

**THE DESIGN AND TESTING OF A PERSONAL HEALTH SYSTEM TO
MOTIVATE ADHERENCE TO INTENSIVE DIABETES MANAGEMENT**

by

Vikram Sheel Kumar

Harvard-MIT Division of Health Sciences and Technology

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Area of Concentration: Diabetes/ Preventive Health Technology
Project Advisor: Alex (Sandy) Pentland, PhD
Author's Prior Degrees: Bachelor of Science / Operations Research

I have reviewed this thesis. It represents work done by the author under my supervision and guidance.

Faculty Sponsor's Signature

ABSTRACT

In chronic diseases such as type 1 diabetes mellitus (T1DM), patients actively participate in the management of their disease by regularly monitoring their physiology. With the exception of patients who have implantable monitoring devices that require no user input, patients must engage their monitoring devices to record a measurement. This involves an interruption to the routine of the patient, and often occurs with some physical discomfort. The limiting step to a patient's management of a chronic disease is often the lack of motivation to regularly use a system with such inconveniences. Non-invasive, continuous and wearable monitoring devices are all in rapid development and make adoption of proactive health technologies easier. However, even in the most automated of systems, patients will need to participate in their care, at the very least by following recommendations to changes in their lifestyle. To motivate such active participation, health systems must engage patients. To achieve this, systems must be interactive and provide benefits perceived as tangible by the patients. My thesis is centered on the development, testing and analysis of a disease management system designed to motivate adherence to an intensive monitoring regimen in patients with T1DM.

The system comprises of an interactive, predictive game called *DiaBetNet*TM that patients play with themselves and others in their wireless community. Visual feedback on their physiology and variable reinforcement through scoring points on the accuracy of glucose predictions are tangible benefits provided to the patients. I developed the system as a portable device with wireless interfaces between a glucose meter and handheld device, and client and server. To test the system, we enrolled forty youth, ages 8-18, with T1DM in the DAILY (Daily Automated Intensive Log for Youth) trial for four weeks. Half of these patients were randomized to receive

the portable system along with *DiaBetNet*. Through *DiaBetNet*, after performing at least three glucose measurements, participants could guess upcoming blood glucose levels. Based on the accuracy of their predictions and participation with the varying levels within *DiaBetNet*, patients were awarded points. To assist patients develop mental models of their disease, in aim of more accurately predicting their glucose levels, data of previous blood glucose values, insulin doses, and carbohydrate intake were displayed graphically prior to the glucose estimation. The Control half of the patients received the system without *DiaBetNet*. All of the participants were instructed to monitor their blood glucose levels at least four times a day. They were taught how to transmit their data through the system to a central server via a wireless modem. At the conclusion of four weeks, feasibility of the system and clinical outcomes were evaluated.

The results of the trial were that 93% of the participants successfully transmitted their data wirelessly to the server. The Game Group transmitted significantly more glucose values than the Control Group ($p < 0.001$). The Game Group also had significantly less hyperglycemia (glucose ≥ 13.9 mmol/l or ≥ 250 mg/dl) than the Control Group ($p < 0.001$). Youth in the Game Group displayed a significant increase in diabetes knowledge over the four-week trial ($p < 0.005$). Finally, there was a trend for more youth in the Game Group to maintain HbA1C values $\leq 8\%$ ($p = 0.06$).

In conclusion, the designed system with the predictive game, *DiaBetNet*, appears to accomplish the goal of motivating greater use of a monitoring technology. Patients using this personal health system had an increase in their frequency of monitoring, reduced occurrences of hyperglycemia, improved diabetes knowledge, and possibly optimized glycemic control.

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Glossary

T1DM	Type 1 Diabetes Mellitus
DAILY	Daily Automated Intensive Log for Youth
PDA	Personal Data Assistant
RS 232	Recommended Standard 232- popular physical interface layer for serial data transmission
I ² C	Inter IC- bus to connect multiple integrated circuits
HIPAA	Health Insurance Portability and Accountability Act
CDPD	Cellular Digital Packed Data
GPS	Global Positioning System
LAN	Local Area Network
FSK	Frequency-shift Keying
GTWM	Georgia Tech Wearable Motherboard
PSM	Personal Status Monitor
CDPD	Cellular Digital Packet Data
API	Application Program Interface
TCP/IP	Transfer Communication Protocol/Internet Protocol
SSL	Secure Sockets Layer
DCCT	Diabetes Control and Complications Trial
EDIC	Epidemiology of Diabetes Interventions and Complications

Introduction

In this thesis I describe a novel system to motivate patients with a chronic illness to monitor more frequently their changing dependent physiology. I will begin this introduction with an account of how the evolution of medical diagnostics has shaped our health system to make such a thesis relevant today. I will make the case for personal monitoring devices and illustrate the state of the technology and direction of wearable monitoring devices. I will then describe a theoretical framework for motivating patients to adhere to a medical regimen. Finally, I will establish how diabetes, as a model chronic illness, benefits from such an intervention as described.

1.1 Technology and depersonalizing healthcare

The earliest proponent of modern diagnostic technology was Hippocrates who first suggested that meaningful, audible sounds emanated from the heart. Later, the seventeenth century scientist William Harvey supported this claim and took it further to correlate observed sounds with pulsations of the heart. However, it was not until 1816 that a young French physician, Rene Laennec, created the first diagnostic device by rolling several sheets of paper into a hollow cylinder to auscultate the heart. Laennec went on to name his invention the “stethoscope”.

The stethoscope was the first diagnostic technology that played a significant role in the transformation of medicine from a narrative art, to an evidence-based science. At the time, physicians managed patients based primarily on data collected through verbal discussions on the relevant history leading to the chief medical complaint. Often physicians had enough confidence in their patients’ reports that they would recommend treatment simply based on a letter

describing symptoms. In such a scenario, the patient was the sole source of information and played a valued role in his medical management. With the advent of diagnostic technologies, the patient's role in his management began to change as the physician could collect objective measures of pathology and not have to rely solely on the patient's recollection of past events.

Two major developments occurred most immediately with the growth of diagnostic technologies. The physical exam became the standard of care and physicians needed the support of a centralized system to have access to the emerging technologies. Both of these changes drove the decentralized health system with independent distributed physicians to its end. Physicians moved to centers where they had greater physical access to their patients and opportunities to develop their diagnostic skills.

While hospitals were growing as central institutions of medical learning, patients were not flocking to them. Those who could avoid them did. The privileged would invite physicians to their homes- often providing extended lodging to physicians when necessary. It took further developments within the later part of the nineteenth century to establish hospitals as safe and desirable for patients. Particularly three innovations influenced this. Joseph Lister developed antiseptics, Florence Nightingale organized the nursing system, and Robert Koch established the theory of germs. Hospitals as the centers for medical care establishment grew, and the practice of home health care withered away.

Hospitals challenged the family doctor's clinic and generalists gradually lost hold over their practices. As specialists gained more prominence, two fundamental developments occurred. First, the practice of medicine became less personal as patients no longer developed long

relationships with single physicians. The care of patients became fragmented among as many providers as the patients had medical problems. While typically a single physician continued to coordinate all this care, he began to spend all of his time doing just that- coordinating; leaving little time to know the patient.

The second development was the specialization of medical information. Data collected on patients by diagnostic technologies was tailored for use by specialists. The patient was kept out of the loop. For instance, the Holter monitor, a device I will describe in more detail below, was designed so that data could be collected on the cardiac rhythms of patients, and then transmitted to specialists. Rather than designing a system to display this data for patients, or educate them on how their symptoms may correlate with aberrant rhythms, emphasis was placed on the specialist side of the equation. In this manner, patients had no access to their own primary data, let alone to systems that helped them develop mental models of the dynamics of their disease.

The mid-1900s saw the growth of hospitals as bigger is better. Diagnostic and therapeutic technology became more sophisticated and expensive. As centers with the resources to afford these advances, hospitals became even more important in the healthcare system. Along the way, technologies such as telecommunications seemed briefly poised to reverse the convergence of medical care, and reestablish decentralized health systems [1]. However, they failed; to my belief because they continued to rely on expertise at the center rather than creating experts out of the patients.

In my thesis, I describe the design of a portable health system to empower patients to view, analyze and manage their own medical information. Through this work, my goal is to motivate a

distribution of intelligence outside the conventional hospital networks [2]. Appropriately designed technology can assist patients become autonomous and self-sufficient nodes within a robust healthcare system. This is necessary both to curb the spiraling costs of modern, centralized healthcare [3], and to involve patients more actively in their own disease management [4], [5].

1.2 Modern medical monitoring devices

Medical monitoring devices can be classified into two categories. The first category includes those that are implanted within a patient and cannot be removed without a surgical intervention. Once these monitors have been placed, patients do not interact with the devices. An internal cardiac defibrillator is an example of this type of device. Its data is not directly available for the patient.

The second category of devices includes those that remain largely external to the patient, with the exception of component biosensors that may be internal. These monitors can be further classified into those that are intended for use *on* patients, or for use *by* patients. In the hospital setting, most of the meters are of the former class- for instance, an ECG monitor records electrophysiological data of the patient, but it is designed for use by others *on* the patient. These others in the health care system ensure that the patient adheres to being monitored by this device, and will physically or pharmacologically restrain patients who attempt otherwise.

I define a personal health system to include that class of diagnostic monitors that is intended for use *by* patients. Particularly, portable and wearable monitoring devices. As patients typically use these in their home environments, no restraints can improve adherence to using them. Patients

have full control over whether or not they choose to carry or wear these devices. As personal monitoring devices are ideally suited to assist patients with chronic diseases to manage their conditions in their daily lives, I will focus the content in my thesis on this class of devices.

In the same way that the personal computer revolution has changed the face of the computer industry, personal health devices are poised to redefine the way patients interact with their healthcare. This comes at a time when patients are looking for alternatives to the traditional medical establishments. As an example, out-of-pocket spending by US consumers for alternative therapies is rivaling that for traditional health services [6]. Personalized health systems can provide both the variety that the patient as a consumer is demanding and a trend toward decentralizing healthcare away from resource-intensive hospitals.

In the management of T1DM, portable diabetes monitors empower patients to view and process their data without needing to depend solely on larger hospital laboratories. At a basic level, just-in-time data from such meters assists patients manage their day-to-day disease states. At a higher level, patients still require consultation from health care providers to make adjustments to their insulin regimens. Thus an ideal system gives patients independence to monitor their physiology in their own homes, and the ability to transfer this data to health care providers via telemetry for further advice and assistance.

Apart from being more consumer-friendly, personal health systems can be more economical. A recent evaluation of a diabetes management system demonstrated that a telemetric approach to transmitting glucose levels every 2 weeks during a six-month period with feedback from health

care providers works out to nearly half the cost of a single clinic visit without any difference in diabetic control [7] .

As personal health systems are intended for use *by* patients, they must be designed with ease-of-use in mind. In cases where a wearable monitor is desirable, the ideal system is lightweight, easy-to-use, unobtrusive, and intelligent. A recently designed pulse oximeter that fits on a finger like a ring is one such emerging wearable monitoring device [8]. In this thesis I describe the design of a portable health system that must be carried by the patient. The main limitation from building a completely wearable system was the need to use standard components such as a FDA approved medical device and management software for use in the pilot study. The grand vision of this work is that one day wearable platforms will allow systems such as this to be easily integrated, even if only for intermittent, occasional use. The work of Vadim Gerasimov of the MIT Media Lab on bio-analytical games is an example of how this concept may be elaborated into a practical, wearable system [9]. While his work focused on healthy people, my thesis looks at patients with a chronic disease to evaluate how an interactive game can assist medical management.

The first record of a wearable device dates back to the 13th century with a written comment by the early scientist, Roger Bacon, on the use of eyeglasses [10]. It was not until nearly 700 years later that the first practical medical wearable monitoring device was developed. A Montana physician, Norman Jeff Holter, invented a 75 pound back-pack that recorded ECG signals from the wearer, and was able to transmit these signals [11]. Holter monitors continue to be worn by patients for monitoring cardiac rhythms, recording all signals for 24-48 hours with the capability for telemetric transfer of this data to specialists. More recently designed portable ‘event

recorders' are becoming popular for patients with intermittent arrhythmias. When a patient perceives a palpitation [4], he places the monitor to his chest to record the prevailing electrophysiological signal. Then the patient transmits this signal to his physician via standard telemetry. In 2001, the FDA approved the first wearable defibrillator [12] that also connects to an external modem for transmission to a specialist. All three of these devices demonstrate the prevailing trend to use a wearable system to collect and send data to a specialist rather than providing local feedback for the patient.

The invention of the telegraph in 1835 and telephone in 1876 set the stage for initial medical telemetry applications. In 1905, the pioneer in electrocardiography, Willem Einthoven, first transmitted medical signals via a telephone wire. He connected his laboratory with the Leyden Hospital 1.5 km away and created the first 'telecardiogram' [13]. Such medical telemetry gradually spread and in 1968 the first use of telecommunications for physical diagnosis was performed. Kenneth Bird, a founder of telemedicine, linked a medical station at Logan Airport in Boston with the Massachusetts General Hospital from where he performed a history and physical on a patient assisted by a remote nurse and television camera. As modes of communication were growing, microelectronics were finding novel, if sometimes illicit, applications. In 1961, two MIT professors, the famous Claude Shannon and Edward Thorp, invented the first wearable computer that they used in casinos to test their mathematical models to predict favorable roulette strategies [14].

Many of the modern wearable monitoring systems were designed initially for the space research program or the military. A current project between NASA and Stanford University called Lifeguard [15] is being designed for use on astronauts for remote physiological surveying. It is a

wearable system that incorporates the capability to connect a particular ECG and respiration sensor, a pulse oximeter, a temperature probe and a blood pressure monitor. It also has an internal three-axis accelerometer for activity assessment. This wearable module, called the CPOD, is the size of a small notebook and fits around the torso. Data is collected, converted from analog to digital, and transmitted through a wireless or serial interface to a BlueTooth or 916 MHz FSK base station. The base station is described as either a handheld computer, or a tablet PC. Using the base station, physiology can be remotely monitored.

While this is promising technology, the CPOD is not ergonomically designed, and unlikely to be widely useful in its current form. Also, the only input built into the interface for the wearer is an 'event button'. The location of the output display is on the front of the CPOD, and hence in the mid-thorax of the wearer. This design does not facilitate easy personal view of the data either. As the monitor records data only for 8 hours, Lifeguard appears best suited for brief telemonitoring of wearers by others.

A collaboration between the US Navy and the Georgia Institute of Technology lead to the invention of the Georgia Tech Wearable Motherboard (GTWM) [16]. The GTWM is a wearable vest that is woven with optical fibers that transmit signals until interrupted- such as by a bullet wound to a soldier. The output of the motherboard feeds to a Personal Status Monitor (PSM) worn at the hip of a soldier that can locate the interruption of the signal, and possible bullet-entry. Peripheral sensors to measure heart rate, temperature and respiration can be incorporated through its flexible bus architecture. Other wearable infrastructures have also been built based on electronic or optical woven fibers [17] and as 'smart vests' [18].

MITHril is a wearable platform being developed at the MIT Media Lab. The first version was developed in 2000 as a platform for distributive body-sensors and computing [19]. The motivation for developing MITHril was the limited general use of the industrial wearable systems of the time (Xybernaut, Fairfax, VA and Charmed Technologies, Santa Monica, CA). Though these platforms claim possible medical monitoring applications, they are too cumbersome to be practically wearable outside the professional context. MITHril has evolved over the years, to its current state as a mobile infrastructure for networks of users and sensors [20]. It uses a linux-PDA for processing and display and the Hoarder sensor hub [21] for monitoring through sensors with RS232 or I²C interfaces (EMG/ECG/GSR, 3-axis accelerometer, temperature sensor). Various versions of MITHril have been used in medical monitoring. For patients with Parkinson's Disease, one application on MITHril helped predict medication state [22]. Another area of growing use of this technology is in the context of elder care. Work done by the MITHril group and the Center for Future Health at the University of Rochester has examined the dynamics in activity, medications and physiology of elderly people in a sensor-embedded environment.

A watch with a wireless connection, GPS and a sensor hub (pulse, 3-lead ECG, temperature, blood pressure, pulse oximeter) has been commercially developed for the elder care market (Digital Angel Corp., St. Paul, MN). If a patient travels outside a pre-set boundary, falls and is down for at least one minute, encounters a significant change in ambient temperature, or triggers the emergency button, an alert is sent wirelessly to a caregiver.

Wearable medical monitors are prevalent in hospitals as wireless telemetry systems [23]. The Micropaq (Welch Allyn, Inc. Beaverton, Oregon) measures ECG signals, heart rate, and SpO₂

and sends this data to an 802.11 wireless LAN. The data can be viewed at the nurse's station, or through a display on the device. The latter feature is groundbreaking as to date, leading hospital telemetry systems have been designed only as transmitters from the patients.

There are two currently approved 'wearable' continuous glucose sensors. They are both in initial forms, requiring daily calibration with serum glucose measurements. The GlucoWatch G2 Biographer (Cygnus Inc., Redwood City, CA) is fundamentally unique in that it presents the glucose levels on a read-out for the patient to view around her wrist. In contrast to this, the Continuous Monitoring System (MiniMed Inc, Sylmar, CA) records glucose levels every 5 minutes for up to 72 hours, but rather than displaying this information for the patient, allows a download for the physician to interpret.

1.3 Adherence

The main objective of *DiaBetNet* is to increase adherence to a recommended glucose-monitoring regimen. In a recent treatise on adherence in chronic diseases, the World Health Organization modified the classic definition of adherence by Haynes [24] to read "the extent to which a person's behavior – taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a health care provider." [25] It is worth distinguishing adherence from compliance, as it implicitly assumes that the patient is in agreement with the management recommendations. Compliance is a cognitive process through which a patient may be willing to follow a scheduled regimen while adherence is an active process through which a patient actually follows such a regimen [26].

An influential theory of adherence is based on the concept of self-efficacy, or belief in one's ability to complete a given task. Albert Bandura describes self-efficacy as one of the belief structures upon which people find motivation to perform [27]. As an illustration of this concept, consider two people who are faced with a similar failure. One person has a strong sense of self-efficacy, and hence blames her failure on inadequate effort. She realizes that in order to overcome her failure, she must work harder in the future. The other person has a poor sense of self-efficacy. She blames her failure on inherent low ability. She is not motivated to try to overcome her failure.

Bandura proposes that self-efficacy influences motivation through four major areas. It determines the goals a person sets, the amount of effort he applies to achieve the goals, how long he perseveres when faced with challenges, and his resilience if he fails. As managing a chronic disease requires self-motivation and tenacity, an intervention that enhances self-efficacy is valuable. In the design of *DiaBetNet*, I applied three concepts that Bandura has theorized to enhance self-efficacy [28].

First, I set a challenge in which success is not guaranteed, but is possible to attain with perseverance. The essence of *DiaBetNet* requires a patient to predict an upcoming glucose level. With the multi-factorial nature of the disease, it is incredibly challenging to predict one's glucose level. However, patients are rewarded points with greater emphasis on qualifying to play than on the accuracy of predictions [see Table 1]. Also, a goal of the system is to train patients through the game to strengthen their cognitive models of diabetes. Thus, in theory, the performance of patients should improve with time.

Second, social models influence how one perceives one's chance at attaining a goal. As an example, if a person sees someone similar to her succeed at a task, she begins to model that behavior and develop greater confidence in her ability to succeed. At the same time, if she watches someone with high efficacy fail, she begins to doubt her own chances of success. Bandura introduces "modeling" as a process through which a person reinforces learning by observing others reinforce themselves. To create such opportunities for patients to model others' behaviors, I designed *DiaBetNet* as a wireless, community-based game. Through the game, patients can view a list of high scorers to assess how they are doing relative to others. As the subtle variations in glycemic control have more to do with the extent and dynamics of an individual's disease, someone who succeeds at *DiaBetNet* scores highly for entering carbohydrate levels, insulin levels and checking glucose levels, *not* for maintaining euglycemia. Thus, patients may see and be motivated by the adherence of others in the network independent of emphasis placed on levels of glycemic control.

I saw this concept at work first-hand at a summer camp for diabetic children where campers reinforced positive behaviors in one another (Elliot P. Joslin Summer Camp, Charlton, MA). Parents reported that during the weeks at camp, their children had better control over their diabetes than at any other times [29]. My goal was to create an electronic medium through *DiaBetNet* to facilitate such healthy interactions in the daily lives of patients.

Finally, social persuasion through encouragement helps strengthen self-efficacy. I organized the participants in our study into various teams. Participants scored points for their team when they viewed and predicted others' glucose levels [see Table 2]. Captains were assigned for each team, with the intent that they would communicate with their teammates to remind them to play,

and hence necessarily adhere. It has been shown that greater social support is related to higher levels of adherence in diabetes management, with most of the studies focused on the role of support by the family [30], [31]. Some studies suggest that support from friends can positively impact adherence to greater blood glucose monitoring [32]. *DiaBetNet* is the first integrated diabetes management system that builds a peer-based virtual support community.

Perhaps the most critical aspect to any intervention towards adherence is maintenance of the desired behavior over time. Bandura emphasizes that the most robust behaviors are those that have intrinsic reinforcement (such as feeling relaxed after a meditation session) or are self-generated (based on observing someone reinforce himself). The challenge in diabetes is that there is no intrinsic reinforcement to monitor glucose levels. The conventional act of glucose monitoring is invasive and somewhat painful. There do not exist any federally approved non-invasive monitoring technologies (both of the minimally invasive, continuous monitoring systems currently require daily calibrations with invasive systems). Hence in *DiaBetNet*, patients were required to perform finger-pricks each time they wanted to measure their glucose levels. Also, patients with diabetes do not feel immediate benefits of increased monitoring. In fact, studies have demonstrated an increase risk for adverse hypoglycemic events in intensive monitoring regimens [33]. Further, the work of B. F Skinner has shown that the shorter the delay between a reward and a behavior, the quicker the behavior will be adopted [34]. Unfortunately, the reward of intensive monitoring is extraordinarily delayed, and that too is the absence of negative long-term complications, not the presence of positive reinforcements.

In the design of *DiaBetNet*, as generating intrinsic reinforcement was unlikely, I focused on the concept of self-generated reinforcement. In *DiaBetNet*, participants are challenged to develop

mental models of their disease to effectively predict future glucose levels. I observed that certain patients have a better intuitive sense of their disease dynamics than others. My belief is that as some patients live with a chronic disease, they learn how to recognize patterns. They may realize that eating a bagel as a snack at 11 am generally pushes up their glucose levels by lunchtime. To this they may incorporate the type of insulin they took in the morning, and the amount of exercise they did to that point. Finally, they add to this model “how they feel” based on their developed intuition or learning to date. My goal through *DiaBetNet* has been to demonstrate the untapped value in the subjective assessment of a patient’s state- an element that is necessarily missing from any closed-loop system in development. Through the game, participants are awarded points if they predict their glucose levels with certain accuracy. To reinforce these internal models, they observe how others predict in the network.

1.4 A personal health system for diabetes management

Diabetes is the fifth largest cause of disease-death in the U.S and accounts for nearly one-fifth of the country’s total annual healthcare expenditures [35]. It is characterized by either insufficient or absent insulin action to regulate glucose homeostasis. I chose to build *DiaBetNet* for youngsters with T1DM as in these patients there is no insulin secretion, and hence patients necessarily perform some level of self-monitoring and insulin administration. This allowed me to define my problem clearly as to motivate a given population to increase adherence to a certain technology, where the population has already adopted the technology. This is unique from other work I have done where the intervention was directed to achieve a more primary health effect [36].

Poor adherence to intensive diabetes management is both prevalent and important in patients with T1DM. A study of 282 children with T1DM showed that only 26% performed the recommended 3 or more glucose measurements per day [37]. Low adherence to an intensive diabetes management regimen is an important problem as it is a major reason that children experience diabetic ketoacidosis and unstable glycemic control [38]. Also, it has been well demonstrated that an intensive diabetes management regimen reduces the risk of long-term complications [33], [39], [40], [41], [42], [43]. A central tenet to intensive management is frequent blood glucose monitoring, the practice of which has been shown to positively impact glycemic control even in the shorter term [44], [30], [45].

Diabetes is a challenging disease as there are significant acute and long-term consequences to daily management decisions. Blood glucose monitoring provides objective data to guide patients through adjusting insulin doses, modifying carbohydrate intake, and integrating exercise into their activities. There have been some video games designed to educate children on the dynamics of diabetes (Starbright Life Adventure Series: Diabetes by Starbright Foundation, Los Angeles, CA; Captain Novolin, Packy & Marlon by Health Hero Network, Mountain View, CA), but they did not address adherence directly. *DiaBetNet* is the first video game, to my knowledge, that has been designed particularly to motivate more frequent glucose monitoring. Other computer-based or telemedicine-directed approaches offer diabetes education and support yielding behavior modification results similar to those found with person-to-person education [46], [47], [48]. An interactive educational freeware diabetes simulator, AIDA (Automated Insulin Dosage Advisor), allows patients to graph glucose values, insulin doses, and carbohydrate intake to see how the components interact [49].

Most interventions designed to improve patient adherence to diabetes management have focused on factors related to socioeconomic, health-system, condition, and therapy issues [25]. Interventions based on patient-related factors have concentrated on patient education [50]. The translation of increased knowledge to behavior change is a subject of ongoing study [51]. The subject of this thesis- designing a game as an intervention to motivate behavior change- is novel in the field.

1.5 Summary

Diagnostic technologies have contributed to the evolution of our health system as impersonal and hospital-based. New innovations in personal health systems can empower patients to more actively participate in the primary management of their own conditions. While wearable monitoring systems are the ideal systems in diseases such as T1DM, I designed a practical, portable system to determine whether a game could enhance adherence to diabetes management. To test my hypothesis and the feasibility of a personal, wireless health system for diabetes, I organized a clinical trial called the Daily Automated Intensive Log for Youth (DAILY).

Methods

2.1 Designing *DiaBetNet*

My goal was to develop a game that was easy to play, interactive, and networked within a community. Studies have explored the accuracy with which patients are able to estimate their glucose levels [52-57]. The objective of these experiments has been primarily to inform health care providers on how their patients think about diabetes. The main conclusion has been that patients are unable to accurately estimate their glucose levels. I came to a similar conclusion when I observed in initial sessions that even those children with many years of diabetes experience had a challenging time predicting their glucose levels. The recommendation from these studies has been to extend the role health care providers play in educating and managing their patients. I believe the uncertainty intrinsic to diabetes can be harnessed through an integrated game.

While it is clear that it is non-trivial to predict glucose levels, the next question is whether there is any structure within glucose dynamics that suggests predicting is a meaningful exercise. Bremer and Gough answered this question by first comparing frequently sampled glucose levels to white noise by running autocorrelation functions [58]. They found autocorrelation coefficients with significant deviation from zero in the glucose data, while non-significant in the random data. This established that the glucose sets had mutually dependent data. Next, they applied simple linear autoregressive integrated moving average models to determine whether they could accurately predict values. By training their model on half of a day's data, they were able to predict values 10 minutes in the future with an error comparable to a standard measurement error (0.2 mmol/l). However, when they tried to predict values 30 minutes out,

they performed only as well as had they simply used the mean of prior levels as an estimate for the future. Thus, the challenge is meaningful, albeit extraordinarily difficult.

The external variables to diabetes physiology are carbohydrate intake, insulin levels, and physical activity. The internal variables are the dynamics of the uptake of administered insulin, metabolism of food, and counter-regulatory hormonal fluctuations associated with growth and stress [49]. *DiaBetNet* can be played only after a patient checks at least three glucose measurements for the day, and enters three records of carbohydrate consumption. Once qualified, a patient views a graph [see figure 1] of her prior data (glucose, carbohydrates and insulin), and is challenged to predict the upcoming glucose measurement. After guessing, the patient measures her glucose level. Depending on the difference between the estimation and true result, the patient receives individual points. The patient also earns points for entering data and qualifying to play the game [see Table 1].

To build the community nature of the game, participants who were randomized to the Game group in the DAILY study were organized into teams. The participants could log onto the wireless network [see Chapter 2.3] to predict the glucose levels of others in the game and earn points for their teams [see Table 2].

As an extension to the concept of an online, peer-based support network, I developed a prototype for a desktop chat program that was not tested through the DAILY trial [see Figure 2]. The proposed system, *DiaBetNet 2.0*, allows patients to both easily send messages to friends, and predict the glucose levels of those with diabetes (given appropriate consideration to concerns of data-privacy). This is an example of a tool that is designed to serve a basic utility

(communication with friends) to enhance ready adoption by patients. The added feature is a seamlessly integrated diabetes data management system.

I believe patients will adopt the use of those health systems that fulfill other needs that they have in their daily lives. Everett Rogers describes how individuals will adopt an innovation if it fulfills a perceived need [59]. As social beings we have a need to communicate and interact with others. However, a preventive innovation such as an electronic diabetes journal gives such delayed benefits that the task to motivate its adoption is formidable. My approach is to couple an immediately useful technology outside the health realm with a chronic health management tool to accomplish adoption and preventive management.

2.2 Mechanical system design

My first decision regarding the system design was to use a portable digital assistant (PDA) as the central processor. I considered using more primitive systems, but needed a platform that was robust and tested. I started with a Palm VII™ (Palm Corporation, Milpitas, CA) as it had an inbuilt wireless modem and an available serial port through which I could transmit data. However, I discontinued development due to the limitations of its proprietary wireless network. At the time, the first wireless CDPD modem was released for the Handspring Platinum Visor™ (Palm Corporation, Milpitas, CA) as a module that fit into its expansion slot. The use of the expansion slot for the modem freed the serial port for its use.

The ideal glucose monitoring system interfaces with a wearable, continuous sensor. However, at the time I started the project, neither continuous monitor under development had received federal approval. Also, my goal was to design a system useful to the widest population, build a

prototype and practically test it through a clinical trial. To accomplish each of these criteria, I decided to use widespread, finger-prick glucose meters.

I began using the OneTouch™ FastTake meter (Lifescan, Milpitas, CA) based on its size, and the initial feedback I received from patients. The meter has a proprietary adapter that can transmit data using the standard RS-232 protocol. A drawback with the meter is that the adapter must be removed each time a glucose strip is placed. To play *DiaBetNet*, patients had to regularly check their glucose levels, and transmit this data to the network through the PDA. To build a mechanical system that facilitated easy placement and replacement of the adapter when needed, I supervised the S.B design thesis of Carla P. Meza [60]. Meza explored various approaches [see figure 3] before we agreed on creating a carry-case in which a patient could place diabetic supplies including the meter and PDA [see figure 4]. Throughout the process it was important for us to design a system that children would feel comfortable using daily. Meza's final solution for the adapter was to build a sliding mechanism for the meter and secure the adapter [see figure 5].

While there was no need for the entire system to be wearable, to measure daily activity we needed an accelerometer that could be worn. I developed a software interface between an accelerometer and the PDA in this direction. The next steps were to make the accelerometer wireless, and then build a casing so that the patients in the trial could conveniently wear it. To build the hardware casing for the device, I supervised the S.B design thesis of Derrick Ang [61]. In the final design of the system, we chose not to incorporate the accelerometer, as we were ultimately unable to convince ourselves that if we were end-users we would go through the hassle of wearing the device everyday.

Ultimately the wired FastTake system that we had designed [see Figure 4] was too cumbersome to envision ready use and I started again by designing a completely wireless system. I chose to use the Accu-chek Active™ meter (Roche Diagnostics Corporation, Indianapolis, IN) as it had a wireless interface to the Visor. A challenge was that unlike the FastTake that had open RS-232 specifications, the Accu-chek transmitted its data to the infrared port of the PDA using a proprietary protocol. Also, any reengineering of the system would violate its safety rating as an approved medical device. To circumvent this problem, I worked directly with a team at Roche Diagnostics to gain access to specifications of the database in which the recorded data was stored in their data management program (Accu-chek Pocket Compass™) on the PDA. The final system that we used for the DAILY study comprised of a PDA fitted with a wireless modem (Minstrel S™ modem, Novatel Wireless Inc., San Diego, CA), and a glucose meter with a lancing device, lancets, test strips, and control solutions (Roche Diagnostics Corporation) [see Figure 6].

2.3 Software system design

I designed the software in C on the Palm OS as three main applications. The first was a program to read data from the Pocket Compass, measure adherence to a prescribed regimen, and draw the graph for *DiaBetNet* when appropriate. The second was a program to transmit this data wirelessly to a server at the Media Lab. The third program sat on the server and organized the incoming data into a local database, ran a web page for patients and health care providers to have access to the data, and allowed participants remote access through their PDAs to play the network game.

We used the Pocket Compass as the interface for patients to enter their insulin, and carbohydrate levels, and transmit their glucose data. We designed the system so that patients would transfer their data daily from their meter to the PDA. After they sent this data and opened the *DiaBetNet* module, our code would look for updated records and determine whether the modifiable criteria for adherence had been attained. For the purpose of the DAILY study, we required patients to check their glucose levels at least three times, and enter at least three carbohydrate counts [see Figure 7]. Those randomized to the Control Group could transmit their data to the network regardless of their level of adherence. Those in the Game Group had to be adherent before they could play *DiaBetNet* or transmit their data to the server. For the patients in the Game Group, we also awarded them points for checking their glucose levels (see Table 1).

The data we collected in the system were carbohydrate, insulin and glucose levels. For calculating carbohydrates consumed, our first iteration was to create a database of foods with the number of grams of carbohydrates per item. It soon became clear that such a system would be unwieldy and inherently incomplete. The next design was to allow the parents to enter through a website the typical foods their children ate to create a personalized database for each patient. This approach took advantage of the fact that most people, especially school going children, eat only a limited subset of foods. We ultimately withdrew this option as poor compliance to it by parents would confound our results. A goal of the DAILY study was to increase diabetes knowledge and we concluded that the best way for children to learn how to carbohydrate count was to have them record their food intake in simple grams of carbohydrates per meal. Thus, carbohydrates were finally entered through the Pocket Compass interface, and read into our database [see Figure 8]. In a similar way, patients entered their insulin levels [see Figure 9].

To transmit glucose levels from meter to the PDA, patients had to line up the infrared ports of the two devices and activate the transfer functions on both the meter and PDA [see Figure 10]. In case patients used a different meter, they could also enter their glucose levels directly into the PDA [see Figure 11]. For those patients who were unsuccessful at transmitting their data from the PDA over the wireless network to our server, we built a web-interface for glucose, carbohydrate and insulin entry. During our study, this feature was never used.

Once patients in the Game group qualified to play the game, a graph was drawn [see Figure 1] representing the glucose, carbohydrate and insulin data from the past 24 hours. Then after predicting and subsequently measuring their blood glucose level, patients were redrawn the graph to show the accuracy of their prediction and the number of points earned. We did not give tangible rewards based on the points, but rather wanted to test how much intrinsic motivation a competitive game such as this could foster. A patient in the Game Group who had not adhered to the regimen was reminded of the required guidelines [see Figure 7a] if he tried to play the game. Regardless of adherence, patients could use their glucose meters at all times. Once they completed the required 3 measurements and 3 carbohydrate entries, they could also skip the game and directly transmit their data.

A critical component to the system was the wireless network. We designed a transmission protocol with a goal to minimize the load on the network at any given time. To do this, we transmitted data in batches of 30 data points until all the data were successfully received at the server. An encrypted header that contained the username and modem number was included in the transmission. Utilizing Berkeley sockets API, the program transferred the records over the

Verizon™ Wireless CDPD network. Data were read via a TCP/IP socket on the secure server utilizing Thawte SSL web certificates on the MIT Media Lab domain. The server program extracted and verified the username before writing the records into a MySQL database (a fast, multi-threaded, multi-user, and robust SQL (Structured Query Language) database server). Through a secure web site, participants and investigators could view blood glucose, insulin dose, and carbohydrate intake listed by date and time.

Patients were identified by anonymous usernames. The web site was password protected and no identifying data was kept on our server. Access to this data by others on the Media Lab network was blocked. Data on the PDA was treated as if it were on the meter itself. Using these measures and transmitting data with SSL security, we designed our data systems to be HIPAA compliant.

2.4 Clinical system design

I chose to embark upon this project with the goal to ultimately build a system that was practical and useful for patients' daily disease management. To test the feasibility of the technology and my hypothesis that *DiaBetNet* would enhance adherence, I collaborated with Dr. Lori Laffel of the Joslin Diabetes Center to run the DAILY study. As the first step, I was successful in raising product donations for the whole system (PDAs, wireless modems, wireless accounts, glucose meters, strips, and other diabetes management material). With Dr. Laffel as the chief clinical investigator, I designed the protocol of our study.

Our prospective randomized clinical trial included 40 insulin-treated children and adolescents between the ages of 8 and 18 years with type 1 (n=39) or type 2 diabetes (n=1). Youth were

eligible if they were routinely monitoring blood glucose levels, were not participating in another trial, and were receiving care at the Joslin Clinic in Boston, Massachusetts. Each participant and a parent/guardian expressed a willingness to monitor blood glucose levels 3-4 times daily, enter data into the PDA for four weeks, and agree to be randomized to either the Game or Control Group. We received approval for our study from the Committees on Human Studies at Joslin Diabetes Center and the Committee on the Uses of Humans as Experimental Subjects at MIT. Each participant and a parent provided written assent and informed consent, respectively. Over an 8-week period, Dr. Laffel and her research assistants approached eligible patients and families until 40 youth and parents agreed to participate.

After we explained the study and obtained assent and consent, we randomized the participants utilizing two age strata, 8-12 and 13-18 years. The Game Group received the blood glucose meter and PDA with data management software including *DiaBetNet* software, while the Control Group received the meter and PDA with data management software alone. I developed training materials, guided the Joslin research assistants through the use of the system, and assisted in training participants on the use of the meter, the PDA, PDA software, and the wireless modem. During the training sessions, we encouraged all of the participants to check blood glucose levels four times daily, upload their blood glucose data from the meter to the PDA, enter insulin doses and carbohydrate intake into the PDA, and transmit the data wirelessly everyday. Throughout the trial I also was responsible for all technical support for the participants and their parents.

2.5 Glycemic control

At study entry, research assistants from the Joslin assessed glycemic control by measuring a Hemoglobin A1C (HbA1C) using HPLC (reference 4.0 to 6.0%; Tosoh 2.2, Tosoh Corporation, Foster City, CA). While the study lasted four weeks, they again reassessed the HbA1C approximately three months later, at the next routine visit. Baseline glycemic control was calculated as the average of the participant's previous HbA1C obtained prior to study entry and the value measured at entry.

2.6 Diabetes knowledge and satisfaction

At study entry and after completion of the four-week trial, each participant and a parent completed surveys concerning diabetes knowledge and general satisfaction. The Diabetes Knowledge survey was adopted from the curriculum for adolescents and families published by the American Diabetes Association [62]. There were 15 questions and scores could range from – 15 to 15, with a higher score indicating greater diabetes specific knowledge. Additional survey questions evaluated satisfaction with the electronic technology.

2.7 Statistics

We performed statistical analysis of the data with SAS v8.0 for Windows (SAS Institute, Cary, NC) and MATLAB® (MathWorks, Natick, MA). Means±SD are presented unless otherwise indicated. Paired and unpaired t tests and χ^2 analyses were performed. Two-tailed *P* values of <0.05 were considered significant.

Results

Of the 40 participants, 19 were randomized to the Game Group and 21 to the Control Group. The mean age of the participants was 13.6 ± 2.5 years and the mean duration of diabetes was 6.4 ± 3.5 years. Participants in the Game and Control Groups had similar ages, durations of diabetes, height and weight, as well as gender distribution (non-significant or NS) (see Table 3). Similarly, 42% and 43% of the participants in the Game and Control Groups, respectively, received either multiple daily injection therapy (≥ 4 shots/day) or continuous insulin infusion via a pump. At entry, participants in each group checked their blood glucose levels an average of 4.1 times daily.

Overall participation (defined as those who wirelessly transmitted their data at least once) during the four-week trial was 94.7% (18/19) for Game Group and 90.5% (19/21) for Control Group (NS). Neither age nor gender predicted success with the technology. There was no significant difference in the mean or median number of daily data transmissions between groups. Thus, the trial demonstrated successful implementation and feasibility of wireless transmission of diabetes management data in a pediatric population.

3.1 Blood glucose monitoring

The number of transmitted blood glucose values was significantly different between the two groups [see Figure 12]. More than three-quarters of Game Group participants (78%) checked blood glucose levels a median of ≥ 4 times daily compared to just over two-thirds of Control Group participants (68%). Overall, participants in the Game Group checked and transmitted

1,662 blood glucose values while those in the Control Group checked and transmitted only 1,471 values ($p < 0.001$).

The next question was whether patients playing the Game checked their glucose levels with different intrinsic patterns than the others. To determine this, we performed spectral analysis and found no significant difference between the groups. On organizing the glucose data based on the time of measurement, we were able to see descriptive patterns. For instance, user #4 checked his glucose level early in the mornings, and in rapid succession at night [see Figure 13]. Before 10pm, this patient typically checked his glucose level only twice on most days. He was in the Game Group, so possibly checked the extra times at night to bring him to his required four checks per day. As *DiaBetNet* can be played only after the day's third measurement, and before the fourth, the fact that this patient left little time between the two measurements made it easy for him to accurately predict. At first I saw his game scores and glucose levels and proposed that he was cheating by manually entering his fourth level after actually checking only minutes before. However, on visualizing the regularity in his monitoring times, it seems more likely that performing well in the game was a byproduct of his skipping required measurements during the day and cramming extras in at night. This demonstrates the incredible challenge in successfully motivating behavior change. It also gives insight into how the game can be improved.

3.2 *DiaBetNet*

We were unable to record all of the predictions on our system by patients in the Game Group. Thus, I am unable to report objectively on how patients overall performed in the game. Analysis of the data that I have demonstrates no significant improvement in predictions over time. This is contrary to my initial hypothesis that patients' predictions would improve as they played [see

Section 1.3], though this may be a consequence of the short duration of the study. Subjectively, I can report users shared excitement in succeeding to accurately predict levels. A particular user who did well on the individual game, went on to be the most active participant in the online game guessing the levels of others' 21 times during the study.

I mention in an earlier section [see Section 2.1] how teams had captains who could communicate with their teammates to remind them to monitor levels and play. Unfortunately, we were unable to provide this level of interaction as we did not have institutional review board clearance to share the identity of patients with one another.

3.3 Insulin dosing and carbohydrate intake

The frequency, with which both groups entered and transmitted insulin dosage and carbohydrate data, was similar. There were also no significant differences between groups in daily insulin dosing (Units/day) or intake of carbohydrate (grams/day) as entered into the PDA database and transmitted via the wireless modem. As carbohydrate intake significantly influences glycemic excursions post-prandially, which in turn contribute significantly to overall glycemic control and HbA1C, we further examined average daily carbohydrate intake [63]. Among participants checking blood glucose levels ≥ 4 times daily, the Game Group reported significantly lower median carbohydrate intake (154 grams/day) than the Control Group (214 grams/day) ($p < 0.05$) [see Figure 14].

3.4 Glycemic control

Baseline glycemic control was similar between groups, with HbA1C equal to $7.8\pm 1.1\%$ and $8.1\pm 0.9\%$ in the Game and Control Groups, respectively (NS). An average of 3.5 to 4 months following study entry, the mean HbA1C results remained similar, with values of $7.9\pm 1.1\%$ and $8.0\pm 0.7\%$ in the Game and Control Groups, respectively (NS). However, during the four-week trial, the frequency of hyperglycemia (BG ≥ 13.9 mmol/l or ≥ 250 mg/dl) was significantly less in the Game Group compared to the Control Group (318 and 377 occurrences, respectively; $p < 0.001$) (see Figure 13). On the other hand, the frequency of hypoglycemia (BG < 3.9 mmol/l or < 70 mg/dl) was similar between groups (NS).

Next, we examined the distribution of HbA1C at entry and found 63% of Game Group participants and 43% of Control Group participants had baseline HbA1C values $\leq 8.0\%$ (NS). At follow-up, there was a trend towards a significant shift in the distribution with 63% of Game Group participants and only 33% of Control Group participants maintaining HbA1C values $\leq 8.0\%$ ($p = 0.06$). In other words, Game Group participants were 3.4 times more likely than Control Group participants to achieve or maintain HbA1C values of $\leq 8\%$.

3.5 Diabetes knowledge and satisfaction

Baseline survey responses revealed similar levels of diabetes knowledge between groups. After the trial, there was no change in parent report of diabetes knowledge. However, child responses to the Diabetes Knowledge Survey indicated acquisition of knowledge in both groups, although

only the Game Group displayed a significant improvement in knowledge scores (Game Group $t=3.27$, $p<0.005$; Control Group $t=1.79$, $p=0.09$).

Youth and parent reports regarding satisfaction with the technologies indicated that both Game and Control Groups adapted equally and readily to the new platforms including the glucose monitor with infrared data transmission and the PDA software. More Game Group youth (72%) compared with Control Group youth (57%) reported satisfaction with the knowledge that their data were available on the Internet (NS). Interestingly, parents reported greater satisfaction than their children, with 81% of Game Group parents and 68% of Control Group parents reporting satisfaction with data availability on the Internet (NS).

Discussion

Treatment of diabetes remains challenging and demands vigilance to achieve optimal control in order to reduce the risk of short- and long-term complications [33, 39, 40, 64, 65]. Recent data from the DCCT and EDIC (Epidemiology of Diabetes Interventions and Complications) confirm the critical importance of early implementation of intensive therapy in order to achieve the greatest risk reduction in complication occurrence [43, 66]. Furthermore, intensive insulin therapy with the avoidance of acute complications mandates routine monitoring blood glucose, carbohydrate intake, and physical activity in order to dose insulin most accurately. Patients with diabetes and their families quickly learn the importance of understanding blood glucose patterns, but on-going management of such dynamic physiology routinely becomes burdensome. This is compounded by the fact that young patients may not sense the urgency for tight control since significant pathology may take years to develop. Thus, we need approaches that motivate and reinforce with patients and their families the importance of ongoing monitoring and attention to diabetes management.

To test how a personal wireless health system with a predictive game could help children with diabetes and their families to monitor blood glucose levels, better understand glycemic excursions, and adopt healthier behaviors, we ran the DAILY trial. The system's multiple components integrated data acquisition, management, presentation, and transmission. Participants could wirelessly transfer their blood glucose data from the infrared port of the meter and manually input insulin and carbohydrate data to a PDA. The *DiaBetNet* software encoded within the PDA accessed for graphical depiction the blood glucose values, insulin doses, and carbohydrate intake and then captured the participant's guesses as to the next blood glucose

level. Finally, via the wireless modem affixed to the PDA, all data were transmitted to the secure central server from where participants and their health care providers remotely could view the data.

Patients between the ages of 8 and 18 years and their families appeared well suited for wireless, PDA technology solutions and this pilot confirmed the feasibility and acceptability of such an integrated approach, independent of age and gender. Apart from one participant who lived outside the range of the wireless network, another who withdrew for family reasons, and a third who never attempted transfer, all participants successfully transmitted data wirelessly.

DiaBetNet appeared to increase the adherence to more frequent blood glucose monitoring, decrease the occurrence of blood glucose levels in the hyperglycemic range, provide for a greater acquisition of diabetes knowledge, and begin a trend towards more optimal glycemic outcomes. There may be several reasons to account for the increased monitoring and decreased hyperglycemia in the Game Group. The participants in the Game Group had a qualification criterion to check their glucose levels at least three times daily in order to play the game. Then, prior to data transmission, they had to check a fourth blood glucose. Alternatively, frequent blood glucose monitoring might have served as a strategy for more accurate predictions because availability of more blood glucose results may have provided greater opportunity for self-correction. This improved self-correction may have helped reduce the occurrence of hyperglycemia in the Game Group.

The significantly lower carbohydrate intake reported by Game Group participants checking blood glucose levels ≥ 4 times daily compared with Control Group participants checking blood

glucose levels ≥ 4 times daily may have also contributed to the lower frequency of hyperglycemia in the Game Group. While both groups could enter carbohydrate intake, only those in the Game Group could view the *DiaBetNet* graph that displayed blood glucose, insulin doses, and carbohydrate intake together to illustrate the influence of the variables upon one another and their impact upon glycemic excursions to aid in the prediction of an upcoming glucose level. The influence of carbohydrate intake on glucose levels graphically displayed may have prompted participants to alter their eating patterns with the ingestion of fewer carbohydrates. Without baseline information on carbohydrate intake, we were unable to assess change in intake during the trial. In general, carbohydrate intake significantly impacts post-prandial glycemic excursions in patients with diabetes and, in turn, contributes to overall control and HbA1C [63, 67]. Together, the increased frequency of blood glucose monitoring, reduced occurrence of hyperglycemia, and lower carbohydrate intake may have helped to maintain the distribution of HbA1C values in the Game Group compared to a trend towards worsening in the Control Group.

Computer and Internet applications can be responsive as demonstrated in a recent randomized trial of an Internet-based weight loss program in adults at risk for type 2 diabetes [68]. The addition of weekly behavioral counseling and feedback via email resulted in greater weight loss over a one year period than the Internet weight loss program without the additional feedback [68]. Other recent Internet-based interventions in adults with diabetes demonstrated equivalent efficacy of Internet-based education applications compared with face-to-face education, as well as equivalent effects of Internet-based diabetes self-management training with and without a behavioral intervention [47, 48]. The latter study highlighted the difficulties in sustaining Internet usage over time.

Through the DAILY trial we demonstrated the feasibility of a diabetes personal health system customized with a wireless PDA, data management software, and a blood glucose predictive game. We proved that such technologies can be effective in collecting high quality data over time [see Figure 16]. The portability of the PDAs and the independence from any required computing infrastructure may have supported high usability.

A weakness of our study was its brief duration. To assess if the interest expressed in the new technologies by the participants and families wanes over time, a longer study is required. The short-term nature of DAILY also requires follow-up investigations of longer duration in order to validate and document a sustained impact on monitoring adherence and glycemic control. As wearable technologies become more robust, there are an increasing number of interventions such as this that can be immediately practical to improving patient care.

In the current trial, parents of youth with diabetes appeared to appreciate the technologic support. The electronic transfer of data, in particular, may aid the parents' efforts to support diabetes management since parents are generally the ones who tabulate their child's glucose data and insulin dosing. Approaches such as ours compliment the trend to encourage family-based teamwork in the implementation of diabetes treatment programs in youth throughout childhood and adolescence [30, 45, 69]. The opportunity for these technologies to increase and maintain attention to diabetes management tasks by pediatric patients and their parents, particularly with respect to adherence to blood glucose monitoring, warrants additional study. During the training sessions of the DAILY study, we failed to emphasize enough the network game that participants could play. Due to the few patients who accessed the server to predict others' data, we have

insufficient data to remark on the impact of the DiaBetNet community game in supporting diabetes management.

Youth with diabetes and their families seem eager to try innovative approaches to optimizing control. While acceptance of some interactive technologies have been slow in general [70, 71], additional opportunities exist [72]. In time, the progress of miniature physiological sensors will likely make the accurate prediction of and reaction to glycemic excursions easier. Nonetheless, such innovations will continue to require the engagement of the patient and the family in order to reap the benefits of improvements in care on the reduction in acute and chronic adverse outcomes.

Conclusions

Through the DAILY study we can conclude that it is feasible to build personalized, wireless health management systems to assist patients live with chronic diseases. Patients are ready to accept new technologies, but motivating behavior change remains a challenging task. Our results demonstrate that a novel, predictive game can motivate greater adherence in youth with diabetes. A longer study is required to determine whether such an intervention achieves sustained results. Interactive games that present feedback on physiology in a reward-based manner can enhance users' knowledge of their condition. The task of predicting a blood glucose value with visual display of food (and insulin) levels can motivate healthier eating behaviors amongst highly motivated patients. Finally, a game such as *DiaBetNet* can impact diabetes control, with fewer hyperglycemic events, and a trend towards better overall control.

Summary

In this thesis, I set out to define my goal of creating and testing a diagnostic technology to improve patient adherence to intensive disease management. To give relevance to my stated objective, I propose a theory for how the growth of diagnostic technologies has fueled the specialization within healthcare providers, and how this has further marginalized patients. As patients are not in the center of the healthcare equation, practical innovations are critical to empower them with knowledge and insight into their diseases. This is especially relevant in chronic diseases such as diabetes where for daily management, patients become their own primary health care providers.

Today, diagnostic technologies are again poised to play an influential role in the evolution of our health system. I theorize that the momentum will come from the wearable-computing field where platforms for body-based sensors are rapidly emerging. However, it is essential that these systems engage the patient. Unless the patient perceives tangible benefits from using a system-physiological feedback, decision support, entertainment value- it will simply be another layer of burden on the patient. I invented a wireless, community-based predictive game called *DiaBetNet* and tested it in a clinical study to challenge the passive role patients play in their own care.

To understand why some patients have poor adherence to prescribed regimens, I introduce the concept of self-efficacy. Self-efficacy is the intrinsic motivation to perform. To enhance the self-efficacy within patients with a chronic disease, I describe the design of a predictive game that is based on self-regulated reinforcement. I then establish the need for such a system in the long-term management by patients with type 1 diabetes.

DiaBetNet is a game to motivate greater glucose monitoring amongst patients with diabetes. My belief was that challenging patients with the task to predict their daily glucose levels would help them build mental models of their illness. To test my theory, I ran a 4-week experiment called the DAILY trial with 40 adolescents with diabetes. As patients would wear or carry our system with them through the day, I emphasize the different approaches we took to build portable and wearable hardware components. I describe the software I designed on the PDA, network, and server for the purpose of our study.

Through this study, I showed that a portable, wireless diabetes management system is technologically feasible. We observed that patients who played *DiaBetNet* checked their glucose levels more frequently, had fewer hyperglycemic episodes, attained greater diabetes knowledge, and tended to have better glycemic control. Highly adherent patients who played *DiaBetNet* also showed healthier eating behaviors. These results are based on a short study with a small sample size, but show promise that the described technologies can have a significantly positive influence on the way patients in the future will manage their health.

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TABLES AND FIGURES

Task	Points
Check and beam glucose level	5
Enter carbohydrate level	5
Enter insulin level	5
Qualify and play <i>DiaBetNet</i>	50
Predict within 20 mg/dl of true level	50
Predict within 50 mg/dl of true level	40
Predict within 100 mg/dl of true level	30
Predict within 150 mg/dl of true level	20
Predict within 200 mg/dl of true level	10

TABLE 1. The schedule for earning individual points in *DiaBetNet*. Greater emphasis is given to qualifying and playing than for accurately predicting glucose levels.

Task	Points
Predict within 20 mg/dl of true level	5
Predict within 50 mg/dl of true level	4
Predict within 100 mg/dl of true level	3
Predict within 150 mg/dl of true level	2
Predict within 200 mg/dl of true level	1

TABLE 2. Participants earned points for their team by accurately predicting the levels of competitors (those not in their teams).

	GAME GROUP (n=19)	CONTROL GROUP (n=21)
Age (yr)	13.9 ± 2.2	13.3 ± 2.8
Duration of DM (yr)	6.4 ± 3.2	6.4 ± 3.7
Gender (% male)	58%	52%
Height (cm)	157.5 ± 12.9	153.0 ± 16.0
Weight (kg)	56.2 ± 15.0	51.6 ± 17.2
BMI (kg/m ²)	22.3 ± 3.4	21.3 ± 4.0
Total Daily Dose (units/day)	48.5 ± 18.1	49.6 ± 25.4
Insulin Treatment (%)		
Two injections/day	15.8%	9.5%
Three injections/day	42.1%	47.6%
Four injections/day	5.3%	14.3%
Pump Use	36.8%	28.6%
BG Monitoring Frequency (times/day)	4.1 ± 1.3	4.1 ± 1.2
Baseline Hemoglobin A1C (%)	7.8 ± 1.1	8.1 ± 0.9

TABLE 3. Characteristics of study participants according to group. There were no significant differences between groups.

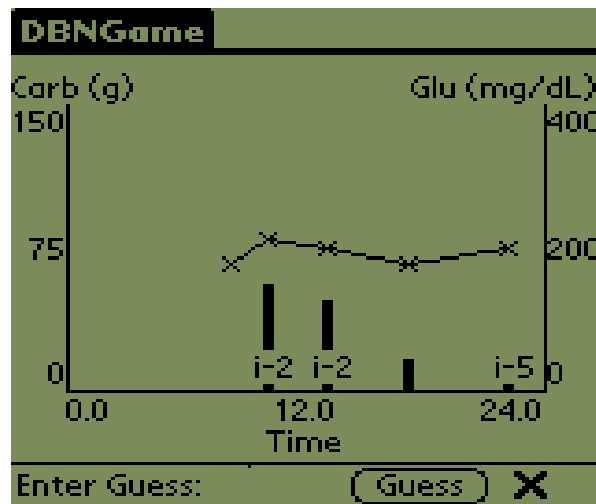


FIGURE 1. A screen from *DiaBetNet* depicting the variables from a participant in the Game Group. The user's insulin doses (noted as i-2, referring to 2 units of insulin), carbohydrates ingested (noted as bars), and glucose levels (noted by X on the line graph) are shown. Glucose values were obtained directly by transfer of data from the infrared port on the glucose monitor to the PDA.

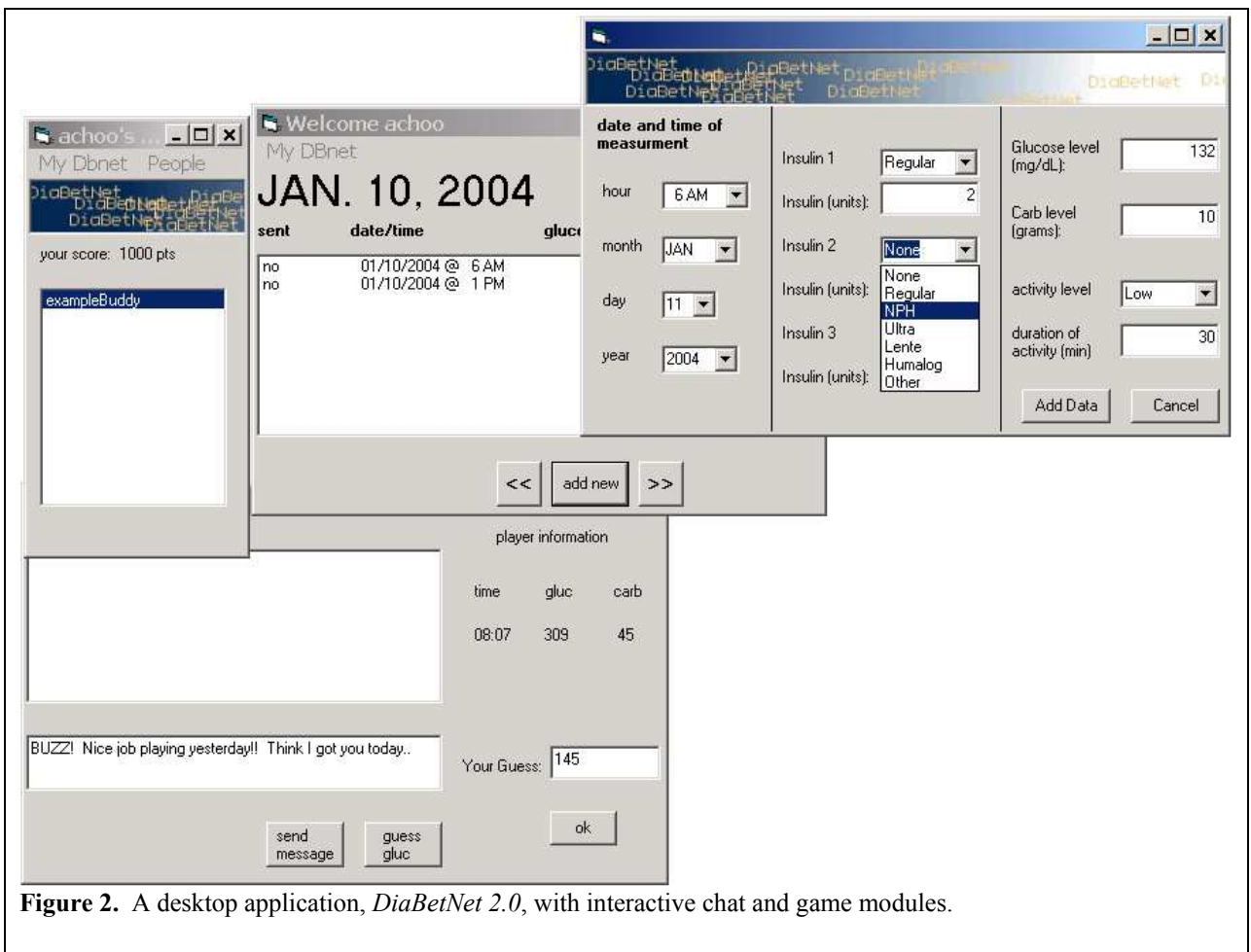


Figure 2. A desktop application, *DiaBetNet 2.0*, with interactive chat and game modules.

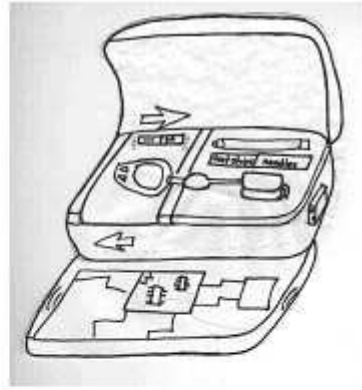
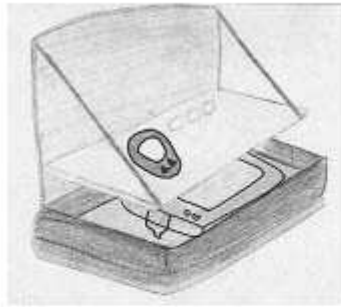


FIGURE 3. Early concept sketches of the *DiaBetNet* system. © 2001 Carla Meza



FIGURE 4. A design of a carrying case for the glucose meter and supplies. There was an external pouch for the PDA.



FIGURE 5. The challenge with using the FastTake meter was that the same slot on the meter had to be used both for glucose strips while measuring, and for the adapter when transmitting data. Shown is the final design by Meza to solve this problem.

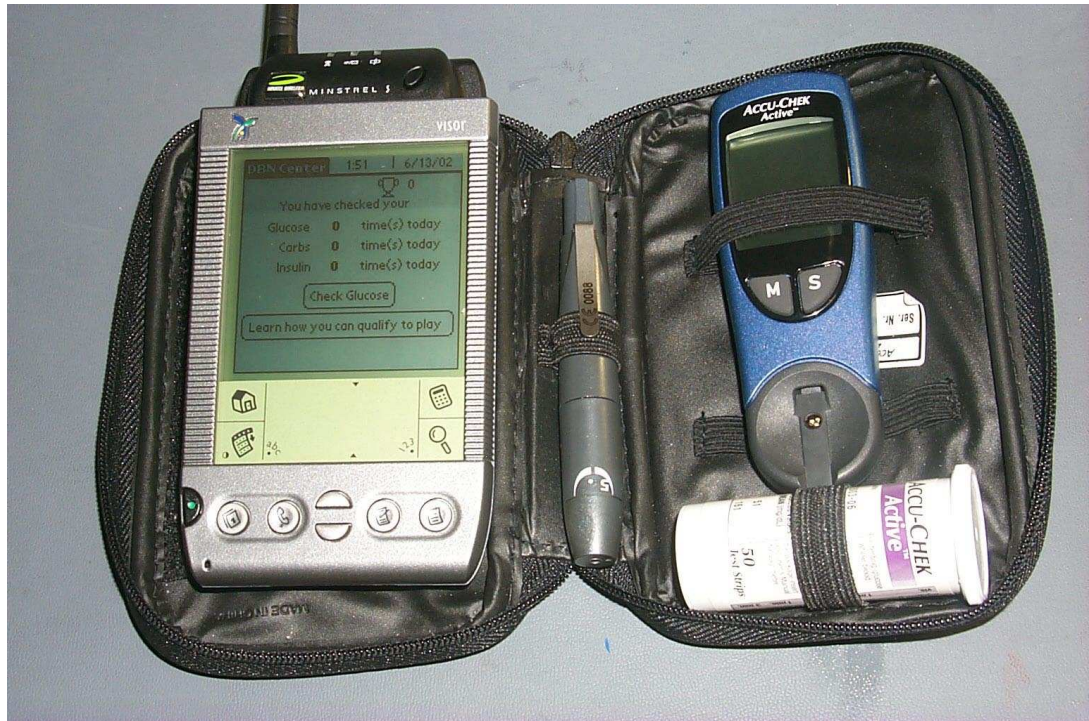


FIGURE 6. The final system used in the DAILY study with PDA, wireless modem, glucometer, lancing device, lancets, and test strips.



FIGURE 7A. A reminder such as this was displayed if patients attempted to play *DiaBetNet* or transmit their data prior to attaining the set adherence.

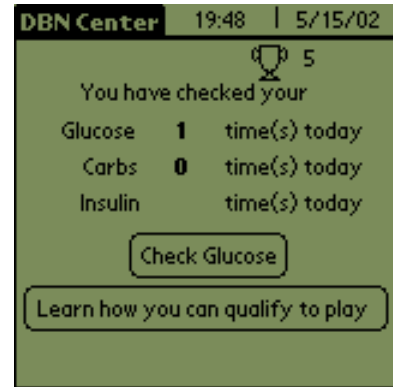


FIGURE 7B. The central interface would update after a user entered data, such as here where she checked one glucose level and earned 5 points.

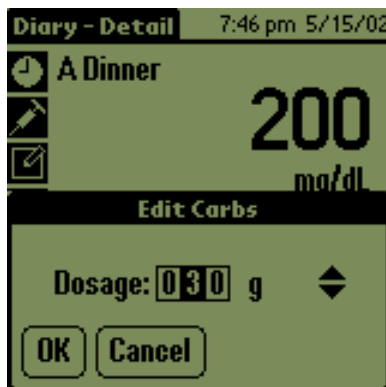


FIGURE 8. The Pocket Compass interface for carbohydrate entry.

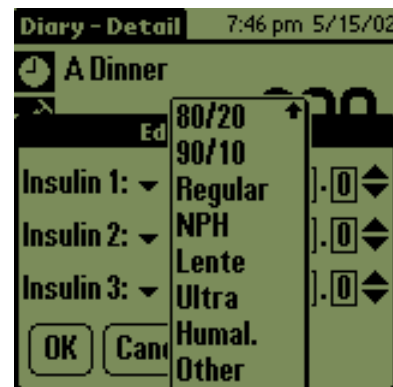


FIGURE 9. The interface for insulin entry.



FIGURE 10. The transfer protocol between meter and PDA.

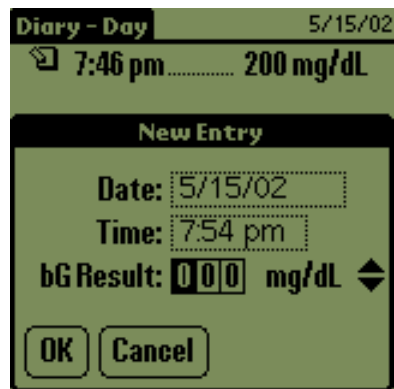


FIGURE 11. The Pocket Compass interface for blood glucose entry.

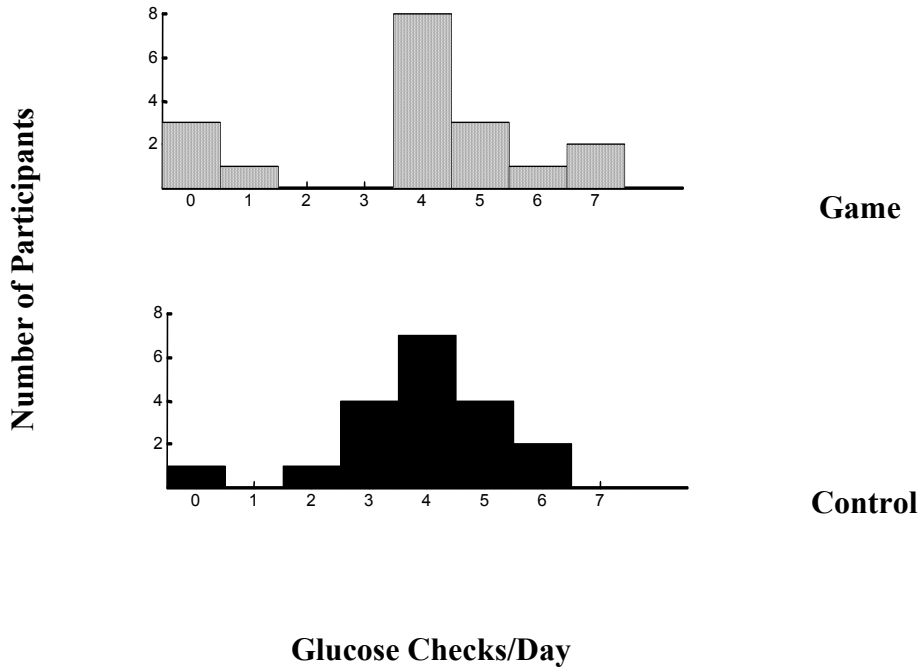


FIGURE 12. Median number of glucose values monitored daily according to Group. A histogram of the median number of glucose values checked per day in the Game and Control Groups. At study entry, six participants in the Game Group and seven participants in the Control Group checked glucose levels ≤ 3 times daily while during the trial, only four participants in the Game Group and six participants in the Control Group checked and transmitted ≤ 3 glucose results daily.

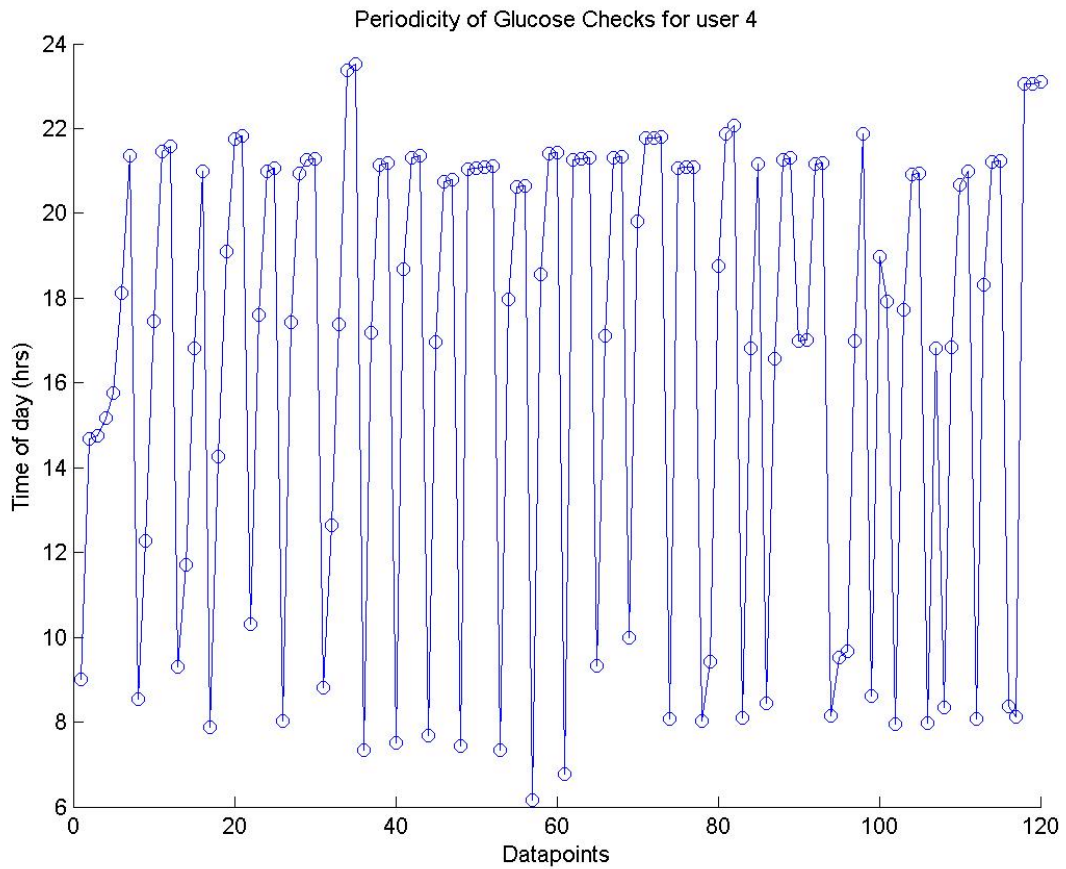
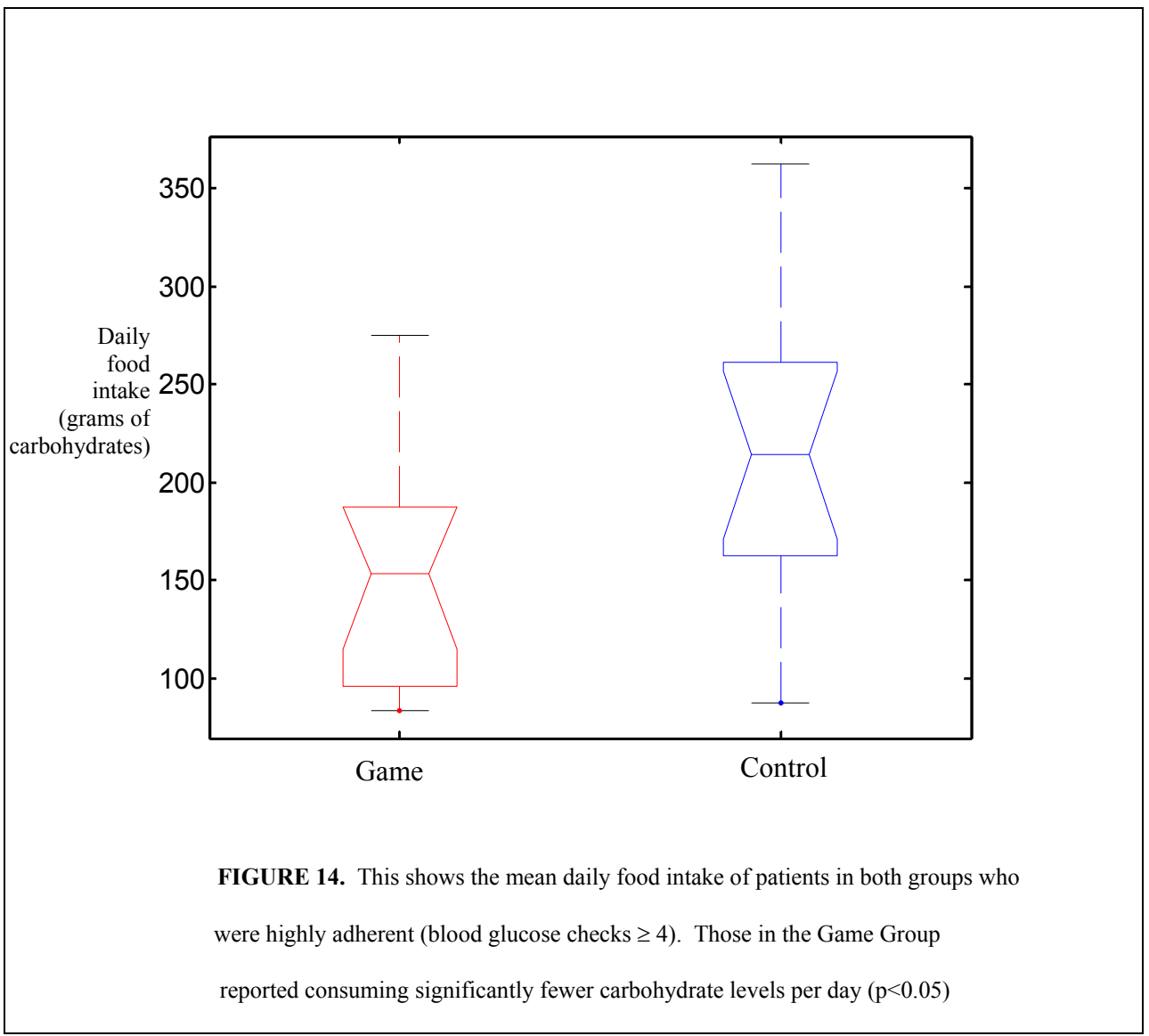


FIGURE 13. Data on the time at which user #4 checked his glucose levels. Note how this user typically performed only two measurements during the day, and then made up for this with sequential entries at night. We were not able to determine whether he actually measured his levels all of these times at night, or measured his level once and manually entered data into the PDA the other times.



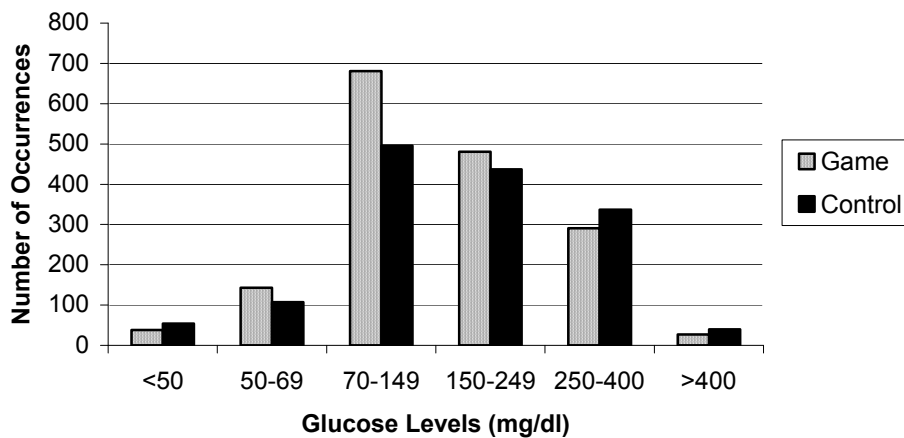


FIGURE 15. Distribution of transmitted glucose values according to Group.

Comparison of the distributions of glucose readings between the Game and Control

Groups. There was significantly greater hyperglycemia (glucose values ≥ 13.9 mmol or ≥ 250 mg/dl) among the participants in the Control Group compared with the Game

Group ($p < 0.001$). There was no difference in the rate of hypoglycemia noted by glucose

readings < 70 mg/dl or < 3.9 mmol between groups. (< 50 mg/dl or < 2.8 mmol/l; 50-69

mg/dl or 2.8-3.8 mmol/l; 70-149 mg/dl or 3.9-8.2 mmol/l; 150-249 mg/dl or 8.3-13.8

mmol/l; 250-400 mg/dl or 13.9-22.2 mmol/l; > 400 mg/dl or > 22.2 mmol/l).

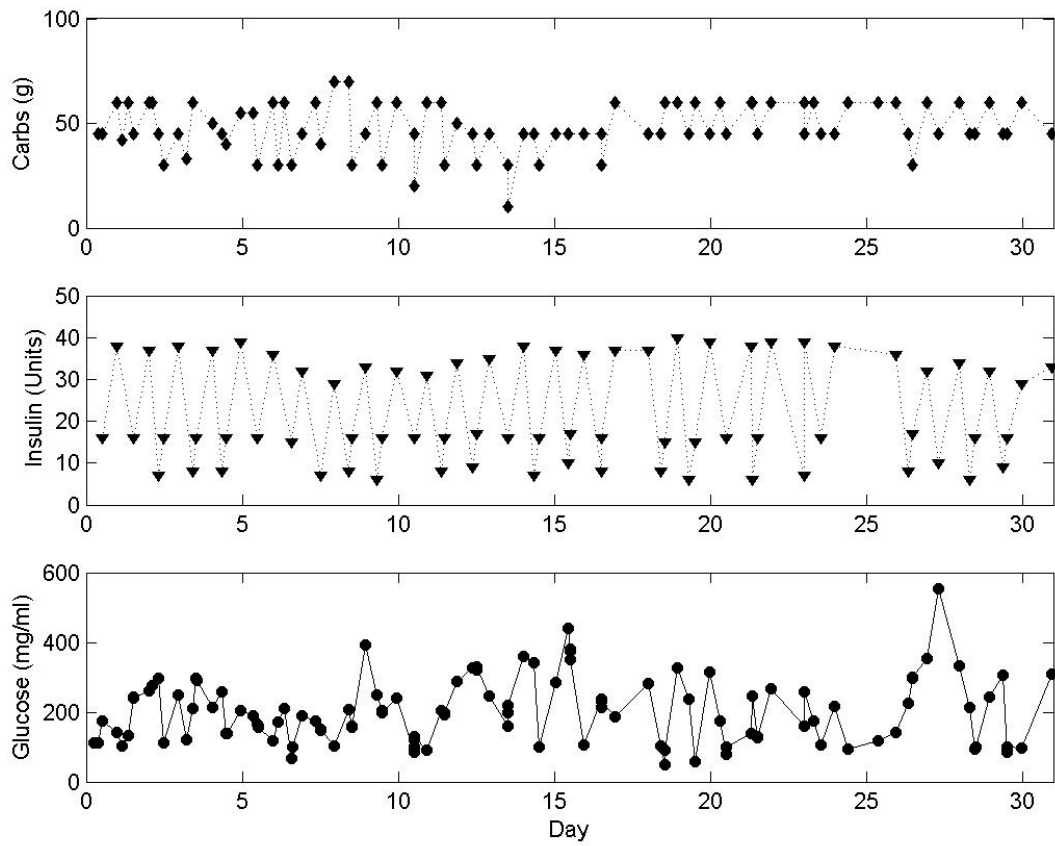


FIGURE 16. Data transmitted to the server by a representative patient in the DAILY study. This illustrates the richness of data that can be collected through a personal health system.