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INCREMENTAL AND MEDICALLY ETHICAL DESIGN OF USABLE EHEALTH SUPPORT FOR DISEASE SELF-REGULATION

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Abstract
The graying of the population leads to an increase in health care needs. Among others, chronically ill patients take up medical resources to maintain quality of life and health. The health care service has difficulties to meet these needs. By offering ICT support to the involved patients, medical and technical specialists, eHealth could mitigate this difficulty. However, the currently designed ICT in health care lags behind other sectors. Primary causes are the lack of user-centered design and the medical ethical sensitivity of designing eHealth technology. Our aim is to design eHealth technology tailored to the users' needs and in medically ethical manner. In the framework of the SuperAssist project, and following the eHealth concept, we are developing personal computer assistants for the supervision of disease self-regulation of patient with lifestyle related diseases, such as diabetes. The computer assistant monitors the patient and provides personalized feedback and moderates communication between the patient and involved specialists. To tailor our approach to the requirements of the complex medical domain, we are designing and evaluating assistance incrementally. We performed a domain analysis, created scenarios, conducted experiments in smart home environments and are currently studying eHealth technology in the field. Results of our studies show that, similar to earlier studies in the naval and space domain, an incremental design approach facilitates the medical ethical design of usable eHealth technology.

1 Introduction

John (aged 52), enjoys his full time occupation as an attorney. Combining his career with his social and family life leaves little room for maintaining a healthy lifestyle. Lately, he experiences some trouble with his health. He visits his physician, who sends him to the policlinic. Test results indicate that he suffers from diabetes type II. The physician strongly recommends him to perform more disease self-regulation activities, including maintaining a healthy diet, performing exercise regularly, using domestic medical instruments and taking medication. Key issues for John are combining self-regulation with his daily tasks while maintaining a good quality of life.

Like John, worldwide, numerous people suffer from lifestyle related diseases, such as obesity and diabetes type II. The health care service has difficulties to meet their care needs. By offering ICT support to the patients and involved medical and technical specialists, eHealth could mitigate this difficulty. eHealth has multiple benefits, such as lowering costs (Eysenbach, 2001), aging in place (Rogers & Mynatt, 2003), motivating the patient (Fogg, 2003), supporting the use of domestic medical instruments (Blanson Henkemans et al., 2006; Blanson Henkemans et al., 2008b), and assessing personal characteristics that influence specific care needs (Stucki et al, 2004).

Currently, ICT use in health care and social work lags behind other branches. Emerging evidence provides support for the beneficial effects of online interactive eHealth programs. However, many challenges remain with respect to research approaches to methodology, implementation, and evaluation (Ahern, 2007). A main issue is that the development of eHealth technology is medically ethically complex. On the one hand, we need to conduct empiric research in the field to validate the usability of eHealth technology. On the other hand, it is essential to keep in mind that the test subject's, i.e., the patient's, wellbeing is at stake (Coyle et al., 2006).

Given the right approach, context and implementation process, investment in eHealth will lead to improved care quality and productivity, which in turn liberates capacity and enables greater access in the healthcare sector (Stroetman et al., 2006). In the past, studies have shown that applying an incremental design approach is beneficial for addressing critical domain and user issues. Cognitive Engineering (CE) applies an incremental approach and facilitates design tailored to the specific needs of an application domain (Hollnagel & Woods, 1983; Rasmussen, 1986; Neerincx & Lindenberg, 2007). Considering the complexity of the health care domain, an incremental design approach may be usable for the design and evaluation of eHealth technology. Consequently, our research question reads, can an incremental and medically ethical approach facilitate design of usable eHealth technology?

In the following sections, we will give an overview of our incremental design of personal computer assistance of disease self-regulation. We will discuss our domain analysis and the design and evaluation of computer assistance in laboratory and field settings. Finally, we will discuss the implications of our findings.

2 The SuperAssist Project

Following the eHealth concept, the SuperAssist project is developing personal computer assistants for the support of disease self-regulation (see Fig. 1). The computer monitors the "patient" performing self-regulation activities in the home environment with the intention of preventing disease, limiting illness, and/or restoring health (Leventhal et al. 2005; Maes & Karoly, 2005). Examples of self-regulation activities are maintaining a healthy diet, performing physical activities, using domestic medical instruments. Based on the patient environment and patient medical record, the assistant provides personalized feedback on the self-regulation activities. In addition, the computer assistant mediates the communication between the patient and the medical specialists who (remotely) supervises the patient's health and between the patient and the technical specialist, who supervises the medical instruments' "health". Each specialist has their computer assistant that supports them with their tasks. The SuperAssist project's scientific partners are developing the models for personal computer assistance for disease self-regulation and business partners bring in their technology and contribute to the development and validation of SuperAssist elements. In the course of the project, there has been collaboration with international partners.

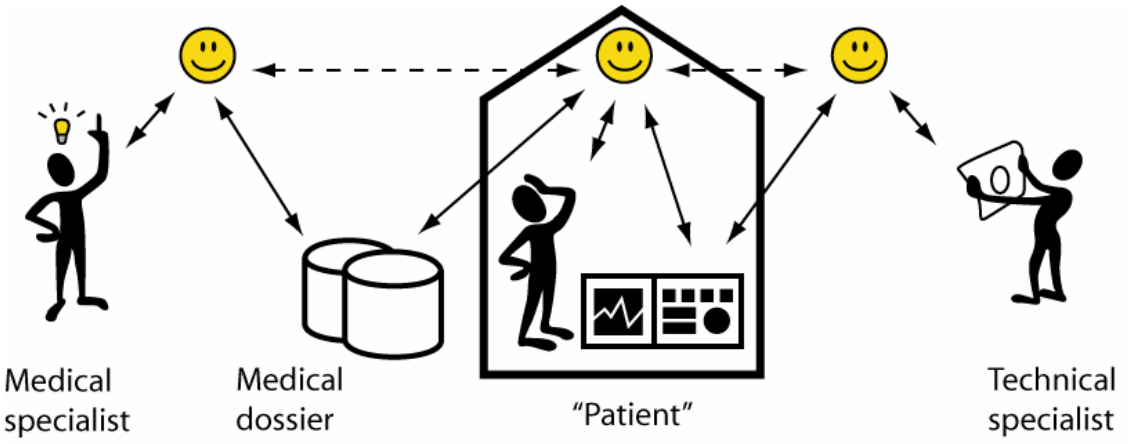

Figure 1: Personal computer assistants supporting disease self-regulation. The assistants monitor the users, provide feedback on their activities, and mediate the communication.

2.1 Cognitive Engineering

Developing usable personal computer assistants supporting disease self-regulation is medically ethically complex. Evaluating usability is optimal when performed in the actual application environment and with the users for whom using the technology is personally relevant. However, this produces two problems. First, it is difficult to conduct controlled testing in the actual application environment. Many factors, which are difficult to observe outside the controlled environment, can influence the interaction. Second, it is difficult to foresee the, possibly harmful, impact of new technology on the user. For example, in pharmaceutical medical research, drugs go through multiple test phases before the Medical

Ethical Testing Commission gives approval for the population's use. Foregoing testing potentially leads to harm to the patient (World Medical Association, 2004).
To address the complexity of developing eHealth technology, we are applying a cognitive engineering (CE) approach. This method guides the incremental development process in which an artifact is specified in growing detail and specifications are assessed iteratively to refine the specification, to test it, and to adjust or extend it. It has proven useful for design of ICT support of different complex domains, such as on naval ships and space stations (Neerincx & Lindenberg, 2007). However, the medical domain has specific requirements. First, we have to take into account the organizational structure of the medical domain. Second, we need to study the human factors of the different users involved, i.e., patients, medical specialists and technical specialists. Finally, we have to address the medical ethics of evaluating eHealth technology with vulnerable participants.
For the SuperAssist projects, applying the cognitive engineering approach implies incrementally designing and evaluating computer assistants for the support of disease self-regulation. Initially, we performed domain, task and scenario analyses and we interviewed prospective users and medical specialists. Then, we conducted usability studies in Smart Home Environments (Blanson Henkemans et al., 2007). Currently, we are conducting a randomized controlled trial to evaluate an online lifestyle diary with computer assistant.

3 Incremental Design

3.1 Domain Analyses and Scenarios

At the start of the project, we conducted an elaborate domain analyses. Amongst others, we performed web searches, literature reviews, document analyses, and interviews (see Table 1). During the domain analysis, we focused on current care processes, requirements of involved patients and medical specialists, and the use of ICT in the health care domain.

Activity	Goal	Domain
Web search	Find relevant projects and products	Dutch projects on patient self-regulation and ICT (e.g., thromboses, hemophilia, hart failure, diabetes, asthma)
Literature research	Find relevant publications	Papers, projects, research groups, journals, conferences
Document analyses	Assess domain requirements	Protocols, medical dossiers, regulations, statistics
Interviews and observations	Assess domain requirements	Medical specialists, patients, patient associations, industry, policlinics

Table 1: Overview of domain analysis activities.

The project organizes biannual multidisciplinary workshops. During the workshops, the scientific partners present their research results and brainstorm about ongoing activities. The members have different backgrounds, e.g., medical specialists, psychologists, interaction

designers, computer scientists, and telecommunication specialists. In addition, a commission, constituting of independent industrial and scientific representatives, guards the projects progression and the business relevance of the scientific results. During the domain analyses, we gained insights in the requirements of ICT and of the different users in the medical domain. First, we laid out the main organizational structure of the health care domain, and mapped out a care plan cycle. The cycle consists of a fixed order of steps, i.e., disease determination, intake, opinion, set care plan, perform care plan, and update patient description (Fig. 2). Then, we determined patient characteristics and their influence on self-regulation, including an overview of the patient's experiences, trade-offs between maintaining a healthy lifestyle and quality of life and personal aspects, such as self-efficacy, motivation, and social support. Finally, we drew out the current use of ICT and possible unknown benefits of ICT in the health care domain (Haan et al., 2005).

Based on the domain analysis, we developed scenarios. A scenario is a description that contains actors, background information on the actors and assumptions about their environment, actors' goals or objectives, and sequences of actions and events (Go & Carroll, 2004). Go and Carroll explain that Scenario-Based Design uses these scenarios as a general representation throughout the entire system lifecycle (analysis, design, and prototype & evaluation). It encourages user involvement, provides shared vocabulary among the system developers, envisions the uncertain future tasks of the system users, and enhances ease of developing instructional materials. Furthermore, it provides a good brainstorming tool for planning and allows the stakeholders to consider alternatives in decision-making

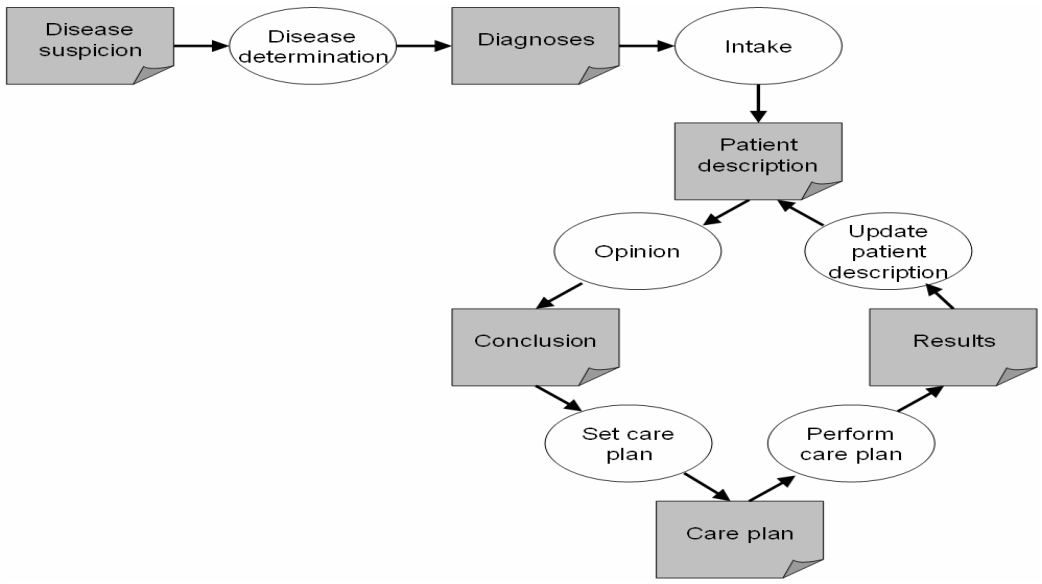

Figure 2: Care plan cycle.

3.2 Smart Home Laboratories

After our domain analysis, we conducted various studies in smart home laboratories. It facilitates testing prototypes by offering a comfortable domestic atmosphere and encourages

natural behavior in an experimental setting (Mynatt, & Rogers, 2002). We made use of the facilities at the Georgia Tech's Aware Home (www.awarehome.gatach.edu) and TNO/Delft University of Technology's (DUT) Experience Labs (http://www.usabilitytesting.nl).
During these studies, participants were asked to empathize with user scenarios, and interact with the computer assistant accordingly. Younger and older adults who did not have medical complication evaluated the influence of different computer assistant feedback styles on the interaction with the computer assistants while performing self-regulation activities. Although these participants did not have exactly the same characteristics as the prospective users, assessing the different user characteristics, such as cognitive abilities (Czaja et al., 2006) and personality traits, facilitated designing user-assistant interaction models applicable in last phase of the project wherein actual patients are recruited. The interaction was evaluated according the usability standards ISO 9241-11 (1998), which covers effectiveness, efficiency, and satisfaction.
Results of our studies showed that different users require different type of computer assistant feedback styles for usable interaction. In accordance, a computer assistant that was context-aware and adapted its feedback style to the user's health situation was most effective and time efficient. In addition, personal characteristics proved to have a moderating effect on how people evaluated the computer assistant support, similarly implying the importance of personalized interaction. Finally, applying the incremental design in smart home lab studies facilitated evaluating the usability of computer assistants and the benefits of eHealth technology (Blanson Henkemans et al., 2006a, Blanson Henkemans et al., 2006b, Blanson Henkemans et al., 2008a, Blanson Henkemans et al., 2008b).

3.3 Randomized Controlled Trial

The domain analysis and the results of the experiments conducted in smart home labs show that personalized computer assistance is usable for support of self-regulation. However, two main drawbacks remain. First, when testing with healthy participants, the subject group does not fully match the conditions of the actual target population. Second, conducting studies in labs creates a lack of knowledge of technology use over a longer period of time and complications that are created in real life settings.
Consequently, we are now conducting a randomized controlled trial with people who are overweight. With the input of the domain analysis and smart home lab studies, we have developed an online lifestyle diary with a personal computer assistant. Participants will use and evaluate the diary over a period of four months from their home setting. The study is under review by the Dutch Medical Ethical Testing Commission (METC). The commission guards human research subjects' rights, safety and welfare through ethical review, administrative review of proposal, and scientific peer review.

4 Discussion

In this article, we give an overview of our incremental design of personal computer assistance of disease self-regulation. Currently, there is little empirical research on eHealth technology.

A main cause for this delay is that design and evaluation of ICT in the medical domain is that it's medically ethically complex. Empiric research in the field to validate the usability of eHealth technology is required. However, it is essential to keep in mind that the test subject's, i.e., the patient's, wellbeing is the primary objective..

Following the cognitive engineering approach in the context of the medical domain, we incrementally designed and evaluated computer assistants for the support of disease self-regulation. In addition, we study the influence user characteristics and computer assistant feedback styles, on the evaluation of the user-computer assistant interaction. We performed domain analyses, designed scenarios, and conducted usability studies in Smart Home Labs. Currently, we are conducting a randomized controlled trial on the influence of personal computer assistant, in the context of eHealth technology, which is reviewed by the Dutch Medical Ethical Testing Commission.

In conclusion, similar to earlier studies in the naval and space domain (Neerincx & Lindenberg, 2007), the cognitive engineering and an incremental design approach has proven successful for medical ethical design of usable eHealth technology. As a result of our approach, the results of our studies are representative and valuable for the different disciplines involved, i.e., the medical, scientific, and industrial domains.

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