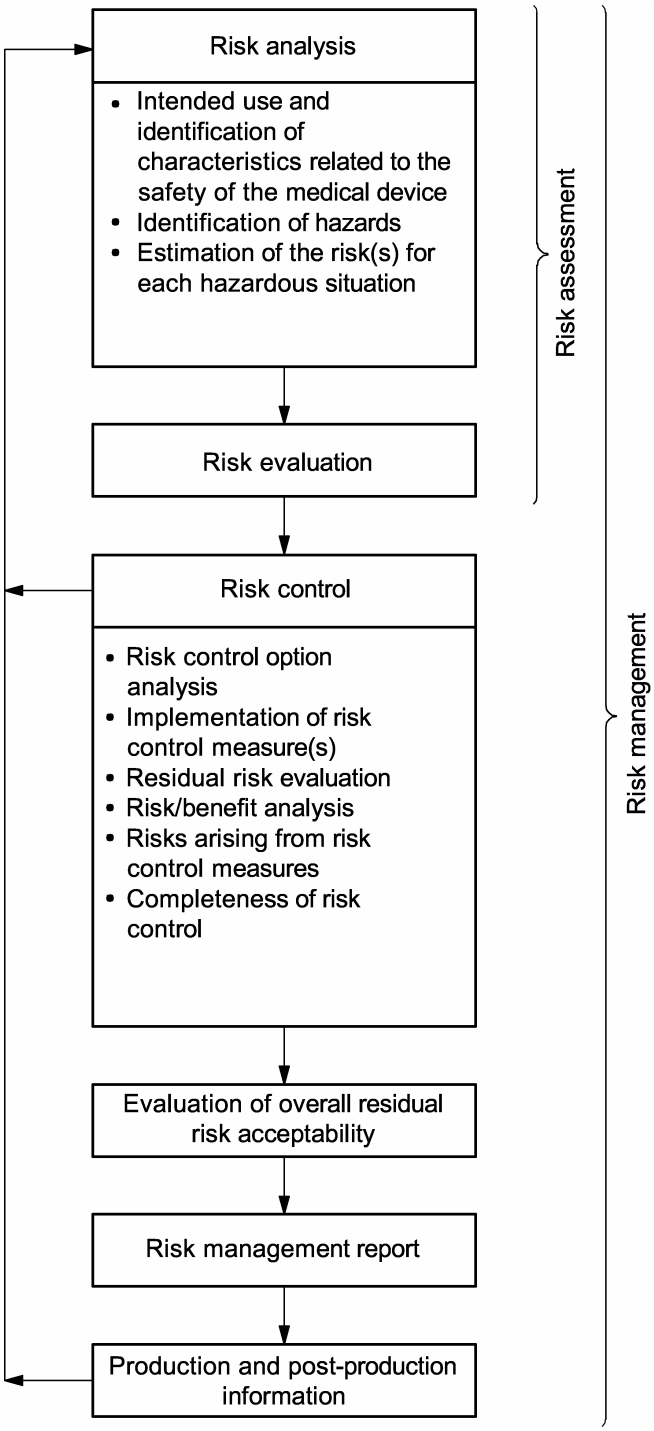


Figure 5.2 A schematic representation of the risk management process (NEN-EN-ISO 14971:2007 (corr. 2012)). [Reproduced with the permission of the Netherlands Standardization Institute (NEN), Delft, www.nen.nl. Copyright remains with NEN]

6 Summaries of recent authoritative reports

During the course of our study three authoritative reports were published which needed to be included in our investigation. The first is the report National Implementation Agenda eHealth, a joint policy paper (Dec. 2011) of the Royal Dutch Medical Association (KNMG), the Federation of Patients and Consumer Organisations (NPCF) and the Health Care Insurers Association (Zorgverzekeraars Nederland). The second is the report 'Health IT and Patient Safety: Building Safer Systems for Better Care' published by the U.S. Institute of Medicine (National Academy of Sciences, Nov. 2011). The third is a report of the Dutch Health care Inspectorate 'State of Health Care 2011. In health care, patient information exchange challenges not resolved with ICT without standardization of processes' (IGZ, Oct. 2011). We present the respective summaries here.

6.1 National Implementation Agenda eHealth (NIA)

In The Netherlands many promising initiatives flourish such as online training programs for young rheumatism patients, online access to personal health files or cost-effective teledermatology. However, eHealth is implemented in a fragmented way, on a small scale. In the 'National Implementation Agenda eHealth' the main stakeholders in the Dutch health care system (patients, care providers, insurers) have laid down their commitment to advance the development and use of online healthcare applications for diagnosis, communication and information. They state that eHealth 'contributes to affordable, accessible, high-quality health care and more direction for patients' and that eHealth should be applied to 'substitute, simplify and improve existing health care' and not for the addition of extra care. The three parties hope their policy initiative encourages other stakeholders to join. Three main themes have been identified:

1. awareness of the opportunities offered by eHealth
2. extension of the responsible use of eHealth solutions and further embedding eHealth structurally in daily health care practice
3. research and development of eHealth.

The three parties agreed to take coordinated action with regard to these themes. Insurers who engage health care providers will watch over a substantial eHealth component in their contracting policies. They will explicitly indicate which parts of health care would be reduced or substituted in favour of eHealth solutions. Healthcare professionals will incorporate eHealth applications in medical guidelines and protocols that will be accommodated for this. Patients' organizations will promote the acceptance of eHealth and will make agreements with regard to the actual involvement of patients in the development and implementation. They will further monitor the experiences of patients with eHealth as to improve professional standards of care and insurers' contracting policies.

The NIA has been attached to a Letter to the Parliament issued by the (then resigned) Minister of Health d.d. June 7, 2012 (Ministry of Health, 2012). In this letter, she expresses her view on eHealth and the policy measures she intends to take in order to expand eHealth in the Dutch health care landscape. Not surprisingly the NIA matches well with these measures.

6.2 Health IT and patient safety: Building safer systems for better care

If designed and used appropriately, health IT is expected to help improve the performance of health professionals, reduce operational and administrative costs, and enhance patient safety. However, some products have begun being associated with increased safety risks for patients. In the wake of more widespread use of health IT, the Department of Health and Human Services in the USA asked the renowned Institute of Medicine (IOM), that previously published seminal reports on patient safety, to evaluate health IT safety concerns and to recommend ways that both government and the private sector can make patient care safer using health IT.

In their report 'Health IT and Patient Safety: Building Safer Systems for Better Care', the IOM Committee on Patient Safety and Health IT examine the safety of health IT products and their effects on patient safety.

Overall, the committee finds the literature about health IT and patient safety to be inconclusive. Some health IT applications are definitively successful at improving medication safety. For example, the number of patients who receive the correct medication in hospitals increases when these hospitals implement well-planned, robust computerized prescribing mechanisms and use bar-coding systems. But even in these instances, the ability to generalize the results across the health care system may be limited. For other products including electronic health records, which are being employed with more and more frequency some studies find improvements in patient safety, while other studies find no effect. More alarming, some case reports suggest that poorly designed health IT can create new hazards in the already complex delivery of care. Although the magnitude of the risk associated with health IT is not known, some examples illustrate the concerns. Dosage errors, failure to detect life-threatening illnesses, interoperability issues and delaying treatment due to poor human–computer interactions or loss of data have led to serious injury and death.

In looking for ways to make health IT–assisted care safer, it is important to recognize that the products are not used in isolation. Rather, they are part of a larger sociotechnical system that also includes people — such as clinicians or patients — organizations, processes, and the external environment. Safety emerges from the interactions of these factors. Comprehensive safety analyses, therefore, should not look for a single 'root cause' of problems but should consider the system as a whole in looking for ways to reduce the likelihood that any given patient will experience an adverse health event. Creating safer systems begins with user-centred design principles and includes adequate testing and quality assurance assessments conducted in actual or simulated clinical environments, or both. Designers and users of health IT should work together to develop, implement, optimize, and maintain health IT products. For most end users, an effective health IT product will provide easy retrieval of accurate, timely, and reliable data; incorporate simple and intuitive data displays; and yield evidence at the point of care to inform decisions. Among other improvements, the product will:

- enhance workflow, perhaps by automating mundane tasks or streamlining work, without increasing physical or cognitive workloads;
- allow easy transfer of information to and from other organizations and providers; and
- cause no unanticipated downtime.

In conclusion, the IOM finds that safe use of health IT relies on several factors, clinicians and patients among them. Safety analyses should not look for a single cause of problems but should consider the system as a whole when looking for ways to make a safer system. Vendors, users, government and the private sector all have roles to play. The IOM's recommendations include improving transparency in the reporting of health IT safety incidents and enhancing monitoring of health IT products. To achieve better health care, a robust infrastructure that supports learning and improving the safety of health IT is essential. Proactive steps must be taken to ensure that health IT is developed and implemented with safety as a primary focus. If appropriately implemented, health IT can help improve health care providers' performance, better communication between patients and providers, and enhance patient safety, which ultimately may lead to better care.

6.3 IGZ report State of Health Care 2011: In health care, patient information exchange challenges not resolved with ICT without standardization of processes

In her 'State of Health Care 2011' report, the Dutch Health Care Inspectorate examines the risks posed to patient care related to one prominent area of eHealth technologies: the use of ICT to transfer patient information. The Inspectorate has found that document management, notably that of patient files, is not always satisfactory. In preparation for this report, the Inspectorate conducted a number of case studies which examined the transfer of information in the diagnosis phase, treatment and aftercare services for patients with lung cancer, CVA (stroke) and bipolar disorder. The findings were evaluated during a number of expert meetings.

The main conclusion is that the most acute risks are caused by bottlenecks in the information flows, regardless of whether those flows rely on ICT applications. Records are not kept up-to-date and often incomplete, lacking information which is relevant to the professionals who use them. The further apart the links in the care chain, the greater the problems. The exchange of information between cure and care and local mental health departments is often poorly organized. The same may be said of aftercare and palliative care for patients, following their discharge from a hospital or psychiatric clinic.

The study confirms that the use of ICT will not automatically resolve such problems. Although an increasing number of hospitals and other care institutions have adopted the use of digital patient files, the exchange of information between those institutions (and their computer systems) remains unsatisfactory. Patient information is often fragmented between several different institutions or even several departments within one and the same institution. A patient who exercises the right to see his or her own records will find that the institution keeps several (digital) files, which may well show inconsistencies. This presents a risk to patient safety.

As a matter of priority, the ongoing problems in information flows must be resolved. Doing so will certainly enhance patient safety. This is illustrated by experience in surgical processes, where improvements to the information transfer procedures have reduced the perioperative mortality rate by some fifty per cent. In principle, the exchange of information between various types of health care providers requires the patient's express consent. This is a legal requirement in The Netherlands. In practice, however, by no means all care providers obtain such consent. In the interests of patient safety, the Inspectorate calls for there to be a single, integrated file for each patient, which may be accessed by all professionals, subject to the patient's consent.

The Inspectorate recommends the following:

- New guidelines and protocols should establish how information transfer processes are to be structured and managed. The Inspectorate requests the Dutch Council for Quality of Health care to include this as a firm requirement in its 'Guidelines for Guidelines' document.
- Health care institutions should implement a formal policy for the responsible transfer of information between professionals, both within and beyond the institution itself, doing so no later than 2013. This policy must also ensure that patients are able to gain access to their own records on request. Health insurers can encourage and facilitate this process.
- There must be norms and standards which apply throughout the health care system, establishing the type of information that is to be kept, how it is to be stored, the terminology to be used, and how the information is to be made available to those who require it. The Inspectorate recommends that the Minister of Health should appoint a commission to examine the relevant aspects. It will fall to the Inspectorate to ensure full compliance with the resultant norms and standards.

6.4 Conclusions

These reports make clear that eHealth technology will substantially change the health care system in the coming decade. 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 and the Letter to the parliament of the Ministry of Health demonstrate the political dynamics necessary to bring about such a change. The scientific back-up for their claims however is not as strong as their political determination. For instance the statement that eHealth 'contributes to affordable, accessible, high-quality healthcare and more direction for patients' is not supported by prevailing evidence as of yet. The NIA also neglects the considerable risks as outlined by the IOM and the Dutch Inspectorate. 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. These developments also drive the other two reports of the IOM and the IGZ. In fact it drives the present report as well.

IOM advances safety as an essential value in health care and favours 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 recommendations to improve patient safety.

7 Expert meeting

This chapter contains the outcomes of discussions of an `invited expert meeting' composed of stakeholders from the field of eHealth during an `invited expert meeting' d.d. Nov. 25th 2011. Participants were selected from our networks and invited to participate (see Appendix II). They received a working draft version of the present report 'under embargo'.

Eventually a focus group (n = 38) could be composed representing stakeholders from health care professionals, patients, industry, academic research and government. This focus group was intended 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.

To achieve this, a professional talk-host led the afternoon meeting that opened with an introduction and a summary of the study outcomes by the authors. This was followed by the one-hour 'knowledge café' method, an informal but systematic way to exchange opinions and ideas between participants. After the break, and a philosophical reflection on technologies and risk, a discussion panel took place wherein representatives of stakeholders actively participated. Outcomes were recorded on paper, analyzed and summarized. For the sake of brevity, we have summarized the outcomes in the tables below.

Table 7.1 Patients' perspective

Patients	Perspective	Too much emphasis on technology: check patients' needs first
		Perspective of patients neglected. What is their interest?
		Patients prefer to stay home as long as possible
	Risk	Confrontation of practice (health care professionals and patients) and an estimation of risk
		eHealth should be integrated in care

Table 7.2 Industry perspective

INDUSTRY	Interoperability	Level playing field: enforce a generic solution for all players
		Industry: don't produce non-standardized products/Care providers: don't buy non-standardized products
	Responsibilities	Post-marketing responsibilities
		Develop quality norms (EU) for eHealth products
		New arrangements for reimbursement by health insurers
		Medical eHealth applications applied by non-medical professionals/laymen
		Arrange for (end-)user-centred design
	Organization	eHealth implies organizational change
		Patients should better use existing complaint-procedures
		Risk management for eHealth risks

Table 7.3 Care perspective

CARE	Risk	It is not about risks of eHealth *tech* but about risk of eHealth *care*
		What about risks *without* eHealth?
		All depends on the risk-benefit relationship
		Balance eHealth risks against risks of conventional care
		A risk is bad implementation and adaptation; bad effect versus no effect
		Reputation damage might be a risk for health care
		Beware of ending eHealth initiatives because of incidents
	Risk management	NEN 8028 Telemedicine describes what needs to be arranged, requirements, documentation, accountability &c. paper tiger or risk management tool?
		Technology use must be an integrated part of a vision on care
		Do not confuse risk with questions of liability, rearrangement of tasks, DP-relationship
		Opportunities of eHealth are as important as risks
		Risk management projects are standard practice in hospitals > connect with these

Table 7.4 Insurers' perspective

INSURERS	Money	Limitations of eHealth
		Obsolete information systems
		Cost-benefit relationship
		High initial costs, postponed effects
		Reimbursement of eHealth still not arranged
		Care providers can discern themselves with good eHealth. Insurers could reward effective eHealth implementation (bonus/malus)
		Investments here are returned there!
	Innovation	Insurers must stimulate innovation and decide per individual eHealth solution for quality
		High expectations and low evidence
	Organization	Clear frame of reference is needed for insurers and professionals
		Substitution of care must take place
		eHealth solutions raise status of care professional

Table 7.5 Policy perspective

POLICY	System	Standardization is needed
		More attention/focus on stakeholders
		Make risks visible for users e.g. in user manuals
		Reference criteria/requirements are needed for eHealth technology
	Policy	Make risks visible by determining suitable care
		An incidents database (such as ECRI) is needed
		What is needed in rules and regulations apart from safeguarding quality and conditions?
		Incorporate eHealth technology in medical education
		Who is responsible for quality of technology and risk? (e.g. medical apps)
		Biggest risk is the care process as it is.
		Too much top-down regulation frustrates innovation
	Research	Why not always record adverse effects in research reports?
		Risks are inevitable, but what is the level of tolerance?

The 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 theme of risks in eHealth.

From the discussion the following themes were inferred that are vital for risk control in eHealth:

- patient-centeredness
- interoperability and standardization
- risk management tools and regulations
- integrative approach of risk in eHealth
- eHealth affects organization of care
- transparency in risk documentation
- education.

We have come across these themes in literature as well. They should play a role in keeping the health care community alert with regard to risk management. The participants of the focus group would certainly support this.

8 Discussion and Recommendations

Increasing use of eHealth technology is one of the major developments in health care. Today's technology will disruptively impact on the health care delivery system in the years to come (Duchatteau & Vink, 2011). There is reason to assume that these technologies will help to achieve integrated care solutions that are so dearly needed to enable better quality of care, increased patient involvement and safety, optimal access to health care and cost-efficient solutions. We observe this in the steadily growing body of promising studies at local, national or global level (cf. Vernooij et al., 2012; Tran et al., 2008; Darkins et al., 2008; Sillow-Caroll et al., 2012; UK Department of Health, 2011; Ziebland & Wyke, 2012). The opportunities of web-based and mobile eHealth technologies should therefore remain central to the global health discourse. For the Netherlands, political determination and consumer expectations are additional drivers of this development. All the more it is required to manage the risks of technological advancement within and without the health care domain (WHO, 2011). Also because the break-through rate of innovative technologies is high and laymen's technologies such as medical mobile 'apps' involve new legal implications and risk control urgencies.

The present study provides a provisional inventory of documented risks that impact on quality of care and the patient safety. It compiles information from several sources that is affirmed and supported by a number of stake-holding parties.

The observed lack of academic interest for risk assessment in eHealth technology should be a matter of concern. Also because risk control eventually relates to institutional trust. Trust is an important social good which most probably defines acceptance, adoption and impact of eHealth.

Patient safety and quality of care deserve a high level of academic awareness when it comes to dealing with new technologies. At present risks only emerge as 'secondary' findings 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 an unintended, though detrimental manner. The outcomes suggest that risks associated with eHealth interventions occur at all three levels of the multi-level approach applied, i.e. the human (end-)user, technology and organization.

While this study is focussed on safety in the context of eHealth systems we recognize the work that has gone on in understanding safety, security and other aspects of health IT such as risks around misidentification of patients in communication between systems, risks with regard to medication ((e-)prescription, dispense, administration) relating to system faults, or errors relating to the lack of semantic interoperability. Considerable work has been done as well in the field of clinical coding to understand issues with different clinical terminology systems and enable mapping between them. This was one of the main issues in the design of the British NHS GP-to-GP electronic records transfer service. A related issue is around heterogeneous broadband and local

loop unbundling[4] as well as the widely debated barriers to innovation that may emerge from patent systems and their role in high tech industries (cf. Iliev et al., 2011). We would like to emphasize that risks that emerge from data management, security, privacy and trust and identity management - although excluded from our study - are equally significant issues to be studied and resolved.

Though both quantity and quality of the reported issues may not seem disturbing at first glance, a wider search delivers a disquieting range and diversity of risks. Given the outcome of our study that none of the RCTs were designed to study risks, we must deduce that they do in fact not represent the studies with the highest evidence level related to our research question. Therefore, an additional follow-up search, including review articles, controlled clinical trials, and perhaps also observational studies should be considered. However, even though RCTs on eHealth interventions so far have not been designed to evaluate risks, it seems evident that the use of eHealth technology in health care brings along risks which can negatively affect patient safety and the quality of care. What is more: their magnitude is not known at all. This legitimizes a higher level of awareness through dissemination, monitoring and research.

Our conclusions are supported by findings in incident databases, grey literature, articles in professional magazines and other (online) sources of different organizational, consumer and academic nature, in which a variety of incidents involving risks have been recorded. While often viewed as avoidable intervention flaws or explained as study (design) artefacts they should not be played down. Problems arise due to the physical distance between the patient and the health care provider, characteristic for eHealth interventions. Failing technology may not even be apparent to the patient or carer, nor is it possible to actively intervene when technology fails.

Stakeholders should be made aware to minimize such risks ex ante. Risk awareness should be part of eHealth policy at a national and institutional level. The results of the present scan are also in accordance with outcomes from the ceHRes study that covers over a decade of eHealth technological development (Van Gemert-Pijnen et al., 2011) as well as with recent authoritative reports treated in Chapter 6. This emphasizes that the ubiquitous trust in technology is quite unjustified and represents a risk in itself for patient safety and quality of care. However the risks of *not* applying eHealth interventions have not been investigated but have clear face validity for instance in cardiovascular telemonitoring (e.g. the 'pacemaker') which has saved many lives already (though the responsibilities when things go wrong are rather unclear in The Netherlands).

To maintain and recover trust in eHealth technology and at the same time protect patient safety it would be helpful to set-up a system to reliably report and document identified incidents consistent with existing systems for medical devices manufacturers. They already have a risk documentation obligation linked to current medical devices directives to improve monitoring and transparency in the reporting of risk prevalence and safety incidents.

[4] https://connect.innovateuk.org/c/document_library/get_file?p_l_id=4110375&folderId=4552173&name=DLFE-48247.pdf [accessed 9 Oct. 2012]

The instruments and the knowledge to reconsider the implementation of eHealth are available when it comes to risk management of web-based and mobile eHealth technologies. This applies to the playing fields of health care, academic research industry. An example of the latter is the involvement of manufacturers of medical devices in the management of risks related to medical devices technology, as part of their own product development (NEN-EN-ISO 14971). Another example is the regulation of risk management for IT-networks incorporating medical devices by ISO IEC 80001-1 which defines roles, responsibilities and activities for all participants. A final example is the Dutch norm NEN 8028 that describes quality requirements for telemedicine with regard to quality management, patient-related procedures and manufacturing processes (NEN Gezondheidszorg, 2011). These examples show that applying existing norms and risk management tools in all phases of the life cycle can be effective in practice (i.e. 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).

To achieve such reconsideration and to prevent or minimize risk for patient safety we recommend four policy actions:

1. Keep the health care community alerted with regard to the risk issue;
2. Carry out follow-up research on the risks of ICT in health care that focuses on establishing the magnitude and nature of such risks;
3. Establish a system to reliably report and document identified incidents consistent with existing systems;
4. Call for the application of existing norms and risk management tools in all phases of the life cycle as per NEN-EN-ISO 14971.

Acknowledgments

Under its 2011 Work plan (Domain Drugs and Medical technology; theme: information- and communication technology), the Dutch Health Care Inspectorate commissioned the National Institute for Public Health and the Environment (RIVM) to conduct this study of which we here present the outcomes. It was carried out in collaboration between the RIVM Centre for Pharmaceutical Affairs and Medical Technology, the RIVM health and care portal kiesBeter and the Center for eHealth Research (IGS Institute for Social sciences and Technology, University of Twente). We thank Ms Fabiola Mueller for her work in the data collection.

We are indebted to the members of the Special Interest Group Telemedicine of the EC New and Emerging Technologies Working Group for their useful comments to the draft version of the report.

Figure 5.2 is taken from NEN-EN-ISO 14971:2007 (corr 2012) and is reproduced with the permission of the Netherlands Standardization Institute (NEN), Delft, www.nen.nl. Copyright remains with NEN.

Parts of Chapters 3 and 5 have been presented as an original research paper at eTELEMED, the 4th International Conference on eHealth, Telemedicine and Social Medicine (Ossebaard et al., 2012). Here it was selected for the 'Best Paper Award'[5], which was disseminated through social media (see for example Appendix V).

An adapted version of the research paper appeared in a thesis on eHealth (Ossebaard, 2012).

Preliminary outcomes were published in a poster presentation at the academic symposium 'Supporting health by technology IV' (d.d. May 22nd, 2012)[6] in Amersfoort, The Netherlands (Appendix IV).

The International Journal On Advances in Systems and Measurements received our submission of the final research paper (2013).

A poster is submitted to the Dutch Public Health Congress (April 2013).

The outcomes will finally be disseminated through various Dutch professional health care journals after publication of the present report.

[5] http://www.iaria.org/conferences2012/AwardseTELEMED12.html [accessed 9 Oct. 2012]

[6] http://www.nehs.nl/symposium/?page_id=185 [accessed 9 Oct. 2012]

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/e-health. 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 UK, 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 more indications on the occurrence of risks though it would not have helped in quantifying their magnitude.

References

Atienza, A.A., Hesse, B.W., Baker, T.B., et al. (2007). Critical issues in eHealth research. *Am J Prev Med;32(5):*S71-S74.

Barben, D. (2010). Analyzing acceptance politics: Towards an epistemological shift in the public understanding of science and technology. *Public Understanding of* Science *19(3),* 274-292.

Beeuwkes Buntin, M., Burke, M.F., Hoaglin, M.C. and Blumenthal, D. (2011) The Benefits of Health Information Technology. *Health Affairs (30)3*, 464-471.

Biermann, E., Dietrich, W., Rihl, J., Standl, E. (2002). Are there time and cost savings by using telemanagement for patients on intensified insulin therapy?: A randomised, controlled trial. *Computer Methods and Programs in Biomedicine, 69*(2), 137-146. doi: 10.1016/s0169-2607(02)00037-8.

Black, A.D., Car, J., Pagliari, C., Anandan, C., Cresswell, K., Bokun, T. et al. (2011). The impact of eHealth on the quality and safety of health care: a systematic overview. *PLoS Med; 8*: e1000387- doi: 10.1371/journal.pmed.1000387.

Bujnowska-Fedak, M.M., Puchała, E., Steciwko, A. (2011). The impact of telehome care on health status and quality of life among patients with diabetes in a primary care setting in Poland. *Telemedicine and e-Health, 17*(3), 153-163. doi: 10.1089/tmj.2010.0113.

Copeland, L.A., Berg, G.D., Johnson, D.M., Bauer, R.L. (2010). An intervention for VA patients with congestive heart failure. *American Journal of Managed Care, 16*(3), 158-165.

Calliope (2011). Call for Interoperability. www.calliope-network.eu.

Croonen (2011). Succesvol werken met e-health. *Medisch Contact 66(2)*, 77-80.

Cruz-Correia, R., Fonseca, J., Lima, L., Araújo, L., Delgado, L., Castel-Branco, M.G., Costa-Pereira, A. (2007). Web-based or paper-based self-management tools for asthma-patients' opinions and quality of data in a randomized crossover study. *Studies in health technology and informatics, 127*, 178-189.

Darkins, A., Ryan, P., Kobb, R., Foster, L., Edmonson, E., Wakefield, B. Lancaster, E. (2008) Care Coordination/Home Telehealth: The systematic implementation of health informatics, home telehealth and disease management to support the care of veteran patients with chronic conditions. *Telemedicine and e-Health 14(10),* 1118-1126.

Department of Health (2005). Building Telecare in England. http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4115644.pdf [accessed 8 Aug. 2012].

Demaerschalk, B.M., Bobrow, B.J., Raman, R., Kiernan, T.E.J., Aguilar, M.I., Ingall, T.J., Meyer, B.C. (2010). Stroke team remote evaluation using a digital observation camera in arizona: The initial mayo clinic experience trial. *Stroke, 41*(6), 1251-1258. doi: 10.1161/strokeaha.109.574509.

Dierkes, M., Von Grote, C. (Eds.)(2000). *Between understanding and trust: the public, science and technology.* Harwood Academic.

Duchatteau, D.C. and Vink, M.D.H. (2011). Medical-technological developments care. Background study. [Medisch-technologische ontwikkelingen zorg 20/20. Achtergrondstudie Den Haag: Council for Public Health and Health Care [Raad voor de Volksgezondheid en Zorg].

EC European Commission (2004). *e-Health: making health care better for European citizens: An action plan for a European e-Health Area.* COM356 final.

EC European Commission (2007). Mandate 403: Standardisation mandate addressed to CEN, CENELEC and ETSI in the field of Information and Communication Technologies.
http://www.ehealth-interop.nen.nl/publicaties/2877&fil_Id=145. [accessed 8 Aug. 2012].

EC European Commission (2008). *Communication on telemedicine for the benefit of patients, health care systems and society.* COM689 final.

ECRI (1997). Telecommunications in Health care; a Primer. *Health Devices 26*(7), 264-285.

ECRI (1999). Telemedicine: An Overview. *Health Devices 28*(3), 88-103.

ECRI (2007). Telemedicine: Risk Analysis. *Medical Technology 3*(17).

ECRI (2009). Videoconferencing Systems, Telemedicine. https://members2.ecri.org/Components/HPCS/Documents/272218.PDF. [accessed 8 Aug. 2012].

epSOS (2011). Safe access to medical data abroad: The epSOS services. www.epsos.eu [accessed 8 Aug. 2012]

Geertsma, R.E., De Bruijn, A.C.P., Hilbers, E.S.M., Hollestelle, M.L., Bakker, G., and Roszek, B. (2007). *New and Emerging Medical Technologies - A horizon scan of opportunities and risks.* RIVM report 360020002. Bilthoven: RIVM.

Flim, C. (2006). KNMG: Telemedicine. *Medisch Contact*(19), 809.
Frank (2000). Ruimte voor de arts op afstand. *Medisch Contact 55*(6).

Glasgow, R.R., eHealth Evaluation and Dissemination (2007) *Research American Journal of Preventive Medicine 32*(5) , 119-126.

Hansson, S.O., Risk, *The Stanford Encyclopedia of Philosophy (Fall 2011 Edition)*, E. N. Zalta (ed.)
http://plato.stanford.edu/archives/fall2011/entries/risk/
[accessed 9 Oct. 2011].

Hardin, R. (2002). *Trust and Trustworthiness*, New York, NY: Russell Sage Foundation.

Hoencamp (2010). Shoppen in een eHealth warenhuis. *Medisch Contact 65*(36), 1799.

IGZ (Dutch Health care Inspectorate)(2008). *State of Health Care 2008 Medical technological risks underestimated [Staat van de gezondheidszorg 2008. Risico's van medische technologie onderschat].* Den Haag: IGZ.

IGZ (Dutch Health care Inspectorate) (2011). *State of Health Care 2011. In health care, patient information exchange challenges not resolved with ICT without standardization of processes [Staat van de gezondheidszorg 2011. Informatie-uitwisseling in de zorg: ICT lost knelpunten zonder standaardisatie van de informatie-uitwisseling niet op].* Utrecht: IGZ

Ikkersheim (2006). Nieuwe vorm van telemonitoring thuis. *Medisch Contact 61*(17), 692-695.

Iliev, I., Tang, P., Tannock, Q. Van de Merwe, H. (2011). *Emerging patent thickets and standards in the medical devices and telehealth space. Innovation, market dynamics and policy options in cross-over technologies* Cambridge: Intellectual Property Ltd.

ISO/IEC Guide 51:1999. *Safety aspects - Guidelines for the inclusion in standards.* Geneva: ISO.

Jansà, M., Vidal, M., Viaplana, J., Levy, I., Conget, I., Gomis, R., Esmatjes, E. (2006). Telecare in a structured therapeutic education programme addressed to patients with type 1 diabetes and poor metabolic control. *Diabetes Research and Clinical Practice, 74*(1), 26-32. doi: 10.1016/j.diabres.2006.03.005.

Keijser, W. (2010). E-health (ingezonden brief). *Medisch Contact*(33), 1635.

Kelders, S.M., Van Gemert-Pijnen, J.E.W.C., Werkman, A., Nijland, N., Seydel, E.R. Effectiveness of a Web-based intervention aimed at healthy dietary and physical activity behavior: a randomized controlled trial about users and usage. *J Med Internet Res. 2011 Apr 14;13(2):*e32.

KNMG (2011). eHealth in Beeld; 21 praktijkverhalen over digitaal dokteren. http://knmg.artsennet.nl/web/file?uuid=8d57725e-de60-4315-ab69-29dd07627761&owner=a8a9ce0e-f42b-47a5-960e-be08025b7b04&contentid=91448. [accessed 8 Aug. 2012].

Maassen (2007). Zorg met een apenstaartje. *Medisch Contact 62*(9), 376-379.

Masa, J.F., González, M.T., Pereira, R., Mota, M., Riesco, J.A., Corral, J., Farré, R. (2011). Validity of spirometry performed online. *European Respiratory Journal, 37*(4), 911-918. doi: 10.1183/09031936.00011510.

McLeod, C, Trust, *The Stanford Encyclopedia of Philosophy (Spring 2011 Edition)*, Edward N. Zalta (ed.) http://plato.stanford.edu/archives/spr2011/entries/trust/ [accessed 9 Oct. 2011].

Ministry of Health (2012). *Letter to the Parliament on eHealth [Brief aan de Tweede Kamer over eHealth]*; Vergaderjaar 2011–2012, MEVA/ICT-3118565.http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2012/06/07/kamerbrief-over-e-health.html [accessed 1 Aug. 2012].

Montori, V.M., Helgemoe, P.K., Guyatt, G.H., Dean, D.S., Leung, T.W., Smith, S.A., Kudva, Y.C. (2004). Telecare for Patients with Type 1 Diabetes and Inadequate Glycemic Control: A randomized controlled trial and meta-analysis. *Diabetes Care, 27*(5), 1088-1094. doi: 10.2337/diacare.27.5.1088.

Morland, L.A., Greene, C.J., Rosen, C.S., Foy, D., Reilly, P., Shore, J., Frueh, B.C. (2010). Telemedicine for anger management therapy in a rural population of combat veterans with posttraumatic stress disorder: A randomized noninferiority trial. *Journal of Clinical Psychiatry, 71*(7), 855-863. doi: 10.4088/JCP.09m05604blu.

MPA Swedish Medical Products Agency (2010). *Proposal for guidelines regarding classification of software based information systems used in health care.* http://www.lakemedelsverket.se/upload/foretag/medicinteknik/en/Medical-Information-Systems-Report_2009-06-18.pdf [accessed 2 Feb. 2012].

National Academy of Sciences (2011). *Health IT and Patient Safety: Building Safer Systems for Better Care.* Washington: Institute of Medicine.

National Implementation Agenda eHealth (December 2011) A joint policy paper of the Royal Dutch Medical Association (KNMG), the Federation of Patients and Consumer Organisations (NPCF) and the Health care insurers Association (Zorgverzekeraars Nederland). http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2012/06/07/nationale-implementatieagenda-e-health-nia.html [accessed 12 Oct. 2012].

NEN Gezondheidszorg (2011). *NEN 8028 Medische Informatica – Kwaliteitseisen telemedicine [Medical informatics – Quality requirements telemedicine].* Delft: NEN Netherlands Standardization Institute.

NEN-EN-ISO 14971:2007. *Medical devices - Application of risk management to medical devices (corrected version 2012).* Delft: Netherlands Standardization Institute.

Nguyen, H.Q., Donesky-Cuenco, D., Wolpin, S., Reinke, L.F., Benditt, J.O., Paul, S.M., Carrieri-Kohlman, V. (2008). Randomized controlled trial of an internet-based versus face-to-face dyspnea self-management program for patients with chronic obstructive pulmonary disease: Pilot study. *Journal of Medical Internet Research, 10*(2). doi: 10.2196/jmir.990.

Nijland, N., Van Gemert-Pijnen, J.E.W.C., Kelders, S.M., Brandenburg, B.J., Seydel, E.R. (2011). Factors Influencing the Use of a Web-Based Application for Supporting the Self-Care of Patients with Type 2 Diabetes: A Longitudinal Study *J Med Internet Res;13(3):*e71.

Nouwt (2010). Hoe gaat het met uw eHealth? *Medisch Contact 65*(20), 932.

Os, V. (2011). Online training voor chronisch zieke. *Medisch Contact 66*(13), 819-821.

Ossebaard, H.C., Geertsma, R.E. Van Gemert-Pijnen, J.E.W.C. (2012). Health Technology Trust: Undeserved or Justified? In: Van Gemert-Pijnen, J.E.W.C., Ossebaard, H.C., Smedberg, A., Wynchank, S. Giacomelli, P. (Eds.) *Proceedings 4th International Conference on eHealth, Telemedicine, and Social Medicine eTELEMED 2012*, pp 134-142. January 30th – February 4th, 2012, Valencia, Spain. Washington: IEEE Computer Society, ISBN 978-1-61208-179-3.

Ossebaard, H.C. (2012). *iHealth: supporting health by technology.* Dissertation. Enschede: University of Twente. http://dx.doi.org/10.3990/1.9789036533751.

Ploeg (2011). De patient als zorgverbeteraar. *Medisch Contact 66*(17): 1089-1091.

Postel, M.G., De Haan, H.A., Ter Huurne, E.D., Becker, E.S., De Jong, C.A.J. (2010). Effectiveness of a web-based intervention for problem drinkers and reasons for dropout: Randomized controlled trial. *Journal of Medical Internet Research, 12*(4), e68p.61-e68p.12. doi: 10.2196/jmir.1642.

Ruffin, M.T., Nease, D.E., Sen, A., Pace, W.D., Wang, C., Acheson, L.S., Gramling, R. (2011). Effect of preventive messages tailored to family history on health behaviors: The family healthware impact trial. *Annals of Family Medicine, 9*(1), 3-11. doi: 10.1370/afm.1197.

Seysener (2001). Huiver voor de technologie thuis. *Medisch Contact*(8).

Silow-Carroll, S., Edwards, J.N., Rodin, D. (2012). *Using Electronic Health Records to Improve Quality and Efficiency: The Experiences of Leading Hospitals*. New York: The Commonwealth Fund.

Spijkerman, R., Roek, M.A.E., Vermulst, A., Lemmers, L., Huiberts, A., Engels, R.C.M.E. (2010). Effectiveness of a Web-based brief alcohol intervention and added value of normative feedback in reducing underage drinking: A randomized controlled trial. *Journal of Medical Internet Research, 12*(5), e65p.61-e65p.14. doi: 10.2196/jmir.1465.

Strayer, S.M., Pelletier, S.L., Martindale, J.R., Rais, S., Powell, J., Schorling, J.B. (2010). A PDA-based counseling tool for improving medical student smoking cessation counseling. *Family Medicine, 42*(5), 350-357.

Tjalsma (2007). Remote control! De toekomst en betekenis van telemedicine voor de zorggebruiker.
http://zoeken.npcf.nl/app/answers/cedz-detail/a_id/17350/kw/Remote%20control!%20De%20toekomst%20en%20betekenis%20van%20telemedicine%20voor%20de%20zorggebruiker
[accessed 1 Feb. 2012].

Tjalsma (2008). De bewezen waarde van telemedicine.
http://zoeken.npcf.nl/app/answers/cedz-detail/a_id/17348/kw/%22De%20bewezen%20waarde%20van%20telemedicine.%22 [accessed 1 Feb. 2012].

Tokmetzis (2007). Is er een IT-specialist in de zaal? *Medisch Contact 50*(13), 2064-2067.

Tran, K., Polisena, J., Coyle, D., Coyle, K., Kluge, E-H.W., Cimon, K., McGill, S., Noorani, H., Palmer, K., Scott, R. (2008) *Home telehealth for chronic disease management* [Technology report number 113]. Ottawa: Canadian Agency for Drugs and Technologies in Health.

UK Department of Health (Dec 2011)*Whole System Demonstrators*
http://www.dh.gov.uk/health/2011/12/wsd-headline-findings/
[accessed 1 June 2012].

Van Gemert-Pijnen, J.E.W.C., Nijland, N., Van Limburg, A.H.M., Ossebaard, H.C., Kelders, S.M., Eysenbach, G., Seydel, E.R. (2011). A holistic framework to improve the uptake and impact of eHealth technologies. *J Med Internet Research;13(4): e111* doi:10.2196/jmir.1672.

Van der Heijden, J.P., De Keizer, N.F., Spuls, P.I., Witkamp, L. (2011). Teledermatology applied following patient selection by general practitioners in daily practice improves efficiency and quality of care at lower costs. *British Journal of Dermatology (165)*:1058-65.

Van der Klauw, D. Flim, C. (2011). *De rol van eHealth en gezondheid 2.0 in het veranderend ziekenhuislandschap. Achtergrondstudie. [The role of eHealth and health 2.0 in a changing hospital landscape. Background study].* Den Haag: RVZ.

Van Limburg AHM, Van Gemert-Pijnen JEWC, Nijland N, Ossebaard HC, Hendrix RMG, Seydel ER (2011). Why business modelling is crucial in the development of eHealth technologies *J Med Internet Res;13(4):e124* doi:10.2196/jmir.1674.

Velde, F. v.d. (2008). E-health en domotica in de zorg: kans of risico? http://www.igz.nl/zoeken/download.aspx?download=E-health_en_domotica_in_de_zorg:_kans_of_risico?.pdf [accessed 1 Feb. 2012]

Venrooij (2011). Minder hartfalen met draadloze monitoring. *Medisch Contact* (7), 406-407.

Venrooij (2011). Weinig bewijs effectiviteit e-health. *Medisch Contact*(4), 214-215.

Verheijden, M., Bakx, J.C., Akkermans, R., Van den Hoogen, H., Godwin, N.M., Rosser, W., Van Weel, C. (2004). Web-based targeted nutrition counselling and social support for patients at increased cardiovascular risk in general practice: Randomized controlled trial. *Journal of Medical Internet Research, 6*(4): e44 doi: 10.2196/jmir.6.4.e44.

Verhoeven, F., Tanja-Dijkstra, K., Nijland, N., Eysenbach, G., Van Gemert-Pijnen, J.E.W.C. Asynchronous and Synchronous Teleconsultation for Diabetes Care: A Systematic Literature Review *J Diabetes Sci Technol. 2010 May; 4(3):* 666–684.

Vernooij, J.W.P., Kaasjager, H.A.H., Van der Graaf, Y., Wierdsma, J., Grandjean, H.M.H., Hovens, M.M.C., De Wit, G.A., Visseren, F.L.J. (2012) Internet based vascular risk factor management for patients with clinically manifest vascular disease: randomised controlled trial*. BMJ* 2012; 344 doi: 10.1136/bmj.e3750.

WHO (2003). *The World Health Report 2003 – Shaping the future.* Geneva: World Health Organization.

WHO Resolution WHA58-28. eHealth. In: *Fifty-eighth World Health Assembly, Geneva, 16-25 May 2005. Resolutions and decisions.* 2005*.* Geneva: World Health Organization.
http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf [accessed 9 May 2011].

WHO (2010). *Global Status Report on Noncommunicable Diseases 2010.* Geneva: World Health Organization.

WHO (2010). *Telemedicine, opportunities and developments in Member States*. Geneva: World Health Organization.

WHO (2011). *mHealth: New horizons for health through mobile technologies.* Geneva: WHO.

WHO (2011) *Safety and security on the Internet: challenges and advances in Member States: based on the findings of the second global survey on eHealth.(Global Observatory for eHealth Series, v. 4).* Geneva: WHO.

Willems, D.C.M., Joore, M.A., Hendriks, J.J.E., Van Duurling, R.A.H., Wouters, E.F.M., Severens, J.L. (2007). Process evaluation of a nurse-led telemonitoring programme for patients with asthma. *Journal of Telemedicine and Telecare, 13*(6), 310-317. doi: 10.1258/135763307781644898.

WRR [Dutch Scientific Council for Government Policy] (2011). *iOverheid* [*iGovernment*]. Amsterdam: Amsterdam University Press.

Yusof, M.M., Kuljis, J., Papazafeiropoulou, A. Stergioulas, L.K. (2008). An evaluation framework for health information systems: human, organization and technology-fit factors (HOT-fit). *Int. J. Med. Inform.* 77(6):386-398. PMID:17964851.

Ziebland, S, Wyke, S. (2012). Health and Illness in a Connected World: How Might Sharing Experiences on the Internet Affect People's Health? *The Milbank Quarterly (90)2*, 219–249.

Zimmerman, L., Barnason, S., Hertzog, M., Young, L., Nieveen, J., Schulz, P., Tu, C. (2011). Gender differences in recovery outcomes after an early recovery symptom management intervention. *Heart and Lung: Journal of Acute and Critical Care*. doi: 10.1016/j.hrtlng.2010.07.018.

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

Flyer Invited expert meeting

Appendix III

Programme Invited expert meeting d.d. 25 Nov. 2011

PROGRAMMA INVITED EXPERT MEETING 25 NOVEMBER 2011
Jaarbeurs Utrecht (nabij CS Utrecht), Centrale Hal 7e Etage
12:00 - 13:00 Inloop Lunch
13:00 - 13:05 Welkom (Johan Melse, cVTV/RIVM dagvoorzitter)
13:05 - 13:10 Opening (Robert Geertsma, cBMT/RIVM)
13:10 - 13:30 Toelichting onderzoek en uitkomsten (Hans Ossebaard, RIVM/UT onderzoeker)
13:30 - 14:30 Kenniscafé (o.l.v. Johan Melse)
14:30 - 15:00 Pauze
15:00 - 15:30 '*Hoe nieuwe technologieën werken – een filosofische reflectie op kansen en risico's*' (Harro van Lente, Universiteit Utrecht/Universiteit Maastricht)
15:30 - 16:30 Panel o.l.v. drs. Johan Melse met prof dr. Harro van Lente, dr. Lisette van Gemert-Pijnen (Universiteit Twente), dr. Jan Vesseur (Inspectie Gezondheidszorg), dr. Marcel Heldoorn (NPCF) en ir. Pim Ketelaar (Vital Innovators, Nederlandse Vereniging voor eHealth) e.a.
16:30 - 16:45 Afsluiting en reflectie IGZ (Paul van Zeijst, IGZ)
17:00 - 18:00 Drankje

Appendix IV

Poster symposium 'Supporting health by technology IV' (22 May, 2012).

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

Magnitude risks of eHealth technologies largely unknown

Authors: Hans Onsebaard[1], Adrie de Bruijn[1], Lisette van Gemert-Pijnen[2], Robert Geertsma[1]
Contact: Robert.Geertsma@rivm.nl

1 RIVM Centre for Public Health Forecasting
2 RIVM Centre for Pharmaceutical affairs and Medical Technology
3 Center for eHealth Research of the IBR Institute for Social sciences and Technology, University of Twente

Introduction

Many expect that eHealth technologies will contribute to the solution of major issues in health and health care. Although their precise impact is still indefinite the number of eHealth applications increase rapidly. The Dutch Healthcare Inspectorate (IGZ) requested the RIVM to carry out an *exploratory* study of the risks associated with the use of eHealth technologies.

Objective

Overview of risks associated with the use of information and communication technologies for both patient safety and quality of care. Data management issues (privacy, security, storage, transmission etc.) are excluded.

Methods

a) Literature quick-scan of randomized controlled trials, web-based sources and data-bases;
b) Focus group of experts from industry, health care, government, patient organizations, insurers and universities.

Outcomes

No randomized controlled trials of eHealth technology risks for patient safety or quality of care have been found in literature. However, risks appear as 'secondary' results:

Table 1: Outcomes literature search of randomized controlled trials

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

Extensive anecdotic evidence of risks is reported in web-based sources, and databases such of FDA (e.g., MAUDE Manufacturer and User Facility Device Experience) and ECRI (e.g., MDSR Medical Device Safety Reports):

Table 2: Outcomes search of web-based sources and databases

Risk level	Description
Human level	Physical, mental, social, cognitive limitations, skills (eHealth literacy); substitution of human contact; doctor-patient relationship, medication
Technology level	Resolution, interference, bandwidth, connection, incompatibility, interoperability, user-unfriendly tech, insufficient error handling, no emergency plan
Organizational level	Training/instruction, management, hardware, money, home situation, liability, reimbursement (health insurer), response speed 24/7

Published by
National Institute for Public Health and the Environment
P.O. Box 1 | 3720 BA Bilthoven | The Netherlands
www.rivm.com

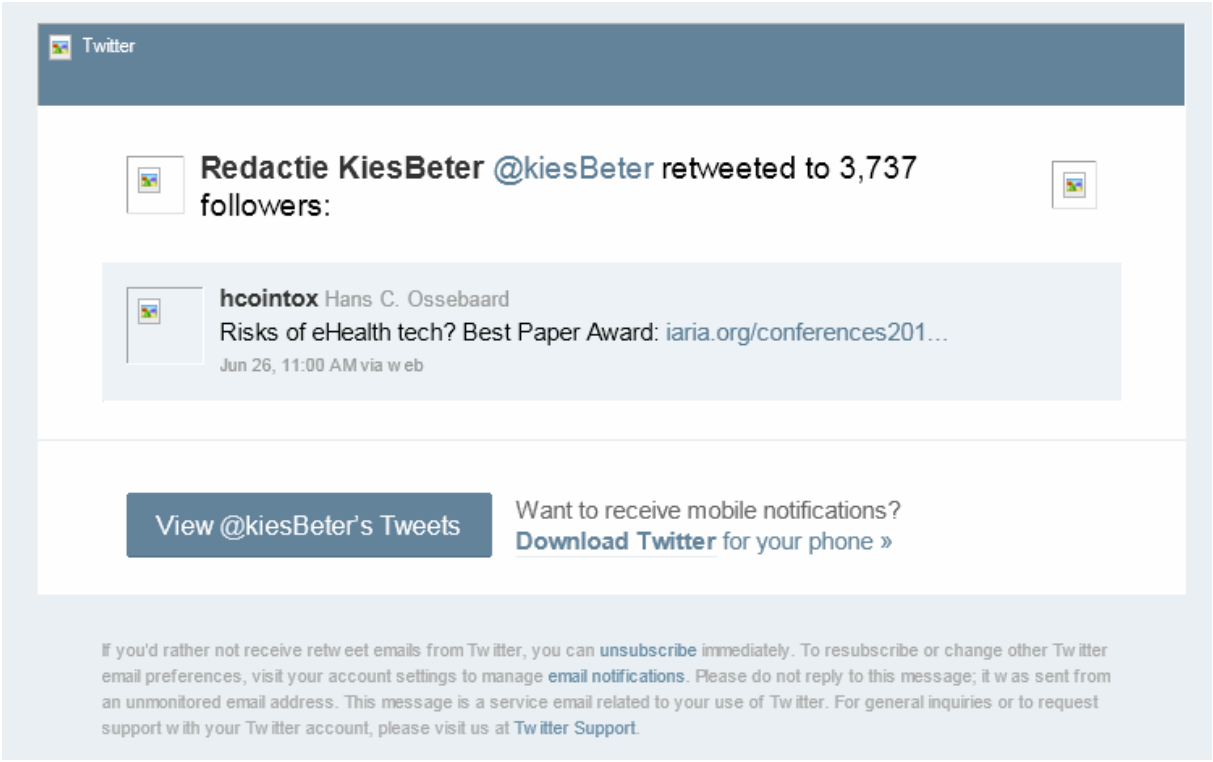
Acknowledgements
- All participants of the expert meeting d.d. Nov. 25th, 2011, Utrecht, The Netherlands
- Special Interest Group (SIG) Telemedicine, part of the EC Working group New & Emerging Technologies.

Conclusions and recommendations

Use of eHealth technology in healthcare can negatively affect patient safety and the quality of care. Risks associated with eHealth interventions occur at the level of the human (end-) user, technology and organization. Not much is known about the magnitude and frequency of their occurrence. Recent authoritative reports substantiate the outcomes of this exploratory study. More research into risks of eHealth technology is needed. A realistic reconsideration of the implementation of eHealth technology, introducing risk management in all phases of the life cycle, is recommendable to avoid such risks. Establishing a system to report and document eHealth technology related risks in health care should be considered.

Appendix V

Disseminating outcomes via social media (example)



**H.C. Ossebaard | A.C.P. de Bruijn |
J.E.W.C. van Gemert-Pijnen | R.E. Geertsma**

RIVM report 360127001/2012

This is a publication of:

**National Institute for Public Health
and the Environment**

P.O. Box 1 | 3720 BA Bilthoven
The Netherlands
www.rivm.nl

January 2013

004713