Integrated System Approach for a Diabetic Monitoring System

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Abstract

To continue impacting the healthcare industry, Texas A&M University at Qatar partnered with Hamad and Sidra Hospitals to design a diabetic monitoring system with Web and Mobile Applications, using a Continuous Glucose Monitoring (CGM) device to transmit patient's' glucose levels to a real-time server and calculating the corresponding Glycohemoglobin (HbA1c). To ensure the most effective and efficient monitoring system is designed, the opinions of current Qatari endocrinologists was taken into consideration in addressing the design process of the system. Based on the practical applications and technical limitations, the diagnostic metrics with crucial impact within diabetic patients are identified, optimal data presentation for medical personnel was studied, and the disadvantages of past manual monitoring systems were investigated. This presentation discusses efforts to evaluate the system design, along with the sociotechnical aspects affecting implementation. In contrast to previous monitoring systems wherein functionality depended on three individual systems, the current version combines systems into three high level functions integrated into a systematic computerized approach, allowing the use of Bluetooth and WiFi.

Keywords: telehealth, CGM, diabetes monitoring

1. Introduction

Diabetes is a pervasive condition affecting around 26 million patients in the United States [1]. Although remote monitoring tools such as Continuous Glucose Monitoring (CGMs) have shown promise, these devices are costly, invasive, and suffer from low reliability in some contexts, such as during sleep and hyper and hypoglycemia events [2]. The US medical industry encounters major loss of time in missed appointments, loss of medical treatment rooms due to in-patient monitoring, and high patient readmission rates [3]. Telemedicine can diminish issues presented in clinical services, with monitoring systems analysis being designed to consider future adaptations, such as combining diabetes monitoring systems with other clinical monitoring devices. The establishment of a unified data network of multiple clinical monitoring systems incorporating data aggregation from individual cloud based databases provides the means to a single end user product that allows online assessment of patient health via real-time monitoring and transmission of multiple diagnostic metrics. Furthermore, while the technology is in place to transfer the glucose level data to clinicians, conclusive research on identification and measurement of diagnostic metrics needed for prediction of critical conditions such as hypo and hyperglycemia, are limited, and a unified system for instruction of patient use for accurate readings is not in place [4]. The systems with higher accuracy typically incorporate a larger number of finger prick calibrations, roughly up to three to four times a day. Those with factory-based calibrations have been subject to scrutiny [5].

Our team at Texas A&M University at Qatar have conducted interviews with endocrinologist to understand opportunities and limitations of CGM alternative systems. One important disadvantage identified of alternative CGM systems is the lack of memory capacity. In particular, if the data is not manually transferred within a month, the CGM automatically erases the patients' prior glucose records (Dr. Goran, personal communication, June 2017). The automatic migration of glucose data to an online server, can contribute to efficient data aggregation and database creation, allowing case-sensitive calculations, and recognition of unforeseen or un-identified patterns within individual patient data.

To address this gap, a group of graduate students from Texas A&M University at Qatar have worked on an RPM technology that supplements Continuous Glucose Monitoring (CGM) tools. The RPM tools consists of a Support Web Application and Support Mobile Application termed HygeiaTel Application [6]. The goal of the HygeiaTel is to alarm the patient and clinicians if complexities in glucose values occur. Based on these glucose readings, the HbA1c (A1c) metric, an important indicator of the risk for developing diabetic complications, can be updated, providing the potential to develop patient-specific prediction models. This tool can also be used to investigate the relationship between the A1c and the particular CGM device being used. The HygeiaTel functions also include recording, analyzing, and transferring glucose level data via a wearable sensor, Internet of Thing, interface to a server at set time intervals [7]**.** Previous systems have incorporated storage devices that transfers data about patient's glucose values, otherwise known as a glucometer. However, such devices do not transmit information to clinicians. HygeiaTel not only functions as glucometer, it also enables RPM. HygeiaTel not only accounts for ergonomics, comfort and usability, specifically in patients with type 1 gestational diabetes such as children, it also makes the entire RPM system more resilient to future adaptations.

A team of undergraduate students at Texas A&M University incorporated front-end analysis and Human Systems Integration (HSI) methods to improve the design of HygeiaTel, to allow optimization of patient-doctor communication, simplifying application usability while considering wide range of stakeholders. A sociotechnical systems approach is used to investigate different technical, social, and organizational factors [8]. This short paper documents the methodology used and briefly discusses the system modeling using Systems Modeling Language (SysML) (Figure 1) [9,10] and user-centered design principles utilized as part of the formal front-end analysis for the improved HygeiaTel interface.

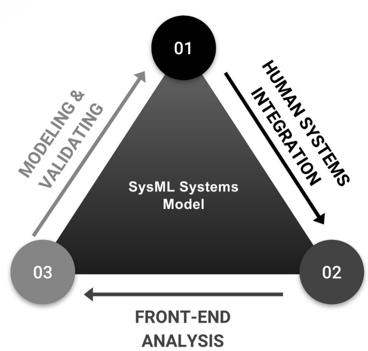

Figure 1 : Proposed SysML Systems Model

2. Human Systems Integration (HSI Design)

Research shows that human-systems that do not consider user needs, limitations and interactions of system activities, resulted in a higher risk for error [9]. A systematic front-end analysis was conducted to investigate stakeholders' expectations and constraints to inform the design of the new interfaces.

2.1 Stakeholders

A formal stakeholder analysis was conducted to identify entities that affect the proposed design or are affected by it. Professors and research students who designed the prototype are considered internal stakeholders because they directly affect the outcome of the product. It is essential to provide these developers with a detailed rubric of necessary intended functions since their initial perception will influence the preliminary design. External stakeholders affect the diabetic market industry. All users, competing manufacturers, and community partners of the HygeiaTel are identified as external stakeholders.

2.2 Constraints

The past CGM models require the glucometer to be connected to a computer via USB in order to upload the glucose levels from the pump. The CGM computer software can be used to create reports, view trends, and send alerts to the user. Eliminating the glucometer in the proposed design increases productivity for patients as it minimizes physical doctor visits. This was accomplished by redesigning the data transfer that resulted in eliminating a system component and implementing the automated transfer of average glucose levels to a server via Bluetooth.

One of the greatest challenges for CGMs is eliminating calibration. Past models have used invasive techniques to calculate average glucose levels, which enhances and assists in the calculation of A1c. In contrast, the new model's design considers designing out the invasive techniques discomforting to patients. Overall, the trend in the medical field is to integrate advanced machine learning algorithms to enable diabetes remote monitoring. The current prototype does not quite accomplish this task, but can be seen as the intermediate step needed to achieve this goal.

3. Front-End Analysis

3.1 User Analysis

A formal human factors analysis was used to identify user characteristics while differentiating between how the proposed model affects users physically and cognitively. With respect to past models, physical factors identified include Type 2 diagnoses, the ability to use glucometers to calibrate, and the ability to record the instance of the calibration. Cognitive factors include knowledge of the need for calibration, glucometer utilization, sensor placement, and data transfer. Physically, proposed model requires less assembly due to the elimination of the glucometer. Furthermore, this simplification has the capability of reducing cognitive requirements to understand the data results; requiring only basic knowledge of smartphones, and removing installation, setup, and continuous maintenance complexities of a separate device, such as the glucometer.

3.2 Information Requirement Analysis

A functional information requirements analysis was used to understand high-level functionality of the system, associated low-level functionality, and to derive the information requirements from both user input and system feedback [11-13]. To humans, many of these details often become second nature and are rarely acknowledged but when developing a new product, it's important to recognize these important requirements. In order to comprehend what is required from the patient and clinician point of view, two separate analysis were developed (Table 1 and Table 2 respectively).

Table 1: Diabetic Monitoring System - From Clinician's Perspective

Diabetic Monitoring System - From Clinician's Perspective		
High-Level Functions	Low-Level Functions	Information Requirement
View Patient Data	Login to server interface portal	Access to internet
		Access to tablet or computer
		Username
		Password
	Select prefferred layout	Scope of analysis
		Predetermined format for each scope
		How to navigate HygeiaTel app
Interpret Patient Data	Decide the timeframe	Determine if there is enough data to make assumptions
	Decide if need further analysis	Acknowledge inconsistent data
	Decide if data is reliable	Glucose meter values
Alerts	Alert sent by email	Patient in critical condition
	Dr. acknowledges the alert	Dr. views the email
	Dr. sends patient alert	Dr. confirms patient critical situation
		How to forward email
Video Consultations	Schedule an appointment	Navigate HygeiaTel app to ask for patient appointment verification
	Access video chat	Navigate tablet or computer
		Navigate HygeiaTel app interface
	Interact with patient	Be familiar with patient's status

Table 2: Diabetic Monitoring System - From Patient's Perspective

Diabetic Monitoring System - From Patient's Perspective		
High-Level Functions	Low-Level Functions	Information Requirement
Request Data	Record blood sugar	How to place sensor on body
		How to connect sensor to app
		How to navigate HygeiaTel app
	Record blood oxygen	How to utilize Ninon Oximeter
		When to utilize Ninon Oximeter
		How to navigate HygeiaTel app
	Record weight	How to utilize Pyle Health weighing scale
		When to utilize Pyle Health weighing scale
	Record blood pressure	How to utilize the Pyle blood pressure monitor
		When to utilize the Pyle blood pressure monitor
Observe Data	View the data	How to navigate HygeiaTel app
Alert	Patient acknowledges the alert	Patient views the email
	Patient schedules consultation	How to navigate HygeiaTel app
		Date of last consultation
Video Consultations	Schedule an appointment	Navigate HygeiaTel app to ask for doctor appointment verification
	Access video chat	Navigate HygeiaTel app interface
	Interact with doctor	Be willing to discuss personal status and symptoms
CGM Calibration	Acknowledge need for calibration	Time since last calibration
	Perform Self-Monitoring-Blood-Glucose test	How to utilize Glucose meter
		How to input data results into CGM device
	Verify proper data transfer	Navigate HygeiaTel app interface
		Ensure data is refreshing

Each table demonstrates essential high-level functions that need to be supported by the system, several low-level functions to support each high-level function, as well as specific pieces of information the interface needs to cover. From the doctor's perspective, viewing data requires a higher level of information requirements, making it the most difficult task. From the patient's perspective, recording data points is the most demanding because it requires a deep understanding of CGM functions and the HygeiaTel. The two tasks may be further analyzed to assist in designing the system, ensuring task simplicity, and assisting with information requirements. Further analysis of requirements enables the identification of more demanding functions and allows certain tasks to use more salient designs to avoid potential interaction issues.

3.3 Task analysis

The main objective of the monitoring system is to track the well-being of the patient and to keep the doctor up to date. A hierarchical task analysis was conducted to understand the task requirements and interaction issues from both patient and clinician perspectives. Four primary goals were analyzed: requesting data, accessing data, video consultations that include doctor/patient perspectives, and patient CGM calibration displayed in Figure 2. In order to successfully implement these goals, a set of subtasks must be chronologically achieved. Each of the these sub-tasks were further decomposed to understand the task requirements in more detail.

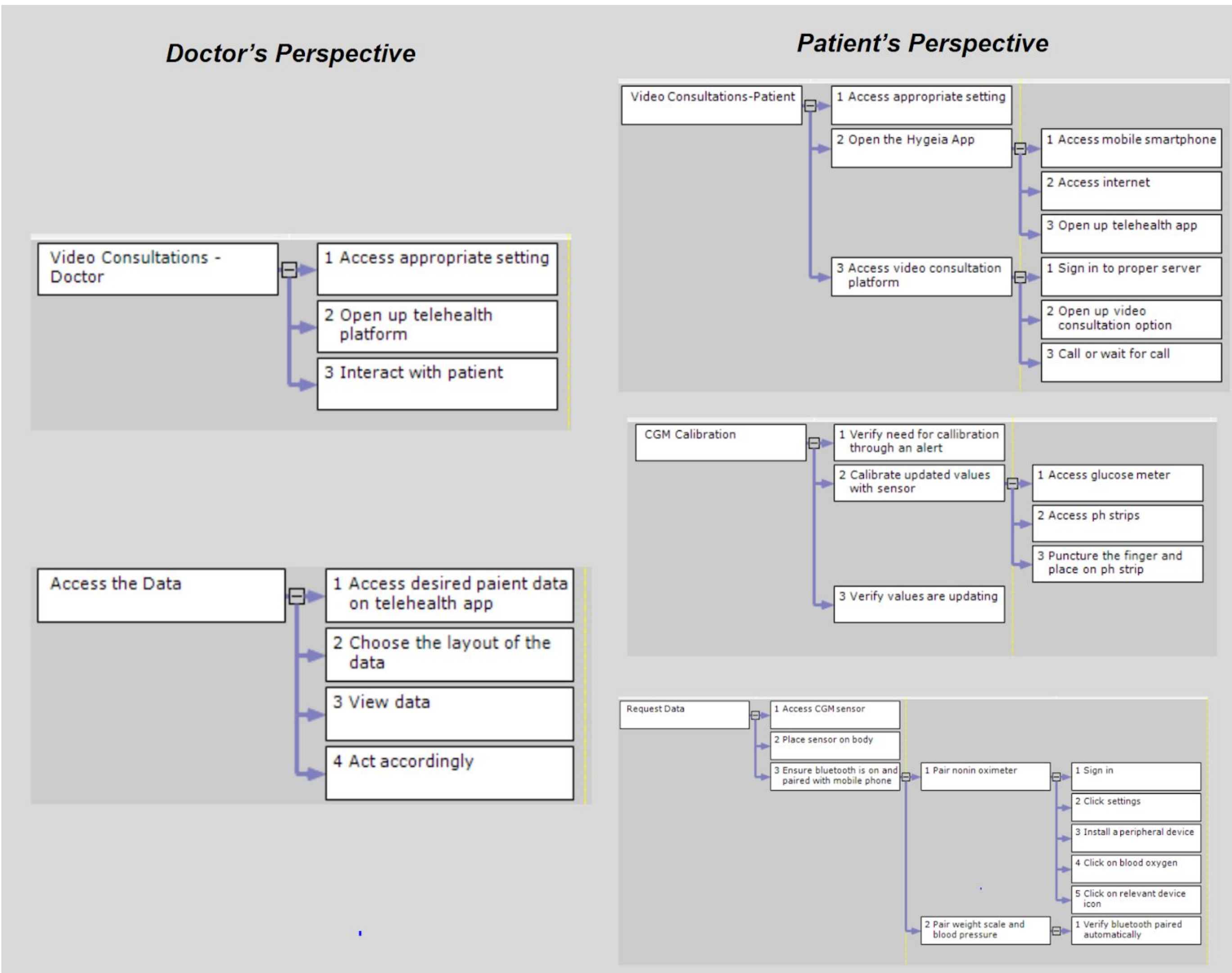

Figure 2: Hierarchical Task Analysis of Primary Tasks

4. Future Work: Modeling and Validation - Future Projects

4.1 Clinician Questionnaire

A questionnaire is in the process of being drafted. The proposed idea is to survey past endocrinologists and request other specialists in the subject to gather further design requirements. The survey takes into consideration system usefulness, human performance evaluation, and the system's effectiveness. Each question will tailor a specific design modification, new function, or difference to past CGMs.

5. Conclusion

A preliminary analysis of the monitoring system was conducted using an HSI framework, and front-end analysis methods to design a novel remote patient monitoring tool for diabetes patients. Methods used by the undergraduate research team included system stakeholders and constraint analysis. High-level information requirements were also derived from high-level functions of the proposed system. The user analysis identified primary stakeholders' cognitive and physical factors that expose necessary system design elements to fulfill user needs. In addition, a task analysis was conducted to outline required user tasks to accomplish several system goals. Overall, this preliminary analysis will inform a user-centered design that facilitates patient and doctor interaction with the system. Future work includes detailed modeling using the Systems Modeling Language (SysML) and validation of such models using extensive user analysis. Findings will then inform improvements to the monitoring system.

While the monitoring system designed has shown promise with regards to assembly simplifications and health informatics adaptations, a systems approach to understand user requirements will improve the usability and sustained adoption of the system under investigation and will inform the design of other RPM technologies.

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