Computerized Automated Reminder Diabetes System (CARDS):

Using web and wireless phone technology to improve diabetes compliance

By

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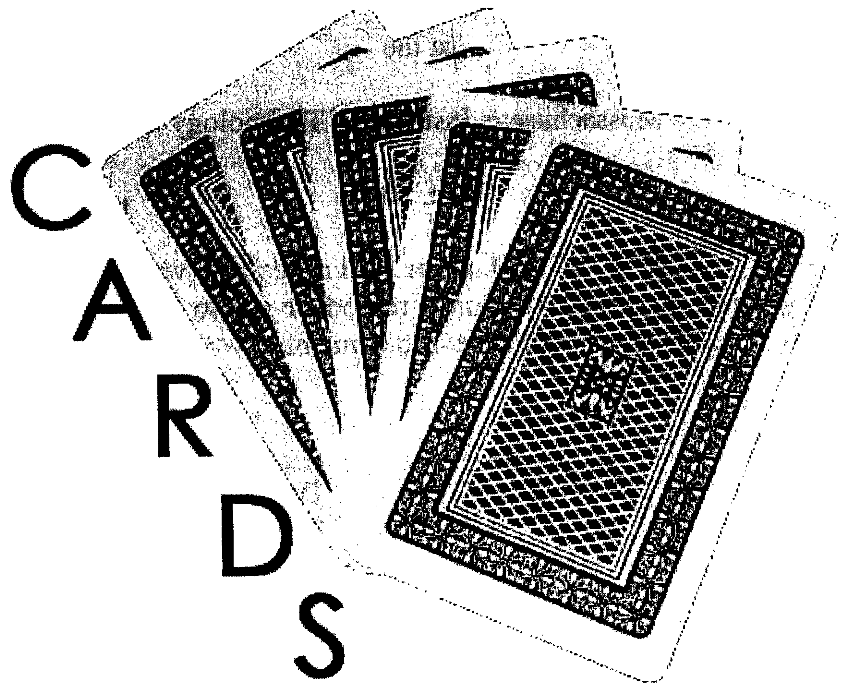
CARDS

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ABSTRACT

Automated computer technologies utilizing e-mail or SMS text messaging reminders can help overcome adherence barriers to optimal glycemic control in patients with diabetes. Text messaging on cellular phones, in particular, has become a popular communications tool among adolescents and young adults. We have created an automated computer system that provides reminders to check blood sugars by e-mail or text messaging on a cellular phone. The reminder schedule is set on a password-protected web site by the user according to his or her preferences. Users can respond to the reminders with their blood sugars, which are time and date stamped and then stored in a database. Text parsing rules allow users to override the time and date and to attach a comment as well. The blood sugar log can later be viewed and edited on the web site. Positive feedback is provided for every blood sugar entered and users also have the option to have both general and diabetes facts sent to them daily at random times via e-mail or text messaging. A randomized, controlled trial comparing e-mail with text messaging is underway at the time of this writing to test the feasibility and utility of this system in patients with diabetes. Preliminary results from 10 users (mean age 18.9 ± 2.0 years) indicate that the system appeals to a subset of the study population. Two of the ten subjects have been using the system consistently, each submitting an average of 1.3 and 2.7 blood sugars per day, respectively. Only 4 of the 51 blood sugars submitted have been via the website, suggesting that submission via e-mail or cell phone is more appealing. Final results will not be obtained until all patients have been enrolled and have completed their three month trial period.

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Section 1

Introduction and Background

1.1 Diabetes: A major public health concern

Diabetes mellitus (DM) is one of the most significant public health concerns in the United States, with more than 18 million affected individuals. It is currently the sixth leading cause of death with over 200,000 Americans dying each year due to diabetes and its complications. Diabetes is estimated to cost the U.S. more than $132 billion each year, with more than $90 billion of this attributed to direct medical costs. In fact, DM comprised over 10% of the total expenditure for health care in the United States in 2002. [1]

Unfortunately, diabetes is becoming more common. The total number of adults diagnosed with diabetes has increased by more than 60% since 1991, and estimates suggest that the incidence will double by the year 2050. In addition to the 18 million Americans already diagnosed with diabetes, another 16 million are considered to have pre-diabetes, a condition which can often lead to diabetes. In fact, it is estimated that one out of every three Americans born in the year 2000 could develop diabetes mellitus at some point in his or her life.[1]

1.2 Glucose metabolism and physiology

Diabetes is a disorder of glucose metabolism. To understand diabetes, it first helps to understand how this process is normally supposed to function. A typical person eats a wide variety of foods containing carbohydrates, fats, and proteins. Carbohydrates are made of simple and complex sugars, although both types can usually be converted into glucose, a type of sugar. Other types of sugars are lactose (milk sugar), sucrose (table sugar), and fructose (fruit sugar), all of which can be converted to glucose.

Glucose is the sugar that the body uses as its prime energy source to carry on most of its daily metabolic processes. For example, estimates suggest that the human brain requires approximately 130 grams (approximately 33 teaspoons) of glucose per day.[2]

Soon after a person eats, the levels of blood sugar often rise as the body absorbs sugars from the intestines where the food is digested. Special cells in the pancreas (an organ near the stomach), known as beta-cells, detect this rise in blood sugar and respond by secreting a hormone known as insulin. Insulin generally helps to move glucose from the blood stream, outside of cells (extracellular), to the inside of cells (intracellular) where the cells can then use the glucose as an energy source. Without this energy source the cells will essentially "starve" to death.

While some of the sugar gets used by the body immediately by moving the glucose into cells that need it, the extra glucose gets stored away in various forms throughout the body including fat in adipose tissue and glycogen in the liver. Insulin aids in this process by promoting the storage of fat and glycogen. In essence, insulin helps to lower blood sugar levels by moving the sugar into the cells where it can be used for fuel or for storing it as fat or glycogen for later use by the body.

Between meals, the cells in the body continue their normal functioning and require glucose around-the-clock. At certain times when the cells use up a lot of the sugar that is in the blood stream, the blood glucose levels can begin to fall. The pancreas then secretes a different hormone known as glucagon. Glucagon generally has the opposite effect of insulin. That is, it helps to increase blood sugar levels by promoting the breakdown of fat and glycogen back into glucose. This glucose then gets released back into the blood to increase the glucose levels and provide the fuel that the cells need to survive.

There is a fine balance between the levels of insulin and glucagon that keeps the blood glucose levels within a very small range. The body normally adjusts the levels of these hormones as needed every second of the day to keep the levels fine-tuned to maintain what is known as homeostasis, which basically means that the body is functioning appropriately. This is done without the person being aware of what is taking place, much as a person will continue to breathe even if he or she does not think about it.

When diabetes occurs, the body is no longer able to maintain its fine-tuned levels of glucose and there is a loss of homeostasis. It is then up to the patients themselves to consciously work toward trying to maintain this homeostasis, which can be a daunting task. [3]

1.3 What is diabetes?

Diabetes Mellitus is a relatively common chronic disease characterized by high levels of glucose (sugar) in the blood. The word "Diabetes" is a Greek word meaning "siphon" and is a combination of the words, "dia", meaning through, and "betes", meaning flowing. This refers to the symptom of frequent urination that many people who have DM experience. The word "Mellitus" is Latin for "honey-sweet" and refers to the sweet taste of the urine (due to high sugar levels), which was how the disease was originally diagnosed before more sophisticated tests replaced the diagnosis-by-taste test. The first mention of diabetes was found on a papyrus document almost 3,500 years old.[4 5]

There are two main types of diabetes, types 1 and 2. Type 1 diabetes was initially referred to as insulin-dependent diabetes mellitus (IDDM) or juvenile diabetes, which referred to the fact that its onset mostly occurred in children as opposed to adults. Type 2 diabetes was initially referred to as non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, because this most often occurred in adults, although this is becoming somewhat of a misnomer since type 2 DM is becoming much more common in children. Other types of diabetes are gestational diabetes, which occurs only during pregnancy, and other rare conditions such as Maturity-Onset Diabetes of Youth (MODY).[6]

Regardless of the type, all individuals with diabetes have elevation of blood glucose (BG) levels, which has been defined in various ways but includes:[7]

- Fasting BG ≥ 126 mg/dL
- BG ≥ 200 mg/dL in response to an oral glucose challenge test, where patients are fed glucose and then have their blood sugar levels tested 2 hours later
- BG ≥ 200 mg/dL in a random sample in addition to having symptoms of diabetes such as polyuria (frequent urination), polydipsia (frequent drinking), glucosuria (sugar in the urine), ketonuria (ketones in the urine), and weight loss not sought by the patient.

1.4 Type 1 diabetes mellitus

Type 1 diabetes mellitus (DM) is the most common endocrine disorder affecting children and adolescents. Approximately 1 out of every 400-500 children under the age of 20 has type 1 DM[8] and the incidence has been rising worldwide, including in the United States.[9] [10] Among racial groups in the U.S. the incidence of type 1 DM in Hispanics is among the highest. Also, the incidence in African-American populations has been rising sharply.[11] While type 1 DM may present at any age, the median age range for the onset is between 7 and 15 years.[12]

Most, but not all, cases of type 1 DM experience autoimmune destruction of the beta-cells of the pancreas. Autoimmune means that the body's own immune system, which normally fights off infections, malfunctions and begins to attack the body itself instead of attacking invading organisms. What causes the autoimmune destruction of pancreatic beta-cells in type 1 DM is unknown, although it is thought to be multi-factorial, meaning that many possible causes might exist. Genetics, as well as environmental factors such as viruses,[13] may play a role in determining who develops type 1 DM.

Whatever the cause, the beta-cells are the cells that produce insulin and, when they are destroyed, the body is no longer able to produce its own (endogenous) insulin. When this happens the levels of glucose in the blood rise. Even though there is plenty of glucose in the blood, the cells have no way of moving the glucose inside (a process normally driven by insulin) where it can be used and they slowly starve. Additionally, since insulin is required to store extra glucose as fat, the person becomes unable to store fat and beings to lose weight.

The extra glucose in the blood stream is more than the kidney can reabsorb and, as a result, a lot of it can eventually be lost in the urine. In fact, patients with high blood glucose levels often urinate more since the extra glucose tends to pull out more water with it, leaving the patients very thirsty and drinking often.

There is no known cure for type 1 DM and, once an individual has type 1 diabetes, for the rest of the person's life, he or she must give him/herself exogenous (made outside the body) insulin injections to provide a source of insulin. Without these injections, patients with type 1 DM will quickly become comatose and die.

1.5 Type 2 diabetes mellitus

Type 2 diabetes mellitus is the most common form of diabetes among the general population, comprising approximately 90-95% of all cases, and affects adults more than children. Type 2 DM occurs more often in certain ethnic populations such as African Americans, American Indians, Hispanic/Latinos, and Asian Americans/Pacific Islanders.[14]

Type 2 DM also occurs more often with older age and especially with obesity. Unfortunately, obesity is now considered to be an epidemic in the United States, and the proportion of obese individuals has been rising, with a concordant increase in type 2 DM.[15] Even children are now being affected more by what was once considered "adult-onset" diabetes. Over the last 4 decades, the prevalence of overweight children ages 6-11 has nearly quadrupled and that of adolescents ages 12-19 has tripled.[16] With this increase in obesity has come a concordant increase in type 2 DM. Whereas only 1-2% of children with diabetes used to have type 2 DM, that number is now estimated to be 8-45%.[17]

While type 1 DM is usually caused by a lack of sufficient insulin, type 2 DM is usually caused by what is referred to as *insulin resistance*. This means that the body can actually make insulin but for some as yet unknown reason, the body is unable to respond appropriately to the insulin. It is almost as if the cells which need the insulin can't "see" that it is around. Once again this leads to higher-than-normal levels of blood glucose, although it is usually not as severe as type 1 DM--patients with type 2 DM often are able to utilize at least some of their glucose and don't typically experience the weight loss that patients with type 1 DM might have.

In fact, weight loss is one way to actually increase insulin sensitivity and decrease insulin resistance, in essence reversing the diabetes. Only 40% of patients with type 2 DM require insulin injections, whereas the rest can try a variety of oral medications (used to increase insulin sensitivity), weight loss, exercise, and other lifestyle modifications.[14]

Type 2 DM may not have manifestations as severe as type 1 DM, and many cases can be missed without proper testing.[18] In fact, between 1/5 and 1/2 of patients already have complications at the time of diagnosis.[19] It should be noted that most patients with type 2 DM who do not treat themselves appropriately will not suffer from immediate negative consequences but rather will suffer from long-term complications instead.

1.6 Complications of diabetes

Complications of diabetes can generally be categorized into short-term complications and long-term complications. Short-term complications are generally more noticeable, whereas the long-term complication are often more silent in their onset even though both types can lead so serious morbidity and mortality. Additionally, most long-term complications only become apparent in adulthood, which makes it very hard for children to see them as being important to worry about.

Many of the long-term complications of diabetes are a direct result of the toxic effects of the elevated levels of sugar in the blood stream, since the elevated sugar levels impact almost every part of the body. About two-thirds of deaths due to diabetes are caused by heart disease, which occurs in diabetic patients up to 4 times more often than those without diabetes. Additionally the risk of a stroke is between 2 and 4 times higher than the general population.

Adults with diabetes also often suffer from kidney disease. In fact, the most common cause of end-stage renal disease is diabetes. Over 140,000 people with diabetes-induced end-stage renal disease were on either chronic kidney dialysis or with a kidney transplant as of 2001. Kidney disease often leads to high blood pressure, which is why almost 3/4 of adults with diabetes have elevated blood pressure.

Cataracts occur more commonly in diabetic patients compared to the general population. Additionally, in the United States, diabetes is the largest cause of blindness among adults between the ages of 20-74 years, accounting for nearly 12,000 to 24,000 new cases of blindness annually. The blindness is usually due to damage to the retina itself (i.e. diabetic retinopathy) and not from cataracts.

Diabetic patients suffer from diseases of the nervous system as well. They can suffer from carpal tunnel syndrome and have impaired sensation of pain response in their extremities. Because they can develop numbness in their extremities, they often have trouble determining if they have suffered from an injury, especially in their feet. This, coupled with the fact that they often have poor blood flow to their extremities, can lead to an increased number of infections and even gangrene. In fact, a major cause of lower-extremity amputations is attributable to problems associated with diabetes. Over 80,000 lower-limb amputations were performed on diabetic patients in the U.S. between 2000 and 2001.

Individuals with diabetes suffer from more infections than the general population. They have a greater likelihood of dying from infections such as influenza or pneumonia. They suffer from increased bladder or kidney infections, and even small cuts on places such as the foot can lead to gangrene as discussed above. They suffer from more periodontal (gum) disease too, and even young adults with diabetes have twice the risk of periodontal disease as those without.[20]

Diabetes in pregnancy can pose serious harm to an unborn infant. Uncontrolled diabetes can cause birth defects in up to 10% of pregnancies (2-3 times higher than the general population) and spontaneous abortions in up to one-fifth of pregnancies. Risks are greater for the mother as well. Compared to pregnant women without diabetes, those with the disease have a greater risk of pyelonephritis (kidney infection), vaginitis, and even pregnancy-induced hypertension.[21]

Short term complications can also be very severe and are often more noticeable than the slow progression of the long-term complications. Additionally, they often occur more often in those persons who require insulin injections in order to appropriately manage their diabetes.

If too much insulin is given, which can occur if the incorrect amount is measured in a syringe, it is possible that the insulin will cause blood sugars levels to fall too low and too quickly. When this happens, the brain may not get a sufficient supply of energy and the individual could potentially lose consciousness and collapse. Severe hypoglycemia (low blood sugar) can lead to coma, brain damage, and death. Less severe bouts of hypoglycemia are also thought to cause problems such as impairments of cognition, memory, and attention span.[22]

If not enough insulin is administered (or none at all is given) in a patient who is insulin-dependent, then severe consequences can also rapidly occur such as diabetic ketoacidosis (DKA) and Hyperglycemic Hyperosmolar Nonketotic Syndrome (HHNS). These conditions can lead to severe dehydration, acidic blood, disruption of normal metabolic processes, coma, seizures, pancreatitis, heart attacks, infections, and even death. DKA occurs at a rate of about 5-8 episodes per 1000 diabetic patients per year and the overall mortality rate for patients who develop DKA ranges from 2 to 10%.[23]

It is unfortunate that any of these problems occur with such frequency, since many of the complications and hospitalizations are considered to be avoidable with proper care and management.[24] The problem is that management is a life-long endeavor that often requires careful monitoring and adherence multiple times a day.

1.7 Typical diabetes management for patients requiring insulin

Virtually all patients with type 1 diabetes mellitus (DM) and 40% of patients with type 2 DM require insulin injections to keep their blood sugar levels within the normal range. Without these injections they can suffer from both the acute and chronic complications of diabetes outlined above. Insulin can't be given in the form of a simple pill like other medications because, being a hormone, it is made of proteins which are typically destroyed by normal digestive processes.[25] While researches have been searching for effective, viable routes for delivering insulin (such as orally[26] or inhaled[27]), patients who require insulin still need to obtain it in the form of subcutaneous (into the skin) injections.

Administering insulin by injection requires knowledge and skill. Patients must understand their correct dose of insulin, which can change throughout the day. In addition, several forms of insulin exist such as porcine (derived from pigs) and human recombinant (derived from humans).[28] There are short-acting and long-acting forms of insulin, in addition to intermediate-acting forms. Sometimes individuals need a combination of two forms in one injection. They must know how to mix and measure insulin appropriately. They must know how to inject it and where on the body to inject it, and they must vary the areas in which they inject it. They must know how to properly clean their skin and handle the syringe to maintain sterility before injecting the insulin. And, since every injection involves a needle in the skin, this process, which often needs to be repeated multiple times a day, can be painful.[29]

Another component of the self-care strategy in diabetes is the measuring and recording of blood glucose (sugar) values. Such self-monitoring of blood glucose (SMBG) has been shown to correlate with improved glycemic (blood sugar) control.[30] Self-monitoring typically involves obtaining a small droplet of blood with which to test for the levels of sugars using a small hand-held meter. To obtain the blood, a small lancet is used to prick the finger which can also be painful. Other methods for obtaining the blood sugar levels are being sought, such as testing the forearm[31] instead of the finger and even a watch which uses electrical impulses to test for blood sugar levels without the use of any needles,[32] but pricking the finger for a drop of blood still remains the standard of care today.

Blood sugars are kept in a diary, most often a simple paper-based log book, but also in the form of a blood glucose meter's electronic memory. The blood sugar numbers obtained through testing are important because the correct dose of insulin often depends on the blood sugar level. If the blood sugar level is very low, then no insulin should be given--in fact, the individual might even have to eat or drink something or take a small glucose tablet to raise his or her blood sugar. If the blood sugar is extremely high, the individual might need to give him/herself extra insulin to bring the level back to normal. The correct dosage is usually determined by what is known as a "sliding scale", which basically dictates how much extra insulin should be given for a certain increase over normal in the blood sugar level.

Each person's insulin dose and sliding scale depends on his/her own particular physiology, but can be estimated based on that person's past history of insulin doses and resulting blood sugar levels. The exact dosing schedule and amounts are usually determined in consultation with a physician, upon reviewing the patient's blood sugar numbers. They are typically reviewed and discussed, allowing for informed discussions and for planning further modifications to that patient's specific insulin and/or diet regimen. Thus, it is important that such logs, or diaries, are reliable and accurate.[33]

Other aspects of diabetes care with which patients must concern themselves include understanding nutrition and meal planning, monitoring themselves for signs of problems such as illnesses and other types of infections, coordinating care with specialists such as endocrinologists and ophthalmologists, and knowing how to recognize and treat hypoglycemia (low blood sugars). Aside from needing to ingest more sugar rapidly, they and their family and close friends also need to know how to administer glucagon, which helps to quickly bring blood sugar levels back up to a safe level.

The tasks outlined above are just some of the many to which people with diabetes must adhere to in order to maintain their health. This can cause great stress for both patients and their families. A few quotes from patients and families with diabetes demonstrate this well:

> "I feel I revolve my life around my diabetes and always know what impact my food choices make on my health. I usually care quite a bit but sometimes I give up and eat whatever I want and end up with high sugar. Then it starts all over again the following day." [34]

> "It [diabetes] is a 24 hour a day commitment--I call it my second unpaid job--and not everyone is supportive." [35]

> "It's been more than a year since our 15-year-old daughter...was diagnosed with juvenile (type 1) diabetes. Fifteen months—that's 1,445 insulin injections, and at least 2,910 finger pricks to test her blood sugar levels...Living with diabetes is a pain. It's 24/7, no weekends off. It has forced our family to understand the body in a way that most people never will. Ask anyone what the pancreas does—chances are he won't have a clue. But we know." [36]

Clearly, diabetes management is complex. It forces patients and their families to accept a high level of daily responsibility, with potentially severe consequences if these tasks are ignored. The many elements of the daily routine to which people with diabetes must attend can be overwhelming and can change how they view themselves. This is perhaps no more evident than in the adolescent/young adult population.

1.8 Psychosocial aspects of diabetes in the adolescent/young adult

Adolescents with diabetes represent one of the most challenging age groups to effectively treat. Older adolescents are generally regarded as having the worst metabolic control among any age group.[37] Among the pediatric population with type 1 diabetes, adolescents generally have the highest rates of hospital readmissions[38] and recent estimates suggest that diabetics ages 15-19 have a 1.5 to 9 times higher risk of death (based on the standard mortality ratio) compared to the general age-matched population.[39 40] According to a recent study, adolescent diabetic females were at highest risk for developing diabetic ketoacidosis (DKA), which, although potentially life-threatening, is considered to be a completely avoidable complication.[41] Additionally, about half of a group in a study survey reported having fear of acute problems such as hypoglycemia,[42] which can result in a loss of consciousness (i.e. "passing out").

The stresses of such fears and consequences are likely to have an impact on how an adolescent might view him/herself in the context of the patient's diabetes and how the person carries on with his/her life. For example, fear of hypoglycemia has been thought to lead to both overeating and administering improperly low insulin doses.[43] A study of 105 young adults with type 1 diabetes found that all of them reported that hypoglycemia had an impact on their lifestyle.[44]

The chronic nature of diabetes can affect how adolescents think about themselves in terms of independence, body integrity, and a desire to be like one's peers.[45 46] Furthermore, it affects how they approach other typical adolescent issues such as school, dating, eating, work, sports, and travel, which can be especially troubling to teens and can be reflected in poor management of their diabetes.[47] According to a study of individuals aged 16-32 years, compared to healthy individuals, those with a chronic disease such as diabetes reported higher rates of depression and lower self-esteem.[48] It has also been suggested that diabetics might experience greater than normal amounts of "social insularity".[47] Unfortunately, this can lead to worse compliance with their diabetes regimen, especially since an adolescent's self-concept is correlated with better health, especially in females.[49]

The attention that must be devoted to the daily details of their treatment serves as a constant reminder to adolescent diabetic that they are different and that their bodies are not fully functional.[45 50] A study of children ages 13-17 showed that almost 40% of the diabetics had a poor sense of "normality". Additionally, half of the study subjects felt that their disease was a threat to their social well-being.[42] Even those adolescents who are able to control their diabetes well often report that they find the disease difficult to manage and perceive the disease as having a negative impact on their life.[51]

The ability of diabetic patients to cope with their disease is correlated with how well they are able to control it.[52] Diabetics who have an increased sense of normality and feel that their disease is not a threat to their emotional well-being exhibit greater compliance than those who have a more dismal outlook.[42] A recent study of adolescent diabetic females found that a lower overall sense of control of one's own body was related to a lower degree of metabolic control[53] and a study from 1998 reported a positive correlation between metabolic control and self-perceived quality of life for adolescents with diabetes.[54]

Additionally, adolescents are at a transition point in their lives and are still developing their understanding of diabetes. They are starting to become aware of their own limitations, the long-term outlook of their disease, and the risks that could lead to serious morbidity or even mortality.[45] They are also at a time in their lives when they are likely to attain more independence to take care of their disorder as they seek greater autonomy or as others impose greater responsibility on them, even though continued parental involvement has been shown to be of benefit to diabetes control.[55] This transition period can create added stresses and conflicts in a family.[56]

The transition period is relevant because an adolescent's understanding of the complexity of the disease and its consequences is not fully developed. For example, ten percent of respondents in a survey did not think their evening insulin shot was necessary.[57] Another survey of 30 adolescent and young adults found that while all of them thought they had moderately good or good control, about one-third of them actually did not, based on Hemoglobin A1c levels, a measure of diabetes control, suggesting that they may not understand their disease as well as they should.[58] Unfortunately, studies have shown that the transition from childhood to adolescence is often accompanied by a dramatic decline in metabolic control.[59]

1.9 Compliance issues

Compliance with one's diabetes regimen and psychosocial issued related to diabetes are so intertwined that it is difficult to discuss one topic without the other. Some researchers don't even like to use the word "compliance" but rather choose "adherence" since compliance suggests doing what one is told versus adherence which suggests doing something in concordance with the health care team's recommendations, a more benign concept. This point is noted simply to emphasize how important the psychosocial factors are in diabetes.[60] Thus, it is perhaps not surprising that because adolescents with diabetes deal with so many issues psychologically and emotionally, their compliance would suffer.

Studies have shown that adolescents are less compliant with their regimen than younger children.[61] A study assessing the adherence to a proper diet in patients with type 1 diabetes showed adolescents to have the worst compliance among any age group.[62] Another study of diabetic patients ages 11-19 found that 80% reported not eating appropriately, including over 50% who reported missing meals and snacks.[57] Even insulin injections, required to sustain life in type 1 diabetes, were shown to be administered at incorrect times[63] or in inadequate doses in about 30% of patients (mean age of 16 years).[64]

However, even those adolescents who are compliant still often have worse control than younger children. Adolescents undergoing puberty experience physiologic changes that can affect hormone levels, growth, metabolism, and even insulin resistance. As a result, even patients who are highly motivated and dedicated to maintaining tight control over their diabetes may have difficulty during this period.[55]

Compliance, like most aspects of the disease, is a multifaceted issue. A study that explored the reasons for not giving shots or doing blood tests found that most patients reported that they "just forgot". In addition, 5% said they did not want to give themselves shots in front of friends.[57] It has been suggested that since adolescents are very sensitive to peer pressure and don't want to be different, they may not appropriately assume the responsibility that is required of them.[38] For example, adolescents may not follow their proper diet when eating among peers.[65] Additionally, adolescents might want to avoid potentially embarrassing situations resulting from hypoglycemia (such as passing out) and thus may be more willing to risk the slowly-progressive, long-term consequences of hyperglycemia (high blood sugar) as opposed to the immediate, attention-grabbing consequence of low blood sugar.[58]

Keeping accurate logs of blood glucose measurements is often done by parents of younger children but typically becomes the responsibility of the patients themselves around adolescence.[30] It is just at this transition time that a precipitous drop occurs in the frequency of blood glucose monitoring. Many patients, especially adolescents, don't like to keep such records using the logbook, even though logs aid in the physician's decision making process, can help patients understand the correlation between their actions and the resulting blood glucose, and may also provide positive reinforcement.[66] Of course, sometime logbooks are not kept simply because blood sugars are not being checked. A survey of young adult type 1 diabetics found that almost a third did not test their blood sugars daily, and 12% never tested at all.[44]

Unfortunately, blood glucose diaries, even when kept, are often unreliable. One study found that over half of the diaries kept by patients were deemed to be clinically inaccurate.[67] Even highly-motivated, pregnant, diabetic women were found to be inconsistent with their record keeping. A study which compared their written logbooks with actual results that were secretly being recorded by their glucose meters found that the reliability of their written measurement was very low, and was less reliable for the more poorly controlled patients.[68] In one of these studies, 97% of the patients failed to record values in their logbooks which had been recorded by the glucose meter.[33]

This failure to keep reliable records may be due to the fact that patients and even physicians often label abnormal values as "bad" and normal values as "good", causing the patient to try to please the physician during the encounter and avoid being blamed for the values.[69] This desire to be viewed in a positive light is thought to lead to such alterations of their data, which is referred to as a "self-preservation bias".[70] Indeed, similar studies of men and women have shown that the changes that patients make to their glucose values usually involve omitting abnormally high or low values and lowering high values to a more normal range.[71] While studies have generally focused on adults, it is reasonable to conclude that adolescents would have even less reliable recorded values.

Given the complexity of the disease, the psychosocial issues, and the problems of maintaining adequate compliance to a regimen which must be followed every day, it is clear that there is no simple answer or strategy which will completely solve the problems that patients with diabetes face. Nevertheless, multiple strategies have been explored and developed to improve compliance for patients with diabetes.

1.10 General strategies for improving compliance for patients with diabetes

Diabetes is a chronic disease with no known cure, resulting in potentially severe psychological and medical morbidity. Unfortunately, even though strict adherence has been shown to be effective in controlling or reducing both short and long-term complications,[72] strategies to increase adherence are not always utilized or are not as effective as they should be. Diabetes has thus been termed a "wasteful" disease because the potential to reduce preventable illness, disability, and their associated costs still remains to be fully realized.[73]

There is no single strategy that has been completely effective in controlling diabetes or any chronic illness.[74] In fact, a wide range of strategies is necessary, especially to appropriately target different age groups. Currently few convincing studies exist that demonstrate which methods have the greatest impact on diabetes management.

Increased involvement from health care professionals, counselors, employers and family are all valid strategies to reduce the devastating consequences of diabetes.[75] However, these interactions are highly labor-intensive and expensive. In addition, the interactions a diabetic has with others who may provide such support can be limited, or at least underutilized, leading to the need for diabetics to control their disease on their own most of the time anyway. For example, a recent study found that one-third of diabetic patients did not keep their appointments with their dieticians.[76] Another study which monitored usage of a diabetes education program found that just slightly more than 20% of the diabetic subjects had actually utilized the program.[77] However, the involvement of a healthcare team is still important and even the simple act of making the patient aware that the data are being recorded and will be subject to evaluation and verification can improve compliance.[70] As one New York Times article stated, "People are more likely to change their behavior...when they know someone is watching them." [78]

Adolescents, with their multitude of complex psychosocial issues, are difficult to appropriately target. In one recent survey of health care professionals, over 70% of physicians and nurses felt that adolescent behaviors and/or psychiatric disorders were a barrier to proper treatment of type 2 diabetes.[79] While it may not be possible to change the behavior of adolescents to improve compliance, it is possible to reduce existing barriers to compliance as much as possible. The more one must change his/her lifestyle to adhere to regimens, the more likely compliance is to suffer. Making sure that health regimens are designed to accommodate the lifestyle of adolescents has been suggested as a way to improve compliance.[42]

Monitoring devices, such as those that can assist in recording blood sugars, are an important component of diabetes self-management, but care must be taken to ensure that they are designed well. A review article using concepts of behavioral medicine described various strategies to improve self-monitoring compliance. Examples of the criteria, as outlined in the review, included: (1) The recordings should be brief and non-intrusive; (2) the procedure should be simple and straightforward; (3) the monitoring devices should be convenient or easily accessible; and (4) monitoring devices should be acceptable to the patient.[70]

Positive feedback for adolescents has also been shown to have an impact in diabetes care, and is more effective than focusing on the negative consequences of non-compliance.[80] A small study of diabetic children found an increase in self-blood glucose monitoring from 7 to 81% by having the parents offer positive reinforcement for testing.[81] Another study of adolescent diabetics also found an increase in blood glucose monitoring when given positive reinforcement.[82]

It is important that good behaviors be continued through adolescence because studies have demonstrated that those with poor adjustment to their disease in early adolescence were likely to continue that into adulthood.[47] Even more importantly, even small, low-cost interventions can have a positive impact on both metabolic complications and hospital/ER use.[83] Thus, any improvement that can be achieved for the adolescent diabetic has the potential for long-term improvement in quality of life.[84]

A growing trend in chronic disease management has been to develop disease management programs as a means to improve the outcomes for patients. Programs that are most likely to be successful have been found to involve complex interventions involving a combination of techniques such as patient education, patient reminders (designed to prompt the patient to perform a specific task related to management of his/her disease), self-monitoring, and reinforcement.[85] [86] In fact, among programs providing reminders to patients with a chronic disease, those involving diabetics were among the most successful.[85]

1.11 Self-management strategies for the home: Desktop Computers

Until a definitive cure for diabetes is found, new methods will continuously need to be developed to help patients manage their disease more effectively. As the use by society of technologies ranging from the Internet to mobile phones becomes increasingly common, the application of such technologies to improving diabetes management will steadily increase. Diabetes, due to its chronic and complex nature, provides multiple pathways for technology development.[87] Furthermore, studies suggest that computer-patient interactions can lead to improved diabetes management.[88] As a result, the use of technology to control diabetes continues to be actively explored, especially as self-management outside of the standard medical setting is increasingly emphasized.[89]

There currently exist multiple web sites dealing with virtually every aspect of diabetes.[90] Some passively educate the public[91] while others are more interactive and provide services such as chat rooms for diabetics to interact with one another.[92] Still others provide interactive games such as one which tests the user's knowledge of diabetes trivia.[93]

Web sites can have disadvantages. While multiple, reliable sources of information exist, such as that offered by the Centers for Disease Control,[94] many other sources have dubious reliability, containing information that may not be complete or wholly accurate.[95] The design of web sites can also have an impact on usability. One such site, used in conjunction with the IDEATel project (discussed below), was described as being cluttered, having poor organization and confusing links. Too much text was also cited as a problem in the design.[96]

A study in rural Canada, using computers which transferred blood glucose data to a medical center via modem once per week, found that the group using the computers had a significant decrease in Hemoglobin A1c levels compared to the control group. The study concluded that those using the computers became more motivated to control blood glucose levels and even performed extra glucose measurements. In addition, cost savings were noted as compared to the standard method for intervention by health care providers.[97]

Columbia University, through its biomedical informatics department, has begun a large initiative to develop home monitoring technology for diabetes, known as Informatics for Diabetes Education and Telemedicine (IDEATel). IDEATel is primarily a web-based service requiring use of a computer at home. It has a lot of functionality, including videoconferencing and the electronic transmission of blood pressure measurements. The focus target group of the study is elderly patients 55 years or older, so no adolescents have been included.[98] [99] [100]

As the IDEATel project illustrates, although there has been a drive to develop applications for diabetics, those currently being developed are not necessarily being designed to target the difficult-to-reach adolescent population. In fact, some technologies may make it to the adolescent slower than to other age groups, partly depending on the comfort levels of their treating doctors. Current programmable insulin pumps, it has been suggested, may not be appropriate for many adolescents due to the wide variability in many aspects of their lives, such as eating, emotional status, and activity level.[101]

Nevertheless, there has been some success in using computer-assisted techniques to help adolescents. A recent study using a system with some components similar to the IDEATel project, such as web access and video transferred over the Internet, was undertaken with pediatric asthmatic patients. Videos of them using their inhalers were transmitted biweekly and education was provided as well. The system was well accepted by the participants.[102]

For patients with diabetes, work has been done to involve them with computerized systems as well. A study from 1989 compared groups using traditional logbooks to a group using a glucose meter that interfaced with a computer. The group using the glucose meters reported an increase in understanding about their disease, an increased perception of the importance of testing, and an increased perception of the quality of interaction with their physician.[103] A more recent study had 30 adolescents with type 1 diabetes transmit their blood glucose values via modem to a health care team instead of going in for a clinic visit. Compared to similar adolescents who continued their normal routine, including clinic visits, those who transferred their data by modem in lieu of a face-to-face encounter did not have any significant difference in outcomes.[104]

A study of 10 patients with type 1 diabetes allowed them to enter blood sugars daily into their computers and some also received advice on how to adjust their insulin dose based on a computer program available over the Internet. Compared to those that adjusted their insulin dose without the aid of the program, those using the program had similar improvements in blood glucose control, but only those using the program showed an improvement in their knowledge of the disease. Patients using the computer program reported a positive experience and a desire to continue using it.[105]

1.12 Self-management strategies for the home: Telephones

Desktop computers are not the only medium used to improve chronic disease self-management. Telephones have also been used for health-care related activities for decades.

Simple contact by telephone has been shown to improve compliance for events such as patient visits. A study done to promote screening mammography which involved people making directed phone calls to appropriate women found that more women had mammography than those who did not receive calls and also reported that such an intervention was well-accepted.[106]

Similar improvements in screening rates have been shown with telephone calls directed at patients eligible for endoscopy,[107] and telephone reminders for patients with diabetes have been shown to increase patient visits as well.[108] Even adolescents increase their visits to physicians when prompted with telephone reminders.[109] [110] Such phone calls, while effective for bringing patients into a clinic, are still labor-intensive in that people are generally making the calls and trying to reach and talk to a person on the other end.

To automate this process more, a system referred to as computer automated telephony (CAT) has been developed in which a computer can automatically make phone calls to patients. While less personal, this can potentially reach a greater number of people and be more cost-effective as well. Such systems can provide what have been referred to as telephone-delivered interventions (TDIs). Systems using TDIs have been divided into two broad categories: (1) reactive, meaning a user initiates a call and the system reacts to what the user enters, and (2) proactive, in which the system itself initiates the call.[111]

These types of systems have been shown to increase show-rates for patient appointments and can even increase patient satisfaction based on the services that can be provided.[112] Although providing reminders has been a major use for CAT, this technology has been used in multiple domains of medicine to provide numerous types of services.[113] One use has been for providing information on various health-related issues (such a herbal medicine, asthma, and lower back pain) by providing small "bites" of information in response to user requests generated by pressing numbers on the keypad. The system is somewhat interactive in that it "speaks" to the user and the user then responds by pressing an appropriate number,[114] which has been referred to as an interactive voice response (IVR) system.[115]

While much work has been done using these systems for appointment reminders (which are not very frequent), and interactive systems to provide useful health information, much less has been done for chronic disease management such as diabetes care. One group used what they referred to as an automated voice messaging (AVM) system, which was part of an automated telephone disease management (ATDM) study, to provide calls to patients with diabetes. Each patient received an average of four calls during the study period and was asked to respond via the keypad to various questions about symptoms, glucose monitoring, and diet. Virtually all (98%) of the patients felt that the calls were helpful and slight more than 3/4 (77%) felt that the calls would improve the quality of their care.[116]

Another study by the same group performed a few years later used a similar system but provided calls to each diabetic patient every two weeks. The system was programmed to make calls at times that patients said were convenient and either made a second attempt or stopped trying to call based on certain criteria such as encountering a busy signal (second attempt) or the patient hanging up (stopped trying). Patients were asked, among other things for the time and result of their most recent blood sugar, which allowed the system to obtain one value every two weeks.

Three-quarters of the patients completed an assessment at least half of the time. About half of the patients (mean age 61 years) reported a blood sugar about 90% of the times that they were called. The results were found to be reliable and, it was suggested, might be even better than that obtained during a clinic visit in which a patient must rely on his or her memory to describe past events that may not have been well-documented at the time. It was also suggested that more frequent interactions using this technique could provide a better idea about changes in the patient's health, allowing for more appropriately timed intervention.[117]

1.13 Self-management strategies away from the home: the personal digital assistant (PDA)

Unfortunately, most interventions, even those that are employing newer technologies, are often still lacking in their ability to be available in a convenient manner at all times for patients. Simple barriers such as ease of accessibility have the potential to greatly affect compliance. Even the best-designed tool is useless if the patient does not carry it with him or her. Diabetes is not a condition that stays at home when the individual is not. It is always with an individual, whether at home, school, out to dinner, or even at parties. Thus, an ideal technology is one that is available at all of those places. Several new types of technologies are much more portable than previously available systems and have the potential to provide portability to help patients manage their conditions virtually anywhere.

Programs have been developed for personal digital assistants (PDAs) to help patients manage their diabetes,[118] including electronic blood sugar diaries to replace paper logbooks.[119] A computer game to teach children about diabetes was developed through the Health, Sciences, and Technology (HST) division of Harvard/MIT for use on a handheld personal digital assistant.[120]

While this is certainly a more portable solution than a home computer, it still may not be ideal in many situations. Physicians, who are often the driving force for developing such technology, may be biased in that PDAs are commonly used in the health-care setting. In fact, physicians were among the early adopters of PDAs, using them as tools to reference clinical information relevant to patient care.[121] Some physicians have even designed diabetes tools using PDAs to help themselves better track their diabetic patients.[122]

However, while the penetration rate of these devices for physicians has reached 40%, the penetration rate for the general population is much less (8%)[123] and thus their effectiveness may be limited. Additionally, using these devices can be difficult. For example, a study of pediatricians' attitudes towards PDA use found that the major drawbacks of using a PDA were the difficulty of entering data, followed by the small screen size.[124] A different study involving neurology residents reported that acceptance of using a PDA was limited and attributed the low acceptance to a poorly designed user interface, slow operation, and the difficulty of entering information.[125]

Another example of the issues surrounding PDA use was recently detailed in a summary of why a PDA trial for young patients with diabetes needed to be stopped early. Reasons for failure included (1) difficulty synchronizing the glucose meter with the PDA, (2) difficulty transmitting the data to a central repository, (3) losing the date-time stamp on the blood sugar values in the glucose meter when the batteries accidentally fell out, and even (4) a lack of available time or "energy" to use the PDA.[126]

This last point is significant because it suggests that using the device did not fit in well with the lifestyle of the patients and likely required considerable attention to make it work. There is another portable electronic device, however, that has been accepted much more for everyday use by people: cell phones.

1.14 The growing phenomenon of cell phones and text messaging

While PDA use may still be low, cell phone use in the Unites States has been increasing at extraordinary rates. Almost half of the American population now uses a cell phone,[127] and the number of hours people spent talking on cell phones increased by 70% between 2000 and 2001.[128] People who own cell phones spend more time talking on their cell phones than on ordinary land lines.[129] Already, at least 3% of Americans are using cell phones as their only phone, and the total number of traditional phone lines has decreased for the first time since the Depression of the 1930s.[130]

Estimates of cell phone ownership by teens vary and range from 25% of teens ages 13-24,[131] to 64% of older teens in a small survey in the Palo Alto, California, region.[132] However, these numbers are from 2002 and are already outdated. A report published in 2000 by the Cahners In-Stat Group predicted that by 2004 up to half of all youths in the United States would own a wireless phone. Indeed, a recent survey found that 56% of children ages 11 to 17 currently use a cell phone, whereas almost a third of 8 to 10 year olds use on as well.[133]

The Cahners In-Stat Group report also found that fashion-conscious teenagers sought a variety of choices when selecting phones, such as shape, colors, and accessories.[134] This highlights the fact that cell phones in this age group are more than simple communication tools. They are a part of the fabric of their lives. A recent New York Times report stated the importance of cell phones in the lives of teens: "It is an accessory, a fashion statement, an instant messenger, a toy, a social prop. It is a symbol of independence second only to the car, many teenagers say, and an extension of their personality." [135]

Young men have been observed using cell phones as "cultural ornaments", displaying them to attract women,[136] much the same way that a peacock might display its feathers to a peahen. It has even been hypothesized that the rise in teen ownership of cell phones is correlated with a concurrent drop in smoking in England. The authors hypothesized that the symbols that cigarettes stood for are now being effectively taken over by cell phones: "adult style, individuality, sociability, rebellion, peer group bonding, and adult aspiration." [137]

Parents are also often happy to provide cell phones to their children. They offer their children cell phones so that they can keep track of their whereabouts better, a phenomenon known as "mobile parenting," which has been reported to be very common in Finland.[138] Although no data are available, parents of children with potentially life-threatening chronic diseases might be even more inclined to make sure that their children have a cell phones to stay in contact for emergencies.

A use of cell phones which is growing in popularity is text messaging with a system known as short messaging services (SMS). These are small messages, roughly 120-160 characters in length that can be entered into a phone by pressing a specific combination of keys and sent to other users who can read the message and then respond. Many cell phones today already have the capability for SMS, even if users don't know that the feature exists. By the first quarter of 2002, approximately 60% of AT&T Wireless and Cingular phones had this capability built-in already.[139]

Initially used by telecommunications engineers in Europe to notify each other of network problems, the usage rates for SMS began to skyrocket when teens in Europe and Asia started using the messaging on their cell phones, and the use of SMS on the phones has become almost as important as the phones themselves, as is well-stated in a recent New York Times article: "If you are a teenager in Europe, you can't have a social life without cell phone text messaging." [140]

While the SMS craze started earlier in Europe and Asia, the trend has now begun to catch on in the United States as well. Whereas 253 million SMS messages were sent in the U.S. in December 2001, that number increased to 1 billion by December of the following year.[141] Estimates suggest that teens and pre-teens in the United States currently send about 50 text messages per month.[133] One 12 year old girl who was recently quoted in a New York Times article stated, "I text-message my friends more than I call them." [133]

The use of SMS has caught on with teens all over the world. Teens have been using SMS to such an extent that researchers have begun taking notice of how adept they have become at typing away at the phone's small keypads, often with their thumbs. A recent observation of teens in Japan was recently published:

> These users are nimble and dexterous, even ambidextrous, and often so proficient that they barely need to look at the keys they use as they make their rapid entries: their knowledge of the layout has become second nature. Their movements are absolutely minimal, with the thumb simply exerting pressure rather than actually tapping at the phone. In Japan, thumbs get even more exercise: games are played

> with the thumbs of two hands; messages and calls are made with one or both. Tokyo's keitai [mobile phone] kids are known as oya yubi sedai, or the thumb generation: 'It's not only on the keitai that they use them,' says one man in his early 20s, to whom today's teenagers are already remote and alien creatures: they even point at things and ring doorbells with their thumbs. These kids are the world's leading textperts.[142]

It is not surprising, then, that with as many messages being sent, SMS has been used in numerous creative ways. Police in Germany have used it to help alert citizens about criminals and missing persons.[143] A few college students were recently caught cheating on an accounting exam by using SMS text messaging to trade answers.[144] Organizations in Seattle, Washington, have used it to help gather groups for protests.[145] Citizens of the United Kingdom were even given the opportunity to receive alerts about pollen counts using cell phone text messaging.[146]

1.15 Self-management strategies away from the home: the wireless, mobile, cellular phone

The use of text messaging on cell phones has begun to catch the attention of the health community as well. If SMS is such a craze in people's' lives, especially adolescents, then it seems as if this enthusiasm could be tapped to promote healthy behaviors as well. It is reasonable to infer that the best technology to target the adolescent population is one with which adolescents are already comfortable using or are anxious to obtain. It is not hard to imagine an adolescent willingly bringing a wireless phone, a vital social connector nowadays, to a party, but it becomes more difficult to imagine one bringing a PDA to a party and willingly bringing it out in full view.

A study conducted in Spain between October 2000 and March 2001 lends further support that phones are perhaps a better technology medium to use than other devices such as personal computers. This study surveyed 244 patients with type 1 diabetes (mean age 34 ± 13 years) who came to their clinic visits. While only 58% owned a home computer, and even less (39%) had Internet access, 77% owned a mobile phone. Of those with mobile phones, 96% used it more than once per week and 87% knew how to use SMS on their phones. The authors concluded that cell phones "show promise as a tool in health care communication technologies." [147]

Potential benefits of using SMS and cell phone technology over other currently available technologies are that the communication capabilities are available wherever the phone is available, and such phones are likely to be more accessible around the clock than desktop computers. This was well summarized in an article in the New York Times:

> "When you send e-mail to a computer, you don't know if the person is logged on and sitting at their computer at that moment," Mr. Botham said. "When you send e-mail [or an SMS] to a cellphone, you know there's a much better chance that the person is going to get the e-mail right there, right now." [148]

Another feature of using SMS technology is that it allows for two-way asynchronous communication of simple messages, allowing users to send small pieces of data, such as blood sugar values, back to a centralized computer system. Interestingly, this concept of submitting data via a phone's numeric keypad was foreseen as early as the 1960s. A 1969 article from the Journal of the American Medical Association, discussing the new types of numeric keypads on phones stated, "Only numeric data can be input manually on a telephone with ease, although alphabetic letters and other symbols can be entered by sequentially depressing two or more buttons for each non-numeric character." [149]

Researches have begun to discuss the potential role of cell phones and SMS text messaging for patient care. One physician in the United Kingdom recently wrote in the British Medical Journal about his experiences with using text messaging for patient care. He allows patients to text message him questions to which he will write back. This is, of course, a very manual and labor-intensive process but his report was positive. He cited the ease and convenience of text messaging, and the potential for it to reach patients at any time of the day. He reported that his practice was considering automated reminders for appointments and also reminders for doing blood and urine tests which, he reported, are often forgotten by patients.[150]

Another article in the British Medical Journal discussed a trial that was to begin shortly in which patients would receive reminders about appointments on their cell phones through text messaging. The messages that were being sent were very short and simple, likely due to the limitation of the length of SMS messages. An example of such a message was given: "You have an appointment at the Homerton at such and such a time, please call this number if you can't make it." The system was described as "largely automated", meaning that staff members entered the time of the appointment into the computer system which then automatically generated the message. In preliminary trials using the new system, missed appointments had decreased by 8%.[151]

Text messaging has been used in South Africa to help patients remember to take their anti-tuberculosis (TB) medications. Depending on the clinic location, between 30-70% of patients had their own cell phone. Patients with TB were sent daily reminders on their phones to take their medication. Initially, patients reported that they were bored with just the reminders, so the system was changed to vary the messages and to also included lifestyle tips and jokes. One 30 year old patient remarked about the system, "This is my second course. I forgot to take my pills the first time round. Now, SMS messages are a brilliant reminder. I have been getting messages at 8am for a month and, so far, I haven't missed a day." [152]

Cell phones have been used to help older adults manage their blood pressure and heart rate, as was discussed in a recent Reuters Health news article. Patients were asked to enter numbers such as blood pressure, heart rate, and body weight using specially developed software for use with their mobile phone. Patients who forgot to report their results were sent a reminder text message. If a patient reported abnormal values, the physician was notified and then called the patient at home to prescribe medication. One of the advantages of this system, as reported by one of the researchers, was that it allowed for the capturing of data during the interval between regularly scheduled visits, a time that is often a black hole in terms of data collection for the health care team. Thus, it allowed for earlier interventions in those patients that needed more immediate attention. The article also mentioned that the research team was planning on applying their ideas to help patients with diabetes in a forthcoming study.[153]

The use of cell phones for asthma has been studied to some degree. A brief report in the British Medical Journal described a system that used mobile phones to deliver short text messages with reminders for patients to use their inhalers. The participants enjoyed the novelty of the medium and it was suggested that the messages might have improved their compliance as well.[154] An article by Reuters discussed another asthma project being tested by a British company, E-San. Reminders to monitor their asthma status are being sent twice each day to children with asthma. One company employee said of the study, "We hope using mobile phones will make monitoring a cooler option, especially for kids." If successful, they hope to also branch out to other conditions, including diabetes.[155]

The role of text messaging on cell phones in patients with diabetes has, so far, been studied only minimally. A pilot study in which diabetic patients were sent automated messages identified nine scenarios where such messages might be beneficial and reported that the patients enjoyed receiving the messages, at least for the three months that the study was conducted. The nine scenarios identified included appointment reminders, medication reminders, medication dosage changes, medication dosing clarification, blood glucose testing reinforcement, meal time reinforcement, exercise reinforcement, dietary reinforcement, and general information.[156]

One study was recently published which used personalized text messages directed at adolescents with type 1 diabetes in order to promote health behavior modification. Text messages were sent to patients that contained personalized information as well as general diabetes information.[157] In another recent study, a prototype was developed to provide monitoring, reminders, and education using wireless phone technology and was tested in patients with either diabetes or congestive heart failure between the ages of 18 and 70. Preliminary reports suggest that the system was well accepted by the patients.[158]

There still remains much work to be done in terms of exploring the role of text messaging for adolescents with diabetes. While studies have suggested that sending messages to patients has been a well-received concept, even less has been studied in terms of patients sending data back to a computer system. Targeting adolescents is an area that seems to have been largely overlooked but may prove to have one of the greatest impacts on diabetes care. If good habits related to diabetes self-management are developed or continued through adolescence, there is a greater likelihood that those patients will have greater compliance as adults as well.

While currently available evidence supports the idea that such a system using SMS technology on cell phones will improve diabetes healthcare for adolescents, it is only with testing through controlled studies that the true impact can be measured and for such a technology to be fully accepted by the medical community. To that end, the Computerized Automated Reminder Diabetes system (CARDS) was created.

Section 2

Methods

2.1 Technical Development

2.1.1 An Overview of CARDS

The Computerized Automated Reminder Diabetes system (CARDS) is a computer system designed to help adolescents and young adults with diabetes. Using a simple web interface it enables reminders to be sent for checking blood sugars and administering insulin, and also offers a convenient way to enter, store, and view blood sugars. CARDS allows for asynchronous communication between the user and the computer system through either e-mail or cell phones. This allows for reminders to be sent to the user and for the user to send blood sugars back to the system, even when not using the web site.

CARDS was designed to exploit the currently increasing popularity of text messaging on cell phones in order to provide a means to increase participation from patients in the target population and to increase patient engagement in the management of their disease. It was designed to be easy to use, with a simple interface. Additionally, aspects of the design were inspired by various elements of successful self-management strategies used to improve compliance as outlined in the background discussion.

All programming, as well creation of the overall design and features of CARDS was done by the author. Various aspects were modified and improved in consultation with Dr. Lori Laffel of the Joslin Diabetes Center in Boston. Additional modifications were made based on comments received while testing the system on various staff members of Joslin who worked with or for Dr. Laffel. This testing occurred over approximately six to eight weeks.

2.1.2 Strategies Implemented in CARDS

One of the major features of CARDS is the customizability of its behavior. Users are able to set the times and the days that they would like reminders to be sent to them. This is so that the system can accommodate the user as much as possible. Additionally, cell phones should easily fit into the lifestyle of adolescents. As a result, adolescents should not need to carry any new or extra devices that they would not normally have with them. They would, of course, still need to have their glucose meter and test strips with them as they ordinarily would.

Using cell phones also has the added benefit of providing reminders on a device that will not make users appear to stand out among their peers. Additionally, cell phones are devices that adolescents should feel very comfortable using, even in full view of others. The messages sent to users are brief and the response that the user should send back can be very short (a simple number is all that is required). Thus, the time investment over current techniques for recording blood sugars is minimal.

The reminders aspect of CARDS is both proactive and reactive. That is, the system is proactive in that it will automatically send reminders to users at specified times, and it is reactive in that once it receives information from the user, it reacts to the information by sending a message back to the user to provide confirmation of receipt and to provide positive feedback. This will be explained in more detail later.

The positive feedback is provided for users every time they submit a new blood sugar. This is done to encourage them to continue submitting blood sugar values. To further engage the users, "factoids" (i.e. small facts) are provided to make using the system more entertaining and to provide small amounts of educational information about diabetes as well. The factoids concept was based on other consumer products which incorporate similar types of ploys designed to engage the consumer. A current example of this is the provision of the small "Real Facts" found under the bottle caps of Snapple beverages. This is depicted in Figure 2.1. Each day two different factoids can be sent to each person. One pertains to diabetes and the other can be about any subject. They are designed to be short, fun, and educational.

Figure 2.1. A current cap from a Snapple beverage bottle. This displays a typical "Real Fact" that was used as a model for the factoids in CARDS. This one states, "The starfish is the only animal that can turn its stomach inside out."

2.1.3 Components of CARDS

CARDS was designed using free or inexpensive software components, along with computer code to integrate the components. The system runs on a Macintosh computer with OS X 10.2.8, although it would likely work on any version that is 10.2 or higher.

The system stores all data in text files, in an organizational scheme similar to the way it might be stored in a relational database. Text files were used as opposed to an actual database because the system is currently being tested for feasibility, and it was easier to make modifications to text files as needed. Also, since only a limited number of users were to be part of the system in the trial, the power of a database was not required.

The website portion of the system is implemented with the free Apache Web Server version 1.3

and the JavaServer Pages operate using the free Jakarta Tomcat JSP server version 4.1.18. Messages are sent and received to and from both e-mail and SMS-enabled cell phones using the scriptable mail program Mail, version 1.2.5 (v553) from Apple Computer.

Also used are custom-made AppleScript applications, created using the free application Script Editor, version 1.9. Two Unix programs included in the Mac BSD (Berkeley Software Design) version of OS X were also utilized: tar (tape archiver), by Keith Muller (1996), was used to join files for daily backup of the data and cron (Vixie cron), by Paul Vixie (1993), was used to coordinate the timing of various functions of the CARDS system. More details of each component are discussed below. A simple schematic diagram showing the system architecture can be found in Figure 2.2.

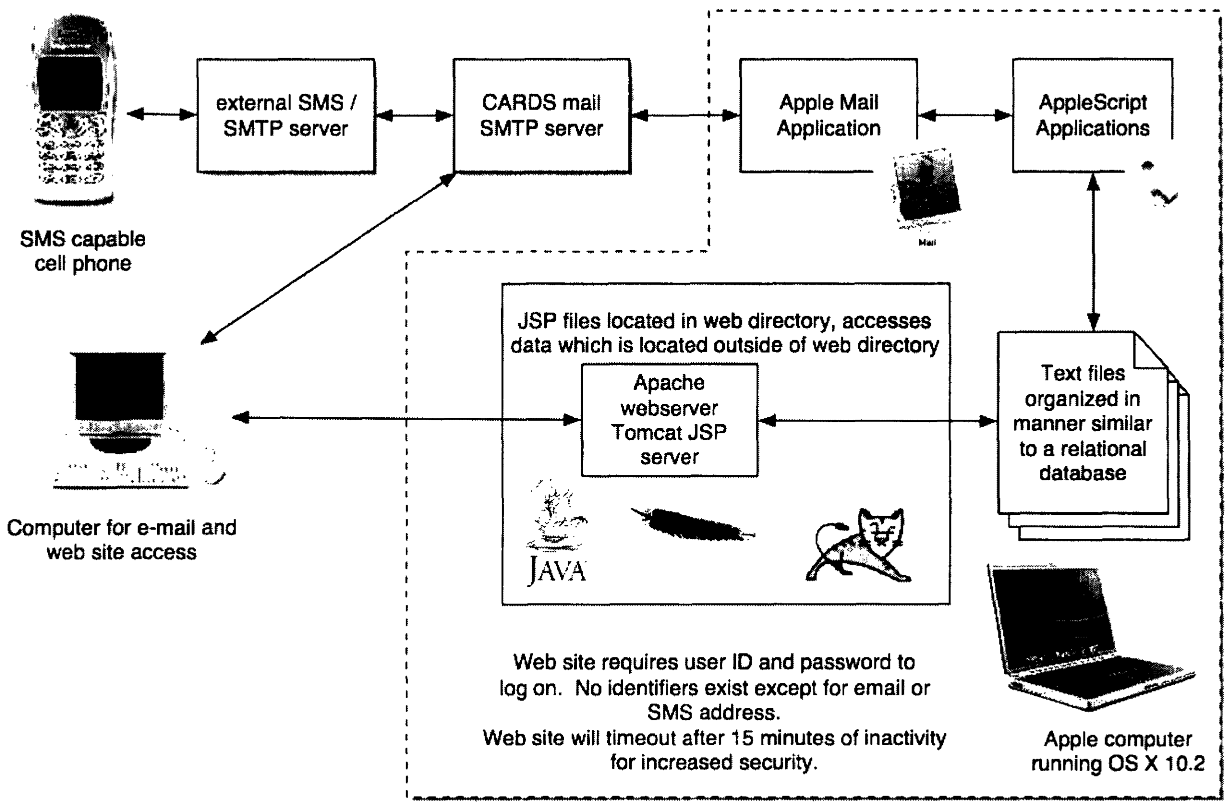

Figure 2.2. This diagram represents the system architecture for CARDS. Everything within the dashed line is located on the CARDS server which, in this case, is a 500 MHz Apple Powerbook G4 laptop.

CARDS was constructed from multiple components that have been integrated to work seamlessly. A description of the various components follows.

2.1.4 SMS (Short Messaging Service)

To understand the manner in which CARDS functions, we first describe how SMS (Short Messaging Service) operates.[159] SMS works with CARDS in both sending and receiving messages between a cell phone and a computer. SMS is a protocol that was designed to have several key features. One is that messages can be sent or received at any time whether or not an active voice call is also taking place. The SMS protocol was designed to be low-bandwidth and to guarantee delivery of messages.

Messages sent by or sent to a phone are directed through an SMS Center (SMSC) server. An SMSC is comprised of both a computer and specialized software to deal with SMS messages. An SMSC can operate with different types of "air interfaces" which are the basic ways in which different cell phone service networks currently operate (such as GSM, TDMA, and CDMA). Also involved in the process are Mobile Switching Centers (MSCs). These MSCs work directly with the phones to communicate data to and from the phone.

The process for sending a message to a particular phone is as follows. When a SMSC receives a message to deliver to a phone, it must first contact a home location register (HLR) which is a database that stores information about the specifics of a particular phone number, such as the carrier providing service for that phone. The HLR can be thought of as being similar to a domain name server (DNS) for web sites. Once the SMSC receives the specific information about a phone from the HLR, it uses a protocol to determine the current MSC that is interacting with the phone at a specific time (in much the same way that different cell phone towers will interact with a phone as the phone is moved around). Once the correct MSC is located the message is transferred from the SMSC to the MSC. The MSC then transfers the message to the phone. If the process is successful the MSC notifies the SMSC that the process was completed. If the process is not successful, such as if a phone is off or otherwise cannot be located, the SMSC will continue to store the message until the message is sent or until a specific time limit has expired. Messages sent from a phone follow a similar path, from an MSC to an SMSC. There are other aspects and variations of how the SMS protocol operates but these will not be described here.

What makes CARDS possible is that these SMSC servers can also interface with typical e-mail SMTP servers. A typical SMS message is sent with just a number (such as 2223334444) and the HLR determines the proper place to send it. This is different from e-mail messages which have two parts (the username and the domain name, separated by an "@" symbol). Most cell phone providers now also have SMTP servers to interact with their SMSC servers so that each user not only has an SMS address but also an equivalent e-mail address. Each cell phone provider uses a different domain name. For example, a Cingular subscriber would have an address such as 2223334444@mobile.mycingular.com and a Verizon subscriber would have an address such as 2223334444@vtext.com. This interface between the SMSC and SMTP servers makes it possible for a cell phone user to send an SMS message to an e-mail address and it also makes it possible for a short e-mail message to be sent to a phone as an SMS message.

2.1.5 CARDS e-mail address

A specific e-mail address for CARDS was set up through the Brigham & Women's Research Information Computer Systems (RICS) department. The benefit of RICS is that the RICS organization provides all of the maintenance and monitoring to make sure that the e-mail servers are operating all of the time. The address set up for this was "cards@rics.bwh.harvard.edu". Thus, using this address, messages could be sent to both regular e-mail and SMS addresses (or the e-mail equivalent of the SMS address). Additionally, both e-mail and SMS users could send messages back to this address.

Another advantage of the RICS e-mail account was the loose limitation on the number of messages that could be sent. The importance of this limitation became apparent when testing the system using a temporary Comcast e-mail address. CARDS is an automated system that sends out messages to users at specific times. For example, if 40 users chose to receive a diabetes factoid, then 40 factoids would be sent to different people in rapid succession by the system. After about three to four messages were sent, the Comcast e-mail servers would refuse any more connections to the mail server until a pre-defined period of time had elapsed. This was set by Comcast as a protection against e-mail spammers but proved troublesome for CARDS when many messages needed to be sent at once.

The RICS mail server also has a similar protection scheme but was much more liberal in how it operated. Its mail server would accept up to 10 messages per second before refusing a connection. Adding a brief delay between messages being sent prevented the RICS mail servers from denying the connection.

2.1.6 The Web Site: Background

The web site is a central component of CARDS. The web server is hosted on the same Macintosh computer that stores all the data. The web site chosen for the system is:

http://cards.gotdns.org/

The unusual name of the site reflects the fact that it uses a free service offered by Dynamic Network Services, Inc. (http://www.dyndns.org). This company offers domain name system (DNS) services. While they charge for completely custom domain names, they offer for free the use of various domain names they own, such as "gotdns.org". Names can be appended to the front of the domain name to create a custom domain name. In this case, "cards" was chosen so that the final domain name was "cards.gotdns.org". Through the use of this company's free services and another free program called DNSUpdate version 2.7 (http://www.dnsupdate.org/) which runs locally in the background in OS X, dynamic DNS could be used for the web site.

Dynamic DNS is used when a web site is not necessarily going to remain at a fixed, static IP address. Normally, a web site would be at a fixed address so that all DNS servers would know where to correctly point a web browser. But for systems that are using dynamic IP addresses, or in which the IP address might change, a dynamic system is better. Since CARDS was tested in various locations such as Brigham and Women's Hospital and then the Joslin Diabetes Center, using dynamic DNS made the most sense.

The dynamic DNS works as follows. When the computer is attached to the Internet, the DNSUpdate program constantly checks to see if the IP address that is assigned to the computer has been stable. If at any time the IP address changes, the DNSUpdate program contacts the DNS server at Dynamic Network Services to let the server know that it should update its database with a new IP address. Then, when a user enters the website "cards.gotdns.org" into his or her web browser, the DNS server will be able to point it to the correct IP address where the computer currently resides. Any time the IP address changes again, the DNSUpdate program will alert the DNS server appropriately. The computer does not even need to be restarted for this to occur.

The web site uses the Apache web server which comes pre-installed on OS X. The Jakarta Tomcat web server was installed manually in order to be able to use JavaServer Pages (JSP) with the web server. JSP uses Java intermixed with standard HTML to dynamically create web pages. This provides considerable power to dynamically create web pages, since using Java enables creation of customized web pages on the fly for each user. The Java portion only runs on the web server computer to create the customized pages, not locally on each user's computer or cell phone.

In the construction of the web site the web languages XHTML (Extensible HyperText Markup Language) and CSS (Cascading Style Sheets) were used to improve the layout and design of the web pages. JavaScript (not to be confused with Java) was used on some of the web pages to add additional functionality. Java and JavaScript are completely different languages. Java is faster and more powerful and can read and write to files. JavaScript is embedded in a web page and is run locally on a user's browser. JavaScript is not capable of reading or writing to files on a user's computer.

2.1.7 The Web Site: Logging On

A user first accesses the web site by typing in the web address http://cards.gotdns.org/. Once the page appears, the user is greeted with a welcome message and given a simple instruction to click the link on the left side of the screen. This general layout sets the precedent for the overall theme and design of the web site. That is, the design is simple with only the commands that are currently available displayed at any given time. The background is a simple, white color, and the logo is always displayed in the upper-left corner of the page. Additionally, all options from which a user can choose are found on the left side of the screen, separated by a vertical line. This introductory welcome screen can be seen in Figure 2.3.

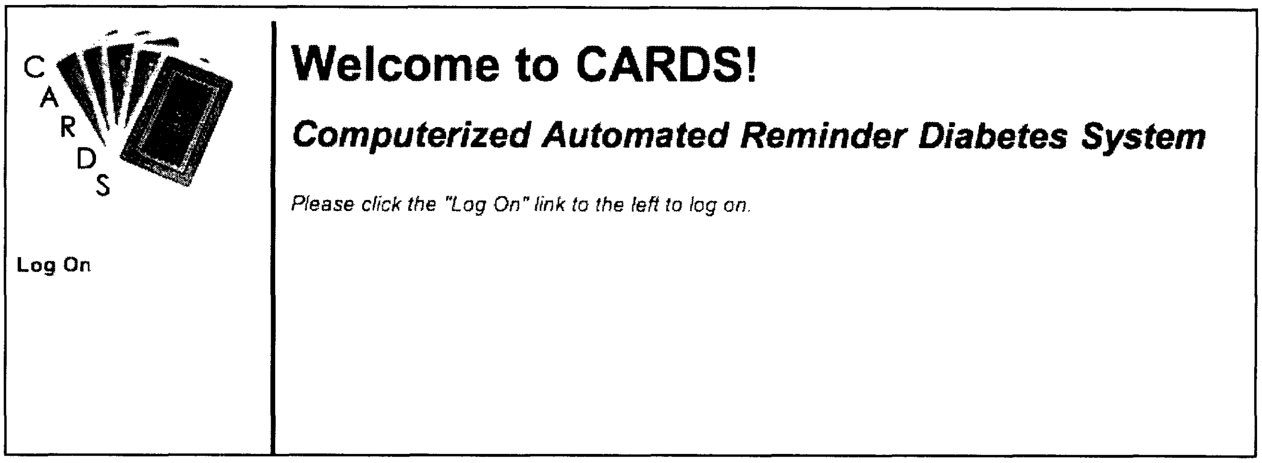

Figure 2.3. The CARDS login screen.

Clicking on the "Log On" link brings up a new page with a few extra commands now visible. The new page appears above the original page in a new window. This window has the typical menu bar options disabled, such as the forward and back browser buttons. This was done to encourage users to use the commands available on the left side of the window to navigate the site and was also done to improve security (discussed below) because the URL becomes hidden. Available options on this page are "About Cards", "Forgot Password", and "Help". This screen can be seen in Figure 2.4. It should also be noted that the screenshot in Figure 2.4 shows that the "User ID" field is highlighted (with a blue border). This is because the page was designed so that as soon as it is loaded, the cursor "focus" is automatically attached to that entry field using JavaScript code. This is an example of how usability issues were considered in the design of the site. Often, when a page is loaded in which someone must enter information, a user must first click in the field and then type the information. By bringing the focus to the correct field, a user can begin to enter information immediately without needing to click on the correct text entry box first; this also helps highlight the correct area on which the user's attention should be focused to enter information.

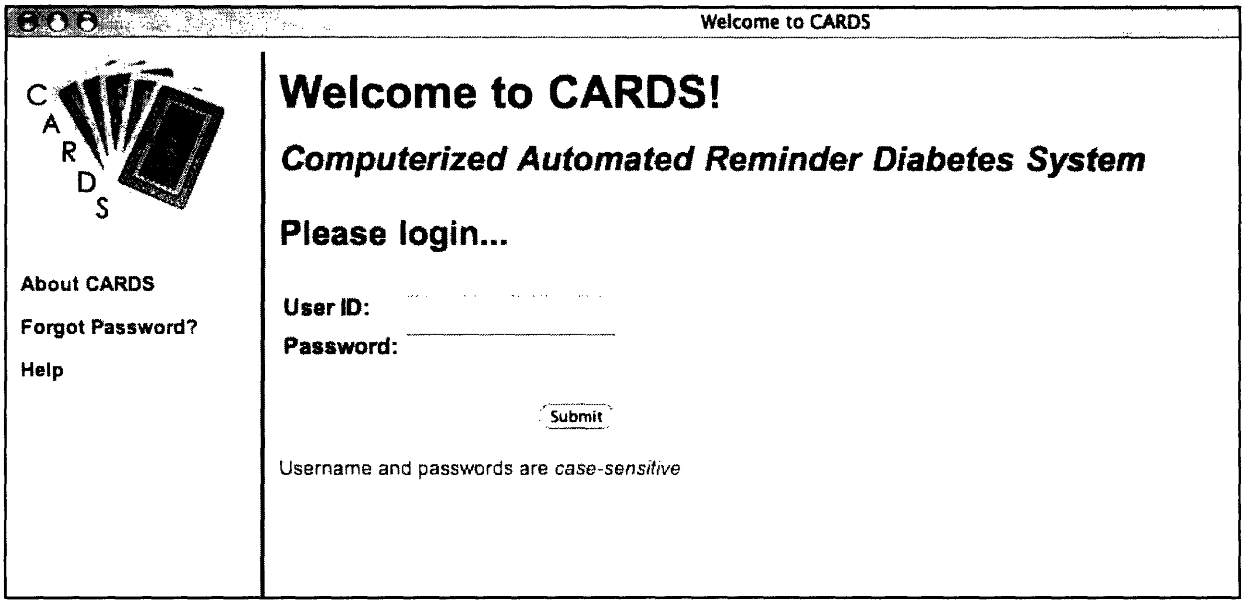

Figure 2.4. The CARDS screen where users log onto the system.

If a user clicks on the "About CARDS" link, information about CARDS is displayed. This offers a detailed explanation of the features available in the system. This screen can be seen in Figure 2.5. As was already discussed, every command that a user can select at a given time is shown to the left of the vertical bar. In this case, the "Log On" link now appears again. That link did not appear in the "Please login..." screen since it would have been redundant in that context. All of the previously displayed options are still available, however.

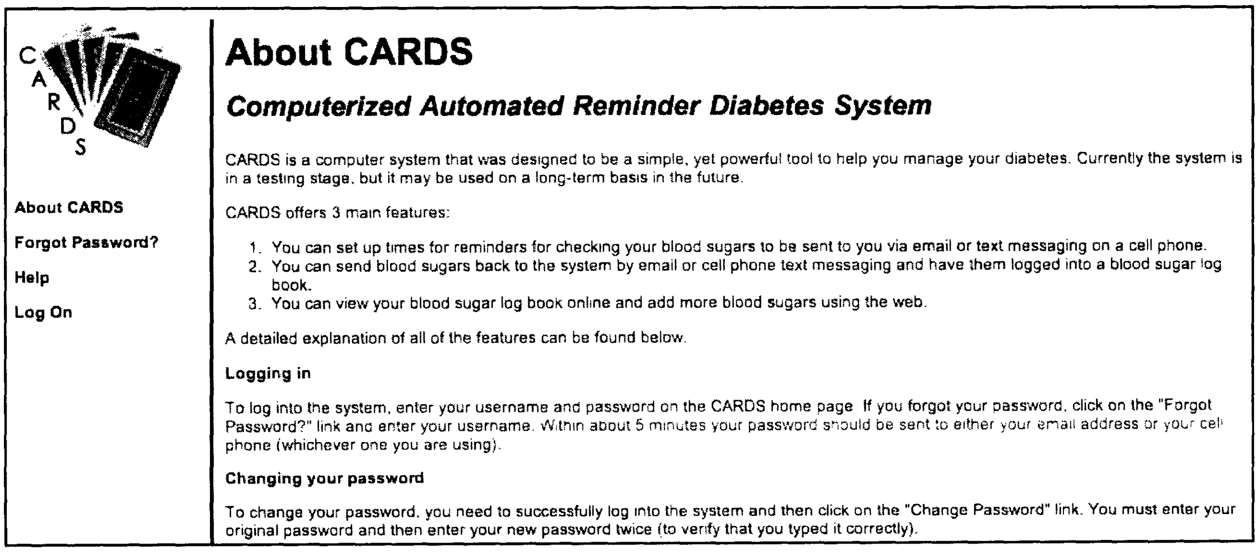

Figure 2.5. Information about CARDS can be displayed by clicking on the "About CARDS" link.

If the user clicks on the "Help" link, a screen appears with some brief information for users who are having trouble. This includes contact information for the user in case he/she is not able to access the web site properly. It provides a phone number and an e-mail address to contact the administrator of CARDS. Additionally, since a user might click on "Help" in the event of a medical emergency, the user is reminded not to rely on CARDS for that type of assistance but should rather call 911 or the user's health care provider:

> "PLEASE NOTE: Use this phone number or e-mail address only if you are having technical difficulties with the CARDS system. If you are having any medical problems, please contact your health care provider or call 911 for emergencies."

This can be seen in Figure 2.6.

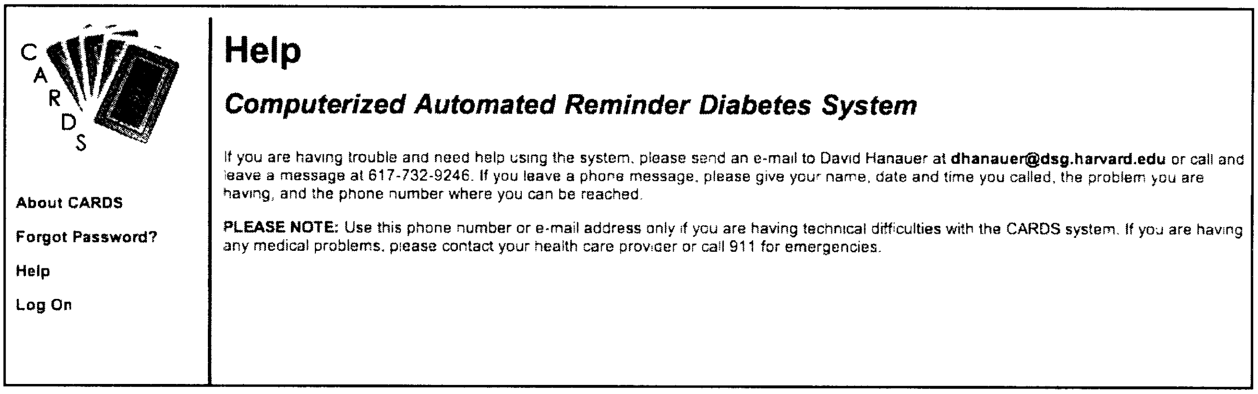

Figure 2.6. The "Help" page in CARDS.

It is possible that a user will forget his/her password. On every screen before the user actually logs on, the "Forgot Password?" link is displayed. If the user clicks on the link he/she will be shown a screen that looks like Figure 2.7.

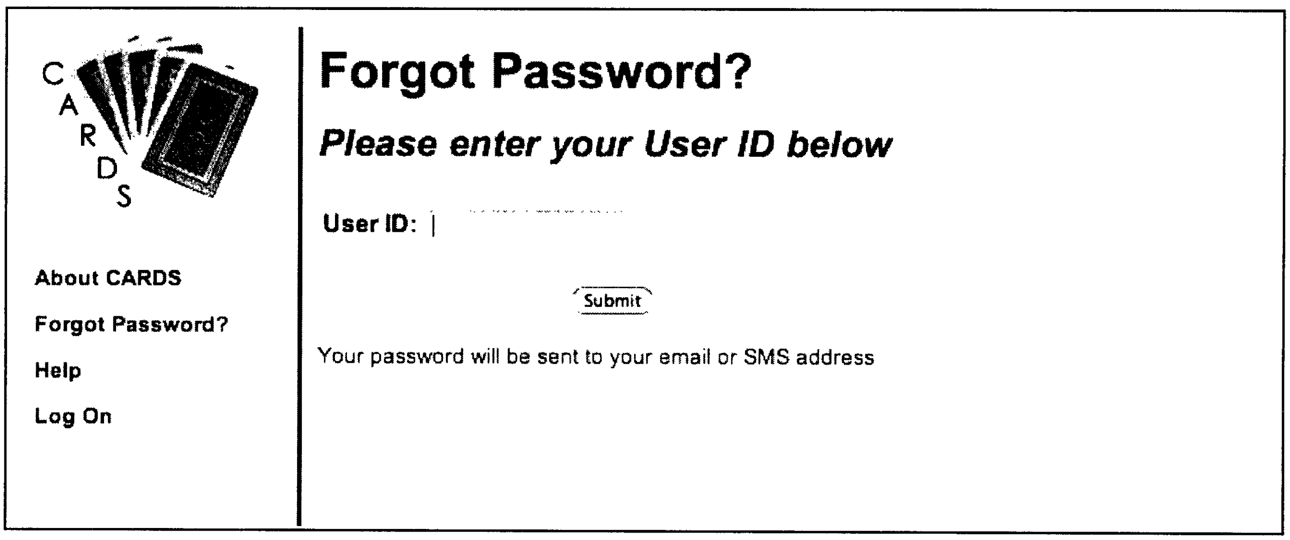

Figure 2.7. The "Forgot Password?" page. Users can have their passwords sent to their e-mail or SMS address.

Again, this page uses a small JavaScript script to bring the cursor focus directly into the text field labeled "User ID" to save the user time and to make it obvious where the user's attention should be directed. After the user enters his/her ID, the user presses the "Submit" button. This button actually does not conform to the rest of the design of the website, where all options are displayed to the left of the vertical divider. However, it made more sense to place the button directly adjacent to the text entry field in this case. In other cases of data entry, the option to save the data is found to the left, although pressing return is equivalent to pressing on a submit button. The process of sending the password will be discussed later. One the user presses "Submit" a screen very similar to that of Figure 2.4 is shown with large red lettering telling the user "Your password will be sent shortly. Please check your email or SMS account for your password." This can be seen in Figure 2.8.

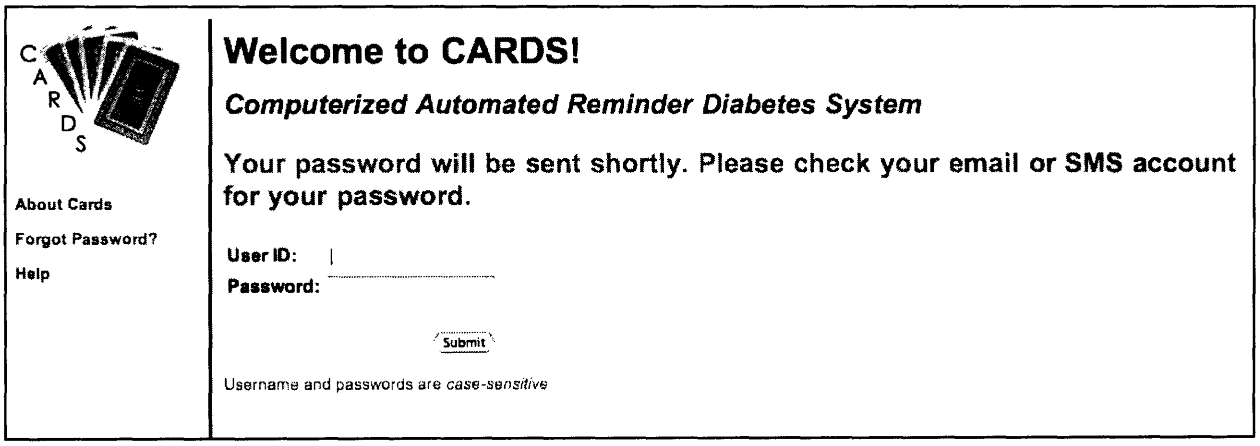

Figure 2.8. The login screen, with extra text to let the user know that his/her password was sent to the appropriate e-mail or SMS account.

Assuming that a valid User ID is submitted, a brief message will be sent to either the user's cell phone SMS address or e-mail address. Whether a user receives messages on either their SMS or e-mail address is determined based on a randomized list, discussed later. Since such messages are not guaranteed to be secure, the word "password" is not sent in the message. This is done to avoid catching the attention of someone who might be eavesdropping on messages, looking for key words to intercept. In this case, the user is sent a message with the subject "A message from CARDS" with the body text stating, "Here is what you forgot:", followed by the password.

Once a user has an ID and password, he/she can enter it into the text fields as shown in Figure 2.4. If a user enters an incorrect combination, a very similar screen is presented with large, red lettering alerting the user about the incorrect user ID and password combination. The color is meant to draw attention to the message, which in this case states, "Oops! Incorrect User ID and password. Please try again..." This can be seen in Figure 2.9. Just like the screen in Figure 2.8, this screen allows the user to enter the login information again. The user then has the option to try again, click on the help link, click on the about link, or have the password sent.

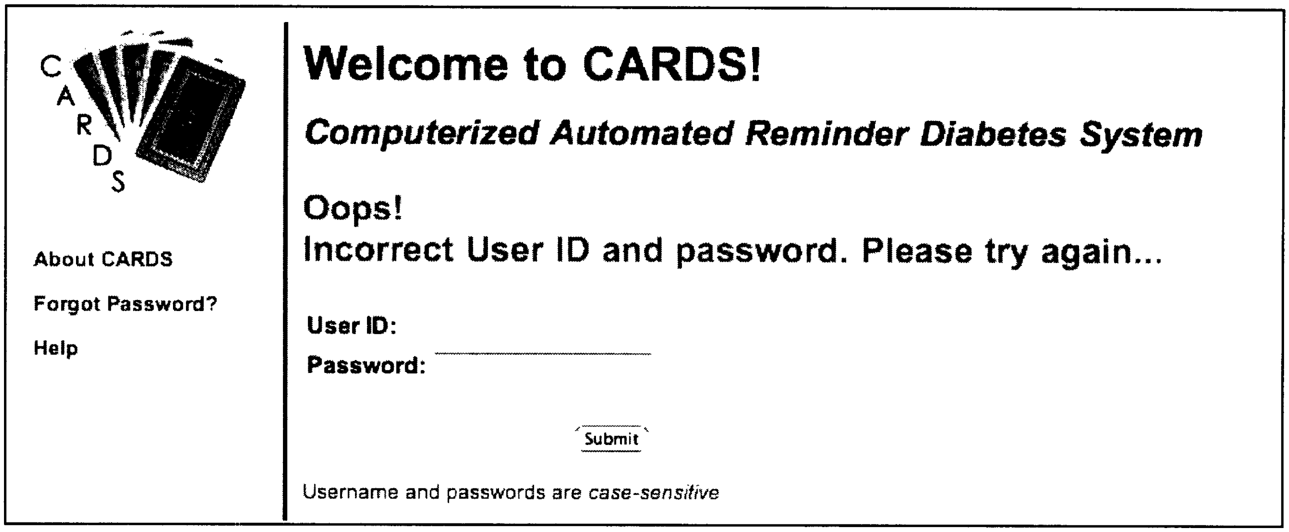

Figure 2.9. The login screen that is displayed when a user unsuccessfully attempts to log on.

After successful log on, the user is immediately shown a welcome screen. This screen also states the user name/user ID of the person for the CARDS system, which can be anything but in this example is "dhanauer". This is shown in Figure 2.10. Also on this page are some brief instructions to help a first-time user get started. This includes letting the user know that all options will be found on the left side of the screen. Also displayed is a warning to emphasize that the system is completely automated and that no person will intervene if a dangerously high or low blood sugar is submitted by the user. The options to the left of the screen are slightly different from those that are present before a user logs on. As before the user logged on, a link to "About CARDS" and "Help" are still displayed. New links that are visible are "Log Book", "Reminders & Factoids", "Password", and "Log Off".

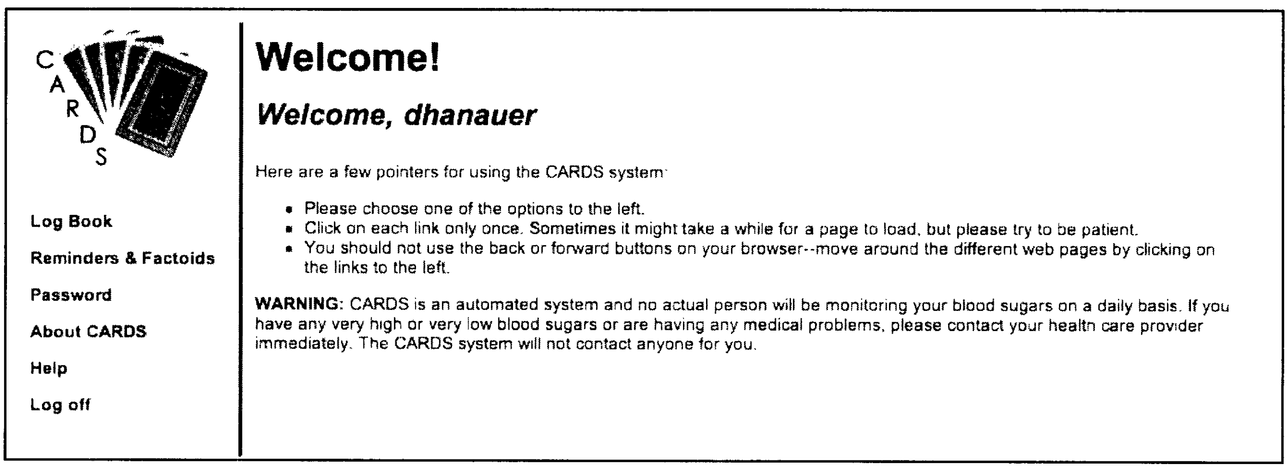

Figure 2.10. The welcome screen that is displayed when a user initially logs onto CARDS.

2.1.8 The Web Site: Log Book

The "log book" feature of this web site is meant to be similar in style and simplicity to the paper log books which are usually carried around by patients with diabetes. Paper log books are the means by which patients with diabetes typically record their blood sugars for reviewing themselves or with their healthcare team. The manner in which log books are used was duplicated as much as possible in the web site to make it well-accepted by users.

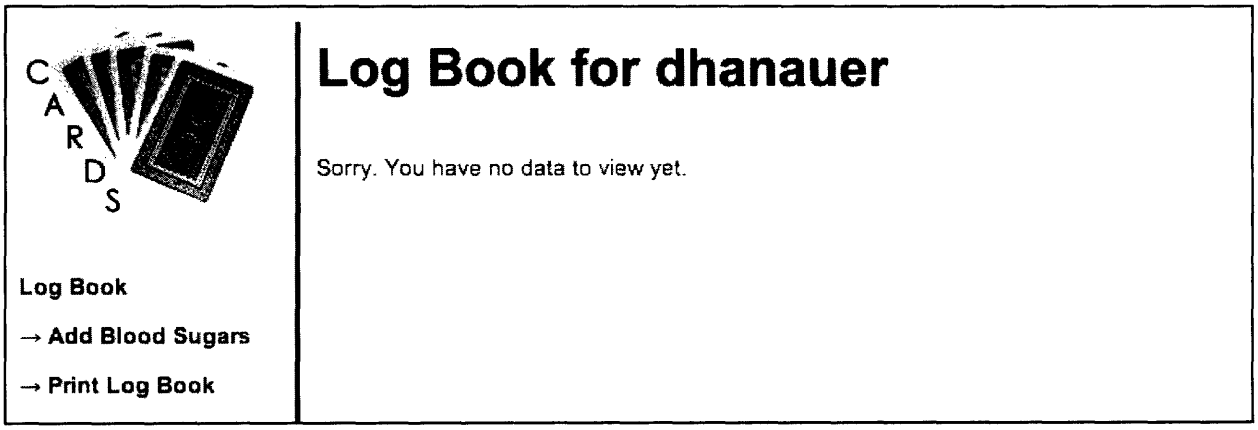

Figure 2.11. The log book screen when no data has been entered.

Typically, clicking on the link would immediately display the log book data for viewing. However, the first time a user clicks on the link, it is likely that no data would yet exist so the user is told this on the screen with "Sorry. You have no data to view yet." (Figure 2.11). Additionally, once the "Log Book" link has been chosen, new links are expanded beneath it, showing the new options that are available for the log book section. Typically there are three options available, which are "Add Blood Sugars", "Print Diary", and "Change Comments." If there are no data to view, the "Change Comments" link is not shown since there are also no comments. In fact, if the user chose to "Print Diary" now the message "Sorry. you have no data to view yet" would appear. Once a user enters a blood sugar, the functionality for viewing and changing comments is available.

Blood sugars can be entered into the system by two different methods. One way is either by e-mail or cell phones (to be discussed later), and the second method is by entry via the web site itself. This is accomplished by clicking on the "Add Blood Sugars" link under the "Log Book" link.

If the "Add Blood Sugars" link is clicked, a new screen is displayed that is shown in Figure 2.12.

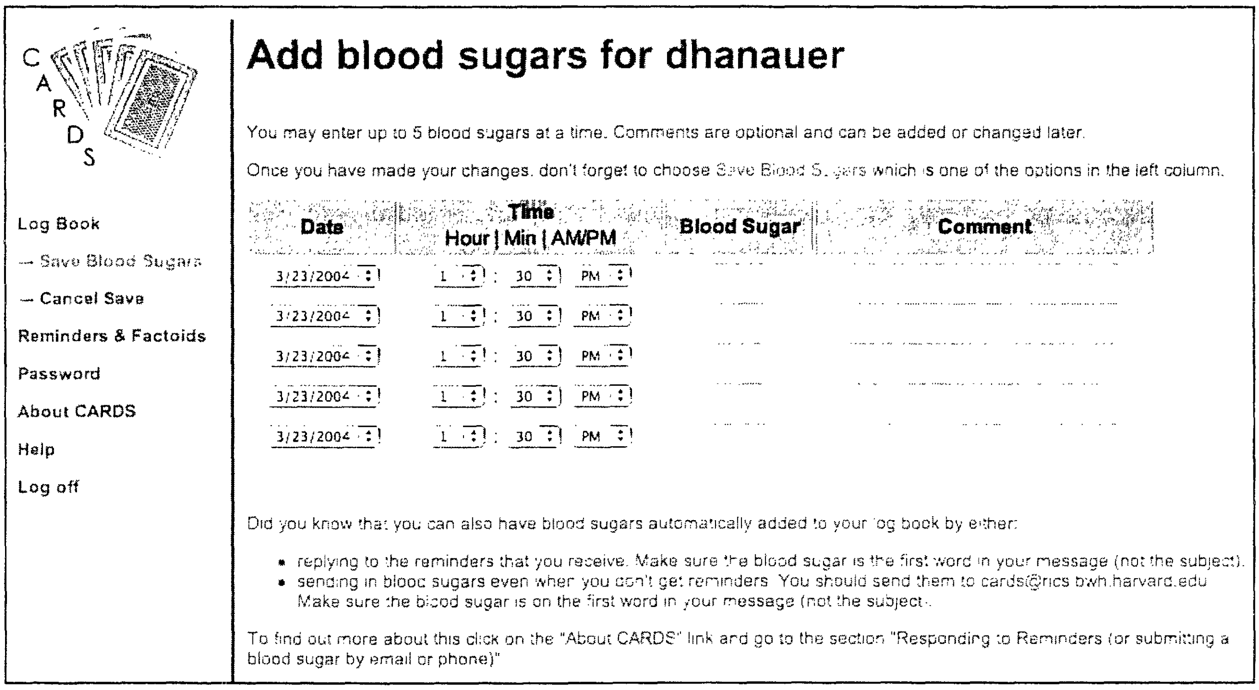

Figure 2.12. The web page which allows users to enter blood sugars

It should be noted that the options displayed on the left side of the screen have changed in response to this new data entry screen being displayed. Under the "Log Book" link the previous choices have disappeared and now two new choices have appeared: "Save Blood Sugars" and "Cancel Save." The Save option is highlighted in red to better ensure that the user remembers to press the link to save the data. Additionally, above the area to enter the data the user is reminded of the importance of doing this with the statement, "Once you have made your changes, don't forget to choose Save Blood Sugars which is one of the options in the left column." The Cancel Save link is truly not needed because the data entry screen is simply a web site and clicking on any other link would, in essence, cancel the saving of the data. But to be consistent with the way most programs work, in which there is both a Save and a Cancel option, this was added as a feature. Clicking on the "Cancel Save" link is equivalent to clicking on the "Log Book" link. That is, it would take the user back to viewing the log book data if any existed.

The screen in which users can enter data has five separate lines where blood sugars can be entered. Each line allows for a date, time, blood sugar, and comment to be added. All five can be used at once, or any combination of them (such as the first and fourth lines) can be used. If the user enters no information and presses the "Save" link, then nothing will be saved. It should be noted that the date and time on all 5 options default to the current date and time. This default is intended to reduce data entry time if the user wants to enter a blood sugar that was just obtained. The user can change this, however, by selecting the drop down menus present in the page.

For the date, a user can select a date in the range from two weeks prior to one day in advance of the current date. The option of allowing the user to enter a date one day in advance was enabled for two reasons: (1) The default settings that the web site uses are the current date and time of the computer on which the site is running. If the user were in a different time zone, then it is possible that he or she would want to enter a time that is beyond what the computer current expects for the current date/time. (2) Since it is possible that the user's clock will show a time that is different from that of the web site's clock (which is set via a network time server), it might occur, especially in the time period around midnight, that the user would enter the date of the following day while the computer would still consider the date to be the current one. A specific time can be entered by using the drop-down menus for Hours, Minutes, and AM/PM.

For the data entry line to be accepted and added to the log, a valid blood sugar must be entered, but adding a comment is optional. Since there are many things that a user can potentially type into the text fields, the lines are checked using Java code before saving them to ensure that all of the entered data are valid. For example if any non-numeric characters are entered for a blood sugar, the value is not considered valid. Additionally, only physiologic values between 1 and 1000 are accepted. If a comment is entered, there must be a blood sugar associated with it. However, as already mentioned, a valid blood sugar could be entered without an associated comment.

If the user enters information that does not pass these criteria, then a new screen is displayed informing the user about the problems and the required corrections. Additionally, to save the user time, the data that the user had already entered are displayed on this new screen so that he/she does not need to re-enter everything but only those entries causing the problem.

An example of this is shown in Figures 2.13 and 2.14. Figure 2.13 shows some valid and invalid information entered in the data entry table. The times and dates can be in any order when entered on this screen.

Date	Time Hour | Min | AM/PM			Blood Sugar	Comment
3/23/2004	1	30	PM	ABC	this is a comment
3/16/2004	10	25	PM		a comment with no sugar
3/9/2004	1	15	PM	102	
3/17/2004	5	30	AM		
3/20/2004	11	40	AM		

Figure 2.13. An example of both valid and invalid data being entered via the "Add Blood Sugars" link. Line 1 is invalid since the blood sugar has non-numeric characters. Line 2 is invalid since it contains a comment with no associated blood sugar. Line 3 is valid since it contains a blood sugar. Lines 4 and 5 are ignored because they are blank.

The following is a description of the problems with respect to the information was entered in the example in Figure 2.13. On the first line, non-numeric characters were entered for the blood sugar (i.e., "ABC"). On the second line, a comment was added with no associated blood sugar. The third line is valid since there is a valid blood sugar and no comment needs to be added. The fourth and fifth lines are also valid since, even though the date and time have been changed from the current default date and time, the blood sugar and comment fields are empty, so the lines would simply be ignored.

Assuming that the user had chosen to Save these data, he/she would be presented with the screen in Figure 2.14. This screen has the word "Errors!" prominently displayed followed by a description of the problems that were encountered. The information that the user entered is presented in the same way that it was entered so that it can be modified or deleted.

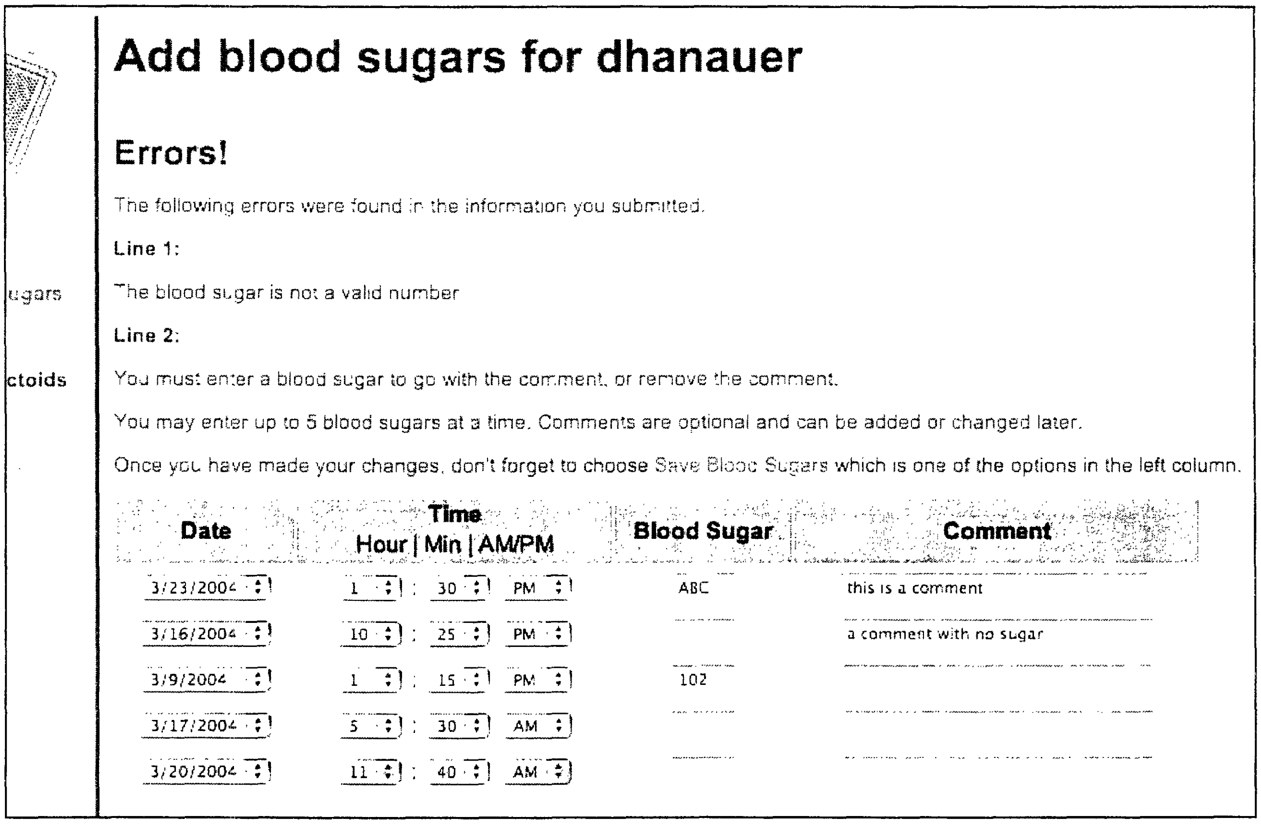

Figure 2.14. The error messages displayed when incorrect information is entered on the "Add blood sugars" screen. The information previously entered is carried over to this screen to allow for rapid editing.

Assuming that the first and second lines were deleted and just the third line was entered, once the save button was pressed the data would be checked and found to be acceptable to save. When that occurs a small dialog is shown to the user providing positive feedback to encourage the user to continue to enter blood sugars. This can be seen in Figure 2.15.

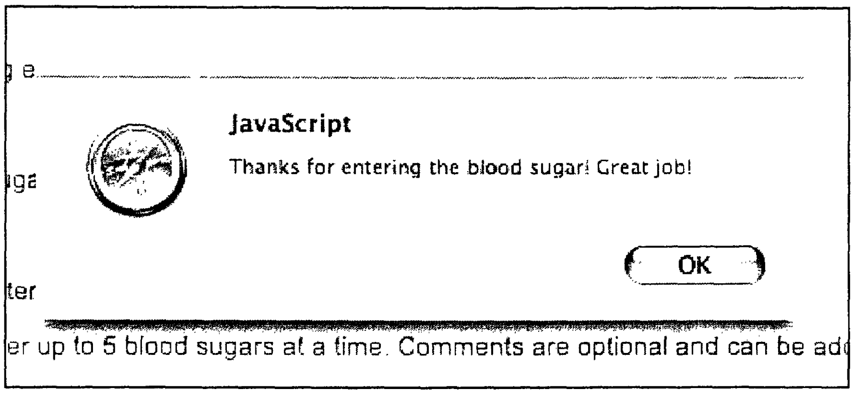

Figure 2.15. The dialog box which provides positive feedback whenever a blood sugar is entered on the web site.

Blood sugars either above 300 or below 70 are considered to be out of range to extent that we consider it necessary that the user follow-up on the blood sugar. Because of this, if a user enters a blood sugar that does not fall between 70 and 300, in addition to receiving positive feedback, he/she is also alerted to the fact that their blood sugar was out of range and should be treated and re-checked. This can be seen in Figure 2.16.

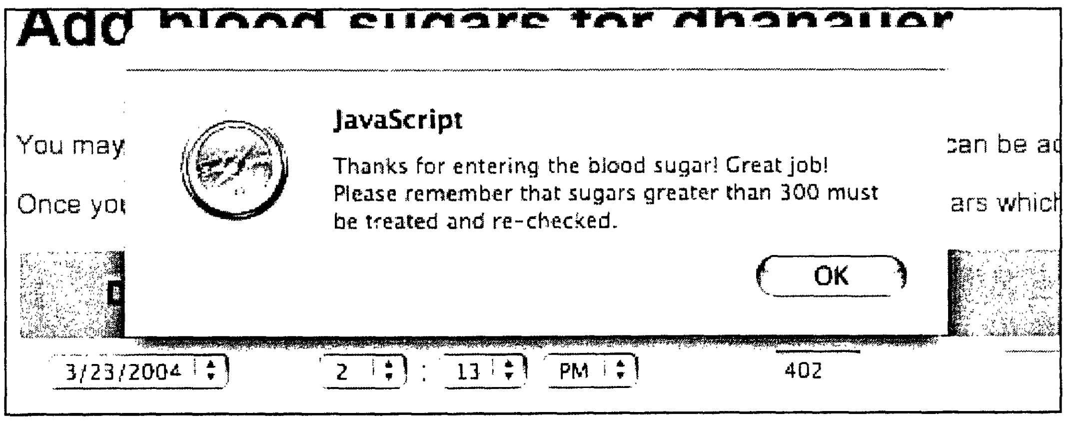

Figure 2.16. The dialog displayed when a user enters a blood sugar that is out of range. Positive feedback is still provided regardless of the value.

Once a blood sugar has been entered it is not possible to change the time, date, or value of the blood sugar. This was done intentionally to prevent individuals from later having second thoughts and removing information that they thought would not be "good". After the blood sugars have been saved, the user is automatically shown the blood sugar log book again with the new data included. Regardless of the order in which the dates and times were entered, the log book always displays the information in chronological order. An additional menu option also appears once data are present in the log book: "Change Comments." This menu option, as well as the way the entered data are presented in the log book, is shown in Figure 2.17.

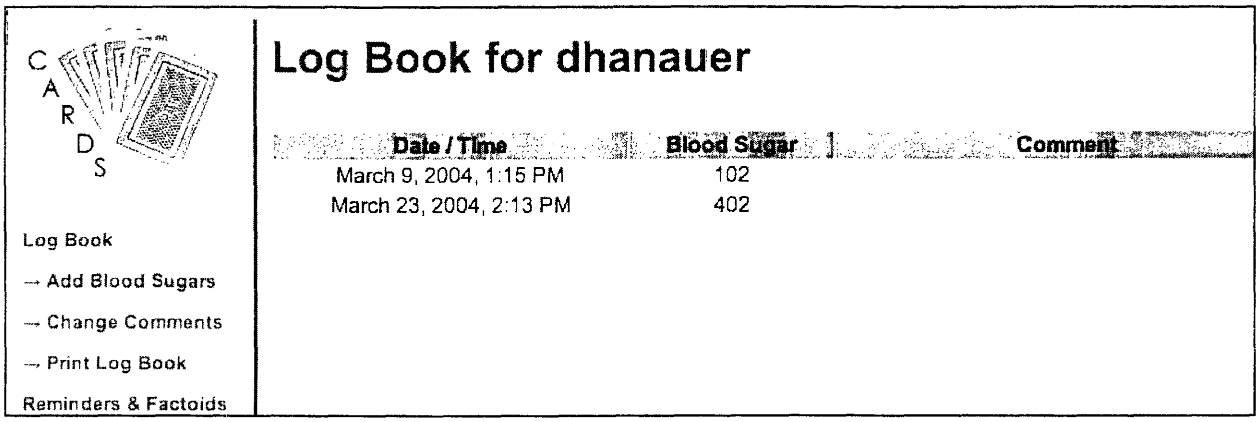

Figure 2.17. The log book with two blood sugars added to the system. Because data are now in the log book, the options in the left column have been modified from those in Figure 2.11. The "Change Comments" option is now available.

Although the actual date, time, and blood sugar values are not editable once entered into the system, the comments can be changed any number of times. Comments can be used to describe why a certain blood sugar was obtained, what was done in response to the blood sugar level, or anything that the user would like to add. Selecting the "Change Comments" link shows the log book in a similar format but with a text entry field for each line. If there was no comment, the field is initially blank. If a comment already exists, that comment would be present in the text field for editing. This can be seen in Figure 2.18.

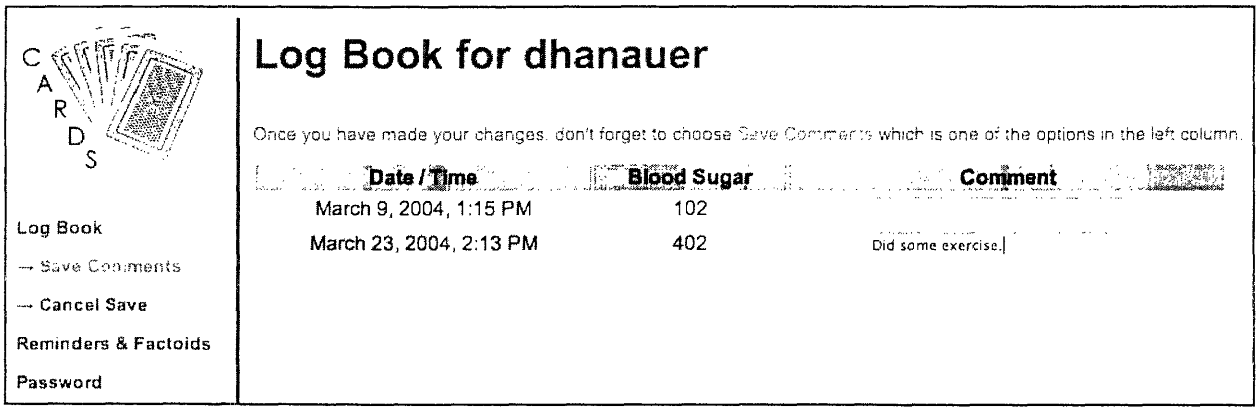

Figure 2.18. The log book with editable comment fields, visible after pressing the "Change Comments" link.

Because the change comments screen is another data entry screen, the menu options again change to "Save" and "Cancel." Additionally, since a user can enter any comment that he or she wants, there is no check done on the information entered. Assuming that a user entered the comment "Did some exercise" as seen in Figure 2.18 and then clicked on "Save Comments", that comment would then be visible in the log book as seen in Figure 2.19. This comment could be changed or deleted at any time by clicking on the "Change Comments" link again.

CARDS

Log Book
→ Add Blood Sugars
→ Change Comments
→ Print Log Book
Reminders & Factoids
Password

Log Book for dhanauer

Date / Time	Blood Sugar	Comment
March 9, 2004, 1:15 PM	102	
March 23, 2004, 2:13 PM	402	Did some exercise.

Figure 2.19. The log book after the comment "Did some exercise" was added.

One last feature is present in the Log Book section of the site; the "Print Log Book" option. Clicking on this link will open up a new window above the windows of the CARDS web site. The blood sugar data in this window are formatted and presented in a different manner. This format can be seen in Figure 2.20.

Blood Sugar Log Book

Date	Breakfast	Morning Snack	Lunch	Afternoon Snack	Dinner	Bedtime Snack	Overnight	Early Morning
	5 AM - 8:59 AM	9 AM - 10:59 AM	11 AM - 1:59 PM	2 PM - 4:29 PM	4:30 PM - 7:59 PM	8 PM - 10:59 PM	11 PM - 1:59 AM	2 AM - 4:49 AM
3/9/2004			102					
3/23/2004				402				

Figure 2.20. The format for the log book when the "Print Log Book" option is chosen.

The printable version of the log book removes any color since it is assumed that most likely it would be printed using black ink or toner. Additionally the menu options that are normally available on the web site are removed, since having them present would decrease the amount of space available to present the data. Only information relevant to viewing the log book is shown. Another very important aspect of the way in which the information is presented is that the printable version of the log book eliminates the comments and instead shows the blood sugars categorized by time of the day. While the comments are useful, they would take up too much space when trying to present the blood sugar values in a succinct manner for easy pattern recognition.

Since insulin is usually supposed to be administered at specific times of the day, it helps to know what the blood sugar values are at those times so that the insulin dose can be adjusted appropriately. For example, since insulin helps to lower blood sugar levels, if the blood sugar was consistently high many days in a row during the "Morning Snack" time period, this might suggest that the morning insulin dose should be increased to help lower the blood sugar levels slightly later. Presenting the information in the table format as shown in Figure 2.20 helps make such patterns more obvious. This is also a very good format for creating a printable record to bring to one's healthcare provider for reviewing if the user chooses to do so.

2.1.9 The Web Site: Reminders & Factoids

The reminders and factoids section of the web site allows the user to view and set his or her preferences for having the factoids and reminders sent. When a user is first added to the system, the default settings are to have the daily factoids setting on and all of the reminder settings off. When the user first clicks on the link "Reminders & Factoids" he/she is shown the current settings along with the option to "Change Settings." The status of Factoids sending is shown above a table that displays the status of each of the 10 possible reminders. The default display of settings can be seen in Figure 2.21.

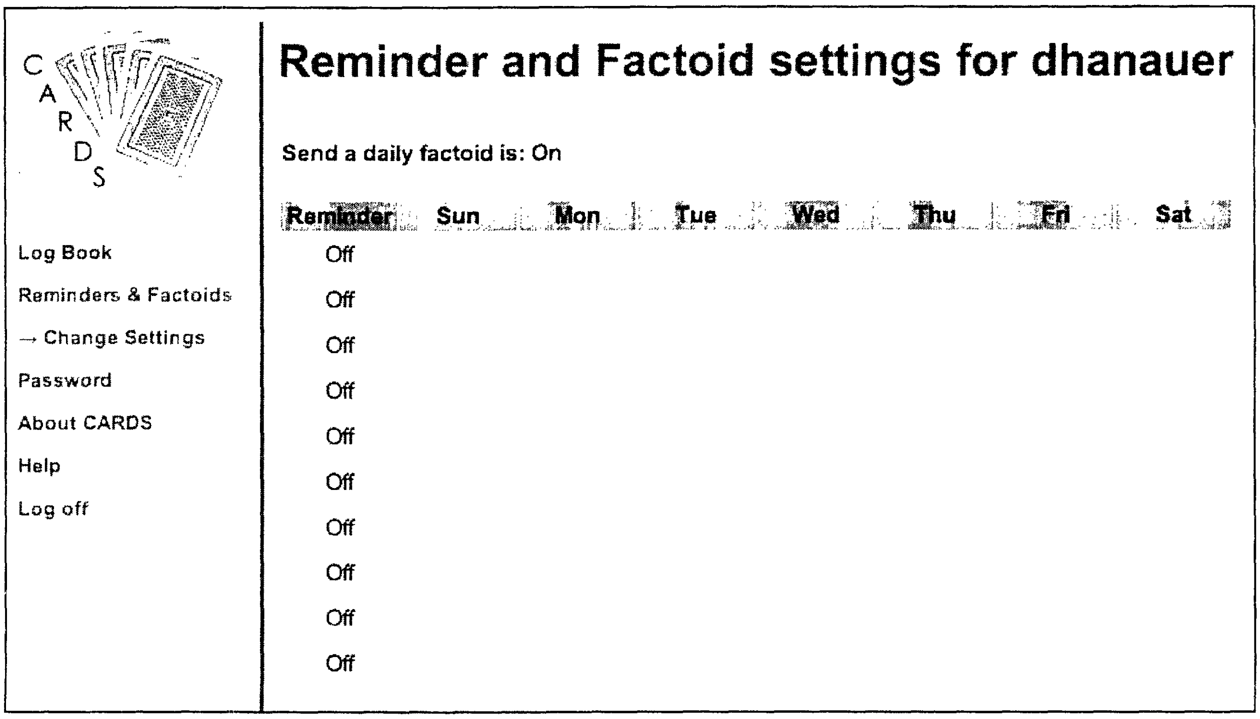

Figure 2.21. The default options for the reminders and factoids when a user first is added to the system.

A total of 10 reminders can be set by each user and can be customized based on when he/she would like to receive them. This customization includes time of the day and day of the week. Such customization is important to allow the user to set the times of reminders to coincide as well as possible with the user's expected weekly activities. For example, a student might want an early morning reminder Monday through Friday before school, but might want a morning reminder to be sent later in the morning on weekends if he/she were to typically sleep late.

When the user clicks on the "Change Settings" link, the display changes to a page in which all the settings can be modified (Figure 2.22.) Pull-down selection menus allow the user to choose either "On" or "Off" for the daily factoids as well as the Hour, Minute, and AM/PM settings for each reminder. The day of the week is chosen for each reminder by selecting a checkbox under the appropriate column. When a reminder is off, the default for the pull-down menus for the hour, minute, and AM/PM is off. For the time of the reminder to be set appropriately, all three of these menus must be changed to something other than "Off". If any of those menus is set to "Off" the reminder will still be considered to be off and the time will not be saved.

Furthermore, if a time is set for a reminder and a user chooses to turn it off, once any one of the items from the Hour, Minute, or AM/PM menus for a given row is changed to "Off" the other two settings will automatically switch to "Off" as well, using JavaScript code. For example, if the Hour menu is set to "5", the Minute menu is set to "30", and the "AM/PM" menu is set to "PM", then the reminder time would be considered to be on. If the user were then to change the "AM/PM" menu to "Off", the Hour and Minute options would automatically change to "Off" as well.

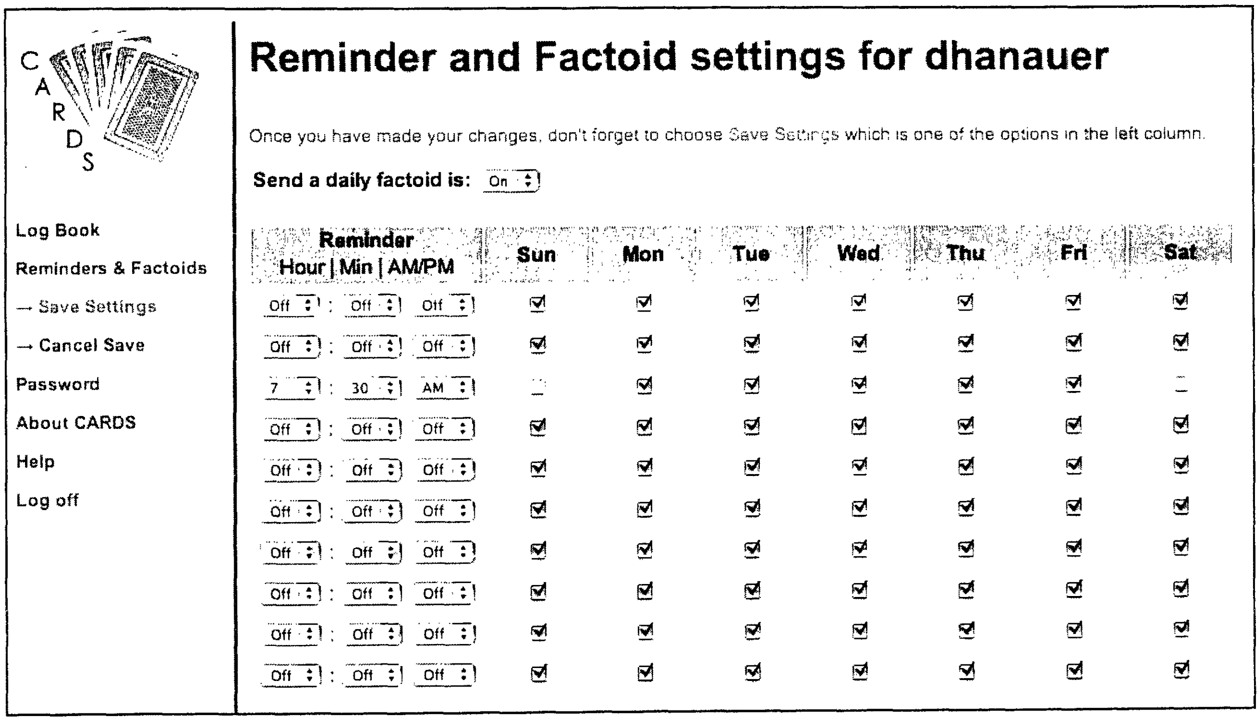

Figure 2.22. The editable reminder and factoids screen.

Once the desired settings have been made for the Factoids and the Reminders, the user can then press "Save Settings", highlighted as a red link to the left. The settings are saved and the new settings displayed again to the user, reflecting the changes that have been made (Figure 2.23).

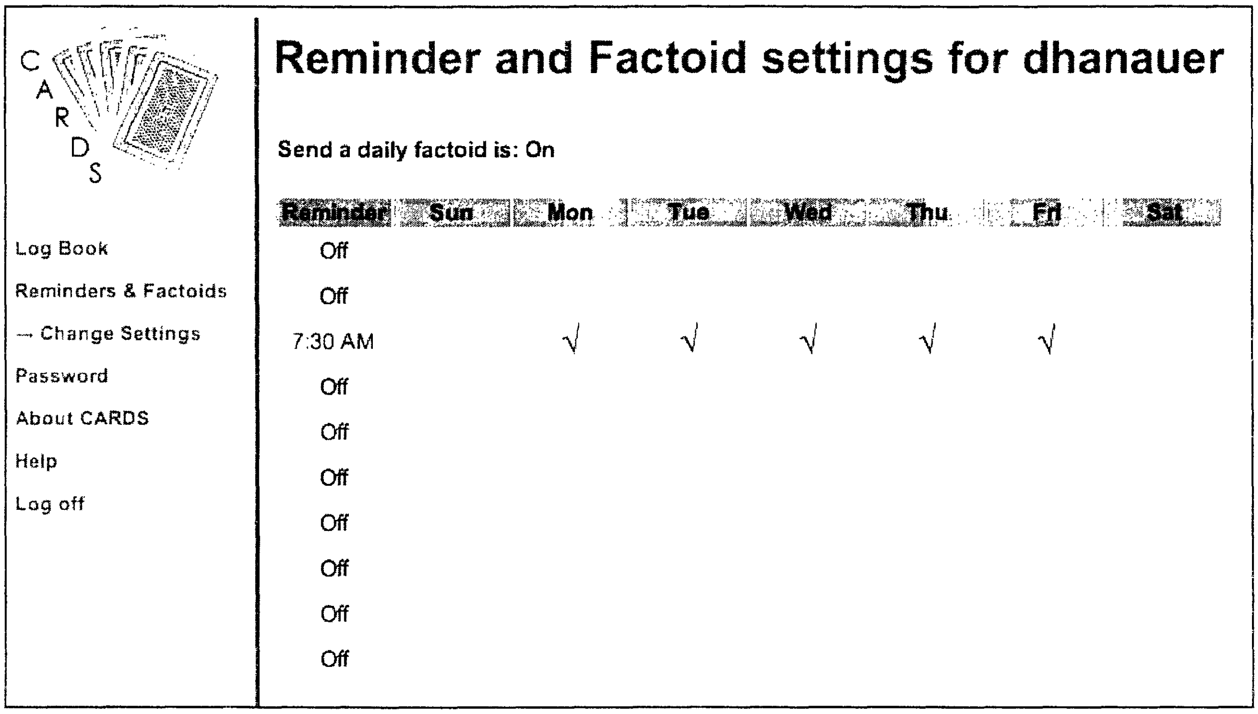

Figure 2.23. The reminder and factoids screen reflecting a change in a reminder setting.

2.1.10 The Web Site: Password

The "Password Link" of the website is very basic. It simply allows users to change their password if they choose. Clicking on the link once brings up a new web page which instructs the user to click on the "Change Password" link if that is what he/she would like to do (Figure 2.24). Clicking on that link brings up a typical change password screen (Figure 2.25) where the user must enter the current password and then type the new password twice (to make sure that it was typed correctly). More information about passwords can be found in the section on Security, below.

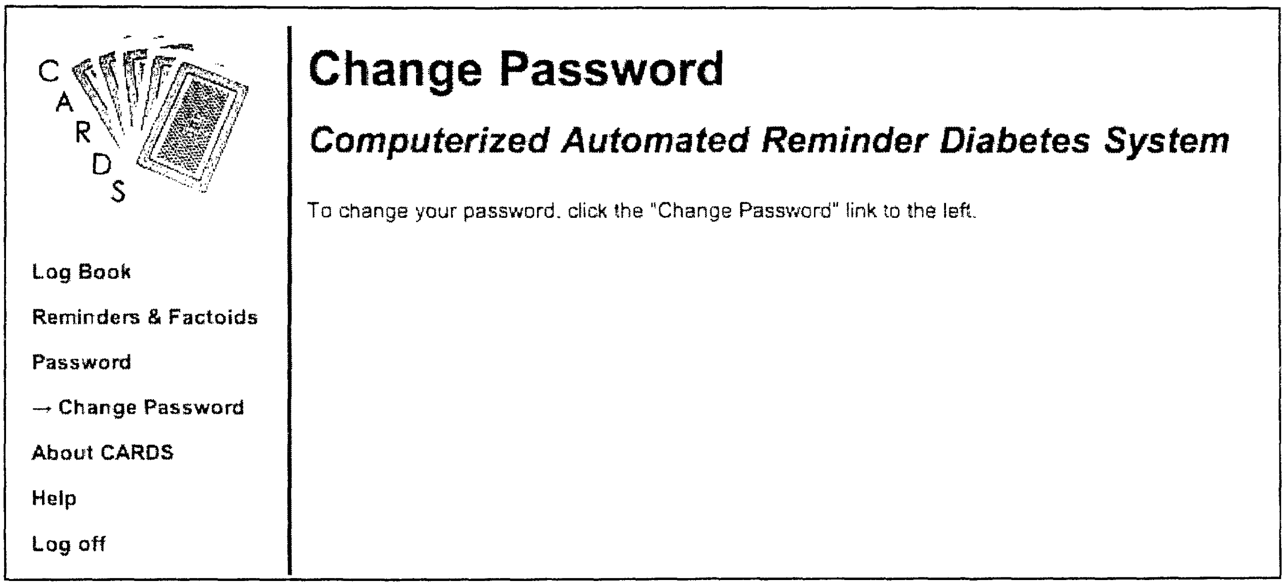

Figure 2.24. The screen that is displayed when a user clicks on the "Password" link.

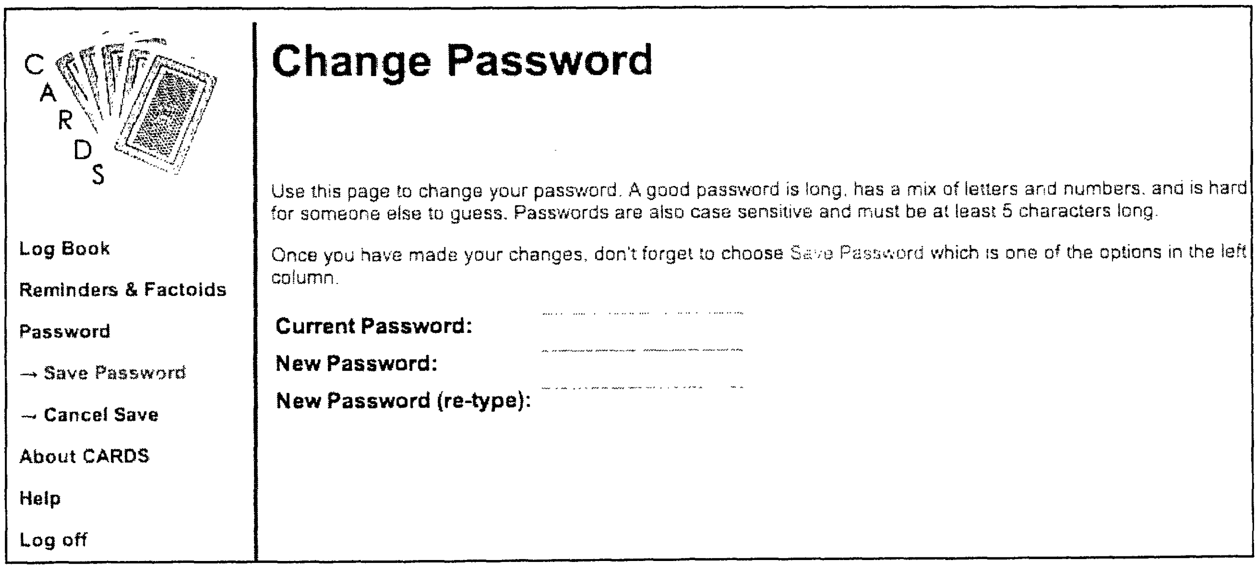

Figure 2.25. The page for users to change their password.

If the password is typed incorrectly, a screen similar to that in Figure 2.25 is shown, with the added text, "Error!", in addition to more details about the problem. In the example in Figure 2.26, the problem was that the user did not enter the current password correctly. Another potential error would be that the new password was not typed the same both times.

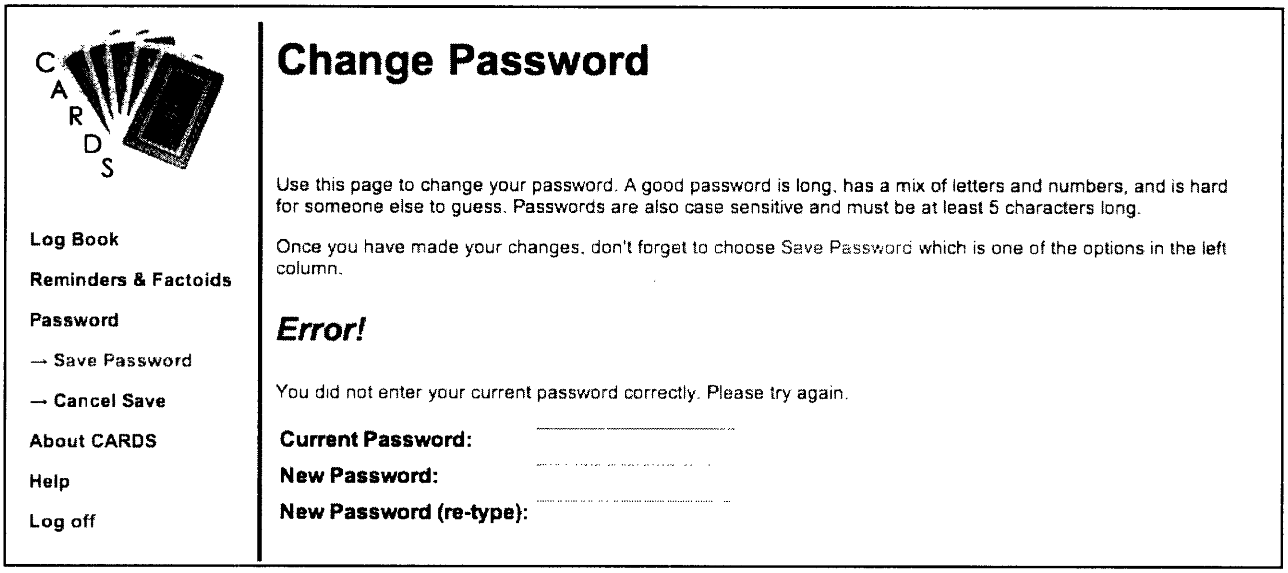

Figure 2.26. The change password screen as displayed when an error occurs.

If the password is changed correctly, the user will be shown a screen as seen in Figure 2.27.

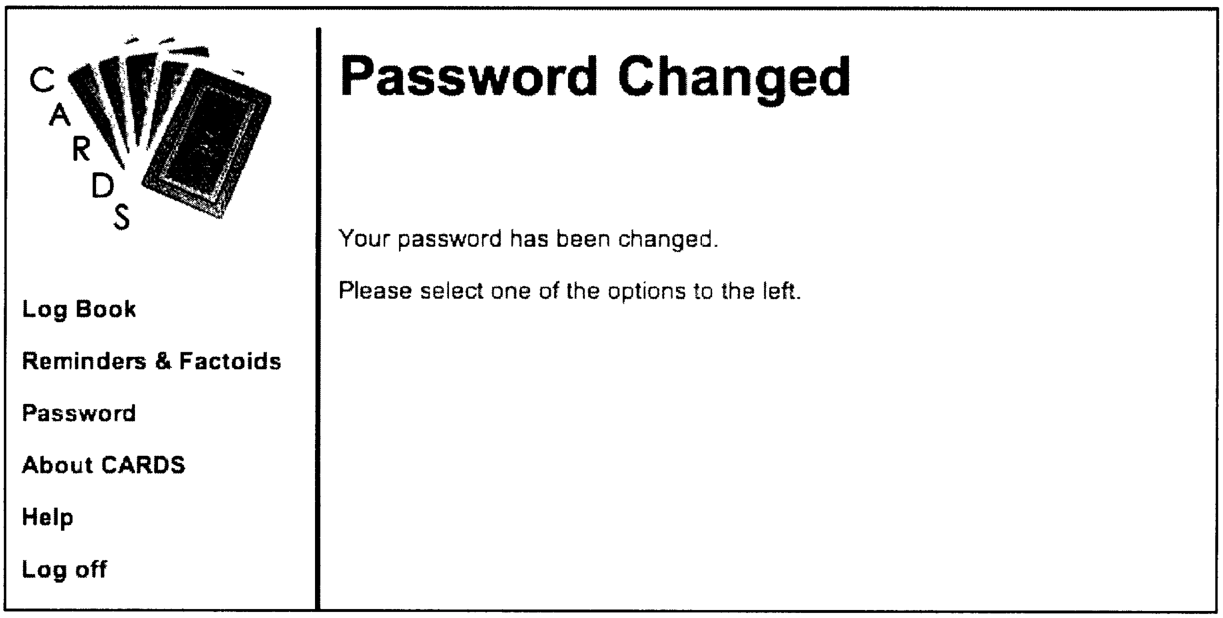

Figure 2.27. The screen displayed when a password has been successfully changed.

2.1.11 Web Site: About CARDS, Help, Logging Off

The "About CARDS" and "Help" links display information that is identical to the similar links that are offered before a user successfully logs on. The "Log Off" link allows a user to log out of the system. This is explained in greater detail in the "Security: Web Site" section, below. The screen in which a user logs off is shown in Figure 2.28. The user is instructed that it is advisable to close the window, which he/she can do either by clicking on the "close window" link (executed through JavaScript) or by closing the window manually. The only link available on the left side of the screen is "Log On." If the user selects that link, then a page that looks identical to that in Figure 2.4 is presented.

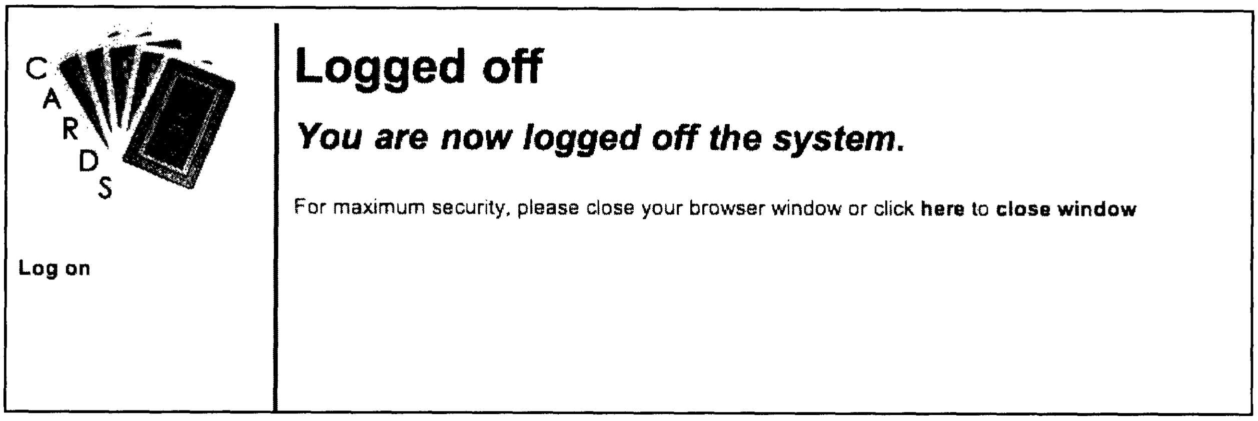

Figure 2.28. The screen displayed after a user clicks on the "Log off" link.

2.1.12 Web Site: Logging the Web Site's Usage

Because CARDS is an experimental system designed to see how well such a system is utilized in actual practice, many aspects of how the system is used are logged to various files. Aspects of the system which are logged for each user include the time and date when a user: logs on, views his/her preferences, changes the preferences, views the log book, etc. The number of reminders sent to each user is also recorded as well as the number of days that factoids are sent to each user. The time and date of a blood sugar in the log is considered to be the time/date stamp for each value.

2.1.13 The CARDS computer: Adding a new user

Because this system is an experimental one, certain aspects have not been fully automated. Adding new users to the system is one such aspect that involves manually editing specific files on the CARDS computer. When a new user is added, his/her username and password need to be added to a file. Additionally, a data directory to hold his or her data also needs to be created. Another file also needs to be edited which connects the user's chosen username with his/her e-mail or SMS address.

As opposed to the website in which a user is identified by a username/password combination, each e-mail or cell phone user is identified when messages are sent by the specific e-mail or SMS address with which he/she registered. One caveat of this requirement is that a user can't borrow someone else's phone or e-mail account to send information to the system. This is because there is no other sign-in process or identification process to verify a user's identity when sending messages to CARDS.

This process of adding a user's e-mail address is somewhat complicated since it is possible that the e-mail address given by the user may simply be an alias for a different e-mail address. For example, the e-mail address "dhanauer@dsg.harvard.edu" is actually an alias for "dhanauer@rics.bwh.harvard.edu". Thus if the former address were used to add to the cards system, mail could be sent to that address. However, if mail was sent to CARDS from the " dsg.harvard.edu", the address that would be seen by CARDS would actually be the "rics.bwh.harvard.edu" one. The e-mail address that is visible to CARDS is the only address that actually mattered for identification purposes.

2.1.14 The CARDS processes: Background

The web site is not the only major component of CARDS. Other components are the small programs that were written to send reminders and receive data sent back to the system from either e-mail or cell phones. This was accomplished using custom-made AppleScript applications which are able to read and write to the same data files that the web site is accessing for patient data. The timing of launching of the applications is controlled by a Unix program called "cron" which acts like a pacemaker, launching applications at the appropriate times and in the appropriate sequences. The AppleScript programs were designed to work with an AppleScript-aware application called "Apple Mail." This mail program is used to send and receive the messages; using this program eliminated the need to develop a program to perform these tasks specifically for CARDS. The following is a description of the various AppleScript programs which are launched at specific times and what those programs do. The AppleScript applications are called "processes" and each process encompasses a specific task. These tasks cycle in order, from 1 to 7 and the cycle repeats every three minutes

2.1.15 The CARDS processes: Process 1, Cleaning up the Mail Application

The first process dealt with correcting any program-specific problems concerning the Mail application. Because the Mail application was written to be used by a human, not all aspects of it were completely automated. One problem discovered during the testing process of CARDS was that occasionally a mail server might not respond when sending messages. If that occurs, a window appears in the application on the CARDS computer, stating that the message could not be sent and a button is displayed to "Close Window" (Figure 2.29).

Because there is typically no person available to watch the automated system, it was necessary to find an automated way to determine whether such a window was open and, if so, how to close it. This was achieved through a small addition known as "UI Scripting" or "User Interface Scripting". This was an AppleScript addition provided as a beta test by Apple Computer to use AppleScript commands to control various aspects of the user interface automatically. Using this addition it was possible to determine that the window was open and then to issue a command to close the window.

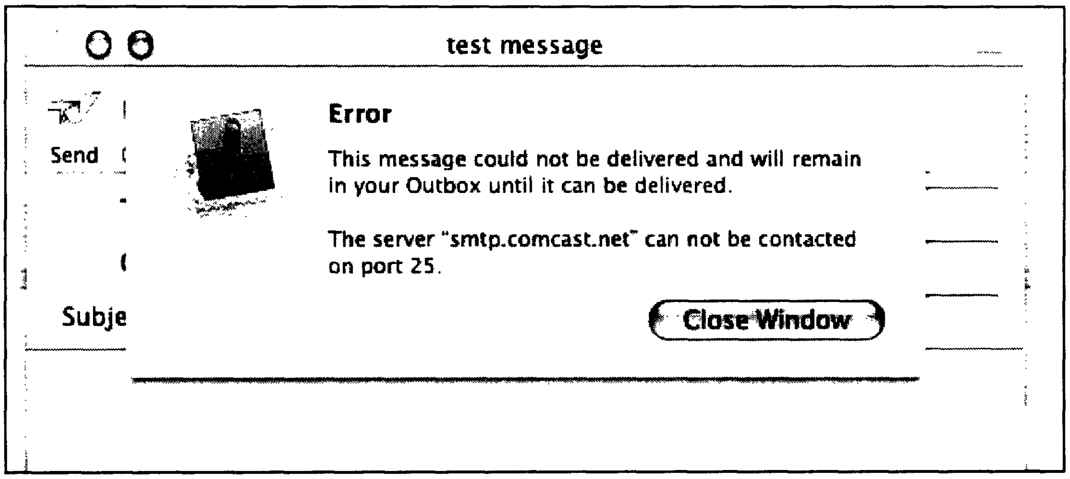

Figure 2.29. The window that is displayed when the Mail program encounters difficulty with sending a message. This must be closed manually or with special User Interface scripting.

The basic function that the Process 1 performed was to ensure that the Apple Mail application was operating at its baseline level without any windows open reporting problems or warnings, and to take care of any problems that might exist. For example, if a message or a group of messages could not be sent, they would be saved for sending later. The sending of these saved messages would often not occur until another new message was sent. To ensure that messages are sent out as soon as a valid connection with the mail server is re-established, Process 1 automatically generates an e-mail to "dhanauer@dsg.harvard.edu" to promote the sending of any other messages that had been delayed and were waiting to be sent. After this process is completed, it launches the second process in the CARDS routine.

2.1.16 The CARDS processes: Process 2, Checking for New Messages

Process 2 is perhaps the most complex application of the small ones written. The first step of the process is to check if any new messages have been sent to the CARDS system. These messages could be sent by users from either an e-mail account or a cell phone SMS account. After all new messages are received, they remain in the Inbox of the mail program. Using AppleScript each message is then examined.

The sender is compared to the list of known users. If a message comes from an unidentified sender, the message is forwarded to the CARDS administrator (the author) for review. The message is then transferred from the Inbox to a different mailbox labeled "Spam." If the message comes from a known user of CARDS then further processing occurs. SMS and e-mail messages are treated in the same manner. The only type of message that can be sent to CARDS is one that contains a blood sugar with optional additional information attached to the message.

When Process 2 of CARDS first examines a message it ignores the subject and only checks information in the message body. It also only examines the first line of the message body and discards all other information. This is because with many e-mail programs, if a person replies to a message, the original message is included. Additionally, many people have signatures automatically appended to the end of the message and this could potentially interfere with the parsing that CARDS would undertake.

Regardless of what is sent to CARDS, a message is always sent back to the user to act as a confirmation that the message was received. If the first line of the message body is blank, a message is automatically generated and sent back to the user with the line: "The message you submitted appears to be blank. Please consider re-sending it." If it the first line is not blank the program then checks whether the basic rules have been followed for constructing the message. The one rule that must be followed every time is that the first item in the message must be a number which represents the blood sugar. If the first item is not a valid number then the user is sent back a message stating, "There was a problem with the message you sent--the first item was not a valid number."

Additional checks done are for blood sugars that are considered to be out of range, and thus likely not real. These are for blood sugars less than zero and greater than 1000. Appropriate messages are sent back to the user for these values as well. If a valid blood sugar is received, the value of the blood sugar, and the time and date that the message was received, are stored in the log book in the same format as data entered via the web site. This blood sugar is then immediately available on the user's web site log book for viewing. Any time a valid blood sugar is received, a positive feedback message is sent back to the user. To prevent users from becoming bored, the positive message is chosen at random from a list of messages stored in a text file. Such messages include, "The blood sugar was received. Great job!", "Your blood sugar should now be available on the web. Thanks!", and "Thanks for sending your blood sugar. You're doing a great job!"

Just as with entering data on the web site, any blood sugars higher then 300 or lower than 70 prompt a special warning that blood sugars out of range should be re-checked. Users are still given positive feedback, though. An example of such a message is "Thanks for sending in your blood sugar! Please remember that sugars less than 70 must be treated and re-checked." This blood sugar would also be added to the user's data file and would then be viewable on the web site.

Sometimes users might not want to send in a simple blood sugar, however. There may be times in which users would also like to add a comment to annotate the sugar, just as they could on the web site. Additionally, it is possible that users might want to enter a blood sugar that was measured at a time or day that is not the same as when he/she eventually sends the message. It is possible to deal with any of these circumstances as long as certain conventions are followed.

The blood sugar must always be the first item in the message. Anything else should be added to the same line as the blood sugar and be separated by spaces. A time and/or date can be added which will override the default time/date that the system would normally use. If a time or date is added, it must follow immediately after the blood sugar. If both are added, they both must follow after the blood sugar, but the order does not matter.

The date must be written in the form of "month-day-year" or "month-day" (in which case the year will be assumed to be the current year). Either dashes ("-") or slashes ("/") can be used to separate the elements of the date. The time should be written in the form of hours:minutes. If an AM or PM is appended then the time will be interpreted on a 12 hour clock. If no AM or PM is appended then the time will be interpreted based on a 24 hour clock (e.g. military or European time). Following the optional time and/or date is any comment that should be added.

Parsing routines were added based on problems encountered during testing. One is to recognize a time, written simply as "8 AM" without the colon or minutes appended. Additionally, it is acceptable if the user does not include a space between the number and the "AM" or "PM". One other parsing feature added is to ignore space(s) between the colon and the hours or minutes.

These rules can probably best be understood by viewing Table 2.1 below. For the purposes of the example, it should be assumed that the current date and time are March 24, 2004 at 2:15 PM.

Message received by CARDS	Date	Time	Blood Sugar	Comments
100	March 24, 2004	2:15 PM	100	
101 7AM	March 24, 2004	7:00 AM	101	
102 7: 15 AM	March 24, 2004	7:15 AM	102	
103 8 AM	March 24, 2004	8:00 AM	103	
104 13:20	March 24, 2004	1:20 PM	104	
105 3-10	March 10, 2004	2:15 PM	105	
106 3/10/03	March 10, 2003	2:25 PM	106	
107 3/10 8AM	March 10, 2004	8:00 AM	107	
108 3:85 AM	*			
109 14/10	*			
110 4-3-02 ate snack	April 3, 2002	2:15 PM	110	ate snack
111 22:10 6-5 running fast	June 5, 2004	10:10 PM	111	running fast
3/15/02 112	*			
113 2:15 AM 3-14 feel good	March 14, 2003	2:15 AM	113	feel good
114 am fine 2:15 AM	March 24, 2004	2:15 PM	114	am fine 2:15 AM
115 snack 5/5 14:10	March 24, 2004	2:15 PM	115	snack 5/5 14:10
116 3-10 candy 4:15 PM	March 10, 2004	2:15 PM	116	candy 4:15 PM

Table 2.1. Examples of messages that could be sent to CARDS and how those messages would be parsed into the date, time, blood sugar, and comment fields. It should be noted that any time or date that follows a comment will get added to the comment and will not be parsed as the current time or date.
* = invalid message (warning will be sent back to user)

Once a valid blood sugar has been received and parsed, the proper information is stored in the user's data file and the message containing positive feedback is sent to the user. After this cycle has been completed for every message received, this process quits and the next process is launched.

2.1.17 The CARDS processes: Process 3, Sending Reminders

Once all new data for a given time have been received, parsed, and added to each user's data file process 3 begins. Its task is to determine who should be sent a reminder. This small program first cycles through each user's preferences and determines if a reminder should be sent at a specific time and day of the week.

A reminder should be sent if the time that the user has set as a reminder is either the current time or has already passed but is within an hour of the current time. The rationale for this may not make intuitive sense, so it will be explained. Since process 3 cycles every few minutes along with the other processes, it is not truly running continuously, and may be unable to automatically send out a reminder at the precise time that it is programmed to be sent. Rather, every few minutes the program determines which reminders are due or overdue and then sends them out if they have not been sent. The reason that up to one hour is allowed is that, under certain circumstances the system could be unavailable such as during routine maintenance. If that were to happen, then once the system was back up and running, any reminders that should have been sent within the last hour should still be sent, but anything more than an hour overdue is considered no longer relevant and not sent.

If the process determines that a reminder should be sent, it then checks the user's data file to determine whether any blood sugars have been entered into the system for that user within the last hour (users can spontaneously send blood sugars by phone or e-mail, or can enter them at any time from the web site). If a valid blood sugar that has been received within an hour of the time a reminder was supposed to be sent, that reminder will instead be suppressed, under the assumption that the user has remembered it already.

Additionally, the process checks whether any blood sugars have been received that are dated up to 1 hour into the future (past the current time of the reminder). If such a blood sugar is found the reminder will also be suppressed. This was done to provide some flexibility in the system to prevent reminders from being sent close to the time of entered values. It is possible that the user's clock and the system's clock are out of sync, so a limited look into the future is considered to be acceptable for suppressing a reminder.

Assuming that a reminder does need to be sent to a user, the reminder is selected from a random list of reminders stored in a text file. Examples of such reminders include, "Reminder--It's time to check your blood sugar", "This would be a great time to check your blood sugar", and "Don't forget--it's time to check your blood sugar." Once the reminder has been sent, the fact that it has been sent is logged by the system.

If the user responds to the reminder with a blood sugar, the sugar will be added to the system (through Process 1), but if no response is received, then a repeat reminder will be sent to the user 15 minutes after the first reminder. After this repeat reminder is sent, no further repeat reminders are sent again until the next scheduled reminder is due. Additionally, if a user submits a blood sugar to CARDS less than 15 minutes after the first reminder was sent, then no repeat reminder will be sent to the user. Repeat reminders, like reminders, are chosen from a random list and include, "In case you missed the first reminder, it's time to check your blood sugar", "Just a repeat reminder, now would be a good time to check your blood sugar", and "Here's a second reminder to check your blood sugar."

There are a few circumstances in which reminders may appear to be behaving in unusual ways even though they are simply following the rules as outlined above. Reminders (or repeat reminders) will not be sent if the user logs onto the website and adds a blood sugar to the system that is ± 1 hour from the time of the reminder. Also, if a reminder is sent and then the user goes to the website and turns the reminder off on the "Reminders & Factoids" settings page, then no repeat reminder will be sent even if no blood sugars were added to the system.

If the current time is 3:00 PM and a user goes to the web site and specifies the option for a new reminder for that day for 2:30 PM, a few minutes later a reminder will be sent to the user since it is still within the 1 hour time window for reminders. However, if the reminder option specified is for 1:00 PM then no reminder would be sent. Lastly, if a reminder is set on the web site for less than an hour prior to the current time and the initial reminder is sent and ignored, a repeat reminder will only be sent if, at the time that the repeat reminder is supposed to be sent, there is still less than an hour between the current time and the time for which the reminder is set.

Once the process cycles through each user and completes its task, it launches the next process.

2.1.18 The CARDS processes: Processes 4 and 5, Sending Factoids

Factoids are sent according to a schedule that is determined at the beginning of each day. Slightly after midnight each day, a time is chosen at random between 4:00 PM and 9:00 PM for the regular Factoids to be sent and a separate random time within the same range is chosen for the diabetes Factoids to be sent. Similar to the way that the other reminders are sent, once the specified time has passed the program selects a factoid from a random list and then cycles through each user's preferences to determine if he/she should receive a factoid. Users who chose to receive factoids are then sent one. These two processes occur back-to-back in rapid succession (first the regular Factoids and then the diabetes Factoids).

Examples of regular factoids include "The flea can jump 350 times its own body length. It's like a person jumping the length of a football field", "Butterflies can taste with their feet", "A strawberry has roughly 200 seeds on it." Examples of diabetes factoids include, "Hunger may be a symptom of low blood sugar or high blood sugar, so it's important to check blood sugars often", "Thirst, frequent urination, and fatigue (tiredness) are some symptoms of high blood sugars", "A glass of non-fat milk has the same amount of protein, vitamin B, potassium and calcium as an 'energy bar.'"

The random nature of the timing of factoids was done for several reasons. The first was to make it more interesting to the users. While the reminders are meant to be sent at pre-determined times, there is no reason why a random fact would need to be sent at a specific time. Furthermore, if participants routinely received messages from other people (such as friends), then if a message came to them at a random time they might be more inclined to read it to see who sent it. Lastly, since on any given day a user might receive a diabetes or a regular factoid first, the user would more likely read at least the first one to see what it was, even if he/she felt that the educational diabetes factoids were not very exciting.

Once the factoids have been sent for a specific day, the fact that they were sent is logged. After this process is complete, the next process is launched.

2.1.19 The CARDS processes: Process 6, Print Diary Reminder

The option to print the blood sugar log, outlined in the section "The Web Site: Log Book", was thought to be a very valuable and educational feature that all users should view at least once per week. As a result it was decided during the CARDS testing phase that every Sunday, between 4:00 PM and 9:00 PM, every user of the system should be sent a reminder to review his/her blood sugars. This is not an option in the user's preferences and there is no way for the user to turn it off. The AppleScript code that invokes this feature is very similar to that of the code that sends out the Factoids. In this case a different message is sent to each user: "It's a great time to print your blood sugar diary and review the numbers." Once this ends, process 7 is launched.

2.1.20 The CARDS processes: Process 7, Sending Forgotten Passwords

The last general process that runs as part of CARDS is a small application which sends out passwords to users who have entered their username and indicated that the password has been forgotten. After a user enters his/her username in the text field on the web site, that name is logged to a file on the CARDS computer. When process 7 runs, it checks that log file for any names and then compares the name to the list of names that have been added to the system. If it finds a match, it then determines the password associated with that name and then sends the password to the e-mail or SMS address associated with the name. The message that is sent is a very simple one "Here is what you forgot: ", followed by the actual password. The word "password" is not included as a security precaution.

If no match is found in the list then no message is sent. Either way, the name is then deleted from the forgotten passwords log file and the process ends. The completion of this process ends a single cycle for the seven processes. This cycle currently repeats every three minutes.

2.1.21 Summarizing Data from CARDS

Another set of two small applications, or processes, was created and set to be launched by cron every hour on the hour. These processes create summaries based on the usage logs for each user of CARDS. Not everyone who uses CARDS will have data summarized. This is so that people like the author can still use the system without affecting the collection of data pertaining to its use. Only those people included in the study are included in the summarization of the usage data. The processes run hourly to provide frequent updates on usage patterns. A master file contains the names of every user of CARDS for which a summary should be created. This file also needs to be updated manually when a new user is added. The file contains the username and also the date that the user started the study. When the first of the two summarizing processes is launched, it examines the master file to determine which users should have their data summarized. For each of those users it then scans the usage logs to determine how many times each event has occurred on a specific day, starting from the day the user was enrolled and lasting for 12 weeks (84 days) from that time. This also allows subjects to continue to use the system even after their full study period has been completed without affecting the data collection from other users.

The output from the first process is a text file for all users with tab-delineated data containing their usage patterns. Even though users may be entered into the study at different times, each users summary log contains information for 12 weeks starting from the day the user was enrolled. Day 4 of a particular user's log might look something like the following (in truncated form):

```
Day   Date        logins diary  prefs  reminders
4     2/12/04     2      0      2      0
```

Certain rules were adhered to in terms of determining usage. For example, each event (such as logging into the web site) was considered to be a unique occurrence only if more than 30 minutes had elapsed between that event and any prior event of the same category. For example, if a user logged onto the site at 3:15 PM and then again at 3:25 PM, the summary would only count that as logging in one time. If the user logged in at 3:15 PM and then again at 3:55 PM that would count as two separate logins since more than 30 minutes had elapsed between the two events. A result of following this rule is that a user who logs in at 3:45 PM, then 4:05 PM, then 4:20 PM will only have one login recorded for all three events since the two latter logins each occurred less than 30 minutes after the preceding one.

Once this summarization process is complete the second summarizing process launches. This program, using data from the previous summarization process, adds all of the different events for all of the users for a given day. Thus, if two different users each logged in twice on a given day then the overall summary for that day would show 4 logins. This second, overall summary is divided into e-mail users and cell phone users. This summary is intended to enable observation of how the system is being used on a day-to-day basis and is not meant for collecting any new data. The results are stored in both a tab-delineated text file and a web page. The web page is automatically saved on the web site so that the summary (which contains no identifiers) can be viewed from any computer, whereas the tab-delineated text files cannot be viewed from a web site. An example of this summary web page can be seen in Figure 2.30.

Summary, updated Wednesday, March 17, 2004 5:00:53 PM

email/SMS	Date	Logins	Total BG	BG SMS/eml	BG web	diary	chng cmnts	vwd prts	fctds	dbts fctds	rmndrs sent	rmndrs rspnse gnrtd	rmndrs ignrd	vwd prnt dry
SMS	1 - 13 - 2004	2	2	0	2	1	0	2	1	1	3	2	1	0
email	1 - 13 - 2004	2	1	1	0	2	0	1	2	2	1	1	0	0
SMS	1 - 14 - 2004	5	2	2	0	4	1	3	1	1	5	3	2	0
email	1 - 14 - 2004	2	0	0	0	1	0	2	1	1	2	0	2	0
SMS	1 - 15 - 2004	4	16	1	15	4	1	4	2	2	5	1	4	0
email	1 - 15 - 2004	1	4	4	0	1	0	1	2	2	2	0	2	0
SMS	1 - 16 - 2004	7	10	0	10	4	0	2	1	1	4	2	2	0
email	1 - 16 - 2004	3	2	1	1	3	1	3	1	1	3	1	2	0
SMS	1 - 17 - 2004	3	1	1	0	3	0	1	1	0	3	1	2	0
email	1 - 17 - 2004	0	0	0	0	0	0	0	1	0	2	0	2	0
SMS	1 - 18 - 2004	3	2	0	2	2	1	3	1	1	4	1	3	0
email	1 - 18 - 2004	3	4	2	2	4	1	3	2	2	2	0	2	0
SMS	1 - 19 - 2004	1	0	0	0	0	0	1	1	1	2	0	2	0

Figure 2.30. A screen shot showing the daily summary table available on the web site. Each day is divided into two rows, one for cell phone SMS users and one for e-mail users. The columns represent the total number of events for all users in one of the two categories for a given day. For example, the first row shows that there were two logins to the web site for SMS users on January 13, 2004.

A final summary created is comprised of any types of errors that might have occurred. There are two types of errors that CARDS was designed to catch. One is a major type of system error with one of the processes, wherein a process is unable to perform its basic function. These errors are stored in a common file but, as of this writing, have not yet occurred.

Errors experienced by individual users are classified as minor errors and these are logged to a separate file for each user. These are errors that occur mostly when the messages sent in by the user cannot be parsed properly or, for example, if a blank message is created. These problems, or errors, are logged to a file so that they can be monitored. This information is collected because if a particular user is generating many such errors, contacting the user and providing remedial action may be desirable.

Two types of summaries are made of these user-specific minor errors. One is a web page that is viewable on the web site from any computer, though not with a URL that is given to the users of CARDS (Figure 2.31). This page describes the type of error and the date, but suppresses the user name (since it could potentially be accessed by anyone on the web). A second version of this error web page is stored locally on the CARDS computer so that it can be viewed and the specific errors can be associated with a specific user (Figure 2.32).

Errors, last updated on Wednesday, March 24, 2004 4:00:19 PM

Number of Mail.app windows open: 1

Overall major error summary

-

Total count for major system errors: 0

Individual user error summary

user id suppressed	Wednesday, February 11, 2004 7:09:34 PM*Message sent to user at Wednesday, February 11, 2004 7:09:34 PM: The message you submitted appears to be blank. Please consider re-sending it.
user id suppressed	Monday, February 23, 2004 11:39:27 AM*Message sent to user at Monday, February 23, 2004 11:39:28 AM: There was a problem with the message you sent--the first item was not a valid number.
user id suppressed	Monday, March 8, 2004 7:45:28 AM*Message sent to user at Monday, March 8, 2004 7:45:28 AM: The message you submitted appears to be blank. Please consider re-sending it.
user id suppressed	Wednesday, March 17, 2004 11:12:28 AM*Message sent to user at Wednesday, March 17, 2004 11:12:28 AM: There was a problem with the message you sent--the first item was not a valid number.
user id suppressed	Tuesday, February 17, 2004 5:18:29 PM*Message sent to user at Tuesday, February 17, 2004 5:18:29 PM: The glucose value you sent was greater than 1000. Please consider re-sending it.

Figure 2.31. An example of the minor errors for individual users that can be viewed on the web site. Since it can potentially be viewed by anyone, user names are suppressed.

Errors, last updated on Monday, February 23, 2004 4:00:42 PM

Number of Mail.app windows open: 1

Overall major error summary

-

Total count for major system errors: 0

Individual user error summary

[redacted]@PARTNERS.ORG	Wednesday, February 11, 2004 7:09:34 PM*Message sent to user at Wednesday, February 11, 2004 7:09:34 PM: The message you submitted appears to be blank. Please consider re-sending it.
[redacted]@PARTNERS.ORG	Monday, February 23, 2004 11:39:27 AM*Message sent to user at Monday, February 23, 2004 11:39:28 AM: There was a problem with the message you sent--the first item was not a valid number.
[redacted]@joslin.harvard.edu	Tuesday, February 17, 2004 5:18:29 PM*Message sent to user at Tuesday, February 17, 2004 5:18:29 PM: The glucose value you sent was greater than 1000. Please consider re-sending it.

Figure 2.32. An example of minor errors that are available for viewing only on the CARDS server. This display does not suppress the user name, although part of each e-mail address is blurred in this example.

2.1.22 Backing up Data From CARDS

To ensure that data can be backed up on a daily basis, another small AppleScript application, or process, was written to perform a back-up routine. This is set to run every day at 2:00 AM because it is likely that the system would not be used much at that time. Also, the BSD Unix in OS X performs various daily maintenance functions starting at 3:00 AM and this back-up routine is set to run at a time that would thus not interfere.

The backup routine is simple. A Unix program called tar is launched by the AppleScript application. Tar combines all the individual data files into a single archive. Then the AppleScript application renames the archive according to the current date. The AppleScript application then commands the AppleScript-aware Mail program to send the single file to a specified e-mail address. In this case the e-mail address chosen was "dhanuaer@dsg.harvard.edu" which is the author's personal address.

These archives can then be stored remotely, away from the original computer, in case a problem were to occur such as a major hard drive crash. The only file that is not sent with the tape archive is the file that links usernames and passwords since the e-mail is not encrypted and there is a slight, albeit remote, chance of someone intercepting the file. After the backup process is completed and the archive file is sent, the computer is then instructed to restart. This is done to ensure that no potential memory leaks from the custom-made programs would cause any problems if the computer were running continuously. A small script was also written to run when the computer restarts to launch the Apache and Tomcat web servers. This ensures continual, non-problematic operation of the system for the duration of the trial.

2.1.23 Security Issues: Firewalls

It is generally accepted that nothing is completely secure from an extremely dedicated person intent on breaking into a system, but security measures can help to deter most individuals. Security issues were taken into consideration for all aspects of the project.

The computer system on which the CARDS system was installed is a Macintosh running OS X 10.2.8. OS X is generally considered safe "out of the box",[160] and is even used by security experts at FBI headquarters.[161] In fact, a survey conducted by the British security consulting firm mi2g found that Mac OS X was the safest operating system from what it called "overt digital attacks", ahead of both Windows and Linux.[162] Nevertheless extra precautions were taken to ensure that the system remains secure during the trial. OS X is built upon BSD Unix which has over a 30 year history in which it has been worked upon and refined.

OS X comes with a built-in Unix firewall called "ipfw" (IP firewall and traffic shaper control program). OS X has a built-in GUI interface for this program, available from the System Preferences. This was configured to only open the ports that are needed to run the CARDS system which are:

PORT	USE
21	FTP (File Transfer Protocol), for occasionally updating files remotely
25	SMTP (Simple Mail Transfer Protocol), for the e-mail/SMS communication
80	HTTP (Hypertext Transfer Protocol), used by the Apache web server
8080	HTTP, used by the Tomcat JSP web server

In addition to the software firewall, the computer is kept between two firewalls run by the Joslin Diabetes Center (JDC). This area was named the DMZ, or demilitarized zone, in reference to the no-man's-land found between North and South Korea. The main firewall is between the CARDS computer and the JDC network environment. This was set up to protect all the normal computer systems at the JDC from any possible problems that might affect the CARDS computer so that even if the CARDS computer were overtaken by hackers, this would not affect the main computer systems at the JDC.

The second firewall is situated between the outside world and the CARDS computer and was added between the computer and the internal DSL (Digital Subscriber Line) maintained by the JDC that is used for CARDS. The use of the DSL line was an additional precaution that the JDC wished to take to truly protect its network systems. This DSL line is not part of their regular network and effectively isolates the CARDS computer from any interaction with the JDC computers.

2.1.24 Security Issues: Encryption

No encryption is used for the CARDS project. This is for several reasons including technical limitations and complexity for the end user.

The SMS protocol for cell phones and the POP3 and SMTP protocols for e-mail do not provide a means for encrypting data automatically. While it is technically possible to encrypt any information, including SMS and e-mail messages, these solutions generally require special software to be installed on both the sending and receiving ends of the messages. It was thought that using such technology would be a hindrance to the ease-of-use which was desired for CARDS and would be quite difficult to implement since each user would be allowed to use his/her own computer system. Typically, such end-to-end solutions that can offer encryption are better suited for institutions or business in which a common platform is adopted by all users.

Lastly, the data being transmitted was not deemed to contain sensitive information and the risk of harm even if the data were intercepted is very low. No identifiable information is being sent via SMS or e-mail. In fact, the only identifiable part of the message is the e-mail or SMS address itself. The JDC's Institutional Review Board (IRB) agreed with this assessment and allowed the study to proceed without encryption.

2.1.25 Security Issues: The Web Site

The web site was made secure through several methods. Every user is required to have a case-sensitive user ID and password to log onto the web site. These passwords must be at least 5 characters long. Additionally, once each user is logged on, the browser window is modified (through a small JavaScript command) to hide the typical menu bar with the back button and the location bar.

Once a user is in the system, he or she can navigate by choosing the links to the left. All available options are always displayed on the left part of the screen so that even though the back-button is disabled, users would still be able to move around appropriately.

Random numbers have been employed to improve various computer security measures,[163] so this was also used on the CARDS web site. Each time a user clicks on a link to navigate to a new page, a 10-digit random number is generated and written to a file on the CARDS computer system. This number is also passed, hidden from the user via the HTTP "method=post" command, to the next web page in the browser window. The web page would then check the number it is passed and compare it to the number written to the file. If those two numbers are not the same then the user would automatically be logged out of the system and no new information would be displayed. This was done to prevent other users from trying to copy and paste a Uniform Resource Locator (URL) to gain access to the system, since each URL is technically unique due to the inclusion of a random number passed as a variable (See Figure 2.33).

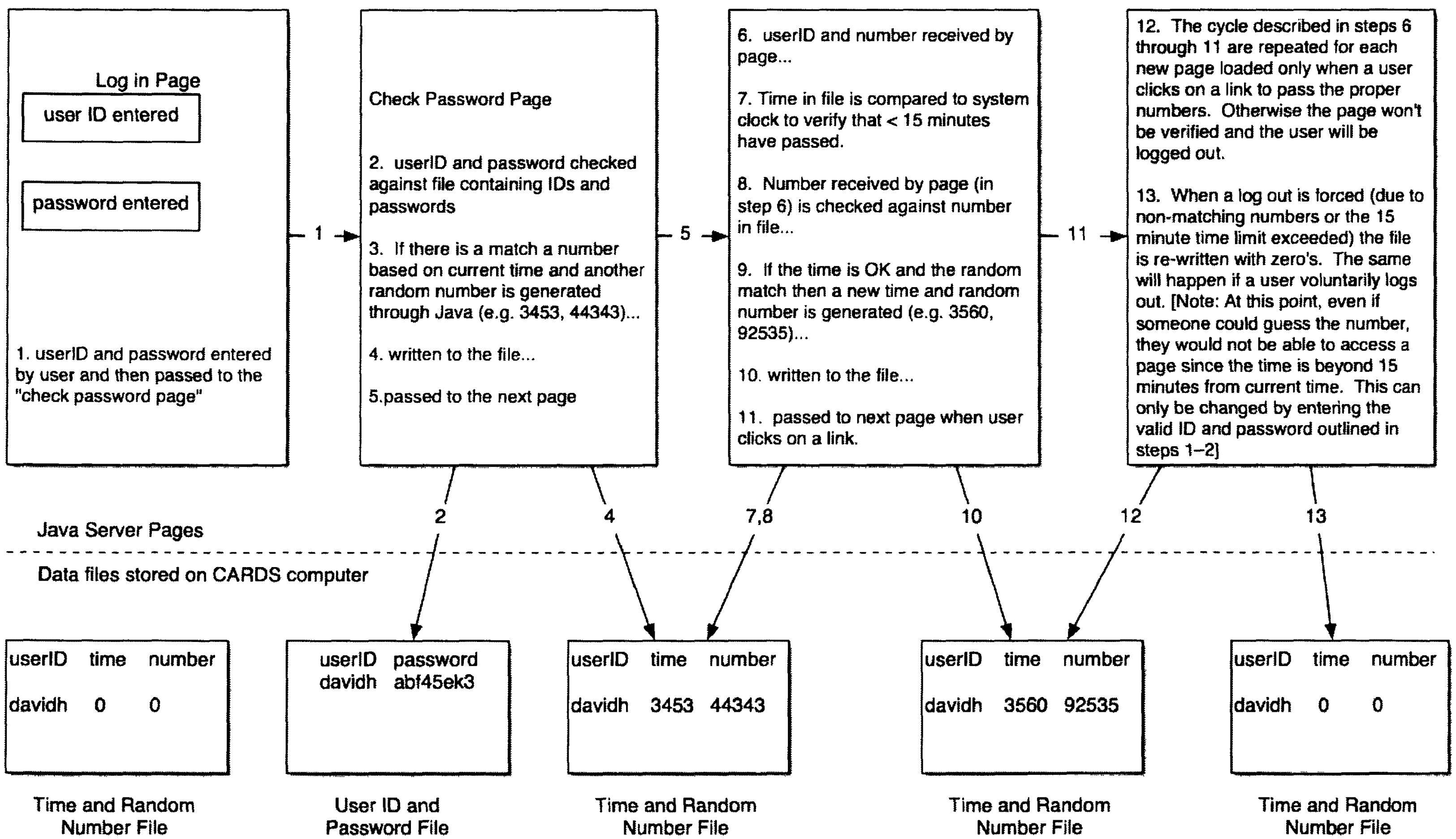

Figure 2.33. A diagram explaining the temporal sequence of events in terms of security features as a user navigates the web site.

Another security measured added was a timeout feature. Similar to the way in which random numbers are generated, the time at which a user logs onto the system is written to a file. Additionally, each time the user clicks on a link to visit another page in CARDS, the time of that action is written to the file. In this way, once a URL is deemed to be valid (based on the random number passed), before the page can be displayed, the system verifies that less than 15 minutes has passed between the last time the system was used by that particular individual. If more than 15 minutes has elapsed then no new information will be displayed and the user will be automatically logged out of the system.

This timeout feature was added so that if a user were to walk away from a computer in a public area, and 15 minutes had passed, no one else would be able to access or change data for that individual even if the web page had been left open. Additionally, users are encouraged to log out of the system by choosing the appropriate link. By doing this, the time written in the file is reset to 0 (January 1, 1970 according to Java), so as long as the CARDS clock is set appropriately, no person can then get back onto the web site with using a correct user ID and password.

Another method to ensure that the data remained secure is to keep all the user's information outside of the web directory. The JSP methods which are invoked are able to access files outside of the web directory, but no one using a web browser is able to see them.

Since very little sensitive information (and no identifiable information) can be found on the web site, it was decided that using additional security measures such as adding Secure Sockets Layering (SSL) would not be necessary and would only add to the complexity of the system. As a result, SSL was not implemented in CARDS.

2.1.26 Security Issues: Viruses, Worms, Trojan Horses

Since Mac OS X was introduced in September 2000, there have been no reports of OS X-specific viruses, worms, or Trojan horses. Viruses are programs which can replicate and execute themselves and require a host file in which to reside. Worms are similar except that they do not require a host file. Trojan horses are similar to viruses except that they require a user to actually launch a program manually.[164] The CARDS program makes use of the freely available Apple Mail program for OS X to send and receive e-mail. It is quite possible that messages, including those infected with viruses, worms, or Trojan horses could be sent to the CARDS system and end up in the program "Inbox".

This should not pose a significant problem, however, because as discussed above, OS X currently is not affected by any of these problems. Further, all e-mail attachments are automatically ignored by CARDS, so if an infected attachment is sent it will not be launched or opened. Additionally, each piece of incoming e-mail is identified by the e-mail or SMS address. If an e-mail message is not from a known user of the CARDS system, the message will not even be analyzed but rather will be quarantined to a mailbox labeled as "Spam" and also be forwarded to the CARDS system administrator (without attachments) for evaluation of its contents.

2.1.27 Security Issues: E-mail

All incoming messages are identified by only the e-mail address (or e-mail equivalent of an SMS address) of the sender. There is no other verification performed to ensure that the individual did actually send the message since no username or password is used to verify the message. The Simple Mail Transfer Protocol (SMTP) is generally the means by which messages are transferred between computers, but SMTP has no way to verify a sender's identity. This does raise the issue of potential security problems wherein a different user could submit a message pretending to be the person who owns the e-mail account. However, since CARDS not only expects e-mail from specific addresses but also expects the information to be sent in a specific format, it is unlikely that erroneous data would be automatically entered into a patient's data file. For example, the first item would need to be a number for any message to be accepted by CARDS. A review of 100 spam e-mail messages received by the author in February 2004 found that none of them contained a number as the first item of the message. Thus, unless someone not only spoofed an e-mail address but also knew the proper formatting for sending messages, it is likely that no problems would occur, or at least that no false data would be entered into the system.

2.2 Study Design

2.2.1 Study Design Overview

A formal evaluation of CARDS was started in March 2004 and is still underway at the time of this writing. The evaluation involves a feasibility trial with patients recruited from the Joslin Diabetes Center. The study is a 12-week, randomized, prospective clinical trial. The following contains further detail about the study design, taken from the application used for the Joslin Diabetes Center Committee on Human Studies.

2.2.2 Primary Objective

To determine if reminders delivered via short messages on a cell phone or via e-mail will increase the frequency of blood glucose monitoring in an adolescent / young adult population. Our hypothesis is that reminders sent via cell-phone will result in greater frequency of blood glucose monitoring compared to both the current standard of care as well as reminders sent via-email. We also hypothesize that such a reminder system will be well accepted by this age group.

2.2.3 Secondary Objectives

To determine whether reminders sent by cell phone will result in greater adherence than reminders sent by e-mail.

To assess the user satisfaction of a reminder system designed for adolescents / young adults.

To determine the ease of use of a reminder system designed for adolescents / young adults.

To determine current technology usage patterns among adolescents / young adults to best determine how to target this age group.

2.2.4 Study Design

This is a 12-week, randomized, prospective clinical trial to assess the feasibility of a computerized system that can deliver reminders to patients via cell-phone or e-mail messages.

Patients will be approached during clinic visits to determine if they are interested in participating in the study or will be recruited by responding to flyers posted throughout the Joslin Diabetes Center. Those that are interested will be randomized, using a computerized random number generator, into two groups: (1) reminder messages via cell-phone (SMS); and (2) reminders via e-mail.

Subjects will be given a brief introduction on how to use SMS or e-mail messages if they are not already familiar with their use and will be required to successfully demonstrate use of SMS or e-mail before being officially enrolled. They will also be instructed that their numbers will not be reviewed on a daily basis by a person and that they should not assume that any dangerously abnormal blood glucose values will result in any response other than messages sent to the user by the computer system.

Prior to beginning the study, subjects will be asked to bring their blood glucose meters to determine their baseline frequency of monitoring. They will also be asked to fill out a brief survey to obtain demographic information as well as information about their comfort with using various technologies (such as PDAs, computers, and cell phones). See Appendix A for the survey.

Both arms of the study group will be given a username and password to access a web site. This web site will allow users to customize the time of day and day of week for which they would like to receive a reminder to check their blood glucose levels. A subject can receive as few as 0 and as many as 10 reminders each day at any time of the day. Subjects will also be allowed to choose whether they would like to receive daily "factoids." Two factoids per day will be sent to users who request them. One will be about any subject and the other will be diabetes-related. The times for the factoids will be randomized each day but will always be between 4:00 PM and 9:00 PM.

The web site will also allow users to view their blood glucose logs as well as to enter new blood glucose measurements or to change comments associated with each value. They will not be allowed to edit or delete a blood glucose value once it has been entered.

Once the reminder schedule has been set by a user, the reminders will be sent to the participant at the designated time to either a cell-phone or to an e-mail address. The messages each participant will be sent will be the same for all subjects in the study and will be short such as "Now is a good time to check your blood sugar." Participants then have the opportunity to respond to the reminder with blood glucose levels that will need to be typed into the phone or as a reply e-mail message. Once they send their blood glucose values back to the system, the values will be available for viewing on the website. Additionally, confirmation with positive feedback will be sent to the users to let them know the values have been received by the system.

Users can send in blood glucose values even when a reminder is not received. Additionally, any value sent within one hour prior to a scheduled reminder will suppress the reminder from being generated. If a reminder is sent and no response is received with a blood glucose value within 15 minutes, an additional reminder will be sent.

A blood glucose value that is sent to the system that is below 70 or above 300 will result in a message being sent to the user that the value is either too high or too low with advice to try to manage the out-of-range blood sugar according to the patient's usual treatment, and to re-check the blood glucose in 20 minutes and call his/her healthcare team about any concerns or questions.

The computer system will record all blood glucose values as well as web site use, such as how often each user logs on to the system, how often users view their on-line diabetes logs, and how often they change their reminder preferences.

At the conclusion of the study, users will be asked to bring in their blood glucose meters to compare the number of blood glucose values sent to the computer system with the number of values in the meter. Subjects will also be given a survey (Appendix B) to assess their satisfaction with the system and the ease of use of the system. Providers will also be given a brief survey to assess their satisfaction with the system.

2.2.5 Inclusion Criteria:

- Age 13 - 25 years
- Type 1 or Type 2 diabetes (insulin treated)
- Diabetes for at least 1 year
- Parent to provide consent if a minor / Assent from child
- Consent from patient if not a minor
- Home Internet access
- Must own a cell phone with SMS capabilities (most cell phones have this)

2.2.6 Exclusion Criteria:

- Any major medical or psychiatric illness
- Unstable home environment
- Major change in insulin therapy in the last 3 months

2.2.7 Data Analysis and Subject Selection

Approximately 20 patients will be assigned to each group. This is a feasibility study, and there are no other studies on which to base a power calculation. However, the following assumptions were made. Assuming that the mean number of baseline blood glucose checks per day is 2 ± 1, and that on average the cell-phone reminders will cause each person to check one more time per day (3 ± 1), whereas the e-mail reminders will not demonstrate any change over baseline, then for a significance of 0.05 and power of 0.8 the number of subjects needed in each group will be 17.

Data will be analyzed to determine differences between means for the two groups. Summary data will also be collected from the surveys. Summary data for usage patterns will be made daily by an automated computer program that will analyze the computer system's usage log.

2.2.8 Possible Benefits

This study has the potential to benefit individuals in several ways. The reminders may help subjects better remember to test their blood sugars and take their insulin. The daily diabetes facts sent each day have the potential to help educate each person. Additionally, the cell phone system may provide a more enjoyable method for recording blood sugar levels, and this also has the potential to increase compliance.

If the system is found to be effective, it could potentially benefit a much larger group of subjects, since it is possible to scale the system to interact with hundreds, if not thousands, of users at a time.

2.2.9 Possible Risks

There are few risks associated with this study, as the study itself does not involve changing any medications, insulin regimens, or diets. In addition, the system created does not provide any advice that could be misinterpreted.

On the other hand, because the system does not provide any advice, users may develop a false sense of security that they are being looked after more carefully and thus may not act on their own to correct any problems that may occur. Potential subjects will be warned about this at the onset of the study and will be encouraged to call their healthcare team with any questions or concerns. This warning will also be included with the feedback statement generated when an out-of-range blood sugar statement is received.

2.2.10 Consent Procedures

Prior to any trial-related activity, the Investigator or co-investigators will give the subject (and/or parents or subject's legally acceptable representative, if applicable) oral and written information about the trial in a form that the subject can read and understand.

A voluntary, signed and dated Informed Consent Form will be obtained from the subject's parent/guardian prior to beginning any trial-related activity. The patient must also give written assent to participate in the study if a minor. The written informed consent must be signed and dated by the person who conducted the informed consent procedure.

If information becomes available that may be relevant to the subject's willingness to continue participating in the trial, the Investigator must inform the subject in a timely manner, and a revised written informed consent must be obtained.

2.2.11 Recruitment / Source of Subjects

Subjects will be selected from the Pediatric and Adolescent Unit of the Joslin Clinic. Health care providers and/or the co-investigators will inform them of the study. Recruitment flyers (Appendix C) will also be utilized in the clinic areas and bulletin boards at Joslin.

2.2.12 Omit / Leaving Study Procedures

Subjects will have full control over the website, including preferences for reminders. If they choose not to receive any reminders at all, then they can continue to perform their current activities as if they have withdrawn from the study, although they can still send blood glucose information to the system if they choose to. These preferences can be changed at any point during the study as many times as desired.

2.2.13 Incentives / Remuneration

There is no payment for participating in the study. Since not all phone plans have free text messaging, subjects (regardless of the group to which they were randomized) will receive $30 to cover the costs of messaging over the three month study period. Additionally, subjects or their parents will receive free parking at the start and at the end of the trial.

Section 3

Results

3.1 Data collection time frame

The CARDS study is still underway at the time of this writing, and patients are still being actively recruited. All data obtained through April 22, 2004 have been included in this section. Ten patients have thus far been enrolled. It should be noted that all results are preliminary. Also, because patients were recruited on different dates, subjects have been using the system for varying lengths of time. The first patient was enrolled on March 24, 2004, and has been in the study for about 1 month. The last five patients were all enrolled on April 20, 2004, and thus have only been in the study for a few days. Because no participants have completed their three-month trial period yet, no post-study survey data have yet been obtained.

3.2 Baseline characteristics

Patients were approached by the pediatric physicians and nurses at the Joslin Diabetes Center to assess their interest in participating in the study. Those who expressed an interest were directed to the author. As a result, the percentage of all patients who met the inclusion/exclusion criteria was not recorded. All patients who learned about the study from the author agreed to participate. Baseline characteristics of the patients who enrolled can be found in Table 3.1. Not all baseline information has yet been obtained since a chart review still needs to be conducted. The author has only limited access to the charts at Joslin, and is awaiting help from a research assistant there to proceed.

Gender	
Male	50%
Female	50%
Age	18.9 ± 2.0 years (range 16.5 to 22.9)
Insulin administration	
By Injection	70%
By Pump	30%
Baseline A1c level	Pending chart review
Duration of diabetes	Pending chart review

Table 3.1. Baseline characteristics of the 10 patients enrolled in the study through April 22, 2004.

3.3 Baseline survey data

Table 3.2 indicates various means that patients own or use to track their diabetes. Memory-enabled meters were used by the majority (80%) of patients to record their blood sugars, followed by paper logbooks (30%). Only 40% of patients owned a PDA, and only 1 of these patients (10% overall) had it with him at the clinic visit. All patients who were enrolled in the study have a cell phone, as an inclusion criterion, and almost all of them (90%) had their phone with them at the time of their routine clinic visit. This was the visit during which patients were approached and enrolled if they expressed interest in the study. Patients did not know ahead of time that they would be approached about the study.

	Do you own or use one?	How do you record your blood sugars?	Which do you currently have with you right now?
Device/medium	% (n)	% (n)	% (n)
Paper logbook	70% (7)	30% (3)	20% (2)
Meter with memory	90% (9)	80% (8)	70% (7)
PDA such as Palm Pilot or Pocket PC	40% (4)	10% (1)	10% (1)
Personal Computer	100% (10)*	0% (0)	0% (0)
Cell phone	100% (10)*	0% (0)	90% (9)

Table 3.2. Survey information obtained from the baseline survey, where patients were asked about how they currently track their blood sugars and what devices they own or had with them at the clinic.
* Having a computer at home and owning a cell phone were part of the eligibility criteria for the study.

Study subjects were also asked to report whether they were able to access their device(s) at either work, school, or home (Table 3.3). Home was the most accessible location for the paper logbooks, meters, PDAs, and personal computers. Cell phones were reported to be more accessible at school than at any other location. Personal computers, while accessible at home, were much less accessible at work or at school.

	Work	School	Home
Device/medium	% (n)	% (n)	% (n)
Paper logbook	14% (1)	43% (3)	71% (5)
Meter with memory	78% (7)	67% (6)	89% (8)
PDA such as Palm Pilot or Pocket PC	50% (2)	25% (1)	100% (4)
Personal Computer	10% (1)	40% (4)	90% (9)
Cell phone	70% (7)	90% (9)	80% (8)

Table 3.3. Percentage of each group owning the device/medium who reported the ability to access the device at work, school, or home.

Figure 3.1 displays the survey results based on the questions that asked how often subjects used instant messaging, SMS messaging, or e-mail. Instant messaging was most popular, with 60% of subjects reporting that they used it daily. Somewhat less popular were e-mail and SMS messaging: 40% of respondents reported using either e-mail or SMS messaging at least 3-5 times each week. Only 10% of respondents did not use either e-mail or instant messaging, whereas slightly more (30%) had not used SMS messaging but did use e-mail.

Patients were also asked about their computer skills. No patients felt that their skills were "limited", whereas 80% felt that their skills were "good." Two patients (20%) reported their computer skills to be "expert."

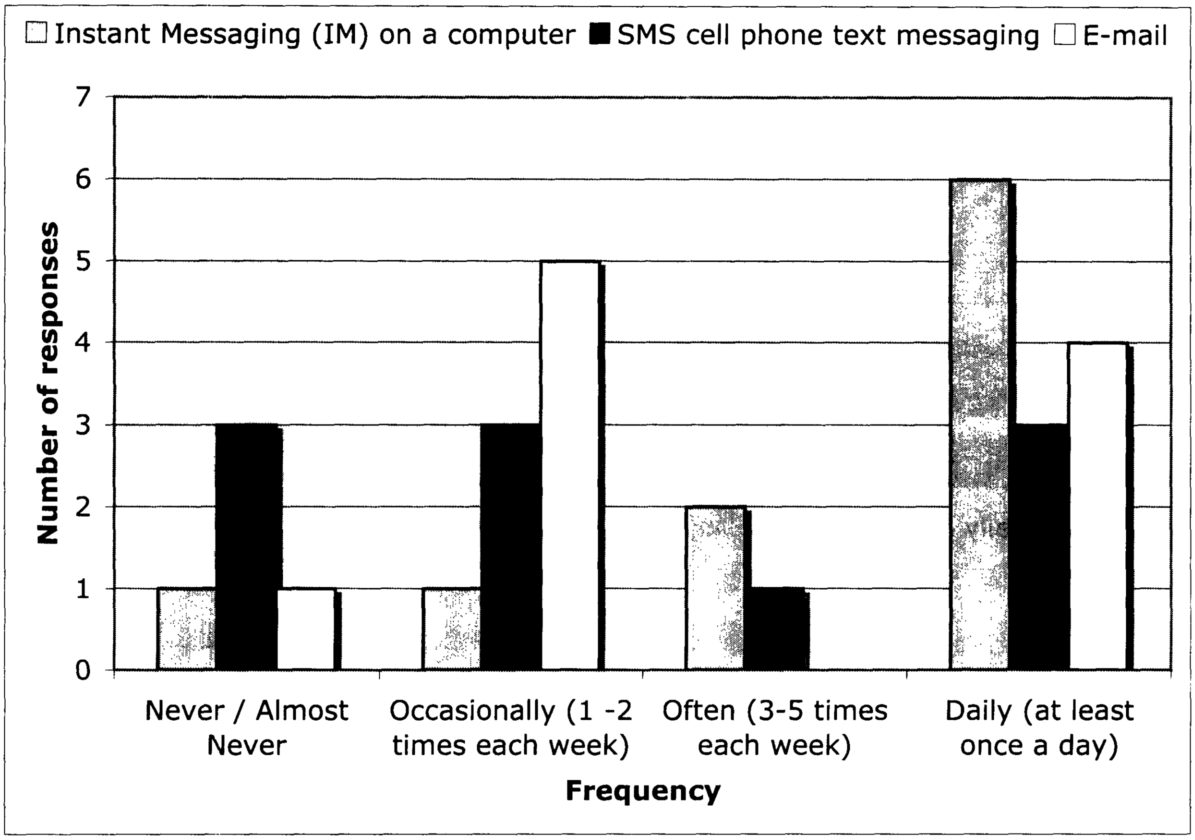

Figure 3.1. Frequency of usage for Instant Messaging, SMS messaging, and e-mail.

Patients were also asked about their own diabetes management. All patients reported that they sometimes forget to check their blood sugars. Five out of ten patients reported forgetting occasionally (1-2 times per week), whereas 40% reported forgetting often (3-5 times each week) or daily. Only one patient (10%) reported forgetting less than once per month.

The main reasons provided for not checking blood sugars were that the patients were busy doing other things (80% of patients), they didn't want to check (40% of patients), and they had no good way to remind themselves (10% of patients).

Subjects were also asked how often they review their own blood sugar numbers and how often they would like members of their healthcare team to be able to review their numbers (Figure 3.2). The majority (70%) of patients only reviewed their blood sugar numbers at their visit.

While some patients (30%) also wanted their healthcare team to see their numbers only at their visit, the rest were willing to have others view their numbers at least once per month.

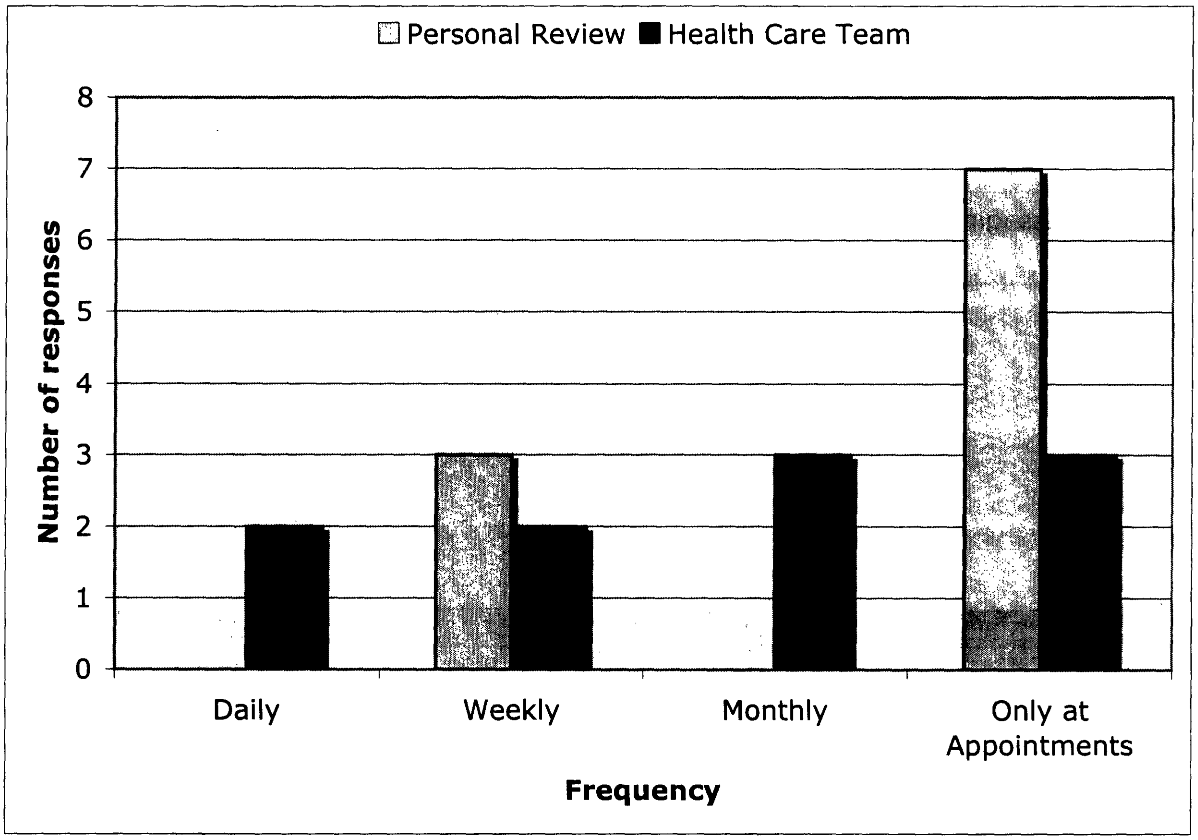

Figure 3.2. Survey responses from the 10 patients based on the questions "How often do you review your own blood sugar numbers?" and "How often would you like your health care team to be able to review your blood sugar numbers?"

3.4 CARDS usage data

Usage patterns for the web site and reminders were obtained from the logs stored on the CARDS server as of 2:00 AM on April 23, 2004. Because only 10 patients have enrolled at the time of this writing, all their data are summarized in Table 3.4. Six of the ten patients have still not logged on even once; among these six patients only 1 individual has submitted a single blood sugar (via cell phone), whereas the others have not submitted any.

Only 4 patients have logged onto the system even once, two in the cell phone group, and 2 in the e-mail group. All the patients who logged into the system have submitted at least one blood sugar. The highest number of blood sugars submitted by a single user has been 39, all entered via cell phone. This patient has been enrolled for 31 days and is also the youngest patient enrolled so far. The next largest number of blood sugars entered is 6, via e-mail, by a patient who has been enrolled for 3 days (patients should typically check their blood sugars 2-4 times a day).

A total of 4 blood sugars have been entered using the web site, and only one user has changed any logbook comments on the web site. Each of the four users who have logged on has viewed his/her diary at least once, although none of the users have chosen the option to reformat and print the diary. Half of the users, however, have still not received even 1 weekly Sunday reminder to do this yet because they have only been enrolled for 3 days.

All users (with the exception of one who was unsure of her cell phone billing options) have had factoids sent to them daily. The user who has been enrolled the longest chose to stop receiving the factoids after 18 days.

A total of 92 reminders have been sent so far, although the majority have been sent to two users who have received 72 and 13 reminders, respectively. The best response rate for reminders has been with a cell phone user who has responded to exactly 50% of the reminders she has received.

Group	Days in Study	Logins	Total BG submitted	BG via phone/e-mail	BG via web	Viewed Diary	Viewed print diary	Changed comments	No. days factoids	Reminders Sent	Reminders with response
Cell	31	2	39	39	0	1	0	0	18*	72	36
Cell	15	0	1	1	0	0	0	0	15	0	0
Cell	10	1	1	0	1	1	0	0	10	6	0
Cell	3	0	0	0	0	0	0	0	0§	0	0
Email	14	0	0	0	0	0	0	0	14	0	0
Email	10	0	0	0	0	0	0	0	10	0	0
Email	3	0	0	0	0	0	0	0	3	0	0
Email	3	4	8	6	2	4	0	0	3	13	5
Email	3	0	0	0	0	0	0	0	3	0	0
Email	3	1	2	1	1	1	0	2	3	1	0

Table 3.4. Summary data for the 10 patients currently enrolled in the study. Numbers are cumulative frequencies for each patient.
BG = Blood Glucose
* Factoids were turned off on day 18.
§ Whereas most users had factoids on by default, this user's was set to off until she was able to verify the text messaging plan on her cell phone with her father

Section 4

Discussion

4.1 General Comments

The preliminary results from this study are mixed, although it is difficult to draw any firm conclusions because only ten patients have been enrolled, and most have been in the study for only a short time. Nevertheless, the information obtained from the baseline survey already demonstrates some interesting findings.

4.2 Monitoring

All patients reported forgetting to check their blood sugars, suggesting that there is a need for aiding patients in remembering to check their sugars. The main reason offered for not checking blood sugars was that patients were busy with other activities. This suggests that any intervention to help them remember should be accessible to the patients during as many of their activities as possible, and cell phones are a good candidate based on ownership and usage data (described in the next section.)

While most (70%) patients reported that they did not review their blood sugars except at the time of their healthcare visit, 70% of subjects were also amenable to having their healthcare team view their numbers more frequently. This disconnect from taking personal responsibility for their own health care is alarming. Involving patients more with their own care using reminders may cause patients to think about their blood sugars more often than every three months (the typical interval between diabetes clinic visits) and this might prove beneficial in the long term.

The four patients who had logged into the system have viewed their diary at least once, but none viewed the diary formatted for printing, with the numbers arranged in columns based on the time of day. Every patient that was enrolled was shown this diary format and was instructed that it was the most informative way to view the data. Additionally, all patients are sent reminders on Sunday to view this diary, although five of the ten have not yet received such a reminder.

Although only two patients have consistently been submitting blood sugars to the system so far, ideally, the process of receiving reminders and submitting the blood sugars is causing them to check more often than they had been. This will eventually be determined by comparing pre- and post- hemoglobin A1c levels as well as comparing the frequency of checking before and after the trial period based on downloaded meter data, all of which will be obtained from a chart review at the end of the study.

4.3 Ownership and usage of electronic devices

The number of patients in the clinic who own cell phones was not ascertained in this study, and only those with cell phones were allowed to enroll. While a few patients were excluded from participating for lack of a cell phone, more were excluded for lack of a home computer even though they did have a cell phone. This information was not recorded and is only reported anecdotally here.

The idea that a cell phone is an "anytime, anywhere" type of device was supported by this study. All patients were recruited from the diabetes clinic and none were asked ahead of time to bring anything in particular with them. That more patients had their cell phones with them compared to their logbooks or glucose meters attests to the fact that this age group is anxious to carry a cell phone and less anxious to carry diabetes-related paraphernalia. It is possible, though, that the logbooks or meters were purposefully not brought to the clinic because they would have demonstrated a lack of blood glucose monitoring or poor glucose control.

Personal Digital Assistants (PDAs), while also portable like cell phones, were owned by only 40% of this population, and only 1 of these was brought to the clinic. This also reinforces the view that cell phones, as opposed to other forms of portable electronic devices, are probably the best medium for delivering health care interventions to this age group. The lower ownership rate of PDAs suggests a lack of interest in this type of device and is perhaps a contributing factor to the failure of prior studies using PDAs to have had an impact in this population.

Also of interest is that no patients reported using a personal computer to record their blood sugars even though most meter manufacturers now provide software to download, review, and even plot blood glucose data. This is not surprising, however, given that most patients reported reviewing their blood sugar numbers only at their appointments. There is no reason to take the extra step of downloading data from a meter to a computer if there is no desire to look at the data.

Additionally, although all users had access to the web site to enter blood sugars, only 4 of 51 (8%) of the blood sugars added to CARDS were submitted via the web site. Using the web site does not appear to be as appealing to users as either e-mail or SMS messaging.

Even though patients were not using their computers to keep track of their diabetes, they did feel comfortable with their computer skills. All patients felt that there skills were at least "good", although this was self-reported and not actually tested.

4.4 Messaging

Patients reported using a variety of messaging protocols. It is interesting to note that patients reported using instant messaging on a computer on a daily basis more than either e-mail or SMS messaging. This suggests that these patients are in front of a computer at least at some point during the day. Patients reported using e-mail daily more often than SMS messaging as well, even though the majority of patients, when enrolled in the study, expressed a desire to get messages on their phones as opposed to e-mail.

Although patients may use e-mail daily, it may only be at one time of the day when they are at home. Most patients suggested during the recruitment process that for them to receive reminders at the appropriate times, the reminders would need to arrive on their phones, since access to e-mail was limited during much of the day. This survey did not ascertain the number of hours per day in which each device was typically accessible to a patient, although future studies might benefit from looking into this. While there was concern about restricted access to cell phones in schools, this appears not to be the case based on the survey data (discussed in the following section).

The baseline use of SMS by patients was lower than expected, although it is possible that this was due to the ages of the subjects recruited. The patient who has been using SMS most frequently also happens to be the youngest subject in the study (16 years old). It is possible that younger teens are more interested in SMS on phones than older teens, although more patients will need to be recruited to determine if such a trend exists.

4.5 Potential problems with cell phone access

The responses received to date from the survey in the current study suggest that cell phones are accessible to users at school. Nine out of ten users said that they are able to use phones at school. However, the survey did not ask about limitations on cell phone use at school, so it is not clear if the phones are allowed only at certain times or with specific restrictions. Future studies should attempt to determine the true extent of cell phone use at schools, especially since there is currently much controversy surrounding the use of cell phones in schools and other public places.

The culture of cell phone use has not been well accepted by all members of society. Cell phone ring tones sometimes interrupt events such as performances and movies. Additionally, the loud and distracting way in which some users talk on their phone, a phenomenon that has been referred to as "cell yell",[165] has caused a backlash by citizens and lawmakers alike.

Aside from "no cell phone" signs, electronic devices have been built that can jam cell phone signals, and some building materials or designs can be used to block transmission of cell phone signals.[166] Other methods include the use of devices that can detect cell phones within a 30 meter radius and sound an alarm or issue an instruction to make sure that cell phones are turned off.[167] The Canadian government has even considered laws allowing restaurants, theaters, and other institutions to block cell phone signals to prevent the potential disruption caused by cell phones and their users. The legality of such jamming devices in the United States is questionable due to a 1934 law that bans the use of devices to block radio transmissions, which was reaffirmed by the Federal Communications Commission in 1999.[168]

Nevertheless, there are other reasons that cell phones or their signals can be blocked. New York City, with its narrow streets and towering structures has multiple locations where cell phone signals are extremely weak, areas known as "dead zones." Furthermore calls can also be dropped or be unsuccessful if there are too many users at a specific time for a given network.[169]

Some businesses, such as fitness clubs, have banned the use of phones that include tiny cameras because individuals have been caught taking photographs in inappropriate places such as changing rooms.[170] Even more importantly for adolescents, some schools also ban the use of cell phones.

School administrators have had a difficult time with students using cell phones in schools at inappropriate times, especially since a small number of students can cause large disruptions. The disruptions can come in many forms such as phones ringing in class, students playing games on the phones, cheating on exams, and even having pizzas delivered to a class in session.[171] [172] While such problems originally occurred with high school students, these issues now arise even in elementary school.[133]

Some schools ban all electronic devices outright, while others have varying limitations on usage, such as allowing them in the school but requiring the phones to be off and out of sight. Interpretation of the rules can be complicated because some phones have capabilities that overlap with electronic organizers that are allowed in school and are relied upon by students during the school day.[171]

Many of the bans on cell phone use originally began in the 1980s when cell phones were seen as the tools of drug dealers and not of children who needed a ride home after school.[173] However, since the September 11, 2001, terrorist attacks, and because many children now come from families in which both parents work and are away from home much of the time, some parents have been pushing for legislation allowing students to carry phones in schools to ensure that their children are accessible in emergencies. In fact, several states, including South Carolina, Georgia, and Illinois, have relaxed their rules on carrying cell phones in school in response to requests by parents.[133]

4.6 Lost SMS messages

While the SMS protocol was designed to ensure that messages were delivered to the appropriate recipient, this may not always be the case. A recent study has found that about 7.5% of SMS messages are not successfully sent or received.[174] For example, one U.S. wireless carrier was found to have failed in receiving messages 8% of the time and in sending messages 14% of the time.

While these problems have been attributed to the difficulty of creating seamless interoperability between the computer systems used by the different wireless carriers, issues still exist even when messages are transmitted among users of the same carrier. In fact, even the currently best-rated network lost up to 2.2% of messages sent to other users in the same network.

Additionally, carriers sometimes erroneously report to users that messages were sent successfully when, in fact, they were not, creating the potential for a false sense of security in the transmission of important messages. Another problem that can potentially occur is the delayed delivery of SMS messages, sometimes taking days.

These problems have been reported to be a factor in the refusal of some countries to consider allowing SMS messaging for emergency calls (as an addition to a 911 system). These problems also suggest that while it may be reasonable to expect CARDS to make diabetes less burdensome, it may be premature to rely on SMS technology for potentially life-threatening blood glucose values.

The final questionnaire given to the subjects in this study includes a question asking patients if they received reminders at the times they expected. This question is intended to help ascertain whether dropped messages were a problem. Until the patients complete the study, however, these data will not be available.

4.7 Limitations of SMS

The SMS technology itself also has several limitations. Beside the lack of ability to encrypt information, another limitation is the upper bound of 140-160 characters for a message, constraining the type of information that can be transmitted. During the development of CARDS another feature that was considered in addition to the factoids was that of adding multiple-choice trivia questions that a patient could answer to win prizes. It was thought that such a game would encourage continuous involvement with the system. Unfortunately, the SMS length limitation prevented the implementation of such a game.

Entering a text message on a phone can be somewhat cumbersome, although reports have suggested that children are able to adapt to the small keypads on the phone well, as was discussed in the introduction. One potential way to circumvent this problem would be to have a small application run on the phone that would be tailored specifically for data entry for diabetes. Such an application could have drop-down menus for blood sugar entry similar to the way in which the CARDS website is structured for blood sugar entry. A message could then be formatted appropriately and sent via SMS to the server.

As phones become increasingly complex, the ability to run applications will increase. Java is one language that is now available for phones,[175] although other development environments, such as BREW (binary run-time environment for wireless), also exist for creating applications.[176] One drawback of this approach, however, is that the number of potential operating systems available for the various cell phones could make developing a standard application to run on all phones infeasible. The advantage of SMS is that the SMS standard is a common denominator among virtually all cell phone providers in the U.S. today.

4.8 Medical-Legal Issues

The CARDS study raises several medical-legal issues that have not been well-addressed to date. One such question centers around the liability issues surrounding SMS messaging on cell phones between patients and the healthcare team (or computer systems, such as CARDS, representing the healthcare team)

SMS messaging has already been embraced by some physicians for communicating with patients and the Medical Defense Union (MDU) in London, England has received several inquiries about using SMS messaging in patient care activities.[177] The advice provided by the MDU included having a system to record the actual messages sent and received as well as the date and time that the messages were sent or received. Any action performed as a result of the message was also expected to be recorded.

CARDS can perform these functions since all messages sent and received are stored by the Mail program and can be sorted by user or date. As long as the clock on the CARDS server is accurate, all messages should be time- and date-stamped appropriately. No actions are taken by CARDS other than sending messages, but if further actions were ever to be taken, additional functionality would likely need to be incorporated into CARDS to ensure that important actions can be recorded appropriately.

Another aspect of text messaging that was highlighted by the MDU was the need to ensure that both senders and receivers agree to and understand a common vocabulary for communicating. This is especially important since the SMS protocol has a finite limit on the number of characters that can be transmitted, and thus it can be difficult to accurately convey complex medical concepts or instructions.

Because no feasible encryption of information is available using SMS, and because of the potential difficulty with identifying the sender of a message (since only a phone number would be visible), using a system of code words was suggested as a way to help identify users and protect confidentiality. The feasibility of doing this, however, was not discussed.

Another medical-legal issue that a system such as CARDS raises is the question of who is to be responsible for monitoring the results. The CARDS server only collected information on the number of times a subject accessed portions of the web site or submitted blood sugars. The values of the blood sugars themselves did not trigger any response by the system other than warning the patient when high or low blood sugar values were submitted, even though it would have been quite feasible to send alerts (by e-mail or SMS) to a doctor or nurse.

If a user were to submit an extremely dangerous, or life-threatening, blood glucose value, should the health care team be both notified and responsible for taking an appropriate action? If so, the question still remains as to who on the health care team should be responsible. And if a life-threatening glucose value were to be reported by a patient, another important issue is how the patient could be located. Cell phone service providers have been working on introducing a system to triangulate the location of cell phone users, so such a task will be technically feasible in the near future in many areas.[178] Also, in the current study, the feedback given to a patient when a high or low value is submitted may give the patient a false sense of security that the healthcare team knows about it, despite the disclaimers.

Another consideration in the current implementation of CARDS is that users type in their blood sugar values. They could lie about the values or mistakenly enter a dangerous value, thus setting off many potential false alarms. The sensitivity and specificity of predicting true adverse events based on submitted blood sugars is an area that may be worthy of study. Otherwise, false alarms generated by the system could potentially strain the resources of an already limited health care system.

If it were possible to ensure the reliability of blood glucose measurements, then it could be possible to apply machine learning algorithms to data collected on a daily, or even hourly, basis in order to detect alarming patterns. One way to help ensure the reliability of transmitted information could be to have an application running on the phone itself to ask a user if submitted values were entered correctly, or to verify values that are considered out of range.

A more advanced approach to better ensure the verity of the blood glucose measurements would be to allow for the transmission of the blood glucose value directly from a meter to a cell phone via a short-range wireless technology such as Bluetooth. The phone could then transmit the message to the server for storage and analysis. Even this may not be an ideal option, since manually entering blood sugars may cause users to think more about what their blood sugar measurements mean. Having it completely automated might cause patients to check their blood sugars, but then not react to them appropriately if the numbers were automatically beamed for storage elsewhere.

4.9 Problems encountered with the CARDS server

As of this writing, there have been only two problems encountered with CARDS, the first of which did not affect the functioning of the system in any way. The first problem occurred as a result of forwarding unidentified mail to the author. During the testing phase, unidentified mail was forwarded to the e-mail account "hanauer@umich.edu". For unknown reasons, one day, the University of Michigan mail servers were refusing all mail from the RICS servers. When an unidentified piece of mail arrived in the Inbox of the CARDS mail program, it was automatically forwarded, via the "cards@rics.bwh.harvard.edu" account, to the "hanauer@umich.edu" account.

The Michigan mail servers refused the message and sent an error message back to the RICS account. This error message also came from an unidentified user and, as a result, a new message was generated by CARDS with the contents of that message and sent to the "hanauer@umich.edu" account. Again, the message was refused and sent back to the RICS account. Thus ensued a cycle wherein the two accounts were sending messages back and forth to each other every 3 minutes, resulting in over 900 messages either sent or received in a single 24 hour period. Even though hundreds of messages were accumulating in the Mail program's In and Out directories, the program still functioned normally. However, it is important to be aware of this problem, especially if storage concerns were an issue.

A second problem was encountered during a brief power outage at the Joslin Diabetes Center on the night of Sunday, April 11, 2004. The next morning it was noted that the web site was no longer accessible from an outside source. While the power outage did not affect the computer itself, which switched immediately to its internal battery, power was lost to the external Linksys firewall that had been configured by the information technology department of Joslin. This loss of power apparently changed the configuration settings on the firewall and had closed the ports for web access (80 and 8080) for the CARDS IP address. As a result, it was not possible to access the web site until the problem was tracked down and the firewall settings reset.

This emphasizes the importance of having a universal power supply (UPS) or other back-up power supply to provide electricity for important electronic devices during outages. While the main systems at Joslin are likely supported with a UPS, CARDS was viewed as being "outside" of the Joslin system and its functioning was not made a priority. This problem also demonstrates that any broken link in the chain can make the entire system malfunction, even if the CARDS server itself is running well. It should be noted, however, that CARDS was still able to send reminders and receive data from users during this time; only the web site was inaccessible.

4.10 Future improvements for CARDS

Many possibilities exist for improving future versions of CARDS. For example, it was noted during the random selection of factoids each day that occasionally some factoids were repeated more often than others; one factoid was even repeated two days in a row. Future versions should make an attempt to remove a factoid once it has been shown to users or to at least better ensure that factoids are shown with equal frequency.

Another feature that could potentially be helpful to users would be to allow each user to set the time zone in which he/she currently resides. This could be useful if patients travel and still want to get reminders sent at their normal times, adjusted for the time zone difference. The system could also be designed to work with multiple languages, based on a user's preference. In fact, the system already can properly parse European and American time formats.

The parsing of messages could also be improved. Currently, times such as 10:00 AM, 10:00AM, and 10AM, can all be parsed appropriately. The time 10A, however would not. It might be worthwhile to also support times such as 10A and 10P, since users might want to submit times based on this shorthand notation.

If a user has a set of reminders and would like to turn them off temporarily, there is currently no way to do this except to log onto the web site and change his/her preferences. This could be inconvenient if a computer were not readily accessible. One way to circumvent this problem would be to allow for a certain code word to be sent to the system to temporarily suppress all reminders (such as the word "stop"). Then, when a user wanted to receive the reminders again according to his/her schedule, the user could send in the word "start" to begin sending reminders again.

The web site could also potentially be improved. SSL encryption could be added at a later time for added security. Additionally, under the current implementation, users could potentially enter information on the site and not save it appropriately if they click on a link for a different page before clicking on the "Save" link. More JavaScript code could be added to the appropriate pages to alert users that any changes should be saved before proceeding to another page.

While training users on the CARDS system, it became evident that it would have been helpful to have a section that offered a simple demonstration of how to type or enter messages properly. It might also be useful to have a web page designed specifically to allow users to practice entering messages to make sure they can be formed properly. This could even be done while patients are being enrolled to ensure that they demonstrate a working understanding of the system before leaving the clinic.

Users are currently entered into the CARDS program manually to ensure that they are randomized appropriately. In the future, it may be useful to allow users to register on the system themselves. It might also be worthwhile to allow users to choose where they would like reminders to be sent. Some might prefer cell phones whereas others might prefer e-mail. Some users might prefer to get some reminders sent to their phone and some to e-mail depending on where they expect to be at specific times of the day. All of this is technically possible, although this feature set was not implemented in the current version of CARDS.

So far, not all users have even logged onto the system to try it out. It may be that a web site designed specifically for diabetes care may not be compelling enough for users to visit. Adding other features to the web site that make it more appealing to this age group, such as diet/nutrition information,[179] may serve as an incentive to get users to log onto the system and set a schedule for reminders.

Reminders for appointments were also not included in CARDS, although this could potentially be useful for patients. A reminder for patients to bring their logbooks or meters to their visit might also be of benefit. Further suggestions for refinements will be asked of users at the conclusion of the study. However, no responses have yet been obtained on this matter.

4.11 Other applications for CARDS

While CARDS was created specifically for diabetes management in adolescents, the concept could be applied to many other medical conditions as well. Adult diabetes could potentially be targeted, although SMS messaging in adult populations may not be as widespread as in teens or young adults.

As discussed in the introduction, systems similar to CARDS have been used for pediatric asthma, for tuberculosis, and for reminding patients about appointments. Actual results on efficacy from such systems are still lacking in the medical literature, however.

Reminders could also be useful for checking (and submitting) blood pressure readings for patients with hypertension, or for submitting weights in patients with obesity or other conditions in which weight checks might be useful, such as renal or cardiac disease.

Reminders to take medications might also be helpful, and this could apply for long-term medications such as oral contraceptives or even short doses of medications such as a course of antibiotics. Reminders could also potentially be used to support people attempting smoking cessation.

The factoids could also be modified to provide other pearls of medical advice, words of wisdom, or even encouragement for following a certain regimen.

4.12 Determining if CARDS is a success

It is still too early to determine if CARDS has been a success. It is also not clear how success should be defined. If only a handful of patients benefited from the system, it could still be considered a success since once the system is up and running, few resources are required to maintain it. Additionally, if CARDS caused patients to think more about their diabetes, that could also be considered a success.

Even for the two patients who have been using the system consistently so far, it remains to be seen whether their use of the system will be maintained or if their interest will wane over time.

If it is found that interest in using the system decreases over time, it may suggest that users are interested in something new, and keeping the system fresh by changing it often may be a way to help keep users engaged. The drawback to such a plan is the added investment in time to maintain novelty in the system for users.

4.13 Study limitations

This study had several limitations. The amount of time devoted to teaching each participant to use the system was limited to about 40 minutes, and this included going over the detailed informed consent forms. It is possible that patients were not able to remember everything that they were shown and later decided that the system was too complicated to warrant using, even though it was made to be as simple and straightforward as possible.

Patients were not all using the same phones for the study, and thus some may have had technical difficulties that were not brought to the attention of the author. However, the fact that patients used their own phones instead of using a phone provided for them also may have had some advantages. Having patients use their own phones better represents usability issues in the real world. Additionally, since patients might have been more likely to use the system if they were given a phone as a reward, this might have falsely elevated the usage levels during the short trial period. In that sense, this study was more realistic in terms of actual usage patterns.

Whereas some studies offer several hundred dollars as a reward for participating, the current study only offered $30 U.S. dollars to help cover the cost of SMS messaging or e-mail access. Thus, patients probably did not feel compelled to use the system for any reason other than wanting to try out a new system. It is possible, though, that some users agreed to participate in the study to please the physicians and nurses at the diabetes clinic.

It is not clear whether the cohort of patients recruited for the study represents the general population of adolescents with diabetes. Those who have cell phones may come from a higher socioeconomic status than those without, although socioeconomic status may not necessarily be a good indicator of diabetes control anyway.

While most patients expressed a desire to receive reminders on their cell phone, some actually wanted to receive reminders via e-mail. However, the randomization process did not always assign subjects to the group that they thought would be most useful to them. The lack of interest by some of the subjects may be a result of the group to which they were randomized. One way to potentially address this problem would be to implement the CARDS study using a cross-over design, where each user would get to try both the e-mail reminders and the cell-phone reminders.

4.14 Completion of the study

The CARDS study is still underway, and completion of the study is still months away. Chart reviews will need to be conducted on all patients who enter the study to obtain additional information such as the length of time each person has had diabetes, as well as hemoglobin A1c levels before and after the study. Blood sugar monitoring frequency will also be obtained based on meter or logbook data obtained from the two clinic visits, provided that the patient did bring his/her meter or logbook to the visit.

It is expected that the requisite number of patients will be enrolled in the study by the conclusion of the author's fellowship (June 30th, 2004). Each patient will still participate for the full three months after enrollment. Details are still being worked out regarding who will be available to complete the study by providing the surveys at the conclusion of each patient's time period. Assurances have been given that someone will be available to help complete the data collection for the study.

There will probably be no one available to work on the CARDS server if problems arise, since the Joslin information technology team does not wish to monitor the server. Limited remote access could be obtained through the CARDS FTP server if it were necessary. Fortunately, the server has worked well, so problems are not anticipated.

4.15 Conclusion

The preliminary results of this study have already provided useful information on current patterns of usage and potential future directions in which to improve CARDS. Of the ten patients who have enrolled so far, most have used SMS text messaging in the past, although they report using e-mail and instant messaging more often. Only four of the ten users have logged onto the system to even try it, and of those four, only two have actually attempted to respond to reminders with any regularity. It remains to be seen whether the reminder system provided by

CARDS will be of benefit for patients, and survey data obtained at the conclusion of the study should shed more light on this matter.

As noted in the Discussion section, the CARDS study also raises some interesting questions that remain unanswered, although their importance will likely increase as technologies such as SMS messaging are incorporated into patient care. Further studies are warranted to explore some of the unanswered questions raised by this study.

Biographical Note

David Alan Hanauer

David grew up in Bucks County, Pennsylvania, a suburb of Philadelphia. After high school he attended Cornell University in Ithaca, New York, where he graduated with a degree in chemistry in 1995. He then spent four years in Ann Arbor, Michigan, at the University of Michigan Medical School and graduated in 1999. After medical school he moved to New York City and completed a three-year residency training program in pediatrics at the New York University-Bellevue Medical Center. Completing his residency in 2002, he moved to Boston, Massachusetts, where is currently completing his Masters in Medical Informatics in the Health Sciences and Technology Division of Harvard-MIT.

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Appendix A

Baseline Survey Questionnaire

CARDS

Baseline Questionnaire

1. Date of birth: ____/____/____
   M D Y

2. Gender: [ ] Male [ ] Female

3. Please check all that apply:

	How do you record your blood sugars?	Do you own or use one?	Which do you currently have with you right now?	Which devices can you use or access at:		
				Work?	School?	Home?
Paper logbook						
Meter memory						
PDA such as Palm Pilot or Pocket PC						
Personal Computer						
Cell phone						
Other						

4. How often do you use the following?

a. Instant Messaging (IM) on computers:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

b. SMS / text messaging on cell phones:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

c. E-mail:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

5. How good are your computer skills?
[ ] Limited [ ] Good [ ] Expert

6. Checking blood sugars:

a. How often do you check your blood sugars?
[ ] Less than every day [ ] 2-3 times per day [ ] 6-7 times per day
[ ] One time per day [ ] 4-5 times per day [ ] 8 ore more times per day

b. It is easy to forget to check blood sugars at times. Do you ever happen to forget to check your blood sugars?
[ ] Yes [ ] No

c. If you answered "Yes" to question 6-b, how often do you forget?
[ ] Less than once per month [ ] Often (3-5 times each week)
[ ] Occasionally (1 -2 times each week) [ ] Daily (at least once each day)

d. If you answered "Yes" to question 6-b, please check all of the reasons you forget:
[ ] Didn't want to check it [ ] No good way to remind myself
[ ] Busy doing other things [ ] Other

e. Do you think reminders would help you check your sugars more often?
[ ]yes [ ] maybe [ ] no

7. Insulin:

a. How many insulin injections do you get each day?
[ ] I'm on the pump [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 or more

b. It is easy to forget insulin shots at times. Do you ever happen to forget your insulin?
[ ] Yes [ ] No

c. If you answered "Yes" to question 7-b, how often do you forget?
[ ] Less than once per month [ ] Often (3-5 times each week)
[ ] Occasionally (1 -2 times each week) [ ] Daily (at least once each day)

d. If you answered "Yes" to question 7-b, please check all of the reasons you forget:
[ ] Didn't want to give shot [ ] No good way to remind myself
[ ] Busy doing other things [ ] Other

e. Do you think reminders would help you give insulin shots more often?
[ ]yes [ ] maybe [ ] no

8. How often would you like your health care team to be able to review your blood sugar numbers?
[ ] Every day [ ] Every week [ ] Every month [ ] Only at my appointments

9. How often do you review your own blood sugar numbers?
[ ] Every day [ ] Every week [ ] Every month [ ] Only at my appointments

10. If you could design the ideal system to help you manage your diabetes, what would you like to see?

____
____
____

Appendix B

Final Survey Questionnaire

CARDS

Final Questionnaire

1. Date of birth: ____/____/____
M D Y

2. Gender: [ ] Male [ ] Female

3. Please check all that apply:

	How do you record your blood sugars?	Do you own or use one?	Which do you currently have with you right now?	Which devices can you use or access at:		
				Work?	School?	Home?
Paper logbook						
Meter memory						
PDA such as Palm Pilot or Pocket PC						
Personal Computer						
Cell phone						
Other						

4. How often do you use the following?

a. Instant Messaging (IM) on computers:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

b. SMS / text messaging on cell phones:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

c. E-mail:
[ ] Never / Almost Never
[ ] Occasionally (1-2 times each week)
[ ] Often (3-5 times each week)
[ ] Daily (at least once a day)

5. How good are your computer skills?
[ ] Limited [ ] Good [ ] Expert

6. Checking blood sugars:

a. How often do you check your blood sugars?

[ ] Less than every day [ ] 2-3 times per day [ ] 6-7 times per day

[ ] One time per day [ ] 4-5 times per day [ ] 8 ore more times per day

b. It is easy to forget to check blood sugars at times. Do you ever happen to forget to check your blood sugars?

[ ] Yes [ ] No

c. If you answered "Yes" to question 6-b, how often do you forget?

[ ] Less than once per month [ ] Often (3-5 times each week)

[ ] Occasionally (1 -2 times each week) [ ] Daily (at least once each day)

d. If you answered "Yes" to question 6-b, please check all of the reasons you forget:

[ ] Didn't want to check it [ ] No good way to remind myself

[ ] Busy doing other things [ ] Other

e. Do you think reminders would help you check your sugars more often?

[ ]yes [ ] maybe [ ] no

7. Insulin:

a. How many insulin injections do you get each day?

[ ] I'm on the pump [ ] 1 [ ] 2 [ ] 3 [ ] 4 [ ] 5 or more

b. It is easy to forget insulin shots at times. Do you ever happen to forget your insulin?

[ ] Yes [ ] No

c. If you answered "Yes" to question 7-b, how often do you forget?

[ ] Less than once per month [ ] Often (3-5 times each week)

[ ] Occasionally (1 -2 times each week) [ ] Daily (at least once each day)

d. If you answered "Yes" to question 7-b, please check all of the reasons you forget:

[ ] Didn't want to give shot [ ] No good way to remind myself

[ ] Busy doing other things [ ] Other

e. Do you think reminders would help you give insulin shots more often?

[ ]yes [ ] maybe [ ] no

8. How often would you like your health care team to be able to review your blood sugar numbers?
[ ] Every day [ ] Every week [ ] Every month [ ] Only at my appointments

9. How often do you review your own blood sugar numbers?
[ ] Every day [ ] Every week [ ] Every month [ ] Only at my appointments

The following questions are about using CARDS:

11. Compared with before this study, how much time did you spend on diabetes management during the study?
[ ] More [ ] About the same [ ] Less

12. Sometimes reminders that were sent can be slow to reach your phone or e-mail account. How often did the reminders come at the time you requested?
[ ] Always [ ] Almost always [ ] About half the time [ ] Rarely [ ] Never

	Agree		Neutral		Disagree	
	1	2	3	4	5	N/A
I am satisfied with how easy it was to use this system						
It was difficult learning how to use the system						
I felt comfortable using this system						
The instructions (such as online help) provided with this system were clear						
The organization of the web site was confusing						
The system did everything I wanted it to be able to do						
I enjoyed getting reminders sent to me by phone/e-mail						
I liked being able to send in my sugars by phone/e-mail						
I enjoyed receiving the daily factoids						
Using CARDS made me think more about my diabetes						
It was easier to remember to check my blood sugars while using CARDS						
Using CARDS did not make it any easier to keep track of my blood sugars compared to before						
I expect my diabetes control to be better because I was using this system						
The extra time it took to use this program was worth what I got out of it						
Using this system was enjoyable						
I think my diabetes control improved with the phone/e-mail reminders						
It was easier to take care of my diabetes with the help of the phone/e-mail reminders						

	Yes	No	Unsure	N/A
Did you have reminders sent to you every day?				
Did you check your blood sugar every time you received a reminder?				
Did you send in a blood sugar every time you received a reminder?				
Would you like your doctor or nurse to be able to view your on-line blood sugars?				
Did you have any difficulties using CARDS				
I would like to continue to be able to use CARDS if it were available				

How many days each week did you...	<2	2-3	4-5	6-7	Never
Have reminders sent to you?					
Log onto the CARDS web site?					
View your blood sugars on the web site?					
Go online to enter data on the web site?					
Print out your blood sugar diary?					

What did you like about CARDS?

____

____

____

What would you change about CARDS?

____

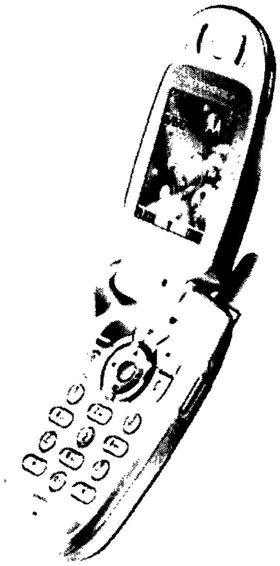
____

____

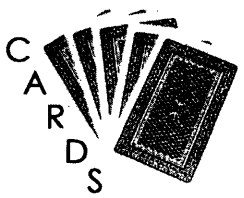
Appendix C

Recruitment Poster

Do you have Type 1 or Type 2 Diabetes? A cell phone? Home Internet & e-mail access?

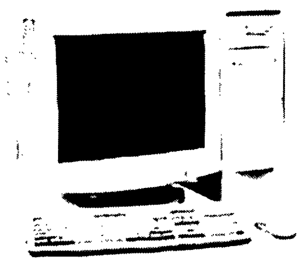


You may be eligible to participate in the CARDS study: Computerized Automated Reminder Diabetes System. The CARDS study will compare the use of cell phone text messaging and e-mail as reminders to check blood sugar to help manage diabetes.



You may be eligible if you:

- Are 13-25 years of age
- Have a cell phone that can send & receive text messages
- Have home Internet & e-mail access
- Have had diabetes for at least 1 year
- Require Insulin
- Are not in another study



Eligible participants will receive:

- Free parking and reimbursement to help cover the cost of text messaging or e-mail

For more information call:
Katie Wentzell
617-732-2699 ext 4475
or
David Hanauer
617-901-2229