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Abstract
INVADE is a successful, evidence-based intervention program for reducing stroke and dementia. Enlisted patients are supervised, monitored and supported at family practices. A web-based application for tablet computers, the INVADE intervention assistant tool (ICAT), has been developed to enhance standardization of intervention delivery and to ensure overall intervention success. ICAT aims at supporting patient consultations, which are a central activity for the intervention conducted by assistant nurses. The application development follows a Design Science approach. Two iterations of problem formulation, development and evaluation have been accomplished. The paper at hand is focused on design and evaluation of the prototype and we reflect evaluation results to conclude on our iterative design approach.

Keywords: Intervention, Tablet Computer, Design Science, Prototype Evaluation

1 Introduction
The INVADE intervention program, established in year 2001, aims at reducing incidence of stroke and dementia by continuous monitoring and treatment of risk factors like hypertension, diabetes, lipometabolic disorder, overweight and sedentary lifestyle as well as stress and smoking. INVADE is a distributed program in the district of Ebersberg, Bavaria. About 60 general practitioners (GP) and approximately 4000 patients are involved. Several studies have
shown positive effects and the intervention success (Sander et al. 2006; Scherpinski et al. 2002; Ulm et al. 2010).

Patients are enlisted by their GPs and are at least 55 years old. Important elements of the intervention are patient consultations conducted by so called intervention assistants, who are specially trained and experienced doctor’s assistants. Following the principle of motivational interviewing (Torsi et al. 2010) intervention assistants record health conditions, educate patients to foster health literacy and set and control health related goals as well as try to motivate patients towards compliant behavior.

Due to the distributed setting of the intervention, INVADE has to meet the challenge of a standardized, consistent delivery. Although intervention assistants undergo standardized education and training for certification, INVADE is facing differences concerning contents and the process of patient consultations. On the one side, intervention assistants tend to focus on topics they favor and they also try to adapt themes and intensity to patients’ progress. On the other side, patients significantly influence consultation through participation and intervention assistants take account of their implicit knowledge about patients' history and personal circumstances, e.g. hobbies, family and partnership. (Radzuweit et al. 2012)

The INVADE management board seeks to improve the intervention standardization by introducing a tablet computer application, which should support the intervention assistants and patients during consultation. The so called INVADE consultation assistant tool (ICAT) is conceived to offer an innovative way of delivery and to further attract and interest patients. ICAT should provide a guideline in terms of a set of standard tasks for the consultation process. The tablet computer solution allows further possibilities for future extensions and advanced use cases.

Following a Design Science (Hevner et al. 2004) approach we develop and evaluate an IT artifact that is indented to solve an organizational problem. IT artifacts are constructs, models, methods or instantiations (March and Smith 1995). Instantiations in forms of prototypes are suitable to address a new problem area and deliver a sufficient problem solution (March and Storey 2008). Building a prototype demonstrates feasibility and evaluation analyzes how well an IT artifacts is solving the organizational problem (March and Smith 1995). We conducted an iterative process of problem formulation, suggestion, development and evaluation (Peffers et al. 2008; Vaishnavi and Kuechler 2004). The built IT artifact from first iteration was a demonstrator, a mock-up of the later ICAT prototype from second iteration.

In the paper at hand we demonstrate the two iterations of developing a tablet computer application for the INVADE intervention program. We further describe and examine results from evaluation of ICAT prototype. By analyzing our iterative research approach, we contribute to an improved understanding of design of applications for tablet computer in the medical domain.

The remainder of this paper is structured as follows. Section 2 exemplifies the two iterations of prototype development. Section 3 explains the theoretical background and methods for evaluation. Section 4 presents results from evaluation. Section 5 discusses evaluation results and conclusions.
2 Building the prototype

Starting point was our attendance in several meetings of the INVADE management board. Overall project goals were defined: (a) Standardization of contents and process of consultation, (b) improved data collection and (c) overall improvement of quality of care through increased effectiveness and efficiency.

First iteration – the demonstrator

Additionally, to enhance the problem formulation and for a deeper understanding of the current consultation setting, we conducted semi-structured interviews with intervention assistants. Five intervention assistants between 20 and 53 years old were interviewed. The participating intervention assistants had at least four years work experience in the INVADE program and were caring for between 40 and 150 patients. (Radzuweit et al. 2012)

Interview results and goal definition of INVADE management influenced the design of the demonstrator. Fostering patients' health literacy is a major aspect of the patient consultations and crucial for the intervention success, as health literacy increases patients’ control over decisions and actions affecting their health (Nutbeam 1998a). Health literacy are »motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health« (Nutbeam 1998b). Hence, a group of educational lessons was developed to avoid differences in subjects discussed during consultations and to provide a general set of information that encompasses topics most relevant for INVADE patients.

Unlike leaflets or brochures, educational lessons for ICAT should not solely provide factual information, which is referred to as “functional health literacy” (Nutbeam 2000). ICAT lessons should also support the consultations by giving advice, so that patients act more self-confidently and independently in combination with motivation by intervention assistants, which is defined as “interactive health literacy” (Nutbeam 2000). For ICAT, an educational lesson is conceived as five to ten pages concentrating on a specific issue, e.g. self-measuring blood pressure or the correlation of overweight and blood pressure. To ensure quality criteria for health information (adopted from Coulter 2011 p. 53), evidence, completeness and readability were checked repeatedly throughout the development process by INVADE management.

The demonstrator was also used to suggest on the application layout. The demonstrator layout is divided in three sections: a header section with primary navigation elements and the current title, a footer section with additional information on the consultation sessions and the main section as content area. Furthermore, icons for menus are introduced to allow an intuitive navigation.

The final demonstrator is a set of slides, which are linked among each other, so we could also design and demonstrate workflows and navigation in this early phase. Three main modules were developed that reflect the main task of intervention assistants during consultation: health status assessment, training patients with educational lessons as well as goal setting and monitoring. These three modules are considered as guideline for consultation and should provide a consistent process for consultation sessions.
A focus group analysis with intervention assistants from initial interviews and members of the INVADE management board was conducted for evaluating the demonstrator. Participants formed groups of two and were simulating consultation sessions, in which they made use of the demonstrator. Results indicated generally acceptance, although not all functions were available. Suggestions for improvements were especially about educational lessons in terms of readability and comprehensibility of text or relevancy of graphics.

**Second iteration – the prototype**

In the beginning of prototype development it was still unclear which tablet computer will be provided in the family practices. Furthermore, ICAT should also be available on desktop computer, when needed. Therefore, the prototype had to be independent from target device operating system (OS). That is why, we chose to develop ICAT as a web application instead of native application programming. Web applications support devices with less effort on programming and deliver adequate performance (Charland and Leroux 2011), which is minor in case of ICAT.

The final prototype is conceived as a three-layered web application following the MVC-Pattern (Reenskaug 2008). The object-oriented PHP framework ZEND (Zend Framework 2006) was used as basis for the application structure and defines process and business logic (Controller) as well as interactions with the database (Model). The data layer is a MySQL database. Thus, no data are stored on the device. The View-Layer is extended with the JavaScript libraries jQuery (jQuery 2013) and jQuery Mobile (jQuery Mobile 2013), which offer a native look and feel.

Figure 1 displays the ICAT main page after an intervention assistant has logged in and loaded a patient record at the beginning of a consultation session. The basic layout described in first iteration’s demonstrator can be recognized.
After sessions start, an intervention assistant can select one out of six modules. The three modules for health status assessment (“Meine Gesundheitsdaten”), educational lessons (“Schulungen”) and goal setting (“Meine Gesundheitsziele”) form the guideline for interventions assistants during consultations. The other three elements are facilitating modules for general patient information (“Patientendaten”), access to archived consultation sessions (“Letzte Sitzungen”) and charts for graphically displaying measured and targeted health data (“Analyse”).

3 Prototype Evaluation

The prototype evaluation was twofold. A focus group analysis with INVADE management board and usability evaluation during patient consultations with observation and questionnaire.

Focus group

The objective of the focus group (Morgan 1996) was to assess the organizational fit of the prototype and tried to answer the question, how the prototype satisfies the project goals set by INVADE management board. Therefore, the INVADE management board was given an introduction to the prototype and an overview about the implementation and technical issues. The live prototype was presented to the audience while explaining tasks and the standard workflow: user login, select patient and start consultation session, record health data, accomplish educational lesson, define and record health goals, save session and logout. After
answering questions the audience had opportunity to try out the prototype on their own with provided tablet computers.

In the following, the members of INVADE management board should express their beliefs about the prototype’s outcome on the identified project goals. Therefore, a workshop technique was used (Andler 2011), in which participants first note associations to a given topic on sticky notes. The center of a white board represents the main topic; sections around the center denote relevant aspects of the topic. Afterwards, sticky notes are arranged on the white board; the more central a note, the more impact is associated with it. A group discussion moderated by two researches (following Byers and Wilcox 1991; Morgan 1996) followed, in which participants explained and discussed their associations and reasons for positioning.

Field study

Usability evaluation was planned as field study with intervention assistants and patients. The question was, how ICAT prototype supports both intervention assistants and patients during consultation. Thus, intervention assistants were asked to invite patients to routine consultation meetings and a tablet computer with the ICAT was provided for each session. Family practices and intervention assistants that took part in interviews and evaluation from demonstrator development were not part of the prototype evaluation to ensure validity.

To assess usability patients were given a questionnaire after consultation meeting, intervention assistants were given a questionnaire after all session. To further analyze usage of ICAT, two researches participated in each session to observe the process and the interaction of intervention assistants as well as patients with the ICAT application.

An observation sheet was created to record and analyze the ICAT usage during consultation and identify shortcomings. Besides patient gender and age, the observation sheet consisted of a timeline and a sketch area. The later was used to layout the general positions of intervention assistants, patients and the tablet computer throughout the consultation session. The timeline was used to record succession of ICAT modules and interactions of the intervention assistant like login, logoff and filling out forms as well as interactions of patients like navigating through educational modules. Difficulties in handling ICAT and patient questions were recorded as well. The timeline was used as it allows drawing conclusions from the sequence of actions while using the system. Additionally, noteworthy comments and remarks from both patients and intervention assistants were recorded on the observation sheet.

All participants were asked for approval before consultations. To avoid data privacy issues fictional user accounts and patient profiles were set up and intervention assistants were instructed to record fictional data as well. Participating intervention assistants were given an introduction to ICAT similar to the presentation during focus group analysis with INVADE management board. To assure comparability between family practices, the introduction followed a written instruction guide containing explanations of the main menu and the consultation process.

The Unified Theory of Acceptance and Use of Technology (UTAUT) (Venkatesh et al. 2003) was basis for questionnaire development. UTAUT is founded on several established models
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from Information Systems Research, Sociology and Psychology and offers a unified view on individual acceptance of technology. Four constructs are influencing the behavioral intention to use a system in UTUAT (Venkatesh et al. 2003): performance expectancy, effort expectancy, social influence and facilitation conditions.

Performance expectancy describes a person’s beliefs that using a system will help to improve his or her job performance. Venkatesh et al. (2003) found performance expectancy as strongest predictor of behavioral intention to use a system. Effort expectancy are a person's beliefs of ease that is associated with system usage. Social influence describes the impact of beliefs about, how other people will perceive individual system use. Facilitating conditions relates to a person’s beliefs on how organizational and technical infrastructure supports use of a system.

For assessing both the patients' and the interventions assistants' perceptions, the questionnaire was developed in two versions with adapted wording. Furthermore, we focused on performance expectancy, effort expectancy and facilitating conditions. Social influence was declined, as ICAT is still prototype and has not been introduced in any INVADE family practice yet. Performance expectancy contained perceptions about improved usefulness, efficiency and quality of patient consultation through ICAT usage. Perceptions about ease of use, time and effort to learn and handle ICAT were summarized by effort expectancy. Considering facilitating conditions, we examined ICAT’s compatibility and fit to the aspects of consultations perceived by patients and intervention assistants.

Furthermore, we wanted to examine if ICAT use is perceived as appealing and pleasant and consequently improves consultations by producing interest and fostering involvement. The construct of perceived enjoyment is defined as perceptions, that using a system is enjoyable ignoring any performance issues (Davis et al. 1992). Perceived enjoyment has been found as cause and effect of perceived ease of use (effort expectancy) depending on the type of information system under research (Sun and Zhang 2006): In terms of utilitarian information systems, that provide value to satisfy external objectives, e.g. improve job performance (van der Heijden 2004), perceived enjoyment is regarded as antecedent to perceived ease of use. In terms of hedonic information systems, that “provide self-fulfilling value to the user” (van der Heijden 2004), perceived enjoyment is regarded as consequence.

ICAT is regarded as primarily utilitarian system, i.e. following the objective of improved medical outcomes and intervention success. Furthermore the purpose of interaction with hedonic systems lies in interaction per se and to promote continued usage is the main objective of hedonic system design (van der Heijden 2004). However, information system design for lifestyle interventions should also consider hedonic aspects from patients for long-term usage to support long-term behavior change.

The final questionnaire was a set of questions rated by 5-point Likert-scale ranging from full agreement to full disagreement. Before attending the consultations for evaluation, we conducted a pre-test of the questionnaire with experts (following Hader 2006). The questionnaire was presented to a group of two intervention assistants and three GPs from INVADE management board. Comprehensibility, structure and wording as well as relevancy of questions were evaluated and adapted if necessary. As a result, questions regarded insufficient, irrelevant or overwhelming for patients were excluded. Thus, the final
questionnaire for interventions assistants contained 26, whereas the final version for patients only had 13 questions.

4 Results from ICAT Evaluation

Four family practices first agreed to take part, but two declined later on due to scheduling conflicts. Subsequently, two intervention and eight patients were part of the evaluation. Patients were aged between 59 and 80 years; five female and three male. The consultations lasted between 15 and 22 minutes. Results from observation, questionnaire and focus group are presented in the following.

Observation

At one family practice, the intervention assistant and the patients were sitting opposite at the table. The tablet computer was laid down between them. At the other office, the intervention assistant was sitting next to the patient on the edge of the table. The intervention assistant was holding the tablet computer during the conversation.

The analysis of the timeline shows that in two out of eight consultations, the intervention assistant started consultation with goal setting instead of health status assessment. The predefined guideline for consultation from health status assessment, educational module to goal setting was used the other times.

Furthermore, observation analysis reveals two other concerns concerning educational modules. Educational modules were partly regarded as too comprehensive. Some patient stated they already knew contents from educational modules, so that the intervention assistant skipped few pages to save time. Whereas patients consider advice at the end of educational lessons as very positive and practicable to foster healthier lifestyle and habits.

Two patients were rather reluctant in first place and leaning backwards in the beginning of the consultation. This changed during consultation progress after about 14 to 16 minutes and both the patients leaned forward for better sight on ICAT during presentation of an educational module. The other participants were rather open-minded, interested and were sitting close to the tablet computer all the time.

Five patients actively used ICAT by operating the application, for instance to navigate through educational lesson. These patients had no uncertainties to control the application, which is remarkable regarding the rather high age of participating patients. However, they were able to navigate through the lessons on their own pace, so that their personal involvement and interest were increased.

Questionnaires

Out of eight questionnaires for patients, one was not completed and was not considered for evaluation. From the remaining seven patients, four rated ICAT in general high and very high, respectively. All patients perceived usefulness and impact of ICAT on efficiency and quality of consultations high and very high except one patient, who rated performance expectancy
very low. This patient was also very critical about effort expectancy. He or she was indicated to be overwhelmed and stated that ICAT was not easy to use at all, whereas all other patients valued ease of use as high, two of them even very high. All patients appreciated ICAT usage during consultation and stated, that ICAT fits to the way his or her intervention assistant executes consultations. Concerning perceived enjoyment, all patients indicated ICAT usage was neither boring nor dull and found it rather interesting and pleasant, but fun and entertainment while using was perceived limited.

The questionnaire results from intervention assistants’ show, that one intervention assistant perceived overall usability as very high; the other was generally a bit more reluctant. One rated all aspects of performance expectancy very high, whereas the other was ambiguous concerning improved efficiency of patient consultation through ICAT usage. ICAT prototype was not perceived as hard to use or frustrating and overwhelming, but both intervention assistants stated that the would need some more time to learn to handle the application.

The observed consultation sessions lasted rather long, as consultations are usually between 10 to 15 minutes (Radzuweit et al. 2012). This might be related to the fact, that intervention assistants had no experience with ICAT before except the introduction given by the researchers. However, both intervention assistants stated, that they would have needed some more time to learn how to handle the application. This must be taken into account for future usage to avoid time-consuming consultations.

Focus group

Focus group analysis shows that ICAT is associated to have a high impact on contents through the educational lessons. The INVADE management board believes that all patient will be better educated and trained trough ICAT in general. Also, it is useful that the same information is provided visually in forms of text and additional pictures. ICAT will give INVADE a new, modern image, according to INVADE management. The tablet computer application will raise interest of patients as well intervention assistants and will further patients’ attention and participation. The impact on data quality is rated to be rather moderate, although ICAT offers opportunities to record patients’ health related goals and to track the lessons patient conducted, which has not been part of the intervention so far.

5 Discussion and Conclusion

Results from prototype evaluation show general acceptance of ICAT by patients and intervention assistants. It is noteworthy, that all patients agreed, that a web application provided on tablet computers like ICAT is suitable and fits the way consultations are executed by intervention assistants. Simultaneously, patients found the ICAT application interesting and pleasant. Thus, the notion of INVADE management board is supported, that a tablet computer can positively influence perception of the intervention program by patients, which lead to a higher level of interest and participation.

Educational lessons are a major benefit for INVADE. Standardization of contents was one primary goal of the project. By delivering contents through ICAT, all participating family practices will work with a common set of information. Thus, the reliability of studies
conducted by INVADE is improved, as all intervention assistants will educate patients according to a corporate standard.

In contrast to native applications for specific OS, ICAT is a web application and is available for any kind of tablet computer or even desktop computers and will be centrally hosted by INVADE management. Thus, there is no need to develop and maintain in accordance with a target OS or environment. Especially distributed intervention programs like INVADE might benefit by introducing a centrally hosted, health application. Nevertheless, web applications have some shortcomings concerning device support. The ICAT application does not fully support typical handling associated with tablet computers, e.g. wiping to navigate. Users mostly interact by pressing touchscreen buttons, which is appropriate for process-oriented applications like ICAT and this benefits INVADE, that is seeking a structured process of delivery.

ICAT is developed for older patients, who are assumed to be less savvy with information technology. That is why it was important to conduct prototype evaluation in real life setting. Although a more comprehensive evaluation was not possible, results were generally satisfying for prototype evaluation. Remarkably, the most important facts came from observation, whereas the developed questionnaire might be useful in a broader, quantitative evaluation, that includes more patients and considers prolonged use. However, the construct of perceived enjoyment might contribute to design of health applications for tablet computer and needs further research.

Understanding target group needs is also important. Negotiation is required, when there are conflicts between targets. While ICAT design, construction of instantiations happened very fast by developing the demonstrator and the prototype, so that mutual understanding, agreement and acceptance of participating intervention assistants and INVADE doctors was ensured.

The execution of two iterations from problem definition through development to evaluation was sufficient for our project. Especially the first iteration, the demonstrator, was a suitable approach. The mock-up already contained the modular scheme with relevant content, primary processes and layout elements without regarding any implementation issues like choice of technology or operating system, which were not clear until then.

Overall positive results from prototype evaluation suggest that ICAT supports consultation and is accepted by INVADE’s target group. Nevertheless, it is important to consider different target group needs while developing the application. Still in case of ICAT, not all aspects of standardization targeted by INVADE management are satisfied, as intervention assistants and also patients demand a flexible process of consultation delivery.

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