Using a Cell Phone Based Glucose Monitoring System for Adolescent Diabetes Management

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ABSTRACT

Introduction: Mobile technology may be useful in addressing several issues in adolescent diabetes management.

Purpose: To assess the feasibility and acceptability of a cell phone glucose monitoring system for both adolescents with type 1 diabetes and their parents.

Methods: We recruited patients with type 1 diabetes who had been diagnosed for at least one year. Each adolescent used the system for 6 months, filling out surveys every three months to measure their usability and satisfaction with using the CPGM system, as well as how use of the system might affect quality of family functioning and diabetes management.

Results: Adolescents reported positive feelings about the technology and the service, even though a concerning number of them had significant technical issues that impacted continued use of the device. Nearly all thought that the clinic involvement in monitoring testing behavior was quite acceptable. The use of the Glucophone™ did not, however, significantly change the quality of life of the adolescents, their level of conflict with their parent(s), their reported self-management of diabetes, or their average glycemic control within the short time frame of the study.

Conclusions: As a feasibility study of the technology, this work was successful in demonstrating that CPGM technology can be used in an adolescent population to track and assist in self-monitoring behavior. We speculate that explicitly attempting to change behavior, perhaps with the use of behavioral contracts, would enhance the technology's ability to improve outcomes.

BACKGROUND

Type 1 diabetes is one of the most common chronic diseases of childhood.[1, 2] In spite of significant technical and medication advances in treatment over the past two decades,[3-5] the quality of glycemic control among young patients has not improved dramatically. A significant number of children have suboptimal control of their blood glucose levels, largely reflecting poor self-management practices.[6-11] This trend is worrisome in that poor glycemic control early in the course of diabetes is associated with significantly increased risks of later morbidity.[12-14]

Mobile technology may be useful in addressing several issues in adolescent diabetes management. We have developed an intervention based upon a integrated cell phone glucose monitoring (CPGM) system that automatically transmits self-monitored blood glucose (SMBG) values, without further action taken by the user, to a host computer monitored by a health care professional. This enables the provider to identify patterns of glycemic control early and alert the patient before they become chronically problematic. Moreover, the CPGM system facilitates the user's ability to rapidly interact with the health care provider directly (via phone call or text message) to gain information and to discuss therapeutic options. Such technology has several potential advantages. It can help providers to monitor glucose value fluctuations and testing frequency and suggest therapeutic options more frequently than is currently feasible. It also has significant potential to impact the interactions between adolescent and parent that are often counterproductive to achieving optimal diabetes control. Often, parents, in efforts to help enforce adaptive regimen behavior, try to exert control over their child's behaviors precisely when the adolescent is attempting to achieve more autonomy. While attempting to break from parental authority by the adolescent are developmentally appropriate, they may result in behaviors that are health-jeopardizing for diabetes control, such as decreased frequency of glucose monitoring

and omission of insulin doses. Optimizing family-patient interactions is crucial to improving the ability of an adolescent to manage his or her diabetes.[8, 15, 16]

We have shown that adolescents with diabetes often feel that they are being excessively nagged by their parents about self management in general and self-monitoring in particular.[17] Similarly, many parents of adolescents with diabetes also report feeling that they are nagging their children and see such interactions as a source of conflict within the family.[18] In this context, the cell phone-based technology has the potential to reduce poor self-management that results from parent-child conflict over diabetes therapy behaviors by reducing parental need for hyper-vigilance (since the child is being remotely monitored by a health care provider). This also allows the health care provider to take responsibility for "nagging" about diabetes self-management behaviors. Moreover, by observing self-monitoring of blood glucoses (SMBG) real-time, health providers can actively prompt the adolescent to obtain important glucose data. Thus, the technology described here has the capacity to eliminate the need for parental supervision of this task.

The objective of this pilot study was to assess the feasibility of a CPGM system and the extent to which it would be acceptable to both adolescents and their parents.

METHODS

Subjects: Subjects were recruited from pediatric and adolescent diabetes clinics at the James Whitcomb Riley Hospital for Children in Indianapolis, Indiana. Eligible patients with type 1 diabetes for at least one year between the ages of 13-18 were identified from a clinical care database. Eligibility criteria included having grossly normal cognitive development and no other chronic diseases other than diabetes, except well-controlled hypothyroidism or asthma.

Adolescents in the study had to intend to remain in the care of participating clinics for the duration of the study (six months) and be able to read and write in English. Patients who had participated in prior studies related to the development of the cell phone technology were excluded.[19]

Participant Recruitment, Consent and Incentives: Families of potentially-eligible participants were sent a letter about the study signed by their diabetes physician and the study principal investigator and instructed to call a research assistant if they were interested in participating. The assistant then obtained assent from the patient and consent from the parent. Only one child per family could participate. Participating adolescents were remunerated $50 for completing each of three evaluations, at baseline, three months, and at six months for a combined $150. In addition, the study provided the integrated cell phone-glucose meter and provided cellular service for the study duration. The protocol was approved by the Indiana University-Purdue University Indianapolis Institutional Review Board.

Intervention and Procedure: This study utilized the Glucophone™ integrated cell-phone and glucose meter (HealthPia USA, Paducah, KY) which has been described elsewhere.[19] As means of summary here, once an individual tests their glucose using the CPGM which is part of the cell phone device, the system automatically uploads the glucose measurement via a cellular connection to a host computer.[19] Self-reported insulin administration data are not uploaded. A healthcare provider can then remotely review the data in this host computer. Each adolescent and their parent could also access this on-line data by logging into the HealthPia website. At the time of the baseline study visit, the adolescent and his or her parent(s) met with the NP and were oriented to use of the CPGM. They were provided with an instruction manual on the CPGM device and information on how to contact study personnel should questions arise. Parents and

adolescents were instructed to contact the NP if they had a cellular service interruption or had error codes indicating Glucophone™ malfunctions.

In addition, parents were strongly urged to reduce their attempts to enforce self-management behavior, notably self-monitoring. Instead, they were encouraged to "allow" the adolescent to interact directly with the NP using the Glucophone™ system as a link. This could be accomplished either by text messaging or by initiating a voice contact via the telephone. During this discussion, it was made clear that we were not advocating that parents relinquish all control of diabetes management to the NP reviewing their child's self-monitoring behaviors. Rather, we encouraged families to work with the CPGM system and allow the NP provider to assist the adolescent in developing a more effective and consistent glycemic monitoring pattern. In this regard, parents were strongly encouraged to try to curb their "nagging" about self-monitoring. All adolescents were included in these discussions and were similarly encouraged to hold up their "end of the bargain" by self-monitoring their blood glucose following a negotiated schedule. Letters were provided to alert schools that the phones were medical devices and would need to be permitted during the day.

All available uploaded blood glucose data were reviewed daily, by the NP, using a specially designed computer software program. This program included a pre-determined prompting algorithm (Table 1) designed to identify blood glucose patterns that needed to be addressed to reduce potential acute and chronic problems. This algorithm guided the need for and frequency of telephone contacts initiated by the NP to the subject. Depending on the quality of the transmitted data, patients might be telephoned or sent a text message by the NP to discuss recent blood glucose values, possible regimen adjustments, or suggest additional contacts. When there was no response to the initial text, a follow-up text or phone call would be made. The

algorithm stated that a parent would be notified if the NP remained unable to contact the adolescent. However, at no time during the study period did a parent need to be notified for adolescent non-response. All insulin adjustments were made by the NP using dose-adjustment algorithms developed by the PI and participating pediatric endocrinologists. Although telephone or text message (SMS) contacts were made directly with the adolescent, parents were notified of this information by email or telephone. Subjects whose data were within the algorithm parameters were also contacted by phone or SMS to praise them for maintaining positive self-management behaviors and good glycemic control.

All subjects attended the diabetes clinic for routine care with their usual pediatric endocrinologist and other members of the diabetes team at approximately 3 month and 6 months after enrollment.

Outcome Measures: The primary outcome of this study was the usability and satisfaction with using the CPGM system. The secondary outcomes were measures of how use of the system might affect quality of family functioning and diabetes management.

To assess the primary outcome, a survey was administered to the adolescents and one of their parents at the end of the study. We asked 6-10 questions in each of four domains: 1) the phone device and the HealthPia Company, 2) the cellular phone/text message service, 3) the study procedures, and 4) perceptions about how the phone affected the home diabetes management. Surveys were filled out by participants and parents themselves, and took less than 10 minutes to complete. For the first three domains, the questions for adolescents and parents were identical; for the fourth, questions were tailored to one of these two groups. Answers were in the form of a likert scale, ranging from “strongly agree” to “agree” to “neutral” to “disagree”

to "strongly disagree". For the purposes of analyses we grouped the two "agree" and "disagree" categories together.

Analysis: The primary analysis was a description of the percentage of participants and parents who agreed with the statements in the survey.

RESULTS:

Over the six-month period, forty patients were enrolled in the study. One patient was asked to withdraw from the study after it was discovered that she had a chronic condition that met exclusion criteria. The remaining 39 patients completed all study surveys. Of these, 19 were female and 20 were male; baseline average hemoglobin a1c was 8.7%. Four patients were asked to stop using the Glucophone™ during the study. One was discontinued due to repeated overages on her text-messaging allowance. Three decided that they no longer wanted to use the Glucophone™, one due to concerns about meter accuracy, and the other two due to the hassles of remaining under the monitoring protocol. All, however, were asked to complete the surveys at all data collection times.

User-reported activities that relate to technical issues that occurred with the devices and subsequent interactions with the company that produced the Glucophone™ are reported in Table 2. These data illuminate the technical issues that can arise when a new product is introduced. Since the company that provided cellular service for the Glucophone did not have uniform cell-phone service, particularly in rural areas, several of the adolescents had issues with cellular service interruptions when they were in "dead zones." This meant that they had to travel with their phones to a serviced area in order for data to upload. About a third of participants reported having to contact the company personally over the course of the study for customer service

issues. Moreover, about three-quarters reported having to send the phones back to the company at some point during the study for service. Only about half found the web-based monitoring service to be easy to follow and helpful. Almost three quarters felt that the meter was accurate and two-thirds felt that the amount of blood needed was not a problem.

User reported activities relating to the LogicMobile cellular service are also reported in Table 3. Fewer participants reported having to contact the cellular service company than the Glucophone company. Most participants felt that the text messaging (600 per month) and minutes (450 per month) provided were adequate. Although somewhere between a third and a half reported some disruption of service over the course of the study, it did not appear to affect use or the desirability of the system. Most participants reported liking the combination of the cell phone and glucose meter in one device, and three quarters reported that they would switch from a normal phone to such a device if it were available from their physician.

User-reported feelings about the study procedures are reported in Table 4. Nearly all participants felt that other adolescents with diabetes would want to participate in a study like this. Nearly all participants felt that the amount of contact they had with the nurse practitioner was exactly right. Over half of participants felt that the use of the Glucophone made them better at reading their own body cues. Very few participants reported that their schools had concerns about allowing them to carry and use the Glucophone devices in school.

Adolescent reported activities and feelings about the Glucophone are reported in Table 5. Very few adolescents reported actually increasing their blood glucose testing because of the Glucophone. However, anecdotally, text messages from the nurse practitioner were reported to

have this effect. Most adolescents reported being more independent in their diabetes management because of the Glucophone, and wanted to use it after the study if they could.

Parent reported activities and feelings about the Glucophone are reported in Table 6. Like the adolescents, parents had reasonably positive feelings about the Glucophone and the study. Most felt it was helpful in managing their child's diabetes and would continue using the phone if possible. More than 80% felt it removed some burden from them in worrying about such management and liked their child using it. About two-thirds felt their adolescent's health benefitted as a direct result of the Glucophone.

CONCLUSIONS:

This study found that the novel Glucophone CPGM system was well received by adolescents with diabetes and their parents. Participants reported positive feelings about the technology and the service, even though a concerning number of them had significant issues with the phone; many requiring exchanges over the six month period. Nearly all thought that the clinic involvement in monitoring testing behavior was perfectly acceptable. Moreover, many reported that they saw potential in the technology. Adolescents thought it might improve their self-management and parents thought it might alleviate their concerns and burdensome feelings because of their child's management.

On average, 2 hours of time was spent daily to text the adolescents in response to the flags the software system created. Call time was minimal since it was the back-up plan to the text communication option. However, calling did occur as complex dose changes were often too difficult to send in a text message. Most often, text messages were not responded to immediately because the adolescents were in school; therefore, another hour of time was spent in the evenings

responding to text messages from the initial daily round of texting. In addition, about two more hours were spent daily updating electronic medical records (EMR) with updated insulin doses, updating clinic charts, and notifying the parents' of the dose changes.

This study, like all research, had limitations that warrant consideration. The gaps in service and technology shortfalls were significant and need further work. A relatively small sample was studied, with the intention of showing the feasibility of the technology, and therefore we could not study have become more apparent in a larger study. This was also a study that lacked a well established integration of the phone system into the entirety of clinical care. The fact that a NP was making therapy adjustments outside of normal practices is not normative in the clinical environment in which the study was conducted. Therefore, integration of this management into all aspects of care might yield different results.

As a feasibility study of the technology, this work was successful in demonstrating that CPGM technology can be used in an adolescent population. At the end of the study protocol, nearly all of the adolescents requested to keep the phones and continue using them. Future work, however, needs to demonstrate that CPGM improves management decisions or glycemic control. Although it is possible that it will be difficult to readily incorporate this technology into clinics as a way of improving care of children with diabetes, we do not believe that this will be the case, based upon our prior work showing CPGM is well suited to adolescent management of diabetes.[18-20] It is more likely that merely as an isolated extra component of diabetes care, without additional behavior changes, the potential of this technology cannot be fully exploited. We speculate that explicitly attempting to change behavior, perhaps with the use of behavioral contracts, would enhance the ability of the technology to be a tool that would improve outcomes. We have already begun work on developing such a contract, and we believe that employing it in

a more integrated clinical setting might finally allow us to capitalize on this technology to improve care for adolescents with diabetes.

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Table 1. Algorithm for Determining Need for Telephone Contact

A. "Positive" phone calls made when mean blood glucose for the 1-week period is in the range of 70 to 150 mg/dL.
B. Telephone contact initiated by NP when fewer than 14 blood glucose readings are recorded in a 1 week period.
C. Text message "check ketones" sent to patient when there are two consecutively scheduled blood glucose readings >250 mg/dL. Patient reminded to call NP if ketones are moderate to high.
D. NP is paged and telephone contact made with patient, if a blood glucose reading is ≤45 mg/dL AND an improved reading is not received within 30 minutes.
E. Telephone contacted initiated by NP when: 1. Same scheduled blood glucose measurement is >200 mg/dL three days in a row 2. Same scheduled blood glucose measurement is <60 mg/dL two days in a row

Table 2: User reported activities and perceptions about the Glucophone™ company

Question Table 2: User reported interactions with and perceptions about the HealthPia Glucophone company	**Adolescents agreeing**	**Parents agreeing**
I had to personally contact HealthPia for a customer service issue.	29%	33%
HealthPia contacted me at some point during the duration of the study.	42%	57%
I had to mail my meter back to HealthPia (or return broken equipment) at some point during the study.	74%	70%
If yes, the repaired phone was returned to me within the promised 3 days.	68%	60%
The customer service provided by HealthPia was helpful and repair instructions were easy to follow.	60%	56%
I used the website to monitor my/my child's blood sugars.	47%	57%
I found the website user-friendly.	50%	65%
The website was a useful tool for monitoring blood sugars and testing patterns.	60%	65%
The cell phone/meter was accurate in reading blood sugars.	71%	63%
The amount of blood required for testing was not a problem for me.	71%	56%

Table 3: User reported activities and perceptions about the cellular service company

Question	**Adolescents agreeing**	**Parents agreeing**
I had to personally contact LogicMobile for a customer service issue.	26%	10%
LogicMobile contacted me at some point during the duration of the study.	35%	13%
The amount of cellular minutes I was provided during the study was sufficient.	77%	78%
The amount of text messages I was provided during the study was sufficient.	87%	74%
I did not experience any disturbance in my cell phone service.	32%	25%
I experienced some disturbance in my cell phone service, but it was resolved quickly enough so that it did not affect my use of the phone for the study.	60%	26%
I liked carrying the cell phone/glucometer combination.	74%	85%
I would switch from my old meter to a Glucophone, if it became available from my doctor.	71%	70%
I liked using the style of phone provided.	48%	56%

Table 4: User reported activities about the study procedures

Question	**Adolescents agreeing**	**Parents agreeing**
I think other adolescents would participate in this study for similar cash incentives.	94%	97%
I had too much contact with the NP.	0%	0%
I had too little contact with the NP.	6%	7%
I feel like I have learned more about reading my own body cues and signals, which will make it easier for me to monitor my own diabetes in the future.	55%	60%
My A1C was lower at the end of the study than when I enrolled.	60%	46%
My school administrators/teachers did not want me to carry the Glucophone during school hours.	16%	15%

Table 5: Adolescent reported activities and feelings about the Glucophone

Question	**Adolescents agreeing**
I increased the number of times I checked my blood sugar during the day, as a direct result of participating in the study.	16%
Receiving text messages from NP helped me remember to check my blood sugar.	94%
I made ongoing insulin adjustments during the study.	87%
It was easier to remember to keep my meter with me because it was connected to a cell phone.	74%
I would use this meter, if it could connect to my own cell phone.	84%
I would use the GlucoPhone, if I could use it with my own cell phone service.	77%
I am more independent in caring for my diabetes, as a direct result of participating in this study.	71%
In general, I liked using the Glucophone.	84%

Table 6: Parent reported activities and feelings about the Glucophone

Question	**Parents agreeing**
The Glucophone was helpful in managing my child's diabetes.	63%
I am pleased with the progress my child has made in caring for himself/herself, as a direct result of participating in this study.	63%
I would use this device in my child's care, if it was covered by insurance.	80%
Knowing that my child had the Glucophone with them, helped me feel more at ease and alleviated some of the burden of caring for a teenager with diabetes.	79%
I believe my child is better capable of recognizing his/her own blood sugar trends, as a direct result of participating in this study.	67%
I would allow my child to use the Glucophone, if he/she could use it with our family's cell phone service.	80%
My child's health benefitted as a direct result of his/her use of the Glucophone.	63%
In general, I liked having my child use the Glucophone.	80%