MOBILE DIABETES SELF-MANAGEMENT SYSTEM FOR THE IPHONE

N. M. Hamming[1], M. Casselman[1], K. Tallevi[1], J. A. Cafazzo[1,2,3], M. Palmert[4,5], D. Katzman[4,6]
[1]Centre for Global eHealth Innovations, Toronto General Hospital
[2]Institute of Biomaterials and Biomedical Engineering, University of Toronto
[3]Health Policy, Management and Evaluation, University of Toronto
[4]Department of Paediatrics, University of Toronto
[5]Division of Endocrinology, Hospital for Sick Children
[6]Division of Adolescent Medicine, Hospital for Sick Children

I. INTRODUCTION

Type 1 diabetes mellitus (T1DM) is among the most common chronic diseases and its incidence is increasing about 3% annually[1]. Often diagnosed in childhood, individuals with T1DM are at risk of related complications later in life; i.e. retinal, renal, neurologic, or cardiovascular disease[2-4]. Risk mitigation is possible with proper disease management focusing on diet, activity, and insulin therapy to maintain normal blood glucose (BG) levels. Levels are determined with regular BG measurements throughout the day. However, data from an international study failed to demonstrate a correlation between insulin regimen and glycemic control[5], suggesting that other factors, i.e. self-management behaviors and educational models, likely have substantial impact on outcomes.

A Diabetes Complications and Control Trial demonstrated that maintaining near-normal BG levels is possible in individuals with T1DM with intensive self-management[2]. Control was achieved with increased frequency of BG monitoring, adjustments to therapy and lifestyle, and data analyses. Analysis of BG data and adjustments were conducted in consultation with the health care team. However, typically T1DM clinical visits occur at 3-month intervals and the individual is responsible for monitoring, performing analyses, and making adjustments in the interim.

A recent global survey indicates that adolescents around the world are adopting mobile technology faster and in a more immersive way than any previous generation[6]. Reports indicate that the mobile phone has become the primary communication tool for the majority of adolescents; 75% of 12-17 year-olds now own mobile phones (up from 45% in 2004)[7-8].

This work investigates the design of a mobile diabetes self-management intervention to improve glycemic control for adolescents. Simply logging and displaying data, i.e. electronic logbook, is not sufficient to improve BG control[9-10]. Rather, augmenting these features with analysis and decision-making tools should promote positive self-management behaviors.

II. MATERIALS

The mobile diabetes self-management system consists of 4 components, Fig. 1. Two are readily available consumer products; a LifeScan OneTouch UltraMini (OTUMini) glucometer and Apple iPhone or iPod Touch. The other components are in-house developed hardware adapter and software application, commonly referred to as bluglu and bant, respectively.

A. Bluglu – Hardware Adaptor

Bluglu attaches to the OTUMini and converts the UART serialized data into Bluetooth. Bluglu is built around an 8-bit microcontroller and includes a Bluetooth module, an Apple specific co-processor, LED status indicators, a micro-USB connector (for battery charging), and various passive components combined on a dual-layer printed circuit board, Fig. 2, that is enclosed in an case. Bluglu uses the Bluetooth Serial Port Profile and communicates with the iPhone via the iPod Accessory Protocol (iAP). Bluglu communicates with bant using an in-house protocol,

Figure 1: Mobile diabetes self-management sytem includes Lifescan OneTouch UltraMini glucometer, Apple iPhone or iPod Touch, bluglu hardware adaptor, and bant software application.

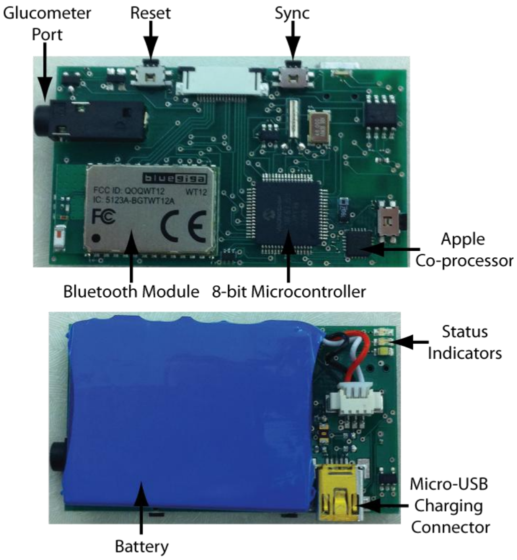

Figure 2: Main components of bluglu.

over iAP, and forwards messages from bant to the OTUMini, and vice versa, as necessary.

Bluglu uses aggressive power management to ensure a long battery life on a single charge only waking up for a limited number of tasks. Mainly, when a BG measurement has been taken on the OTUMini, bluglu wakes, authenticates with the iPhone, and then transfer the data without any user intervention. Bluglu also supports a pulling feature (sync button), which allows multi-measurement data transfer with a single connection. To ensure a secure data transfer, bluglu implements Simple Secure Pairing to prevent interception by unauthorized parties.

B. Bant – Software Application

Bant is an iOS 4 application for an Apple iPhone or iPod touch coded in Objective-C using iOS SDK. Bant assists diabetes self-management with wireless BG data transfer, trending tools, user notifications and alerts, web-based personal health record (PHR) integration, peer support, and a reward system.

Bluglu transfers BG measurements wireless from the glucometer to bant, Figs 3(a) and (b). Measurements are defined by their context, typically the meal in relation to the measurement but also customizable by the user. Reminders can be set to notify the user when a measurement of a certain context should be taken, Fig. 3(c). As well, the user defines a goal range, visualized as the blue hashed region in Figs. 3(a), (d), and (g), which bant uses for data analysis. Once the data is in bant, it is analyzed, with trend detection, and richly visualized.

Two trend patterns are used to analyze BG data. Bant applies a 50/30/20 pattern, where BG data over a time period, typically 2 weeks, are analyzed and determined if 50% is out of the goal range, 30% above the goal range or 20% below the goal range. If this pattern is recognized, bant alerts the user as shown in Fig. 3(d). The second pattern detects consecutive out-of-range measurements. Over a minimum 3-day period, if 3 or more consecutive measurements of the same context are either above or below the goal range, bant alerts the user. The alert walks the user through a wizard to conduct retrospective analysis of this adverse event, Fig. 2 (f). The user selects possible causes and fixes, which are stored and available for review, Fig. 2(g).

Data collected by bant is forwarded to the user's PHR, TELUS health space (a localized version of Microsoft HealthVault), for ease of sharing with their support team. Also, sharing is available with a like-minded community via micro-blogging, Fig. 2(e). Finally, users receive game-like "experience points" (XP), for taking BG measurements regularly throughout the day, to exchange for gifts, Fig. 2(h).

III. METHODS

A. User-Centered Design

Many interventions based on existing health care system structures may not be as efficacious as those that include end users in the design process[11]. As well, system designers often base their designs on assumptions that are not validated with primary user input. These systems may lack key features, and subsequent evaluations of the effectiveness of the intervention may be compromised[12]. For this work, ethnographic interviews were conducted with patients and family caregivers (parents) to inform the design and development of the mobile self-management system. In addition, focus group sessions were held with a cross-section of clinical team representatives from the Division of Adolescent Medicine and the Diabetes Program in the Division of Endocrinology at the Hospital for Sick Children (SickKids).

B. Pilot Study

The mobile diabetes self-management system is being piloted in a study organized in concert with SickKids. The study commenced February 2011 and rosters 20 participants. Target participants are 12-15 year old T1DM diabetics with hemoglobin A1c (HbA1c) in the 8-10 range. Participants will be on the system for the 3-month interim between regular clinical visits. Participant's glucometer data was collected during the clinical visit prior to the pilot and each participant's

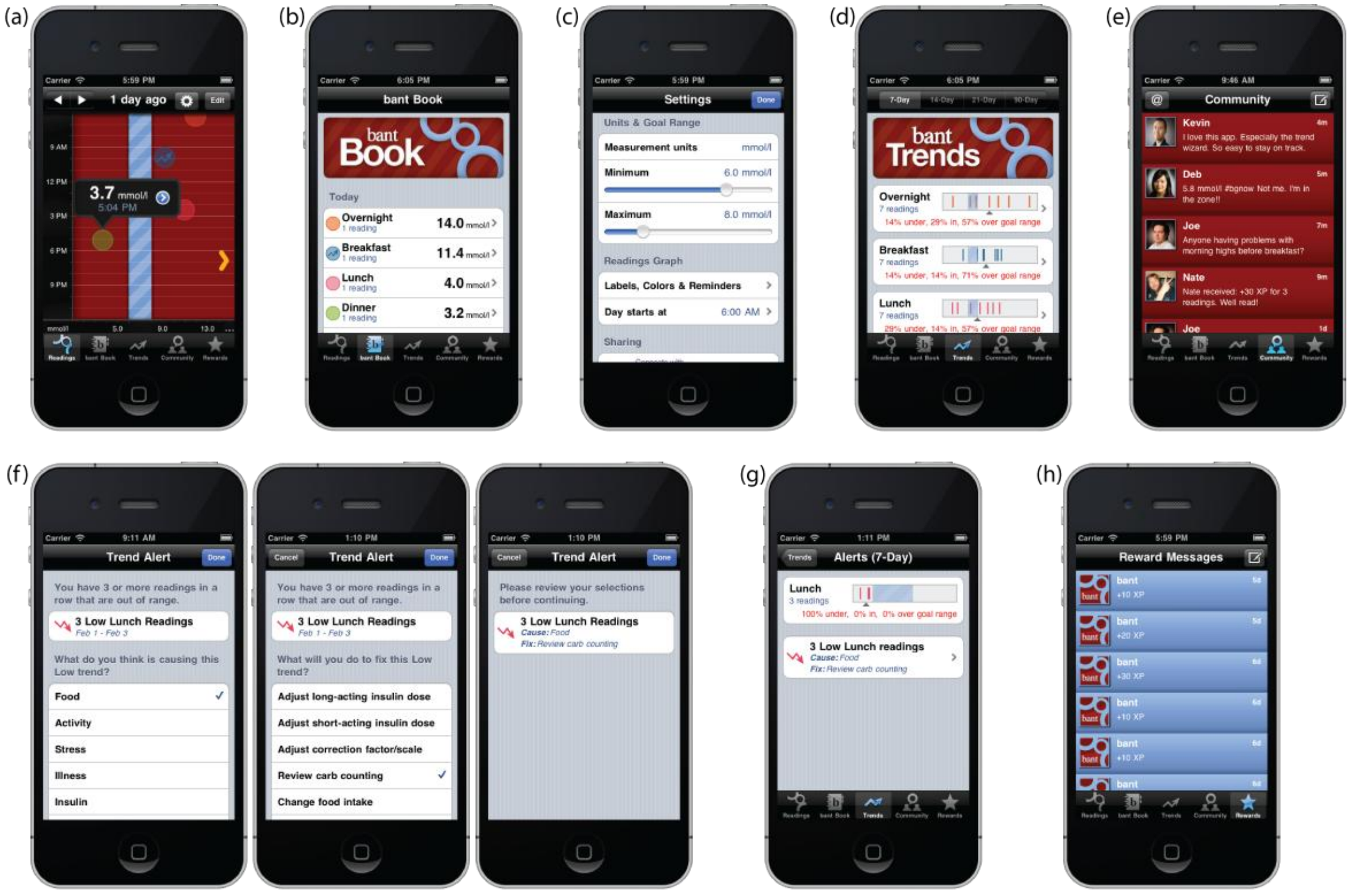

Figure 2: Bant screenshots. (a) Agenda-like BG measurement viewer with goal range. (b) Electronic logbook. (c) Bant settings; ie. adjust goal range, customize measurement contexts, and add reminders. (d) Visualization of 50/30/20 trends. (e) Peer-support via micro-blogging. (f) Alert wizard to assist analysis of consecutive out-of-range measurements. (g) Alert history viewer. (h) Log of experience points earned to be exchanged for gifts.

HbA1c will be measured during the clinical visit prior to and post study. Analyses will consider adherence, active self-management, and HbA1c as metrics.

IV. RESULTS

A. Ethnographic Interviews

The ethnographic interviews were conducted by the research coordinator and based on the study objectives and a priori knowledge of diabetes management, behaviour change theory, and health care software design. A general inductive method was used in the analysis of the recorded notes. Data saturation was achieved upon completion of the sixth set of patient/parent semi-structured interviews. The following major themes emerged, and were used to inform the design and development of the mobile self-management system.

Several participants noted that they did not use analysis tools to review BG measurements because the data was “siloed” in the glucometer. There seemed to be tension between the “tester/collector” and “analyst/decision-maker” roles. In response, bant provides rich data visualization and decision support that integrates into daily BG measurements workflow. Such, users can engage in analysis and decision-making tasks in a timely manner leading to more proactive management. Bant’s novel visulization has been validated by human factors experts, clinicians, application design specialists, and T1DM adolescents and provides the user with an at-a-glance summary of daily glycemic control, associates each measurement with a context, and highlights out-of-range BG data.

Almost all participants noted the need for fast transactions in the order of seconds. Several interviewees commented that social embarrassment was a key factor leading to their avoidance of testing in public. To ensure interactions with the system are fast, bant uses wizards (algorithms used to provide prompts based on available data) to guide user interaction where possible. As well, bluglu provides simple, efficient, and accurate wireless data transfer without any user intervention. Once data is available to bant, the analysis tools assess the data so that the user gets feedback in real time.

In some cases, adolescents were making too few adjustments to their therapy regimen, even when the BG data suggested otherwise. To help adolescents identify BG trends, bant promotes cognitive processing related to identifying and correcting the trend. For consecutive out-of-range measurements, bant prompts the user for decision-making about the cause and how to manage the trend. In addition, bant provides data analysis and trending screens that display the 50/30/20 trending by context. To keep the user engaged, bant incorporates a rewards system that allocates XP for adhering to regular BG measurements. Experience points incentives are redeemed for Apple iTunes and App Store gifts.

Several participants and parents described an ad hoc approach to day-to-day sharing of diabetes-related information including BG measurements. Teens generally expressed willingness to share data with parents, and valued their input when it was requested. Bant provides opportunities for adolescents to safely share BG data and diabetes-related information with parents (as well as peers and clinic staff) via secure online tools and communities. Bant is integrated with a secure online PHR, TELUS health space, where user data is stored and optionally shared with parents and providers. This PHR is the only certified consumer platform approved by the Federal agency Canada Health Infoway. As well, users can share with peers in the secure community via micro-blogging.

Patients' ability to recall rationale for BG trends prior to 2 weeks is relatively low. Furthermore, identifying and annotating trends in a traditional log book is strenuous. In addition to providing user alerts related to BG trends, bant captures input from the user about the possible cause(s) and the changes that the he/she proposes to address the trend. These data will be available for review by patient and clinical team, reducing the chance of recall error and providing more accurate trend and context data for discussion at quarterly clinic visits.

V. DISCUSSION

At the end of the pilot study we expect to contribute a new and more complete understanding of the benefits of smartphone-based health applications for T1DM management in adolescents. The mobile diabetes self-management system is expected to support blood glucose measurement adherence with peer-support and rewards. Alerts should increase the participant self-management by encouraging retrospective analysis of adverse events. Given the system achieves these goals, participants' HbA1c levels should decrease, which will reduce the risk of diabetes related complications.

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REFERENCES

[1] R.M. Shulman, D. Daneman, "Type 1 diabetes mellitus in childhood" Medicine, vol. 38, issue 12, pp. 679-685, 2010

[2] The 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" *New England Journal of Medicine*, vol. 329, issue 14, pp. 977-986, 1993

[3] D.M. Nathan. et al., "Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes" *New England Journal of Medicine*, vol. 353, issue 25, pp. 2643-53, 2005

[4] N.H. White et al., "Beneficial effects of intensive therapy of diabetes during adolescence: outcomes after the conclusion of the Diabetes Control and Complications Trial" *Journal of Pediatrics*, vol. 139, issue 6, pp. 804-12, 2001

[5] C.E. de Beaufort et al., "Continuing stability of center differences in pediatric diabetes care: do advances in diabetes treatment improve outcome? The Hvidoere Study Group on Childhood Diabetes" *Diabetes Care*, vol. 30, issue 9, pp. 2245-2250, 2007

[6] Nielsen Company, "Mobile Youth Around the World", 2010. http://www.nielsen.com/us/en/insights/reports-downloads/2010/mobile-youth-around-the-world.html. Accessed January 18, 2011.

[7] A. Lenhart, R. Ling, S. Campbell, K. Purcell, "Teens and mobile phones. Pew Internet & American Life Project", 2010. http://pewinternet.org/Reports/2010/Teens-and-Mobile-Phones.aspx. Accessed January 18, 2011.

[8] A. Lenhart, K. Purcell, A. Smith, K. Zickuhr, "Social media & mobile Internet use among teens and young adults. Pew Internet & American Life Project", 2010 http://pewinternet.org/Reports/2010/Social-Media-and-Young-Adults.aspx. Accessed January 18, 2011.

[9] A.G. Logan et al., "A mobile phone based remote patient monitoring system for management of hypertension in diabetic patient" *American Journal of Hypertension*, vol. 20, issue 9, pp. 942-948, 2007

[10] E. Seto, J.A. Cafazzo, "Attitudes of Heart Failure Patients and Healthcare Providers to using Mobile Phone-Based Remote Monitoring" *Journal of Medical Internet Research*, vol. 12, issue 4, 2010

[11] F. Verhoeven, K. Tanja-Dijkstra, N. Nijland, G. Eysenbach, L. van Gemert-Pijnen, "Asynchronous and Synchronous Teleconsultation for Diabetes Care: A Systematic Literature Review" *Journal of Diabetes Science and Technology*, vol. 4, issue 3, pp. 666-684, 2010

[12] J.A. Cafazzo, K. Leonard, A.C. Easty, P.G. Rossos, C.T. Chan, "The user-centered approach in the development of a complex hospital-at-home intervention" *Studies in Health Technology and Informatics*, vol. 143, pp. 328-33, 2009