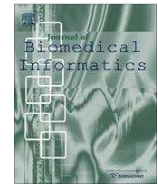


Contents lists available at ScienceDirect

Journal of Biomedical Informatics

journal homepage: www.elsevier.com/locate/yjbin

Evolution of a web-based, prototype Personal Health Application for diabetes self-management

Stephanie J. Fonda^{a,*}, Richard J. Kedziora^b, Robert A. Vigersky^a, Sven-Erik Bursell^c

^a Endocrinology Service, Department of Medicine, Walter Reed Army Medical Center, Washington, DC, USA

^b Estenda Solutions Inc., Conshohocken, PA, USA

^c Telehealth Research Institute, John A. Burns School of Medicine, University of Hawaii, Honolulu, HI, USA

ARTICLE INFO

Keywords:

Diabetes
Internet
Self-management
Telemedicine

ABSTRACT

Behaviors carried out by the person with diabetes (e.g., healthy eating, physical activity, judicious use of medication, glucose monitoring, coping and problem-solving, regular clinic visits, etc.) are of central importance in diabetes management. To assist with these behaviors, we developed a prototype PHA for diabetes self-management that was based on User-Centered Design principles and congruent with the anticipatory vision of Project Health Design (PHD). This article presents aspects of the prototype PHA's functionality as conceived under PHD and describes modifications to the PHA now being undertaken under new sponsorship, in response to user feedback and timing tests we have performed. In brief, the prototype Personal Health Application (PHA) receives data on the major diabetes management domains from a Personal Health Record (PHR) and analyzes and provides feedback based on clinically vetted educational content. The information is presented within "gadgets" within a portal-based website. The PHR used for the first implementation was the Common Platform developed by PHD. Key changes include a re-conceptualization of the gadgets by topic areas originally defined by the American Association of Diabetes Educators, a refocusing on low-cost approaches to diabetes monitoring and data entry, and synchronization with a new PHR, Microsoft® HealthVault™.

© 2010 Elsevier Inc. All rights reserved.

1. Introduction

Under the auspices of the Robert Wood Johnson Foundation's Project Health Design (PHD), we designed a prototype Personal Health Application (PHA) to assist with self-management aspects of diabetes self-management. The design process, requirements, certain prototype basics, and user feedback have been previously described [1]. This article elaborates aspects of the prototype PHA's functionality as conceived under PHD and not presented elsewhere. It then describes modifications to the PHA now being undertaken under new sponsorship.

2. Project goals and design requirements

Diabetes is frequently associated with complications that are potentially disabling and life-threatening. These complications

can be mitigated through a complex, variable regimen involving healthy nutrition, physical activity, judicious use of medication, glucose monitoring, coping and problem-solving, regular clinic visits, laboratory studies, foot care, and eye care [2–7]. These are the cornerstones of diabetes management—much of which is self-management. However, people with diabetes often struggle to adhere to many of the aspects of an appropriate self-management regimen; e.g., many people report not testing their glucose and/or not injecting insulin as frequently as required [8–11], and survey and surveillance system data [12–14] show that only 50–70% of Americans with diabetes receive the recommended eye examinations to prevent severe vision loss.

In response to this need, the goal of this project was to design and develop a prototype PHA for diabetes self-management that was based on User-Centered Design (UCD) principles [15] and congruent with the vision of PHD. Thus, as previously described [1], the design requirements for the PHD prototype PHA were determined through a series of 90-min focus groups with people with diabetes. For the focus groups ($n = 3$ groups of about 7 participants each), we recruited 21 adults with diabetes from the Joslin Diabetes Center (Boston, MA) and met with them twice; once to assess their needs and once to assess their reaction to prototype ideas derived from the first focus groups. Later in the project's timeline, we

Abbreviations: PHA, Personal Health Application; PHR, Personal Health Record; PHD, Project Health Design; UCD, User-Centered Design.

* Corresponding author. Address: Endocrinology Service, Department of Medicine, Walter Reed Army Medical Center, 6900 Georgia Avenue NW, Building 2, Room 7D08, Washington, DC 20307, USA. Fax: +1 202 782 0187.

E-mail address: fondasj@gmail.com (S.J. Fonda).

also conducted one-on-one demonstrations of a partially functioning version of the prototype with people with diabetes to obtain further feedback.

Additionally, PHD encouraged grantees to anticipate Personal Health Records (PHRs) and other technologies 5–10 years from the initiation of the program in 2006. This vision also shaped the prototype's design requirements.

The design and development process under PHD—always intended to be iterative—has continued to be so since the end of PHD as our project team continues to make modifications with new funding. Some of these modifications resulted from user evaluations completed with PHD, in the one-on-one demonstrations of the initial implementation of the PHA. Other changes resulted from systematic observations of the project developer and systems architect, who tested the prototype PHA's data retrieval functionality with an early version of the Common Platform PHR created by Sujansky and associates, LLC (San Carlos, CA; www.sujansky.com) for PHD.

3. Prototype description

3.1. Overview

The prototype PHA developed in collaboration with PHD receives data on the major self-management domains from a web-based PHR data repository. The PHA then analyzes (i.e., notes the occurrence of an event, provides summary statistics of data for which they are appropriate, such as blood glucose readings, notes extremes as specified by the user and/or clinical guidelines, etc.), provides feedback of the analyses in graphical form and/or text, and makes simple recommendations based on clinically vetted educational content. The feedback and recommendations are presented within a collection of flexible, re-usable, small web applications called “gadgets” within a portal-based website. The gadgets share data through a common repository, so input in one can be reflected in another. Before using the application, users must obtain a secure PHR account and complete set-up surveys on their health, current diabetes management, goals, and preferences for self-management (note that versions created under PHD are published at www.projehealthdesign.org). The answers to the survey questions provide input to the PHA's rules and algorithms regarding feedback and recommendations.

3.2. Original implementation of gadgets

For each of the aforementioned cornerstones of diabetes self-management, we created one or more gadgets (see Appendix 1 for a sampling). We chose the iGoogle portal to display the gadgets, which is accessible in both desktop and mobile platforms. The gadgets require a secure login to access the content, as does the user's iGoogle account.

3.2.1. Nutrition and physical activity

The prototype PHA captures meal and snack data from external sources and services such as the [USDA.gov](http://www.usda.gov) website. Users also have the option of logging their meals and snacks using digital photography, but these photographs are not analyzed by the PHA. With nutrition data from the external sources, the nutrition gadget displays various nutrition facts; e.g., nutrient content over a number of meals and how well those meals comply with the self- or provider-established caloric, fat, and/or carbohydrate goals. This gadget provides feedback and specific recommendations determined by the user's responses to questions about their history, type of diet, and goals in surveys created for the application and that the user completes before using it.

The prototype PHA collects activity monitor data from external sources, or allows users to specify their physical activity. The physical gadget provides an estimate of calories burned for a particular activity as well as for a total time period requested by the user. Feedback and recommendations in this gadget again reflect user's responses to questions about their history, exercise preferences, and goals in the set-up of the application.

3.2.2. Glucose

The glucose gadget collects data from fingerstick-based glucose monitors or continuous glucose monitors. The gadget displays a graph of the glucose data over time with data about physical activity, meals eaten, and diabetes medications taken superimposed on the graph allowing the user to see the relationship between the various events and trends of their glucose readings. The user controls which data are superimposed and for what time period the data are displayed.

The glucose gadget also has an alerting function if used with real-time data. Based on the user's preferences indicated in the surveys for set-up, the system can alert them when their glucose trends too high, too low, or varies too much. These alerts can be an email message, text message, phone call or a message within the application itself. The user configures the method of receiving alerts and the times of day when they do not want to receive alerts. They can specify that another trusted person be alerted as well.

3.2.3. Medications

The medication gadgets display adherence data for prescribed diabetes-related drugs. The medication list is either captured electronically through a PHR or entered manually by the user. The gadget also has links to information about each drug. Specific information sources are being evaluated for usability including sites such as www.drugs.com and www.fda.gov.

An insulin calculator gadget is available for those users taking meal-time insulin. This calculates the amount of insulin needed based on three factors: (1) the provider-estimated insulin sensitivity factor (i.e., defined as the mg/dL that blood glucose declines per 1.0 unit of insulin); (2) the provider-estimated insulin-to-carbohydrate ratio (i.e., the units of insulin needed per a certain amount of carbohydrates in a meal to prevent a large increase in blood glucose); and (3) the user's current glucose level, which is required to estimate the amount of insulin needed to correct back to the glucose goal. The first two factors are entered by the user during set-up using surveys we created for the application.

3.2.4. “What if Analysis”

This gadget comes in two forms: one is for physical activity and the other for nutrition. This gadget allows the user to enter information about planned activities related to nutrition or physical activity and receive feedback on how it will affect their glucose levels.

3.2.5. Mood

This gadget allows the user to indicate their current mood by selecting the appropriate icon. Mood can be plotted against glucose data in the glucose gadget.

3.2.6. Diabetes “Tip of the Day”

This gadget displays text- or video-based diabetes tips based on the user's preference in terms of topic area and desired medium. It also provides reminders for recommended care, such as annual eye exams, using data input by the user at set-up and/or their PHR data for dates of previous exams and tests.

3.3. Original strategy for retrieving self-management data

From the focus groups, it was clear that the less data entry the PHA required users do, the more useful to them it would be. These requirements led us to design the prototype so that some of the gadgets would draw self-management data from external, third-party sources, and PHR data repositories. The use of PHR's was also a priority for PHD. Further, certain data would originate from the most advanced biomonitoring technology available at the time, particularly physical activity monitors, such as the one created by BodyMedia[®], and real-time continuous glucose monitors, which collect data automatically as the user wears them. The initial solution for the PHA used the Common Platform PHR created as part of PHD and discussed elsewhere in this volume. The Common Platform became the data repository for the large volumes of self-management data uploaded from biomonitoring devices, and also for nutrition information and photographs that could be uploaded by the user.

4. Subsequent changes to the prototype

4.1. Changes to the gadgets

Because gadgets can be used independently of each other or altogether, depending on the user's preferences, users who evaluated the prototype PHA in one-on-one sessions said the choice of

which gadgets to use was confusing. They required an overview gadget that would list events and point to other gadgets the user should look at. Some thought that diabetes is so overwhelming and complicated to manage that they did not want choices in gadget selection—they wanted the gadgets to all be available and they could look at them or not. This feedback led to two changes in the conceptualization of the gadgets. First, under PHD, we created a My Diabetes Data Tracker gadget (Appendix 1) to bring the different components of the prototype PHA together. As data are brought into the application, this gadget displays a listing of events, such as a meal or low glucose reading, with feedback and links to educational information. Where appropriate, this gadget makes suggestions to use other gadgets, allowing the user to explore connections between different events and discover new functionality.

Second, under the new sponsorship, we reorganized the gadgets around the American Association of Diabetes Educators' [16] seven topic areas for the facilitation of diabetes self-management: healthy eating; being active; medications; reducing risks and monitoring; and problem-solving/coping. The reorganization led to: (1) grouping of certain gadgets developed under PHD (e.g., reducing risks and monitoring groups weight-related gadgets, glucose-related gadgets, and lab test data); (2) duplication of certain functions or gadget types across self-management topic areas (e.g., manual data entry should the user prefer this option, links to outside sites for further educational content); and (3) the addition of more functionality (e.g., the topic area of problem-solving/coping

Table 1
PHA gadget functions by diabetes self-management category.

Domain	Overview of gadget functions
Healthy eating	<p>Allows users to enter servings eaten for a nutrition category, time of meal/snack</p> <p>Users can personalize daily required servings for food groups based on their needs</p> <p>Provides feedback on their progress for the day or past 7 days</p> <p>Users can do "what if" analysis by entering estimated future servings of a food or foods. Provides feedback using actual and estimated food intake data vs. daily goals</p> <p>Provides information about the nutritional categories</p> <p>Provides a list of additional external vetted sources (websites) of information about nutrition</p>
Being active	<p>Allows users to enter minutes engaged in a specific activity, start time, level of intensity, and/or calories burned during an activity</p> <p>Allows users to use a monitoring device that is integrated with a PHR</p> <p>Provides feedback on activity level trends, progress towards goals based on time and calories burned</p> <p>Allows users to enter estimated activities for "what if" analysis</p> <p>Allows the user to enter daily and weekly goals for exercise categories, and to reset their goals</p> <p>Provides feedback using actual and estimated activity data vs. daily and weekly goals</p> <p>Provides information about the categories of activity</p> <p>Provides a list of additional external vetted sources (websites) of information about activity</p>
Medications	<p>Generates a reminder for each medication dose. Reminders include: time the medication is supposed to be taken, name of the medication, prescribed dosage, image of the medication, link to externally maintained medication reference materials, and link to allow the user to indicate if/when the dosage was actually taken, to close reminder and not track compliance, or to remind again in a certain number of minutes</p> <p>Provides users a method for inputting and managing their medication regimen</p> <p>Enables users to manage all preferences related to medication reminders (e.g., reminder timing, blackout periods, delivery mechanism)</p> <p>Provides an insulin calculator for users who take meal-time insulin</p> <p>Permits links to vetted sites with medication information</p>
Reducing risks and monitoring	<p>Synchronizes lab, appointment, glucometer, and weight data with PHR</p> <p>Allows users to enter lab test dates and values and past examination data for certain exams</p> <p>Allows users to enter and modify future appointment data, and to mark as kept, closed, etc.</p> <p>Users can configure mode of delivery for lab and appointment reminders</p> <p>Provides information about the need/rationale for lab tests</p> <p>Allows users to enter blood glucose information including date/time of reading, result, and what time period the reading falls into (before/after breakfast, etc.)</p> <p>Allows users to personalize blood glucose high/low values (defaults based on clinical guidelines)</p> <p>Displays a blood glucose trending graph for user's-specified number of days</p> <p>Allows users to display additional information on the graphs (medication timing, activity data, etc.)</p> <p>Allows users to enter weight information including date/time of reading and the weight in pounds</p> <p>Displays weight trending graph for user's-specified number of days</p>
Problem-solving and coping	<p>Provides ability to indicate current mood</p> <p>Provides a graphic representation of the recorded mood data</p> <p>Presents brief, validated questionnaires based on a pre-determined schedule, user preferences and/or responses to daily mood updates</p> <p>System automatically scores questionnaire data to provide feedback and recommendations</p>

Notes: Although not identical, the domains are largely based on the American Association for Diabetes Educators 7 Self-Care Behaviors[™] [14]. There are multiple gadgets per domain.

incorporated the aforementioned mood gadget and led to the addition of systematic collection of psychosocial data using validated questionnaires with risk scoring). This reorganization was expected to facilitate having all of the gadgets viewable at all times, whether the user chooses to view them all or not.

Table 1 lists general functions of the revised gadgets by diabetes self-management category.

4.2. Changes in strategies for retrieving self-management data

To evaluate the prototype's service-oriented architecture and ability to interface with a PHR, we implemented our initial solution using the Common Platform PHR. The project team was particularly concerned with the PHR's ability to transmit large amounts of biomonitoring data to the PHA and for the PHA to access it. The reason is that current generation physical activity monitors record multiple readings every minute, and continuous glucose monitors record glucose readings every 5 min (e.g., CGM records 288 readings per day) [17]. Thus, we performed basic timing experiments working with biomonitoring data. Overall this effort proved successful, but because the prototype retrieved all biomonitoring data from the Common Platform every time it needed it, response times for analyses and rendering the gadgets were unacceptably lengthy. This finding suggested the need for a local data repository; caching the data in a local repository could decrease response times.

Another modification resulted from the feedback given during the one-on-one demonstrations late in the PHD phase of our work, in which a potential user and a healthcare provider commented that lifestyle advice should be provided using data obtained in less complex and costly ways. Thus, we now have re-designed the prototype PHA so that it does not have to rely on the use of advanced, high-cost, continuous biomonitoring devices; instead, it gives users the choice to use automated devices or to do manual data entry. The new data entry functionality, for example, includes the ability to enter manually a single glucose reading obtained by fingerstick. Alternatively, for users who wish to use automated devices, they may use any and all devices integrated with the PHR we have chosen to synchronize the PHA with going forward. To our knowledge, continuous-feed biomonitoring devices are not yet integrated with the large PHRs.

Regarding the choice of PHR for a fully functioning PHA evolving from the prototype developed under PHD, we have opted to synchronize with Microsoft® HealthVault™. At the initiation of PHD in 2006, Microsoft® HealthVault™ was not available as a data repository for the project team's developing PHAs. As of now, Microsoft® HealthVault™ has long-term viability because it is backed by Microsoft®, is a trustworthy and known source that is in use by major insurance carriers, has authentication and security practices in place, and is integrated with an increasingly large number of device manufacturers and data tracking service providers.

5. Discussion and implications

It is generally recognized that lifestyle modification not only forms the foundation for all subsequent diabetes management necessary to reduce complications and costs, but in addition, such management routinely fails in the absence of appropriate lifestyle intervention(s) with support. The PHA prototype we developed with PHD and are further refining with ongoing, separate sponsorship has the potential to assist with the necessary lifestyle modification and sustainment critical to diabetes management.

Since this is a tool for self-management, a key to its success in improving self-management will be the user's self-motivation and how the PHA "fits" with the user's needs, preferences, abilities, and current social and physical contexts. Guided by the vision of

PHD, we sought to maximize "fit" by beginning the design process with a needs assessment with the anticipated users, continuing to engage users, and refining the prototype iteratively in response to user feedback and changes in available technology. We sought to further facilitate "fit" by designing the application to be flexible with respect to specification of goals, devices or data services, and platform (desktop or mobile). The application provides valid feedback (i.e., consistent with the clinical guidelines of the American Diabetes Association and the American Association of Diabetes Educators) about the user's specific circumstances, when the user makes data regarding their circumstances available.

Our team now is completing the modifications to the application resulting from the users' responses in one-on-one demonstrations and tests we performed late in development under PHD. We are planning for another round of user feedback following the modifications. Our experience is an example of how, with each major revision, users must be consulted again to see whether their perceived needs have been addressed by the changes.

Our new funding also permits us to conduct a 6-month prospective, randomized trial of a mobile version of the PHA to evaluate its clinical efficacy among people with diabetes who will use it for 6 months. If successful, this test will be among the first to demonstrate the potential of PHRs and PHAs for improving lifestyle-related self-management among people with diabetes. Such a demonstration may encourage adoption of PHAs by healthcare providers, who can recommend their use to their patients. In short, a successful demonstration can affect how we deliver healthcare by putting better tools into the hands of people with chronic diseases.

Ultimately our team and the other PHD grantees are concerned with keeping our potential end-users engaged *long-term*. In addition to the aforementioned "fit," we believe that to keep the user engaged long-term, the user-PHA interaction must be dynamic in nature, promote discovery and evolve with changes in the user's lifestyle and environment. This has implications for the UCD process itself, which can continue late into development and result in new versions, as we have experienced. It also means that the feedback and recommendations such tools provide should be fresh and contextually and temporally relevant. To remain *most* fresh and relevant, the future of such applications may lie in their ability to incorporate some form of machine intelligence based on cognitive learning models. While our prototype and the first trial version will not include such technology, the vision is to be able to: (1) discover causes in the world of the user; (2) infer causes of novel input or recognize behavioral pattern shifts; (3) make predictions; and (4) direct behavior [18].

6. Overview of implications

Our team and the other PHD grantees are concerned with keeping our potential end-users engaged *long-term*. To keep the user engaged long-term, user-PHA "fit" is required, the user-PHA interaction must be dynamic in nature, and it must promote discovery and evolve with changes in the user's lifestyle and environment. This has implications for the UCD process itself, which can continue late into development and result in new versions.

Disclosures

The authors declare that there are no conflicts of interest.

Acknowledgments

This work was supported by Grant 59888 (Fonda and Bursell) and Grants 63415 and 64533 (Fonda) from the Robert Wood John-

son Foundation and the California HealthCare Foundation. Refinement of the work under the first grants has been supported by Grant W81XWH-09-2-0196 from U.S. Army Medical Research and Materiel Command (Fonda).

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.jbi.2010.05.006.

References

- [1] Fonda SJ, Kedziora RJ, Vigersky RA, Bursell SE. Combining iGoogle and personal health records to create a prototype personal health application for diabetes self-management. *Telemed eHealth* 2010 [Epub ahead of print].
- [2] Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med* 1993;329:977–86.
- [3] United Kingdom Prevention of Diabetes Study, Prospective Diabetes Study Group. Intensive blood glucose control with sulfonylureas or insulin compared with conventional treatment and risk of complications with type 2 diabetes. *Lancet* 1998;352:837–53.
- [4] Robiner W, Keel PK. Self-management behaviors and adherence in diabetes mellitus. *Semin Clin Neuropsychiatr* 1997;2:40–56.
- [5] Ruggiero L, Glasgow R, Dryfoos JM, Rossi JS, Prochaska JO, Orleans CT, et al. Diabetes self-management. Self-reported recommendations and patterns in a large population. *Diabetes Care* 1997;20:568–76.
- [6] Glasgow RE, Eakin EG. Medical office-based interventions. In: Snoek FJ, Skinner TC, editors. *Psychology in diabetes care*. Chichester: John Wiley; 2000. p. 141–68.
- [7] Rubin RR. Psychotherapy and counseling in diabetes mellitus. In: Snoek FJ, Skinner TC, editors. *Psychology in diabetes care*. Chichester: John Wiley; 2000. p. 235–63.
- [8] Koro CE, Bowlin SJ, Bourgeois N, Fedder DO. Glycemic control from 1988 to 2000 among U.S. adults diagnosed with type 2 diabetes: a preliminary report. *Diabetes Care* 2004;27:17–20.
- [9] Franciosi M, Pellegrini F, De Berardis G, Belfiglio M, Cavaliere D, Di Nardo B, et al. The impact of blood glucose self-monitoring on metabolic control and quality of life in type 2 diabetic patients. *Diabetes Care* 2001;24:1870–7.
- [10] Harris M. Frequency of blood glucose monitoring in relation to glycemic control in patients with type 2 diabetes. *Diabetes Care* 2001;24:979–82.
- [11] Evans JMM, Newton RW, Ruta DA, MacDonald TM, Stevenson RJ, Morris AD. Frequency of blood glucose monitoring in relation to glycaemic control: observational study with diabetes database. *BMJ* 1999;319:83–6.
- [12] Brechner RJ, Cowie CC, Howie LJ, Herman WH, Will JC, Harris MI. Ophthalmic examination among adults with diagnosed diabetes mellitus. *JAMA* 1993;270:1714–8.
- [13] Zhang X, Saaddine JB, Lee PP, Grabowski DC, Kanjilal S, Duenas MR, et al. Eye care in the United States: do we deliver to high-risk people who can benefit most from it? *Arch Ophthalmol* 2007;125:411–8.
- [14] Saaddine JB, Engelgau MM, Beckles GL, Gregg EW, Thompson TJ, Narayan KMV. A diabetes report card for the United States: quality of care in the 1990s. *Ann Intern Med* 2002;136:565–74.
- [15] Norman DA. *The design of everyday things*. New York: Basic Books; 1988.
- [16] Mensing C, Cypress M, Halstenson C, McLaughlin S, Walker EA, editors. *The art and science of diabetes self-management education: a desk reference for healthcare professionals*. Chicago: American Association of Diabetes Educators; 2006.
- [17] Hirsch IB, Armstrong D, Bergenstal RM, Buckingham B, Childs BP, Clarke WL, et al. Clinical application of emerging sensor technologies in diabetes management: consensus guidelines for continuous glucose monitoring (CGM). *Diabetes Technol Ther* 2008;10:232–44.
- [18] Hawkins J, Dileep G. Hierarchical temporal memory: concepts, theory, and terminology. Numenta; 2006. Available from: http://www.numenta.com/Numenta_HTM_Concepts.pdf.