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Design of a Mobile, Safety-Critical in-Patient Glucose Management System

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Abstract. Diabetes mellitus is one of the most widespread diseases in the world. People with diabetes usually have long stays in hospitals and need specific treatment. In order to support in-patient care, we designed a prototypical mobile in-patient glucose management system with decision support for insulin dosing. In this paper we discuss the engineering process and the lessons learned from the iterative design and development phases of the prototype. We followed a user-centered development process, including real-life usability testing from the outset. Paper mock-ups in particular proved to be very valuable in gaining insight into the workflows and processes, with the result that user interfaces could be designed exactly to the specific needs of the hospital personnel in their daily routine.

Keywords. Diabetes Mellitus, User-Computer Interface, Mobile Computing, Computer-Assisted Drug Therapy, Workflow

1. Introduction

Diabetes mellitus is one of the most widespread diseases in the world. People with diabetes are more likely to be hospitalized and to have longer durations of hospital stay than those without diabetes. It is estimated that 22% of all in-patient days were accounted by people with diabetes and that in-patient care accounted for half of the total US medical expenditures associated with this disease [1]. These findings are due, in part, to the continued worldwide expansion of type 2 diabetes.

The in-patient glycemic control of acute diseased patients with diabetes is often considered secondary in importance. However, studies demonstrate that in-patient hyperglycaemia has been found to be an important marker of poor clinical outcome and mortality among diabetic patients and that aggressive treatment of diabetes and

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hyperglycaemia results in reduced mortality and morbidity [2]. Therefore, patients suffering from diabetes require continuous glycemic control during in-patient stays including close monitoring of blood glucose and determination of suitable treatment strategies. In this paper we discuss the requirement engineering process and the lessons learned from the iterative design and development phases of a mobile in-patient glucose management system with decision support for insulin dosing.

2. Methods

The development of mobile applications in a medical context provides engineers with a complex task. In addition to the aim of supporting workflow requirements, usability and clinical safety are important issues to consider when designing the user interfaces and system functionalities. Therefore, the consistent pursuit of an user-centered design is a crucial condition and must include an understanding of the users, their environment and the context in which the application is used [3,4,5,6,7].

A team consisting of physicians and nurses of the Division of Endocrinology and Metabolism at the Medical University of Graz, as well as engineers from JOANNEUM RESEARCH and the Medical University of Graz, was established to develop the user interface design and the functionalities of the in-patient glucose management system, tailored to the needs of the end-users. Project partners from the Foundation for Research and Technology Hellas performed a first design of the conceptual data model starting from the first user interface mock-up and organised external reviews of the obtained results. We discussed each design decision relating to the user interface, system functionality and the underlying protocol for decision support for insulin dosage within this team. We integrated the results into an intuitive software system based on essential, but user-tailored functionalities. Figure 1 shows the iterative development process of the in-patient glucose management system.

In the first step we interviewed physicians and nurses about current treatment workflows for type 2 diabetic patients at the Division of Endocrinology, in order to understand and determine workflow patterns for medical decision-making and problems and risks associated with glucose management.

We generated a status report describing current workflows, based on various patient scenarios, as a starting point for the target analysis. We then identified and discussed relevant publications related to the ideal in-patient management of hyperglycaemia including validated glucose control protocols with diabetes specialists [8,9,10,11]. The protocol based on a basal/bolus regimen as provided by the RABBIT 2 Trials[2] proved to be most promising for the clinical diabetes experts due to its straightforward advice for insulin dosing, which was shown to be associated with improved outcomes. In the final step, we extracted the most important user requirements from the status report and the findings of the protocol reviews. These were then implemented in a software prototype.

[2] RABBIT 2 - Randomized Study of Basal-Bolus Insulin Therapy in the In-patient Management of Patients With Type 2 Diabetes

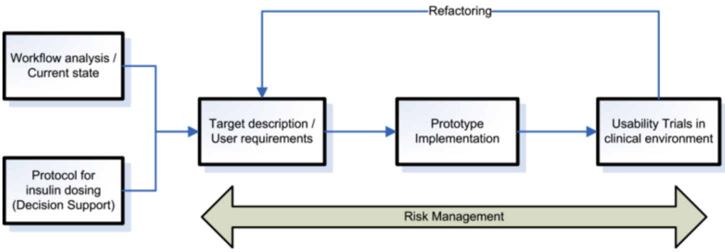

Figure 1. Process chart of prototype design

The last step of the first iteration of the development process, involved performing real-life usability trials with three diabetes specialists as participants. We used the Thinking Aloud testing method [12] followed by a semi-structured interview. We documented all tests on video, interpreted the results and integrated suggested improvements into the revised requirement specification document. The second design iteration consisted of integrating test results into the requirement set and developing a detailed user-interface for the application using paper-mockups. The development process is accompanied by continuous interdisciplinary meetings regarding risk identification, evaluation and the setting of appropriate measures to avoid these risks. Emphasis is placed on both technical and medical risks.

3. Results

This section reports the results of the prototype development and the usability tests. In the first development iteration, we demonstrated the identified basic functionality using Microsoft Excel with VBA Scripts. Microsoft Excel was chosen, due to the extensive display options of charts, the quick and easy visualization of glucose and insulin profiles, as well as optical alarm borders.

The user evaluation of the first glucose management prototype resulted in an extensive requirement specification document with the following main conclusions, which formed the starting point for the second design iteration:

- Execution of the application via a mobile device to allow activities to be performed directly at the patient's bed.
- No data storage on the mobile device. Wireless communication via web services to an external server, on which the data should be placed.
- Documentation and visualization of the most important parameters relating to diabetes care on the mobile device.
- Automated decision support for insulin dosage.
- Reminder for open tasks through an active task management.
- Avoidance of manual (and multiple) inputs. A connection to the hospital and laboratory information system is necessary in order to transfer administrative data automatically.

We designed the revised user requirements using Visio stencils for Android in a paper mockup screenplay consisting of all functionalities of the glucose management system and again discussed the results in the team. Based on the design and functionality, which was identified through the mockups, we are currently implementing an Android-based mobile client application, which communicates via web services (Apache CXF) with a java-based web server running on Apache Tomcat.

The server application has been implemented using Hibernate and the Spring Framework based on a model driven design and development approach and transfers data securely from and to the HIS of the hospital via HL7 v2.4 interface.

Figure 2 shows the already implemented main screen with the visualization of the most important measurement and insulin administration parameters of the mobile in-patient glucose management application. In addition, the figure shows the main functionalities of the application. 'Patient List' presents all patients administered at the ward including a filter function to show only patients enrolled for the glucose management. 'Open Tasks' reminds users of the system to perform all recommended tasks like 'Blood Glucose Measurement', 'Insulin Administration' or 'Therapy Adjustment' in time. 'Blood Glucose Measurement' enables users to retrieve the blood glucose value directly from the laboratory information system and documents the measured values in the glucose management system. Physicians approve the current therapy for the patient (e.g. insulin medication, current insulin dosage, hypoglycemia borders) using the function 'Therapy Adjustment'. Finally, the decision support protocol for insulin dosing suggests the needed insulin dosage of the patient based on the measured blood glucose values and administered food using the function 'Insulin Administration'.

Figure 2. Screenshot of the Android-based Prototype

4. Conclusions and Future Research

In this paper, we presented the user-centered design process of a safety-critical in-patient glucose management system. Medical end-users have been involved in every step of the design phase. In other words, clinicians have conceptualized the design of the system. Engineers now have to implement the design in an optimal software solution.

Our experiences through the first and second iteration steps show that clinicians and engineers have very different points of view concerning software. While engineers often focus on gathering as much functionality as possible, clinicians prefer software which offers only the required base functionality but a well sophisticated user interface, tailored to current workflow patterns. A problem we encountered during the requirement analysis is that end-users without a trigger, often do not know what specific functions should be provided by a software solution. Therefore, as a result of the first iteration step, a Microsoft Excel prototype was used as a trigger to give clinicians a preliminary idea as to how an in-patient glucose management system, including a computerized decision support, could look. After the presentation of the prototype, the participants were able to give a clearer idea of their requirements for a glucose management system, which were then used as inputs for the second iteration step. We used paper mockups of the second iteration step, which simulate the full system functionality on a mobile device, as the next trigger. At the moment we are implementing the server application and an Android-based mobile prototype, which already contains full functionality. We will test the resulting prototype of the second iteration in a clinical study.

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