A mHealth Architecture for Diabetes Self-Management System

Research-in-Progress

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ABSTRACT

Recent advancement in smartphones coupled with the proliferation of data connectivity has resulted in increased interest and unprecedented growth in mobile applications for diabetes self-management. Nevertheless, a review of the literature highlights critical gaps between available functionality and user requirements and expectations. In this paper, we present a mHealth architecture of diabetes self-management system. The architecture has the following functionalities: automated data-entry through the use of wireless sensors; adherence to clinical guidelines; advanced statistical techniques for diabetes modeling and prediction; and advanced charting capabilities for data presentation and quality control.

Keywords

Diabetes, Self-management, mHealth, Design Science Research

INTRODUCTION

According to the National Diabetes Clearinghouse, in 2005- 2008, 35% of the U.S. adults aged 20 years and older had pre-diabetes and 8.3% of the U.S. population had diabetes (NDIC, 2011). In the U.S. alone, the direct and indirect cost of diabetes in 2007 was 116 and 58 billion dollars, respectively. As a chronic disease, diabetes patients require ongoing medical care and engagement in self-management education and support to reduce the risk of long-term disability and complications (American Diabetes Association, 2012). The mismanagement of diabetes can lead to serious complications that include cardiovascular disease, kidney failure, non-traumatic lower limb amputations, and blindness. In fact, diabetes was found to be the 7th leading cause of mortality in the U.S. (NDIC, 2011).

In designing an effective self-management strategy, consideration should be given to the patient's age, school or work schedule, physical activity, eating patterns, social situations, cultural factors, and presence of other health related complications (American Diabetes Association, 2012). Self-management processes are inherently data intensive requiring the acquisition, storage, and analysis of large amounts of data on a regular basis. Logbooks require significant commitment to maintain, and are prone to documentation errors and inclusion of phantom data (Kalergis, Nadeau, Pacaud, Yared and Yale, 2006). Attempts to leverage IT in diabetes self-management date back to the late seventies and have shown promising outcomes (Bellazzi, 2008). Recent advancements in smartphones coupled with the proliferation of data connectivity have resulted in increased interest and unprecedented growth in mobile applications for diabetes self-management. Nevertheless, those applications have not yet realized their potential, particularly in regard to usability (data entry, data presentation, and general usability), meeting clinical guidelines and enabling clinician-patient communication, clinicians' expectations, and decision support capabilities.

This article presents a mobile health (mHealth) architecture for diabetes self-management. The architecture is designed to respond to requirements and limitations of existing approaches. Specifically, the design enhances the data collection processes for diabetes self-management, incorporates a decision support component that provides personalized evidence-based recommendations, and improves the data presentation and quality control. From a practical perspective, the resulting system represents a novel artifact for diabetes self-management that promotes adherence to treatment and clinical guidelines; improves the usability and adoption; and enhances the integration of the self-management system in the patient's daily routine. From the theoretical perspective, the resulting system provides a context for evaluating user acceptance and diffusion of mHealth for self-management of chronic diseases (most notably diabetes), evaluating the use of IT and mobile technologies for impacting behavioral change, and experimenting with various behavioral change theories.

The research adopts a design science methodology and follows Peffers et al. (2007) guidelines for design science research (Figure 1). Accordingly, the paper is organized as follows: the next section elaborates on the problem followed by an articulation of the requirements (defining the objectives of the research). The following section, illustrates the design and development of our architecture followed by the evaluation and demonstration plans for the proposed artifact. The last section presents a brief discussion and concludes the paper.

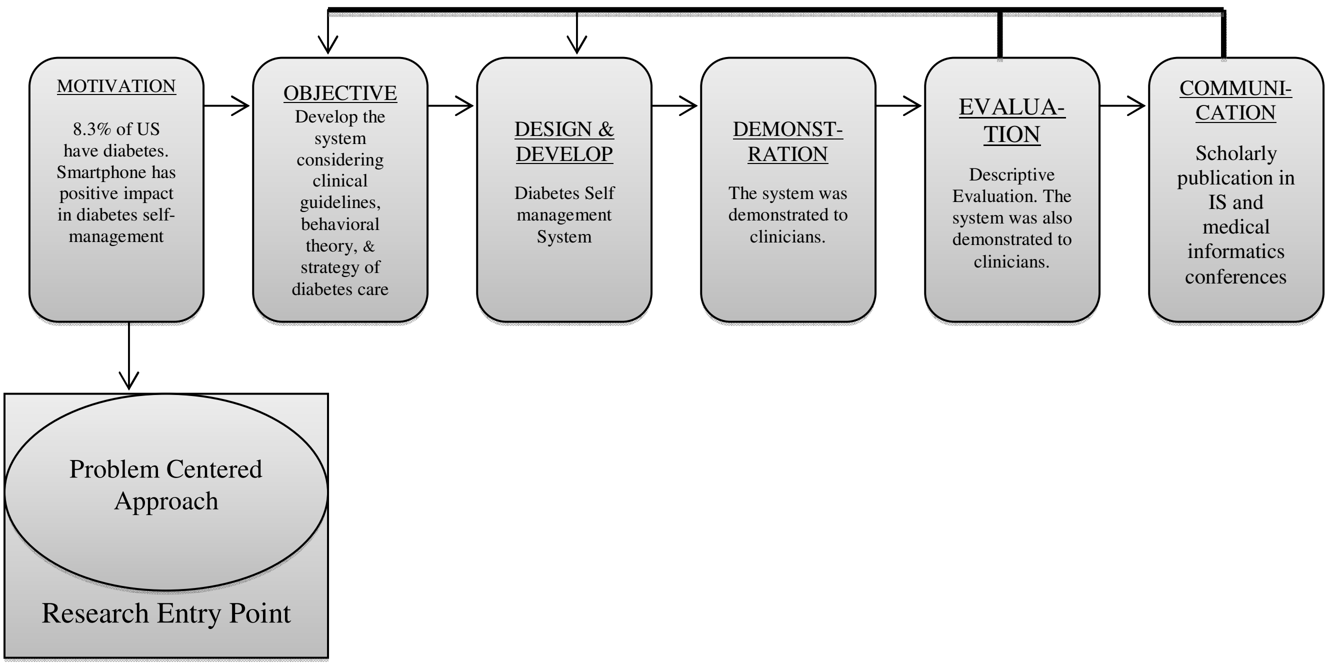

Figure 1. Design Science research Methodology Process according to Peffers et al. (2007) Guidelines

PROBLEM IDENTIFICATION

Self-monitoring of daily physiological behaviors may be significantly enhanced by IT interventions such as, the Internet, computers, mobile phones, and decision support techniques (Gimenez-Perez, Gallach, Acera, Prieto, Carro, Ortega, Gonzalez-Clemente and Mauricio, 2002). Prior research has shown sufficient evidence that mobile-based self-management is beneficial in terms of clinical outcome, and also in terms of usability issues (Chomutare, Fernandez-Luque, Arsand and Hartvigsen, 2011; Forjuoh, Reis, Couchman and Ory, 2008; Quinn, Clough, Minor, Lender, Okafor and Gruber-Baldini, 2008; Sultan and Mohan, 2012; Wickramasinghe and Goldberg, 2011). Recent advances in mobile phones, most notably the development of smartphones, allows those phones to serve as the universal patient terminal in telemedicine scenarios and data service including diabetes self-management. Smartphone applications are currently used for storing, analyzing and presenting physiological and support data. Other features include communication with the provider, social networking, alerts, reminders, and some decision support. For example, in a study by (Rossi, 2009), patients record their blood glucose level and diet using a mobile application; the application quantifies the amount of carbohydrates consumed and provides feedback about insulin dosage; the data is transferred to clinicians through SMS. *Track3 Diabetes Planner and Carbohydrate Counter* allows the patient to enter the physiological data, and the app provides a graphical visualization of their glucose level. The application provides personalized education based on patients data, and allows communication with the physician through email. In a systematic review of 71 applications commercially available and 16 articles, we identified a number of issues with existing approaches to diabetes self-management (El-Gayar, Timsina, Nawar and Eid, 2013). In the following paragraphs, we will briefly discuss the limitations and issues with these approaches and hence generate the system requirements for our architecture.

Issue 1—Diabetes Data Collection: Adequate and accurate data collection from patients is the initial step of the diabetes self-management procedure. However, research has shown that timely and accurate data entry by patients may be challenging. Cavan, Everett, Plougmann and Hejlesen (2003) found that patients were hesitant to upload their readings. Also, when patients were asked to enter the data manually, there was a big chance of error; patients may type the wrong value or enter incorrect date and time. Moreover, Kildegaard, Randlv, Poulsen and Hejlesen (2007) found ±30% estimation error of carbohydrate intake by patients. If the collection method is too complex and time consuming then patients tends not to comply due to the extra burden placed upon them (Duke, Thorpe, Schneider and Torre, 2009). In another research, Harper, Nicholl, McTear, Wallace, Black and Kearney (2008) indicated that patients desired multiple methods of data entry; through text, image, or automation. The latter technique is preferred as it eliminates the manual procedure of typing the data in mobile devices, and provides accurate and complete data. Yet, very few applications have taken advantage of modern biomedical sensors by automating data entry. Therefore, architecture for supporting diabetes self-management should automate data entry with an objective to minimize the burden placed on patients for data collection.

Issue 2—Clinical Guidelines and Practical Strategies for Diabetes Care: A diabetes self-management system and supporting architecture must support the tasks that an individual must take to live well with diabetes. The tasks may be the medical management, role management, or emotional management (Adams, Greiner and Corrigan, 2004). Diabetes self-management includes four key tasks: self-monitoring of the insulin, physical activity or exercise, nutrition, and medication (Thomas, Peterson and Goldstein, 1997). In addition to these basic tasks, recent advances reflected in the clinical guidelines recommend the following features as the important tasks of diabetes self-management (American Diabetes Association, 2012): self-management education and personalized feedback; weight management; blood pressure management; communication and patient monitoring by clinicians; developing personal strategies to promote health and behavior change; long term complication management; and goal setting & necessary activities. In addition to supporting the self-management tasks, ADA has suggested practical strategies for improving the diabetes care (American Diabetes Association, 2012). One such strategy emphasizes that care should align to components of a chronic care model: delivery system design, self-management support, decision support, clinical information system, community resources and policies, and health system. Other important strategies include the need to optimize provider and patient's communication, and the need to accommodate a patient- centered communication style. In so far, existing applications do not support all the tasks defined in the clinical guidelines. Future developments must support self-management protocols, align with evidence-based clinical guidelines and support the behavioral change for healthy living.

Issue 3—Decision Support: Mobile applications may offer some advantages to patients upgrading from a paper logbook to an electronic system. However, without support in decision-making, there is little incentive for patients to enter data regularly. Automated analysis and rule-based interpretation of transmitted data on an individual basis would be helpful (Quinn, Shardell, Terrin, Barr, Ballew and Gruber-Baldini, 2011). The decision support tool may be located in the patient's mobile device or in the provider's EMR to process the transmitted data and provide feedback to the patient's mobile device. Decision support capabilities provided insulin dosage suggestion, and personalized feedback relating to nutrition, lifestyle change & self-management education (Preuveneers, 2008). Nevertheless, a review of existing applications indicates that decision support is mainly used for the insulin dosage suggestion and do not seem to be used effectively. To sum up, there is a need of automated analysis of patient data, and provison of personalized decision support for medication, education, and healthy behavior (preferrably in real-time).

Issue 4—Data Presentation: The clinical and behavioral outcome of the whole system is significantly affected by data presentation and quality control techniques. Existing applications and systems provide some mechanisms to visualize patients' data in the form of tables or graphs. While graphical plots are more useful than table formats, the charts do not provide additional information to help assess the performance of the self-management processes. Accordingly, further work is needed to employ visual analytics techniques that better leverages sensor data to improve decision making of patients and providers, and ultimately the underlying self-management processes.

System Requirements

The requirements for the proposed architecture are synthesized and generalized from the previous section and supporting literature review. The input from multiple discussion sessions with endocrinologists was used to validate the requirements. In effect, the proposed architecture should support the following requirements:

- *Automated data entry:* The system must eliminate the manual process of entering data to the farthest extent possible. Moreover, the data entry techniques should promote the accuracy, efficiency, networked and completeness of data acquired. By automating the data entry, the system should improve the perceived easiness of using the system.

- *Support for evidence-based clinical practices and guidelines:* The decision support and recommendations should be grounded in evidence-based clinical guidelines and practices.
- *Personalized and automated (to the extent possible) decision support*: The architecture should support the ability to devise personalized recommendations for patients in real-time based on specific patient data and evidence-based clinical guidelines. The decision support capability should also be able to alert clinicians when intervention is needed. The capability is likely to support clinicians in managing their workload attempting to respond to increased data availability. Examples of recommendations include personalized education, food, physical activity suggestion and insulin dosage recommendation (if applicable).
- *Rich data presentation and communication:* The portal should allow viewing the patient's data, generating reports, and analyzing the overall patient's condition. The portal should also provide the mechanism for communication between clinicians and patients.

DESIGN AND DEVELOPMENT

System Architecture

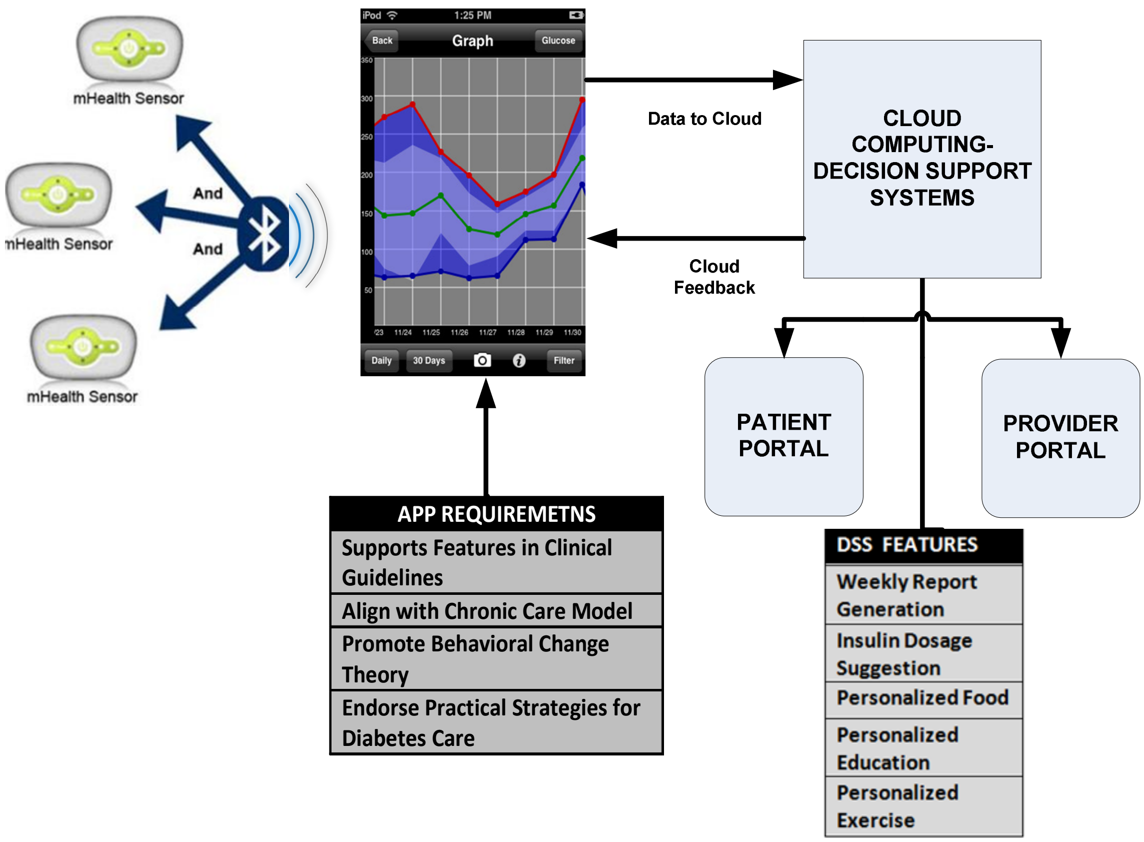

Figure 2. Architecture for Diabetes Self-management

Figure 2 depicts the diabetes self-management architecture. The architecture consists of five components: an acquisition component, a mobile client, a cloud-based decision support, a patient portal, and a provider portal. Physiological data are acquired via sensors and are transferred to the mobile device. The data is then transferred to the cloud in real time. DSS tools in the cloud analyze the data and provide feedback to the patient. If an abnormal situation is detected, an alert is sent to the patient and to their registered clinicians. Since, the data is also stored in the patient's mobile device; the patient may view it at any time. Patients can also view their data, generate the summary report, communicate with clinicians, and analyze their overall condition through the patient portal. Clinicians use the provider portal to monitor and analyze the patient's condition, and to provide therapeutic advice. In the following sections we describe each of the components in brief.

Data Acquisition

The architecture allows the automated data acquisition from the sensor devices to the diabetes mobile device using Bluetooth^{TM} technology. The automatically uploaded data includes blood glucose, blood pressure, weight, physical activity and diet. Generally, three techniques are used to quantify physical activity: exercise logs, heart rate measurement, and accelerometers to measure the movement. However, existing literature has only used the accelerometer techniques (pedometer) to automate the data entry of physical activity (Arsand, Tatara, Ostengen and Hartvigsen, 2010). For our design, we selected Body Media Sensewear^{TM} that uses accelerometers to measure movement, thermometers to measure skin temperature, and skin sensors to measure galvanic skin responses to estimate the amount of calories burned per minute (Body Media, 2012). Another challenge of automating data acquisition is food intake. Patients are usually asked to perform Carb counting and to insert the value in the system manually, which can result in an estimation error. (Kildegaard et al., 2007). Another problem with Carb estimation is the variety of cuisines such as Asian, Middle-Eastern, etc., while most of the Carb counting materials come from western sources and do not apply to the other ethnic food. In this research, we propose two options. In the first option, the patient chooses the image of food (from our food database that includes standard food e.g. pizza slice from Pizza Hut or burger from MacDonald's) and the system automatically enters the Carb count In the second option, the patient takes a picture of the food and a dietician estimates the number of calories. The patient adds the custom food to his/her food database. Later, by simply selecting the picture of the food, the system enters the calorie intake as well as the percentage of calories from carbohydrates, proteins, and fat. This is an important contribution in our research as earlier research only considered Carb intake and with limited automation capability.

Mobile Client Application

The mobile client supports two sets of features. The primary set of features of diabetes self-management includes monitoring of medication, blood glucose, diet, and physical exercise. Whereas, the secondary set of features includes weight, blood pressure, educational materials, communication with a physician through email; long term complication management facilities (foot care, eye care, vaccination); integration with social networking sites such as Facebook, Twitter; integration with cloud system; alert facilities; tagging of data recorded; and security that matches the HIPPA standards. Figure 3 depicts the features for the mobile client application.

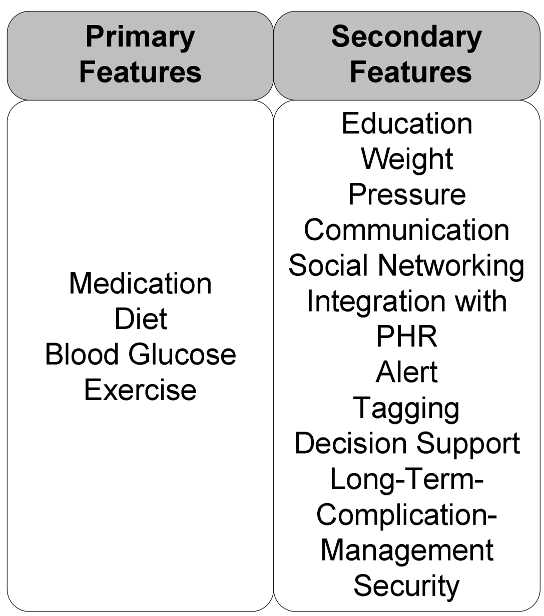

Figure 3. Features of Smartphone App

Cloud-based decision support

In addition to serving as an electronic logbook, automated analysis and rule-based interpretation of transmitted data on an individual basis would be helpful (Kollmann, Riedl, Kastner, Schreier and Ludvik, 2007). These tools are employed to process large and complex data, and provide feedback relating to the insulin dosage, carbohydrate intake, and healthy behavior. For example, decision support tools may be employed to provide insulin dosage recommendation based on blood glucose level, body mass index (BMI), and carbohydrate intake. Here, the decision support in the cloud provides the recommendation for the insulin dose, exercise suggestion, calorie suggestion, and educational materials to the patient based on the patient age, sex, diabetes condition, weight, and blood pressure. Rules for insulin dose suggestion are based on an algorithm provided by the American Association of Clinical Endocrinologists (WWW Machealth Pty Ltd, 2011). The system would also have a database of various educational materials. The materials would be tagged with corresponding keywords: Asian Food Information, Material for poorly Controlled Diabetes, Pregnant Woman, and Exercise for the Woman and matched to patient data to provide personalized support.

Patient and Provider Portals

The system generates two kinds of therapeutic advices: real time, and retrospective advice. Real time advice includes the insulin dosage suggestion, food, exercise, and educational materials recommendations. While, retrospective advice includes the summary progress at the end of each week and is delivered via the patient and provider portals. Patients can view their data, generate the summary report, communicate with clinicians, and analyze their overall condition through the patient portal. Clinicians use the provider portal for monitoring the patient's condition, analyzing the patient's condition and providing therapeutic advice. In that regard, continuous quality improvement techniques that are being successfully used in the industry are increasingly identified to be useful in the medical field. Statistical Process Control (SPC) charts are aimed to monitor a process and its variability (Benneyan, Lloyd and Plsek, 2003; Oniki, Clemmer, Care, Arthur and Linford, 1995). The charts are used to monitor glucose reading, reveal variations, and illustrate the effect of new protocols designed to manage glucose levels. SPC reveals the normal variation on glucose reading with unusual or uncontrolled variation. The XMR chart is one of the most famous charts that could be used for glucose monitoring (Mohammed, Worthington and Woodall, 2008). For example, we set the limiting value of XMR chart at each week. Based on the limiting value, system generates the report that illustrate whether the patient is improving or not. Patient may monitors their daily measurement in using statistical process control charts. If the data is out of the limiting value, the system triggers the clinician and patient. The new limiting value of the XMR Char is calculated each week. The key idea is to optimize the mean value of glucose, and also to match the range of glucose reading with patient's goal.

EVALUATION AND FUTURE PLANS

As a preliminary evaluation, we validated the requirements and architecture of the system using a series of focus groups of clinicians. The feedback obtained was used to identify the key requirements identified in this article and develop a supporting technical architecture. Future research and development activities will proceed in a modular fashion addressing one component at a time, starting with data acquisition and culminating with integration of various components into one working prototype. Adopting an agile development methodology, each component will be developed and tested with extensive input from key stakeholders (patients, clinicians, and provider organizations). Once an integrated working prototype is in place, further evaluation will employ qualitative (e.g., focus groups of patients and providers) and quantitative approaches. Randomized control trials will emphasize clinical outcomes, e.g., improvements in HbA1c, while user-acceptance studies will explore the acceptance and use of the proposed technology by clinicians and patients.

DISCUSSION AND CONCLUSION

This study proposes a mHealth architecture for diabetes self-management. Based on the comprehensive literature and commercial application review, we identified four key issues with existing IT based solutions. We claim that the proposed architecture overcomes those issues and provides the novel practical and theoretical contributions. Some key features of the proposed architecture are emphasizing the use and compliance with evidence-based clinical guidelines, automating data acquisition, personalized and real-time feedback, and enabling patient-provider communication. From a practical perspective, the proposed architecture is expected to promote adherence to treatment and clinical guidelines; to improve the usability and adoption; and to enhance the integration of self-management tasks in the patient's daily routine. From the theoretical perspective, the resulting system will provide a context for evaluating user acceptance and diffusion of mHealth for self-management of chronic diseases (most notably diabetes), evaluating the use of IT and mobile technologies for impacting behavioral change, and experiment with various behavioral change theories.

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