DESIGN AND EVALUATION OF PERSONAL DIGITAL ASSISTANTS IN DIABETES MANAGEMENT

Albert Tseng
B.A.Sc.

A thesis submitted in partial fulfillment of the requirements for the degree of

Master of Health Science
in Clinical Engineering

Institute of Biomaterials & Biomedical Engineering
University of Toronto

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Abstract

The objective of this thesis was to design and evaluate the use of personal digital assistants (PDAs) in diabetes management. Diabetes requires patients to record daily blood sugar levels and insulin doses, causing it to be an extremely data intensive disease. Clinicians can better manage and educate patients if they have access to all this data. Results of this study showed that the technology was able to transfer significantly more data to the clinician than was possible before the technology was implemented. A time study analysis showed that the technology has potential to significantly decrease the amount of staff time spent collecting patient data. Although the results of this study can not yet be applied to the entire diabetic population, it has shown that PDA technology is a tool that can assist clinicians to more efficiently provide intensive therapy for diabetic patients.
Acknowledgments

This thesis could not have been completed without the help of many individuals whom I have been honored and delighted to work with in the past two years.

My sincerest thanks to Nick Zamora and Brent McGaw at OPTIUM Health Solutions for not only funding the project, but also investing the time and energy into its development. Your knowledge of technology in the health care industry has been an invaluable resource and without your vision, this project would not have taken flight. Thanks also to Steve Raymond and the staff at Personal Health Technologies who programmed and supplied the PDAs and technology infrastructure for the project. Your experience and expertise with this technology has been of enormous help. I would also like to thank Professor Alfred Dolan at the Institute of Biomaterials and Biomedical Engineering for supervising this project and more importantly, introducing me to the world of Biomedical Engineering.

Many, many thanks to the Charles H. Best Diabetes Centre for being the pilot site for this technology. It is exciting to know that there are clinicians in health care that realize the potential of technology and are willing to support it. Thanks goes to Marlene, Karyn, Irma, Zoë, and Dr. Lewis for all your help and cooperation throughout the study. A special thanks to Marlene Grass for spending countless hours explaining the needs of both clinicians and diabetics. Your dedication and enthusiasm for the health of your patients is inspirational. My sincerest gratitude goes to the ten diabetics at the Best Centre who allowed this technology into their lives. With further research, your perseverance and patience will not only help diabetics, but all patients who benefit from this technology.

To my friends who have supported me in the last few years, I thank you for continually contributing to my growth. I would like to show my respect, pride, and unconditional love towards my family for showing the same towards me.

Finally, I thank God for my existence, and for continually teaching me as He paves my way through life.
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**Albert Tseng**  
**August 1999**

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Summary of Research

The objective of this project was to design and evaluate the use of personal digital assistants (PDA) in diabetes management. The intent of this project was to conduct initial research into the technology, design the system, collect preliminary data, and make recommendations to serve as a foundation for future larger scale research studies. This project involved a set of 10 patients.

The hypothesis was that if a PDA is properly designed and utilized in conjunction with Web-based technology:

1. The use of PDAs with Web-based technology by the 10 study patients will increase the amount of patient data accessible by the clinician.
2. The use of PDAs with Web-based technology by the 10 study patients will increase the number of clinical interventions.
3. A time study will indicate that an inordinate amount of staff time is spent collecting patient data.

Another objective of the project was to collect information through patient interviews to discover new and better ways to design the PDAs.

These objectives and the hypotheses will be tested by the following research plan.

Stage 1 – Collection of previous patient data
The first stage was to gather old patient data from the subjects and analyze how much data the patients collected using traditional paper diaries.

Stage 2 – Time study
This stage involved the collection of task times of the staff at the center over a two-week period to determine which tasks could be removed by implementation of the technology. A reengineering assessment with process diagrams was conducted to aid in determining these tasks. An estimation of the time that clinicians could expect to save was made.
Stage 3 – PDA Trial
This stage involved collection of patient data using the PDAs and analysis of whether the amount of data collected increased over traditional data collection methods.

Stage 4 – Patient Interviews
Interviews were conducted with patients at the end of the trial. These interviews were conducted to identify problems the patients experienced with the PDAs and whether there were any changes that needed to be made to the design of the system.
1 Introduction

1.1 What is Diabetes?

1.1.1 Diabetes Mellitus

Diabetes Mellitus is a disorder of metabolism - the way our bodies use digested food for growth and energy. Most of the food we eat is broken down by the digestive juices into the simple sugar glucose. Glucose is the main source of fuel for the body. After digestion, the glucose passes into our bloodstream where it is available for body cells to use for growth and energy. For the glucose to get into the cells, insulin must be present. Insulin is a hormone produced by the pancreas, a large gland behind the stomach. (NIDDK, 1999)

In a non-diabetic patient, the pancreas automatically produces the right amount of insulin in order to move the glucose from our blood into our cells. The pancreas in people with diabetes either produces little or no insulin, or the body cells do not respond to the insulin that is produced. As a result, glucose builds up in the blood, overflows into the urine, and passes out of the body. Thus, the body loses its main source of fuel even though the blood contains large amounts of glucose. (NIDDK, 1999)

Diabetes is associated with long-term complications that affect almost every major part of the body. It contributes to blindness, heart disease, strokes, kidney failure, amputations, and nerve damage. Uncontrolled diabetes can complicate pregnancy, and birth defects are more common in babies born to women with diabetes. (NIDDK, 1999) Diabetes is the seventh leading cause of death in both Canada and the United States. (Health Canada Website, 1999) & (CDC, 1999)

There are three main types of diabetes. Type I, Type II, and Gestational Diabetes.

1.1.2 Type I diabetes (IDDM)

Type I diabetes, known also as insulin-dependent diabetes mellitus (IDDM), is considered an autoimmune disease. An autoimmune disease results when the body's system for fighting infection turns against a part of the body. In diabetes, the immune
system attacks the insulin-producing beta cells of the pancreas and destroys them, resulting in little or no production of insulin. At present, scientists do not know exactly what causes the body's immune system to attack the beta cells, but they believe that both genetic factors and viruses are involved (NIDDK, 1999).

Someone with Type I diabetes needs daily injections of insulin to live. Before the discovery of insulin in 1921, all people with Type I diabetes died within a few years after the appearance of the disease. Although insulin is not considered a cure for diabetes, its discovery was the first major breakthrough in diabetes treatment (NIDDK, 1999). Type I diabetes accounts for about 5 to 10 percent of diagnosed diabetes in North America.

Type I diabetes develops most often in children and young adults, but the disorder can appear at any age. Symptoms of Type I diabetes usually develop over a short period, although beta cell destruction can begin years earlier. Symptoms include increased thirst and urination, constant hunger, weight loss, blurred vision, and extreme tiredness. If not diagnosed and treated with insulin, a person can lapse into a life-threatening coma.

1.1.3 Type II diabetes (NIDDM)

The most common form of diabetes is Type II diabetes (also known as noninsulin-dependent diabetes mellitus or NIDDM). About 90 to 95 percent of people with diabetes have Type II diabetes. This form of diabetes usually develops in adults over the age of 40 and is most common among adults over age 55. About 80 percent of people with Type II diabetes are overweight (NIDDK, 1999).

In Type II diabetes, the pancreas usually produces insulin, but for some reason, the body cannot use the insulin effectively. The end result is the same as for Type I diabetes - an unhealthy buildup of glucose in the blood and an inability of the body to make efficient use of its main source of fuel.

The symptoms of Type II diabetes develop gradually and are not as noticeable as in Type I diabetes. Symptoms include feeling tired or ill, frequent urination, unusual thirst, weight loss, blurred vision, frequent infections, and slow healing of sores.
1.1.4 Gestational Diabetes

Gestational diabetes develops or is discovered during pregnancy. This type usually disappears when the pregnancy is over, but women who have had gestational diabetes have a greater risk of developing Type II diabetes later in their lives.

1.2 Prevalence and Cost Impact of Diabetes

1.2.1 Prevalance

The World Health Organization (WHO) estimates the total number of people with diabetes in the world will double to 299 million by the year 2025 (Table 1). The full chart of world estimates is shown in Appendix A.

Table 1 - WHO Diabetes Mellitus Estimates 1995 - 2025 (in thousands of cases) (WHO, 1999)

<table>
<thead>
<tr>
<th></th>
<th>1995</th>
<th>1997</th>
<th>2000</th>
<th>2025</th>
</tr>
</thead>
<tbody>
<tr>
<td>Canada</td>
<td>1532</td>
<td>1600</td>
<td>1701</td>
<td>2618</td>
</tr>
<tr>
<td>United States</td>
<td>13853</td>
<td>14315</td>
<td>15009</td>
<td>21892</td>
</tr>
<tr>
<td>World</td>
<td>135286</td>
<td>142538</td>
<td>154392</td>
<td>299974</td>
</tr>
</tbody>
</table>

As shown in Table 1, it is estimated that in Canada, there are 1.7 million people in Canada with diabetes mellitus. In the United States this number is much greater with an estimated 15 million diabetic individuals. About half of these people do not know they have diabetes and are not under care for the disorder. In the U.S., about 798,000 people are diagnosed with diabetes each year. (NIDDK, 1999)

Although diabetes occurs most often in older adults, it is one of the most common chronic disorders in children in the United States. About 123,000 children and teenagers age 19 and younger have diabetes. (NIDDK, 1999)

The number of diabetes deaths in Canada in the past years and projections into the future are shown in Figure 1. There were 5,447 deaths (2701 males; 2746 females) in
1996 for which diabetes was certified as the underlying cause. This ranks diabetes as the seventh leading cause of death in Canada (Health Canada Website, 1999). However, the actual number of deaths for which diabetes was a contributing factor is probably five times this number according to recent Canadian studies. People with diabetes usually die from the late complications of the condition such as ischemic heart disease and it is these complications which are in most cases coded as the underlying cause of death.

![Figure 1 - Number of Diabetes Deaths (1950-1995) and Projections to Year 2016 by Sex in Canada (Health Canada, 1999)](image)

Diabetes is also widely recognized as one of the leading causes of death and disability in the United States. Studies have found death rates to be twice as high among middle-aged people with diabetes as among middle-aged people without diabetes. According to death certificate data, diabetes contributed to the deaths of more than 193,140 persons in 1996 (NIDDK, 1999).

1.2.2 Cost Impact of Diabetes

Studies have shown that a person with diabetes incurs two to five times higher medical costs than a person without diabetes. This is due to more frequent medical visits, purchase of supplies and medication, and higher likelihood of being admitted to a nursing home (NIDDK, 1999). There are many costs involved in the care and management of diabetes for both the individual with diabetes and the health care
The direct medical costs include in-patient care, out-patient care, medications, medical equipment, supplies, and laboratory tests. Indirect medical costs include transportation, lodging, and childcare. Indirect non-medical costs include a decrease in productivity due to absence from work, decreased earning potential because of potential disabilities, lost earnings due to premature mortality and increased insurance (NIDDK, 1999).

The WHO estimates that four to five percent of health budgets are spent on diabetes-related illness (WHO, 1999). In Canada, it is estimated that at least $6 billion is spent annually on treating people with diabetes and its complications. The health care portion of this money is allotted to the following areas: acute care hospitals; provincial health insurance physician billing; supplies and medicine; and home care.

According to the American Diabetes Association, diabetes cost the United States $98 billion in 1997. Indirect costs, including disability payments, time lost from work, and premature death, totaled $54 billion; medical costs for diabetes care, including hospitalizations, medical care, and treatment supplies, totaled $44 billion (NIDDK, 1999).

About 40.5% of all U.S. expenditures for diabetes in 1992 were related to inpatient hospital care, while only 1.03% was spent on prevention or diagnosis (NIDDK, 1999). Although much of health care expenditures for diabetes are spent on treating complications, there is increasing focus on prevention of complications of diabetes. In Canada, both hospital separations (end of hospital stay due to discharge or death) and hospital days due to diabetes have been gradually decreasing since the early 1980s. Since 1983, hospital days have dropped by 42% while hospital separations have decreased by about 25%. This decrease in hospital utilization most likely reflects a general shift from institutionalized to community care in Canada's health care system. This shift will be discussed in Section 2.1. Another reason for the decrease in hospital utilization can be from the increased understanding that diabetics need to learn how to control their blood sugar in their normal environment (Health Canada, 1999).

With growing awareness of the prevalence and cost impact of diabetes in Canada, the government budgeted $55 million over three years to the Canadian Diabetes Prevention and Control Strategy in the 1997 Budget (Health Canada, 1999). This strategy will focus
on combating diabetes, public education, treatment, community support and surveillance, and will include attention to juvenile diabetes.

1.3 Diabetes Research

In response to the growing health burden of diabetes mellitus, three approaches to dealing with the disease have arisen:

1. Cure diabetes;
2. Prevent diabetes;
3. Manage diabetes to prevent devastating complications.

Several approaches to "cure" diabetes are being pursued including pancreas transplantation, islet cell transplantation (islet cells produce insulin), artificial pancreas development, and genetic manipulation (NIDDK, 1999).

Diabetes research has not only led to substantial progress towards a cure for diabetes, but also has led to the identification of preventive measures and improved treatments for the debilitating and costly complications associated with this disease. As an example of research in prevention, researchers have located genetic markers for diabetes, which may make it possible to identify high-risk candidates before they develop diabetes and its complications (JDF, 1999). Researchers are also studying whether small doses of insulin given either orally or by injection to pre-diabetic patients can make the insulin-producing beta cells of the pancreas less of a target for attack by the immune system (Joslin, 1998).

Although research into curing and preventing diabetes is important, the focus of this paper will be the management of Type I diabetes utilizing innovative technology. A major research breakthrough in Type I diabetes management was the Diabetes Control and Complications Trial. This is discussed in more detail in the next section.

1.4 Diabetes Control and Complications Trial (DCCT)

The Diabetes Control and Complications Trial (DCCT) was a landmark, 10 year multi-center study of people with Type I diabetes. The study's goal was to determine whether
people with diabetes can greatly reduce their risk of long-term diabetes complications by keeping their blood sugars as close to normal as possible (Joslin, 1999).

The trial was designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the complications of Type I diabetes. Conventional therapy consisted of one or two insulin injections per day, daily self-monitoring of urine or blood glucose, and education about diet and exercise. (DCCT, 1993: 978)

Intensive therapy included (DCCT, 1993: 978):
- Testing blood sugar levels 4 or more times a day
- Four daily insulin injections or use of an insulin pump
- Adjustment of insulin doses according to blood sugar levels, dietary intake and anticipated exercise
- Monthly visits to the medical center as well as more frequent telephone contact to review and adjust their regimens

The goals of intensive therapy (DCCT, 1993: 978) were:
- Preprandial blood glucose concentrations between 70 and 120 mg per deciliter
- Postprandial concentrations of less than 180 mg per deciliter
- A weekly 3:00am measurement greater than 65 mg per deciliter
- Monthly glycosylated hemoglobin (hemoglobin $\mathrm{A}_{1c}$) within the normal range of less than 6.05 percent

Through their extensive study of 1441 patients at 29 medical centers in North America, the Diabetes Control and Complications Trial (DCCT) Research Group concluded that (DCCT, 1993):

"Intensive therapy effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with IDDM."
The question of whether the results of the DCCT are achievable for most people with diabetes has been asked many times since the conclusion of the landmark study. In theory, the answer is yes. However, in the real world, great effort would be required to reproduce the results of the DCCT. The study group was young, generally healthy, and highly motivated. The professional personnel conducting the study were trained endocrinologists and diabetes educators in academic centers who were highly motivated and careful in their management of the study subjects. The intensively treated group received far more attention and medical services than are routinely available in clinical practice. Broad implementation of intensive therapy will require expanded health care teams (knowledgeable physicians, diabetes educators, nutritionists, and social workers), major professional and patient educational efforts, and an enhanced partnership between specialists and primary care providers (NIDDK, 1999).

It is recognized that there will be substantially increased costs of widely applying the recommendations of the DCCT study in North America. Moreover, additional efforts are necessary to ensure that health practitioners are educated in the ability to implement the DCCT intensive therapy effectively and safely. It is hoped that the long-term benefits of healthier, more productive lives with fewer complications will offset the costs of tight control (NIDDK, 1999). Although the initial costs of intensive therapy are two to three times greater than conventional therapy, the long-term costs are significantly less. The incremental cost per year of life gained with intensive treatment as calculated by the DCCT in 1996 was $30,400 (DHESG, 1999). It is hoped that innovative information and communication technologies can be used to revolutionize diabetes health care delivery, allowing a significant decrease in these costs while maintaining comparable intensive treatment.
1.5 Importance of Data in Type I Diabetes Care

Lack of insulin production by the pancreas makes Type I diabetes particularly difficult to control. Treatment requires a strict regimen that typically includes a carefully calculated diet, planned physical activity, home blood glucose testing several times a day, and multiple daily insulin injections (ADA, 1999).

As discussed in the last section, the DCCT intensive treatment involved helping patients to keep their blood glucose levels as close to normal as possible. For this to be done, clinicians needed to be able to monitor the four or more daily blood glucose levels taken by the patients. In addition, in order to adjust insulin doses effectively, clinicians needed to monitor insulin doses as well as exercise patterns and diet. This demonstrates that the monitoring and recording of patient data was critically important in DCCT intensive treatment.

The American Diabetes Association recognized the importance of patient data and stated in its clinical practice guidelines that “a complete, organized medical record system is essential to providing ongoing care of people with diabetes. The records must always be accessible to the diabetes treatment team and organized so that they not only document what has occurred but also serve as a reminder of what should be done at appropriate intervals” (ADA, 1999).

Diabetes care should be “patient driven” because the majority of the data is collected by the patients in the context of their daily lives. Patients must accept responsibility and be made to realize the importance of the data in managing their care. The management plan should be “formulated as an individualized therapeutic alliance among the patient and family, the physician, and other members of the health care team skilled in the management of diabetes to achieve the desired level of diabetes control” (ADA, 1999).

As well as collecting the data, the plan should emphasize the involvement of the patient in problem solving as much as possible. A variety of strategies and techniques should be employed to provide adequate education and development of problem-solving skills in the various aspects of diabetes management.
In formulating this management plan, consideration should be given to the patient's age, school or work schedule and conditions, physical activity, eating patterns, social situation and personality, cultural factors, and presence of complications of diabetes or other medical conditions. Each aspect of the management plan should be understood and agreed on by the patient and the care providers (ADA, 1999).

After formulation of the plan, the patient's compliance to the plan must be monitored through continuing care. Continuing care is essential in the management of every patient with diabetes. At each visit, the patient's progress in achieving treatment goals should be evaluated by the health care team, and problems that have occurred should be reviewed. If goals are not being met, the management plan needs to be revised and/or the goals need to be reassessed (ADA, 1999).
2 Health Care Policy

2.1 Health Care Reform

The major objectives of health care reform across Canada are similar and include (CIHI, 1999: 1)

- increased emphasis on health promotion and disease prevention;
- decentralization of accountability and decision-making;
- shift from hospital to community-based services;
- integration of agencies, programs and services; and
- increased efficiency and effectiveness in service delivery.

While Canada has a well-developed health care system, it also has one of the highest rates of institutionalization in the world. It is recognized that health services encompass much more than institutional services and includes self-care, disease prevention, health promotion and protection, community support, ambulatory primary care and rehabilitative services. It is increasingly apparent that many individuals being treated in institutional settings could be more appropriately seen in a community setting, receiving their services in the context of their daily lives (Wanke et al., 1995).

In 1997, the Health Services Restructuring Commission of Ontario established a vision (HSRC, 1997) that involved a dramatic change in the concept of a health services system, from one with a hospital at the center, to a system which revolves around the users. The current model and new model are shown in Figure 2 below. As shown in the new model, hospital care is shown on the periphery orbit, while community care is shown close to the patient at the center.
Current Model

![Diagram of Current Model]

New Model

![Diagram of New Model]

Figure 2 - Shift in health care system concept (HSRC, 1997)

Although no universally accepted definition of community-based health services exists, most would agree that it means "bringing services as close as possible to where people live and work, and providing health services outside of hospitals and other institutions" (Wanke et. al, 1995).

The literature on community-based health services models indicates that, in general, integrated, multi service, multidisciplinary models are less costly, and more cost-effective, than comparable services provided by single-service providers and institutional providers (Church et. al, 1995). This is particularly evident when comparing the
community health center organizational model with solo fee-for-service physician practice. The major cost saving appears to occur through a reduction in the use of hospital outpatient and inpatient services by populations receiving services from community health centers. Community health centers not only offer a cost savings, but also offer patients increased access to care (Church et. al, 1995).

2.2 Health Care Investment in Information Technology

In the 1999 Canadian budget, the federal government is providing $328 million over three years to start building a truly national network of information about health and health services to strengthen the health care system and make it more accountable to Canadians (ACHI, 1999). This amount was a part of a $1.4 billion package of key federal health initiatives.

"If we are to build a better health system, we need a better information-sharing system. With the federal investment in the health lane on the information highway, we all stand to benefit: Canadians, health care providers and decision-makers."

- Health Minister of Canada, Allan Rock (ACHI, 1999).

Canada is not alone in this type of investment in information infrastructure. European countries, Japan and the United States are all investing heavily in information and communications technology applications for the health sector. In September 1998, the British government released an ambitious and far-ranging strategic plan to spend more than £1 billion over seven years on such an initiative (ACHI, 1999).

Canada’s expenditures on information technology in the health field are expected to rise from less than $1 billion a year in 1996 to more than $1.5 billion by the year 2000 (ACHI, 1999). Much of this money is now being used to build health information infrastructures at the provincial, territorial and regional levels. In addition to other key federal initiatives, these represent essential building blocks for the Canada Health Infoway.
The aim of Canadian investment in health information and communications technologies is (ACHI, 1999):

1. to give Canadians the information they need to provide Canadians with the facts they need to make informed decisions about their health;
2. to improve delivery of health services through such innovations as telehealth and tele-homecare; and
3. to provide broader and better access to the facts so that all governments and all health providers are accountable to Canadians.

In terms of health care delivery, Health Canada intends to support innovative applications of communications and information technology to improve health service delivery. This includes "renewed support for not-for-profit organizations delivering health services and the exploration of ways to facilitate the development of trial and demonstration projects that would apply advanced information and communications technologies in the health sector" (Health Canada, 1999)
### 3 Data Collection Technology

#### 3.1 Data Collection Methods

Various data collection options were considered and the advantages and disadvantages of the different technologies were compiled in the following matrix shown in Table 2.

**Table 2 – Data Collection Technologies**

<table>
<thead>
<tr>
<th>Technology</th>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
<tbody>
<tr>
<td>Paper Based Forms</td>
<td>• Low equipment needs</td>
<td>• Data entry: high labor/prone to errors</td>
</tr>
<tr>
<td></td>
<td>• Low capital cost</td>
<td>• Information transfer slow</td>
</tr>
<tr>
<td></td>
<td>• Familiar to users</td>
<td>• Easily lost/misplaced</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be read by one person</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Legibility</td>
</tr>
<tr>
<td>Fax Forms &amp; OCR (Optical Character Recognition)</td>
<td>• Low equipment needs</td>
<td>• OCR effectiveness unsure/may require some checking of data</td>
</tr>
<tr>
<td></td>
<td>• Low capital cost</td>
<td>• Slow (often requires user verification of data)</td>
</tr>
<tr>
<td></td>
<td>• Familiar to users (write on paper)</td>
<td>• Potential to be lost/misplaced</td>
</tr>
<tr>
<td></td>
<td>• Most of data (OCR) automatically entered into computer</td>
<td></td>
</tr>
<tr>
<td>Tele-service (Telephony)</td>
<td>• Low equipment needs</td>
<td>• Limitations on complexity of questions</td>
</tr>
<tr>
<td></td>
<td>• Eliminates secondary data entry</td>
<td>• Patients unable to go at their own speed</td>
</tr>
<tr>
<td></td>
<td>• Able to control data quality at the source</td>
<td>• Accessibility for hearing impaired</td>
</tr>
<tr>
<td></td>
<td>• Some familiarity to users</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Fast info transfer</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Can be conducted from any telephone</td>
<td></td>
</tr>
<tr>
<td>Dedicated Computer Terminals</td>
<td>• Can be used for other data collection</td>
<td>• Intimidating for non-computer users</td>
</tr>
<tr>
<td></td>
<td>• Eliminates secondary data entry</td>
<td>• Only one person at a time</td>
</tr>
<tr>
<td></td>
<td>• Easily correctable</td>
<td>• Non-portable</td>
</tr>
<tr>
<td></td>
<td>• Minimize data entry</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Data available faster</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Hard to lose data</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Ability to design “smart” questionnaires</td>
<td></td>
</tr>
</tbody>
</table>
Table 2 shows that PDA technology has many advantages over alternative data collection methods.

### 3.2 PDA Technology in Health Care

A "Personal Digital Assistant" (PDA) is a palm-size computer that has been mainly marketed for assisting business people with time management and organization. In the past, the relatively large size of PDAs limited its use, but recent advances in PDA technology has led to a significant decrease in the size of the devices and has opened up the door to many new applications. Although the manufacturers of these devices tend to concentrate on the mainstream functions of the PDA (contacts, note takers, schedules, etc), they strongly encourage software development by third party companies for more specific applications. This has created a wealth of software for these devices.
The health care field is an example of an industry where the benefits of PDAs could be enormous. On PalmCentral.com (www.palmcentral.com), a website that has PDA software for many applications, there are over one hundred different medical software packages available for download by health care professionals. However, these have generally been developed as supplementary tools and have not been integrated into health care processes. For this reason, the use of PDAs by health care professionals is not yet widespread.

There have been numerous "pilot" experiments that have suggested the benefit of the use of PDAs in clinical care settings. In one 1995 paper, the expected usefulness of a PDA in a few different clinical scenarios is described (Karshmer & Karshmer, 1995). In another paper, a PDA based computerized patient record allowing physicians to draw and hand-write with the "same flexibility of paper" is explained (Lussier et al., 1993). A recent 1998 paper documented the experience of eight home health nurses utilizing wireless, pen-based computing in the inner-city, home care environment (Wilson & Fulmer, 1998).

To a lesser extent, there have been some studies directed towards patient interaction with PDAs. An example of such a paper was written in 1995 and studied the benefits of utilizing PDAs to collect health-related quality of life information from breast cancer patients in an outpatient clinic (Le, Kohane & Weeks, 1995). However, this was again a pilot study and at the time of the paper, the study had not yet commenced.

Although the health care community and researchers have definitely shown an interest in the use of PDAs, there have been no conclusive studies that show the benefit of these devices. However, with the recent decrease in size and cost of these devices, interest will grow even more, which will lead to researchers taking a keen interest in proving their worth.
4 The Charles H. Best Diabetes Centre

4.1 Description

The Charles H. Best Diabetes Centre for Children and Youth is the site for this study. It is a community-based pediatric diabetes center that assists children and youth in the Durham region to properly manage diabetes. The center has been active for over 10 years and currently serves a patient population of over 350 diabetic children, adolescents, and young adults. The center consists of a physician, two registered nurses, a registered dietician, and a few volunteers. The Best Centre is a system that is currently being evaluated as a model for diabetes management in the province of Ontario.

As discussed in Section 1.5, consideration should be given to a patient's lifestyle when formulating the diabetes management plan. A major aspect that needs to be addressed is the patient's age, particularly if the patient is a child or adolescent. Approximately three-quarters of all newly diagnosed cases of Type I diabetes occur in individuals younger than 18 years (ADA, 1999). Care of this group requires integration of diabetes management with the complicated physical and emotional growth needs of children, adolescents, and their families. Diabetes care for children of this age group should be provided by a team that can deal with these special medical, educational, nutritional, and behavioral issues. The Charles H. Best Diabetes Center is an example of such a team.

The treatment of people with diabetes has historically been limited to a few days of patient education after initial diagnosis of the disease. This often is not enough, causing the patients to have complications and be readmitted to the hospital. In contrast, patients who are treated by the Best Centre are monitored frequently by visits to the center every two or three months at which point the patients' blood sugar and insulin data is reviewed and clinicians offer feedback on how to better manage their diabetes. Additionally, there is a 24-hour hotline where a clinician can always be reached when the patients and families have a question about their diabetes care. This ongoing education of the patients and families teaches them how to self manage diabetes by showing them how to adjust their treatment based on the collected data and other factors.
4.2 Process Diagram and Description

Shown in Figure 3 on the next page is a process diagram showing the flow of a patient through the Best Centre. The following paragraphs describe each of the steps of the process diagram for a better understanding of the process.

A patient first enters the Best Centre system through a referral from a physician. Often, this is when a patient is first diagnosed with the disease either at a hospital or at a doctor's office. A patient can also be referred from another diabetes management program. In either case, the referring physician must fill out a Physician Referral Form (Appendix B-1) so that the Best Centre has enough initial information about the patient.

Next, a Best Centre nurse will perform an initial assessment of the patient. If the patient is newly diagnosed, the nurse will likely perform the assessment at the hospital. Otherwise, the assessment will occur during an appointment at the Best Centre. Here, the nurse completes the Initial Assessment Form (Appendix B-2). At this point, the nurse will also begin to educate the patient and family on how to manage his/her diabetes. This would involve teaching the patient about how to monitor blood sugar levels, how to administer and adjust insulin doses, and how to adjust his/her lifestyle to life with diabetes.

A dietitian also meets with the patient and family to make an initial assessment and to formulate a meal pattern. In parallel with the insulin regimen, the meal pattern is what the patient will use in daily life to help better control his/her blood sugar levels. The dietitian will fill out the Diet History/Dietitian Worksheet form (Appendix B-3), a copy of which is given to the patient. The patient is instructed to follow this meal pattern to decide what to eat and how much insulin to take. In some special cases where an intensified meal pattern is desired, the patient will record what they eat for a few weeks in order for the dietitian to better formulate a pattern.
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Figure 3 - Process Diagram
The patient is then given a paper diary in which he is to monitor his glucose (blood sugar) levels and insulin doses. An example of a paper diary is shown in Appendix B-4. Patients are encouraged to take at least 4 blood sugar tests per day as well as at least 4 insulin doses per day. All of this data should be recorded in the paper diary that in most cases hold a month's worth of data. Additionally, patients are encouraged to record exercise activity and incidences of low or high blood sugar and their symptoms. This data is collected so that clinicians can help patients analyze the long term trends in the data to better manage the disease.

The next step is getting the data in the diary to the clinicians at the Best Centre. In some cases, this data is transferred to the Best Centre when the patient brings his diary to appointments (once every two or three months). However, patients who need more frequent monitoring will get their data to the Center by either faxing the data in or calling the Center and dictating the blood sugar and insulin levels while the clinician at the Center transcribes. Table 3 below shows the distribution of the pediatric patients based on data collection method.

<table>
<thead>
<tr>
<th>Type of Patient</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not submit data at all</td>
<td>23</td>
<td>19.8%</td>
</tr>
<tr>
<td>Submit data at bi-monthly visits</td>
<td>22</td>
<td>18.9%</td>
</tr>
<tr>
<td>Fax in their data</td>
<td>16</td>
<td>13.8%</td>
</tr>
<tr>
<td>Call in their data</td>
<td>55</td>
<td>47.4%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>116</td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

During an appointment, the clinician will add to the Appointment Record Form (Appendix B-5) which summarizes the changes in patient parameters between visits with the Best Centre staff. The clinician will then review the data in the patient's diary and identify any issues. The clinician will educate the patient and family on how to recognize trends in the data and how to adjust his/her treatment to take into account these trends. Finally, the patient's data will be recorded for the Best Centre patient chart, usually by photocopying the paper diary.

In the event that a patient requires assistance from the Best Centre, they can contact a clinician 24 hours a day, 7 days a week via phone or pager. When a connection is made
between the patient and clinician, the clinician will decide whether they require blood sugar and insulin patient data. If they are at the Center, there will be data in the patient medical record. However, the usefulness of this data will depend on the last time the patient submitted data to the Center. In addition, if the patient requires assistance during off hours, the clinician will likely not be at the Center, thus having no access to the patient medical record. If the clinician does not have sufficient data, they may request that the patient fax or dictate his/her recent data to them. Based on this data, the nurse will educate the patient on how to deal with his/her question.

4.3 The Best Centre Technology Model

4.3.1 Description of the Model

Model for Diabetes Care

As discussed in Section 1.4 and shown in Figure 4, the four components of intensive therapy are four daily blood sugars, four daily insulin doses, dose adjustment, and monthly visits. The model proposed in Figure 4 suggests that the combination of PDA technology and the Best Centre can together simulate the intensive therapy of the DCCT. The PDA technology can monitor the collection of blood sugars and insulin doses while the Best Centre can help
patients adjust their doses and coordinate monthly visits. The World Wide Web serves as the medium in which information is securely transferred from patient PDAs to the Best Centre clinicians. It is hoped that this model will help patients achieve their goal of keeping blood sugars as close to normal as possible, thus decreasing their risk of long term complications.

4.3.2 Description of the Technology

![Diagram of the Best Centre Technology Model]

**Figure 5 - Best Centre Technology Model**
The diagram shown in Figure 5 is a graphical representation of the technology used within the Best Centre Technology Model. The various components are described below.

1. Software – The software on the PDA has been designed specifically for diabetes management. The screens have been designed to make data entry easy for the patient. This is discussed more in Section 5.
2. Personal Digital Assistant – The PDA is the handheld device used to collect patient data. The patient will enter data using a plastic pen by touching the surface of the screen.
3. Modem – The modem is the device that is used to transfer patient data from the PDA to the central database. Every night, the patient will connect the PDA to the modem and the modem to the telephone line. By selecting to send patient data from the main menu, the PDA will establish a connection to the central database (through a toll free number) to send and receive data.
4. Central Database – The central database stores all patient data that is received from the PDAs. This database has security so that only those with permission can access the data.
5. World Wide Web – The World Wide Web is a network that permits access from anywhere that a phone connection can be made.
6. Computer Access – Nurses, dieticians, and doctors will be able to access patient data through a computer at the Best Centre. Additionally, if a clinician has a portable computer, they can also access the data remotely from home, hospitals, or anywhere with a phone connection.

4.3.3 Advantages of the Reengineered Process

The technology discussed above will enable the Best Centre to improve the care of their patients through a reengineered process. The process can be transformed from that shown in Figure 3, to that shown in Figure 6 on the next page. The beige colored stages represent stages that are to be reengineered with the technology. The purple colored steps represent stages that could be reengineered with the technology in a future phase.
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Figure 6 - Reengineered Process Diagram
The existence of paper diaries in the current process requires a great deal of photocopying, faxing, and transcribing of patient data in order to get the information into the hands of the Best Centre clinicians. Collecting patient data represents a large portion of the workload of the clinicians, reducing the amount of time available to analyze patient data, and educate the patients. As shown by Figure 5, the new technology allows patients to enter their data in with a PDA device. By entering in this data in digital form, the patients are able to upload this information daily through a normal telephone line. This means that both the Best Centre and the families of the patient do not need to make photocopies, retrieve patient charts, read or transcribe patient data.

In the existing paper system, if a patient calls in with a problem or question, the clinician would often find that the patient chart is not up to date. This would involve the time consuming task of requesting past data via fax or dictation. With the new process, the PDA technology will allow patient data to be uploaded daily so that the patient chart will be populated with recent information.

In the existing system, data is often not complete, missing blood sugar and insulin values, and especially exercise and episode data. The PDA technology offers an easy way to enter blood sugar, insulin, exercise, and episode data and is expected to result in more complete patient data.

Another limitation of paper records is that even when patient data is collected regularly, clinicians have to be at the Best Centre to view the data. This is often restrictive when clinicians are off-site and are paged with patient questions. It is difficult to advise and educate the patient without access to the patient chart. With the Web-based technology, the electronic patient chart will be posted on a secure web server, allowing the Best Centre clinicians to access the most up to date data from any computer with internet access. This is particularly useful when the clinician is off-site and needs to access patient information. In addition, more than one clinician can be accessing the data at once, whereas with paper, only one person can review the patient chart at one time.

Another advantage of having the patient data in digital form is that the information can be manipulated into different formats that allow the clinician to easily analyze the data. For example, the data could be transferred into a spreadsheet program where graphs
and tables could be drawn to show trends in the data. In a paper based system, this would not be possible unless secondary data entry was performed.

One problem with the paper system is that patients begin to realize that the data that they collect is often not used by the clinicians due to the difficulty in getting it in time to analyze it. This could lead to patients not filling out their diaries due to the feeling that no one is monitoring it. With the PDA and Web-based technology, patients know that clinicians have daily access to data at any time and that their data will be monitored. This will likely increase patients' compliance in recording data.

Finally, in the existing process, patients often are reluctant to contact the Best Centre clinicians because they do not want to disturb them. With the technology, patients are able to ask questions and receive answers through their personal PDA when they upload and download data daily.

To summarize, the new process is expected to offer the following advantages over the existing process.

1. Reduction in time spent photocopying, faxing, dictating, and faxing patient data, allowing clinicians more time to analyze patient data and educate the patient.
2. Information is uploaded daily as opposed to every few months (for normal patients) or weeks (for intensive patients).
3. Patient data will be more complete due to an easier way to input data.
4. Patient data is accessible anywhere there is Internet access.
5. Patient data can be viewed by more than one clinician at a time.
6. Patient data can be manipulated into different graphical formats
7. Patient's will record more information as they will know that the data is being monitored and reviewed by clinicians.

Through the use of the PDA/Web technology, the intensive therapy described in the Diabetes Control and Complications Trial can be emulated because patient data will be transferred to the center on a daily basis, allowing clinicians to monitor blood sugar levels, exercise, and episodes. The technology will allow clinicians to spend less time collecting patient data, and more time monitoring and analyzing it. Through this
monitoring and analysis, the clinicians are better able to educate the patients on managing their diabetes by showing them the effects and trends in their own data. If this can be accomplished through the use of technology, the PDA/Web technology used by a center such as the Best Centre should provide care comparable to the intensive therapy specified by the DCCT, and similarly, help patients achieve a decrease in long term diabetic complications.
5 Design of PDA Patient Interface

5.1 Limitations and Criteria of Screen Design

As previously described, the care of those with diabetes is extremely data intensive. Therefore, the most important clinical need is up-to-date, high quality patient data. In order to ensure the regular collection and submission of this data, the patient interface with the PDA must be designed to facilitate input from the user. This interface is the software that runs on the PDA. Design of the software screens should make the device easy to use, convenient, and valuable to the patient.

The main and always present technological limitation of screen design for a PDA is screen size. Given this limitation, the criteria on how well a screen is designed are:

1. Readability
2. Ease of use
3. Minimal number of screen touches
4. Quick data entry
5. Retrospective data entry

The screens were designed through many iterations using MS Powerpoint. In fact, between the designer (this Master's student) and the programming company (Personal Health Technologies), there were 8 major revisions made before the final functional specifications were completed (Appendix C). Personal Health Technologies has had extensive experience with the use of PDAs in clinical trials and was extremely helpful in advising on screen design. Through these iterations, it was clearly understood by the designer that there was a definite balance between screen size and optimization of the various criteria.

Given that PDAs are meant to be small for portability, the amount of text or images to be displayed is restricted. Often, the designer attempted to fit more on the screen by decreasing the font size of the text. However, below a certain font size, the results were unreadable, causing the first criteria to be sacrificed. Based on the PHT's experience, a minimum font size of 10 was agreed upon.
The screen size limitation was the greatest problem when designing the screens that let patients view their own data. These screens were difficult because there was a lot of data to display on the small screen (Appendix C, Screen 11.0). Scrolling was incorporated into these screens so that more information could be displayed. These screens were complicated by the fact that the data had to be shown in a tabular format similar to the layout found in paper diaries, so patients would be familiar with the data and understand the trends in the data.

In terms of ease of use, it was decided that the character recognition capabilities of the PDA would not be used because this would require the user to learn the new entry method. Instead, the screens were designed with user selectable menus so that patients could easily point to their selections. Once again, limited screen size made design of user selectable menus difficult because there were often many options for a patient to choose.

The number of screen touches should be minimized to make the user interface simpler as well as to minimize the amount of time it takes for patients to enter data. This means that one screen with more data is more desirable than many screens with lesser amounts of data per screen. This was a balance between readability and minimizing the number of screen touches. An example of a user selectable menu where a lot of information is fit on a single screen is shown in Appendix C, Screen 3.0.

The ability of the patient to quickly enter data was another criteria. As discussed, minimizing the number of screen touches can minimize the amount of data entry time. Other ways to shorten the amount of time for data entry were the use of incremental arrows for number entry, and VAS (scales from Mild to Severe) for easy graphical entry of intensity of symptom data. These tools are shown in Appendix C, Screen 3.1.

Another issue was deciding whether patients would be allowed to enter retrospective data. If patients were expected to enter data at the time of measurement, it would not be necessary to enter in the time of measurement or dose because the time could be obtained from the clock in the PDA. However, it was felt that if patients were only allowed to enter in the data at the time of the measurement or dose, there would be a significant decrease in the amount of data collected because patients could forget or
choose to leave their PDAs at home. In contrast, by introducing the ability to enter retrospective data, the quality of data could decrease because patients would need to enter the date and time of the event (i.e. date and time of blood sugar measurement or administration of insulin). If the incorrect date and time was entered, the patient data could be skewed. For example, a retrospectively entered breakfast blood sugar measurement taken at 9:00am but incorrectly entered as taken at 1:00pm, could show the breakfast measurement as taken after the lunch measurement. In contrast, if retrospective data entry was not allowed the data quality would be improved, but the quantity of patient data collected could decrease because patients could forget their PDAs at home, or might want to enter their data into the PDA at home. In an effort to balance the need for data quantity and data quality, the final decision was to allow retrospective data, but only for the same calendar date. This would allow some retrospective data while minimizing data errors to at least the same date.

5.2 Added Functionality

Through the process of designing the screens, the clinicians realized the ability of the PDA to collect information that they were currently unable to easily collect. There are two examples of this type of added functionality.

The first example involves the Symptoms, Causes, and Reaction screens (Appendix C, Screens 3.0 – 3.3 & Screens 3.5 – 3.8) which were created after it was discovered that this is the information that clinicians try to get from patients when they interview them after they have experienced symptoms. This is information that is currently not recorded in the paper diary and is something that could be of great assistance to the clinician in educating the patient. Those screens emulate the thought processes that the clinician is trying to teach the patient and it is hoped that the PDA can encourage the patient to think in that way. These screens were developed after many iterations with the clinicians at the Best Centre.

The second example is the Exercise screen (Appendix C, Screen 10.0) in which information that was not collected in great detail with paper records is easily collected with the PDA. Although information about the time of the exercise might be collected in the paper record, the intensity and duration of this exercise is not generally recorded.
5.3 Patient Training

It was anticipated that many of the users of the device would not have previous experience with the use of PDAs. For this reason, training sessions were planned and a training manual was developed to explain how to use the device. This training manual is shown in Appendix D.
6 Objective

The objective of this project is to design and evaluate the use of personal digital assistants in diabetes management. This project is the prototype stage in which preliminary data will be collected to serve as a foundation for future larger scale research studies. This project will involve a patient study of 10 patients, whereas future research will involve 100 patients or more.

The intent of this preliminary study is to collect data to suggest that utilizing Personal Digital Assistants with Web-based technology will:

1. Increase the amount of patient data accessible by the clinician;
2. Increase the number of clinical interventions; and
3. Decrease the amount of staff time spent collecting patient data.

Another objective of the project is to collect information through patient interviews to discover new and better ways to design the PDAs. Finally, problems with the way the study is conducted will be investigated in order to make recommendations for the design of future clinical trials of the technology.
7 Hypotheses

Hypothesis 1:

The use of PDAs with Web-based technology by the 10 study patients will increase the amount of patient data accessible by the clinician.

Hypothesis 2:

The use of PDAs with Web-based technology by the 10 study patients will increase the number of clinical interventions.

Hypothesis 3:

A time study will indicate that an inordinate amount of staff time is spent collecting patient data.
8 Study Design

In this study, three areas of improvement were measured and device usability was evaluated by obtaining patient feedback. First, the study attempted to show that through the use of the technology, the amount of patient data available to the clinician increased. Secondly, the increase in the number of clinical interventions made by clinicians to improve care was measured. Thirdly, a time study was performed to indicate the amount of staff time spent on tasks that could be potentially eliminated through the use of the technology. Finally, the patients were interviewed at the end of the study to obtain feedback on problems with the device and how to improve it.

8.1 Increased Data Capture

The hypothesis that the PDAWeb technology will increase the amount of information that is available to the clinician was tested by measuring the following indicators before and after implementation of the technology.

1. Number of days of data collected compared with:
   - the data available in patient charts at the Best Centre;
   - the paper diary.
2. Average number of blood sugar measurements taken per day.
3. Number of insulin doses collected per patient.
4. Number of exercise activities recorded.
5. Number of low or high blood sugar episodes collected per patient.

In order to take these measurements before implementation of the technology, patient charts and patient diaries of the same 10 patients in the preliminary trial were examined for a 50-day period before the start of the trial.

The measurement of the above indicators after the implementation of the technology were taken by examination of the electronic patient chart produced by the technology.
8.2 Increased Clinical Interventions

In diabetes care, clinicians intervene by advising and educating patients on how to adjust their insulin dose according to their blood sugar levels, diet, and exercise levels. In order to test the hypothesis that the technology will enable the clinician to make more clinical interventions, the number of insulin dose adjustments made during the course of care was measured before and after the implementation of technology.

The adjustments before implementation of the technology were measured through the examination of the patients' charts for the 50-day period immediately before implementation of the technology. These adjustments should be noted by the clinicians in the patient chart.

The adjustments made after implementation of the technology were measured through analysis of the electronic patient record.

8.3 Time Study

A time study was performed to attempt to show that an inordinate amount of staff time is spent collecting patient data. This part of the study involved a two-week time study that detailed the amount of staff time spent on various tasks. The list of tasks and the timesheet that each staff member completed was developed with the assistance of the Best Centre staff and is shown in Appendix E.

After completion of the time study, the time spent on each task was tabulated. From the reengineered system (Figure 6), the tasks that should be eliminated using the technology were identified. Totaling the amount of time for these identified tasks allowed an estimate of the amount of time saved by the staff.
Another important part of the study was to get feedback from the patients and their parents about the usability of the device. Patients and parents were asked to comment on data entry, data display, and display format. They were also asked about how often they carried the device with them, who entered the data and when, and how long it took to enter data. Patients and parents were also given the opportunity to report any specific problems with the functionality of the PDA. Finally, they were asked to compare the usability of the device as compared to a paper diary. The following are the list of questions that were asked.

1. Who enters the data?
2. Does the child carry the device everywhere with them?
3. How easily is it to enter information?
4. How easy is it to read the information displayed on the screen?
5. How do you like the format the blood sugar and insulin data is displayed in?
6. How satisfied are you with the amount of time it takes to enter data?
7. Does it take more time or less time than keeping a paper diary?
8. What do you like about the device?
9. What don't you like about the device
10. What would you like to see on the device?
11. Specific Problems
12. Is it better than paper?
9 Patient Selection

As shown in Table 3 of Section 4.2, patients at the Best Centre can be categorized into four types based on their data submission patterns. The 10 patient study should be a close representation of the population of patients at the Best Centre. Therefore, the number of patients by group that will be enrolled in the study should be as shown in Table 4.

Table 4 - Patient types required in Preliminary Trial

<table>
<thead>
<tr>
<th>Type of Patient</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does not submit data</td>
<td>2</td>
</tr>
<tr>
<td>Submit data at bi-monthly visits</td>
<td>2</td>
</tr>
<tr>
<td>Fax in their data</td>
<td>2</td>
</tr>
<tr>
<td>Call in their data</td>
<td>4</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>10</strong></td>
</tr>
</tbody>
</table>

After checking availability and willingness of potential patients, the following patients were chosen for the study (Table 5)

Table 5 - Participant Profiles

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>105</td>
<td>F</td>
<td>19</td>
<td>Does not submit data</td>
</tr>
<tr>
<td>106</td>
<td>F</td>
<td>10</td>
<td>Does not submit data</td>
</tr>
<tr>
<td>112</td>
<td>F</td>
<td>11</td>
<td>Does not submit data</td>
</tr>
<tr>
<td>101</td>
<td>M</td>
<td>10</td>
<td>Submit data at bi-monthly visit</td>
</tr>
<tr>
<td>104</td>
<td>F</td>
<td>16</td>
<td>Submit data at bi-monthly visit</td>
</tr>
<tr>
<td>107</td>
<td>M</td>
<td>10</td>
<td>Submit data at bi-monthly visit</td>
</tr>
<tr>
<td>109</td>
<td>F</td>
<td>33</td>
<td>Fax in data</td>
</tr>
<tr>
<td>110</td>
<td>M</td>
<td>5</td>
<td>Fax in data</td>
</tr>
<tr>
<td>103</td>
<td>F</td>
<td>10</td>
<td>Call in data</td>
</tr>
<tr>
<td>111</td>
<td>F</td>
<td>13</td>
<td>Call in data</td>
</tr>
</tbody>
</table>

These 10 patients signed a patient consent form (Appendix F), giving permission to study their past and present data for the purpose of the study.
10 Research Phases

In order to address the objectives, the project was separated into four phases.

Phase 1 – Collection of previous patient data (April 4, 1999 – June 30, 1999)

The first stage was to gather old patient data from the subjects and to analyze the amount of data the patients collected using traditional paper diaries.

<table>
<thead>
<tr>
<th></th>
<th>Start Date – Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Selection &amp; Patient Consent</td>
<td>April 4, 1999 – May 17, 1999</td>
</tr>
<tr>
<td>Gather old patient data</td>
<td>May 17, 1999 – May 23, 1999</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>May 24, 1999 – June 30, 1999</td>
</tr>
</tbody>
</table>

Phase 2 – Time study (April 4, 1999 – June 7, 1999)

This stage involved a reengineering assessment to determine which tasks would be removed by implementation of the technology. During this period, a list of tasks was also formulated. The next stage was the collection of task times of the staff at the center over a two-week period. Finally, data analysis was performed to estimate the amount of time that the technology could save.

<table>
<thead>
<tr>
<th></th>
<th>Start Date – Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reengineering assessment</td>
<td>April 4, 1999 – May 1, 1999</td>
</tr>
<tr>
<td>Formulation of Task lists</td>
<td>April 4, 1999 – May 1, 1999</td>
</tr>
<tr>
<td>Time Study</td>
<td>May 10, 1999 – May 23, 1999</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>May 24, 1999 – June 7, 1999</td>
</tr>
</tbody>
</table>
Stage 3 – PDA Trial (April 4, 1999 – August 6, 1999)

This stage involved the collection of patient data using PDAs and the analysis of whether the amount of data collected increased over traditional data collection methods.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Start Date – Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Selection &amp; Patient Consent</td>
<td>April 4, 1999 – May 17, 1999</td>
</tr>
<tr>
<td>Patient Training</td>
<td>June 7, 1999 – June 11, 1999</td>
</tr>
<tr>
<td>Preliminary trial</td>
<td>June 14, 1999 – August 14, 1999</td>
</tr>
<tr>
<td>Data Analysis</td>
<td>July 14, 1999 – August 21, 1999</td>
</tr>
</tbody>
</table>

Stage 4 – Patient Interviews (August 14, 1999)

Interviews were conducted with patients at the end of the trial. The purpose of the interviews was to identify what problems the patients had experienced with the PDA and whether there were any changes that needed to be made to the design of the PDA/Web system. The list of interview questions is shown in Section 8.4.
11 Implementation

After developing the specifications, the PDA software was designed by Personal Health Technologies, Inc. The patients were brought together on one evening to train them on the use of the PDA. For patient safety reasons, patients were instructed that this was a prototype system and they were to continue to maintain their paper diaries and treat the PDA as a duplicate entry.

Due to time constraints and deadlines, the PDAs were deployed before the Web interface was developed with the intention of making the data available to the clinician as soon as possible. There were problems with this Web development that caused the clinicians not to have access to the data until the last 7 days of the 50-day trial.

The trial period measured was the 50-day period from June 28th, 1999 to August 16th, 1999.
12 Results

12.1 Increased Data Capture

12.1.1 Number of days of data

Patient data was collected for a period of 50 days during the study (June 28th to August 16th). This portion of the study was to measure how many days of data were collected by each patient during this 50-day period.

Figure 7 - Number of Days of Data (PDA/Web)

![Bar chart showing number of patients categorized by number of days of data collected.]

Figure 7 above shows the number of participants categorized into groups depending on the number of days of data collected. The mean number of days of data collected for the ten patients was 31.3 with a standard deviation of 17.45. If the two patients who dropped out from the study are removed from the sample, the mean number of days of data collected for the eight patients was 39.1 with a standard deviation of 6.47.

During the first two weeks, two of the patients (Participants 103 and 106) dropped out of the study without transferring any information to the web server. Participant 103 (a 10-year old girl) did not enjoy using the technology and also was away from her mother one week into the study. Her mother had been the person doing most of the data entry. Participant 106 had other health issues and was removed from the study by family. They felt they should focus their time on attending other health issues first. If the technology were improved to make data entry easier and quicker, participants 103 and 106 might have chosen to continue using the PDA.
Four participants (101, 105, 110, 112) were in the range of 31 to 35 days of data collected. Participants 101 and 105 had many consecutive days logged into the system, but they had not transferred their data over the telephone lines in quite some time. If the patients uploaded their data daily, more data would have been available to the clinician because the data would be recorded centrally and not only on the patient's PDA.

Participant 110 had missing days due to the fact that data could not be entered retrospectively for the previous day. If retrospective data beyond one day were allowed, there would be fewer missing days of data (see Section 5.1 for explanation of the reasons for limiting retrospective data entry). Participant 112 had missing days throughout her data because there was a computer problem that required reinstalling the software onto the device thereby preventing 10 days of data entry. Assuming that this computer problem had not occurred, the number of days of data collected would have been much better.

There was only one participant (111) who fell into the range of 36 to 40 days of data collected (39 days). Participant 111 also had the computer problem as discussed above. Without the 10-day interruption of data collection due to the problem, this patient would have likely had close to all of the fifty days of data collected. There was one participant (107) who was in the range of 41 to 45 days of data collected. The few missing days were due to the inability to enter retrospective data past midnight.

Two participants (104, 109) had near perfect number of days of data collected with 48 days each. They were both missing a few days at the end of the study, indicating that they likely had not transferred data to the web server over the last few days. If they had uploaded the data daily, then all data could be expected to be available.

The above mentioned problems could be easily corrected to produce better results with more days of data. These changes are suggested in Section 13.1. Another potential reason for missing data could be because the patients were not receiving any feedback based on the data that they were transferring to the Best Centre. This lack of feedback was due to the fact that the clinicians did not have access to the data until the last seven days of the study. With no feedback, patients would not have seen the true benefits of the technology and might not have put the extra effort to duplicate the entry into the PDAs.
Figure 8 below shows a comparison between the number of days collected by the PDA/Web system with both the data historically available at the Best Centre and in the paper diaries. The Best Centre and paper diary data were measures of the data available for the 50-day period before implementation of the technology.

**Figure 8 - Comparison of Number of Days of Data**

As mentioned in the previous section, the mean number of days of data collected by the PDA/Web system for these eight patients was 39.1 with a standard deviation of 6.47. The mean number of days of data available at the Best Centre was 12.8 with a standard deviation of 17.85. The mean number of days of data in the paper diaries was 45.0 with a standard deviation of 14.14. Note that the standard deviation for the Best Centre is large due to the large variance in number of days of data available. In many cases, no days of data or very little data was available at the Best Centre (as shown in Figure 8 by Participants 104, 105, 107, and 112). The standard deviation for the paper diary was large due to Participant 110 who only had 10 days of data in his paper diary. This was because the patient had forgot his paper diary at the cottage. This type of situation is common and demonstrates the weakness of paper based documentation versus data stored electronically and made available on the WWW.
With the exception of participant 109, each participant case demonstrated that the PDA/Web solution provided more data to the clinician than what was available at the Best Centre. This result was completely due to the technology as there was no additional workload required by Best Centre staff. A comparison with the number of days of data available at the Best Centre shows a dramatic improvement through the use of the technology. Figure 9 below shows the number of participants categorized by the number of days difference between data collected by the PDA/Web solution and the number of days of data available at the Best Centre. The figure shows that six of the eight patients had 21 days or more data by using the PDA/Web technology than using the previous methods of data transfer to the Best Centre. The calculated mean difference between the PDA/Web solution and the methods currently used at the Best Centre was 26.4 days with a standard deviation of 16.72. This mean difference is statistically significant with 95% confidence (see calculations in Appendix H). This means that there is 95% confidence that there is a difference between the number of days of data collected using the PDA/Web solution and the number of days of data collected at the Best Centre through existing means.

Figure 9 - Difference in Days of Data (PDA/Web - Best Centre)

Figure 10 on the next page shows the number of participants categorized by the number of days difference between data collected by the PDA/Web solution and the number of days of data available in the paper diary. Although the paper diary still collects more information than the PDA/Web solution, it was less than 20 days difference in all cases.
The calculated mean difference between the PDA/Web and paper diary methods was 5.9 days (in favor of paper diary) with a standard deviation of 13.54. However, the difference is not statistically significant with a confidence level of 95% (see calculations in Appendix H). This means that there isn't 95% confidence that there is a difference between the number of days of data collected using the PDA/Web solution and the paper diary.

With the improvements suggested in Section 13.1, it is expected that the PDA will be able to collect much more data and compete very well with the paper diary for the number of days of data collected.

**Figure 10 - Difference in Number of Days (Paper Diary – PDA/Web)**

12.1.2 Average number of blood sugars collected per day

Figure 11 shown on the next page compares the average number of blood sugar measurements recorded per day in the PDA/Web solution, in the Best Centre records, and in the paper diary. This data was calculated by dividing the number of blood sugars recorded by the number of days of data collection. As shown in the figure, for each participant, the average number of blood sugars recorded per day is fairly constant across all three different forms of the data. In some cases (104,105,107,112), the Best Centre had no data resulting in a null value as shown in the figure. In three participants (109,110,111), the average number of blood sugar measurements is significantly lower than that in the paper diary, resulting from non-entry of blood sugar measurements into the PDA for reasons discussed in Section 12.1.1.
It is interesting to note that the PDA only increased the number of blood sugars taken by one patient (Participant 112). This was due to the fact that the patients in the study were already very good in terms of compliance to taking between four and six blood sugar measurements per day. The use of the technology could not improve the compliance for this set of patients. In order to show an improvement in compliance, a set of patients with poor compliance to four to six blood sugar measurements a day would have to be chosen. It is recommended that a study on a non-compliant set of patients not be done until the technology has been developed to a point where it is very easy to use and has few technical problems. Patients with low compliance generally do not spend much time on their diabetes management therefore problematic technology might easily discourage them from using it.
12.1.3 Other measures

In the study design, it was thought that analyzing recorded changes in the number of insulin doses might suggest some benefit of the technology. However, it was learned that insulin dose changes occur frequently and a comparison of the number of insulin doses administered might not be attributed to the influence of the technology.

The number of exercise activities as well as the number of low or high blood sugar episodes recorded was minimal. This could have been attributable to patients being unaccustomed to entering information in this fashion. For this reason, this portion of the analysis was removed from the thesis.

12.2 Increased Clinical Interventions

Although the data was correctly being transferred from the PDAs to the web server, problems with programming prevented the display of patient data to the clinicians at the Best Centre. The data was not displayed in a way that was familiar or useful to the clinician. Unfortunately, programming resources were unavailable at that time to make suggested changes, resulting in no clinical interventions being attributable to usage of the technology. The programming changes were finally made with only one week of the study for clinicians to utilize the technology.

There were also some difficulties in measuring the number of clinical interventions. The study was designed to count the number of clinical interventions noted in patient charts so that a comparison between the number of clinical interventions made before and after implementation of the technology could be made. However, from reviewing patients' old paper diaries, it was also found to be difficult to distinguish a clinical intervention from a patient controlled change in insulin dosing. In future studies, some attempt should be made to have a clearer understanding of how to measure changes in the number of clinical interventions due to the technology. One way to do this might be to choose a subset of the patients who are known not to make their own insulin dose adjustments. Therefore, every change in insulin dosing could be counted as a clinical intervention.
12.3 Time Study

This portion of the study was performed to create a better understanding of the time requirements for many of the tasks performed at the Best Centre. Of particular interest were those tasks that would be eliminated if PDA/Web technology was implemented for all patients. As described in section 8.3, each of the three staff members at the Best Centre were requested to fill in timesheets to document the activities performed and the time associated with each task. Staff member 1 is the Executive Director of the Best Centre and is the main Diabetic Nurse Educator. Staff member 2 is the Diabetic Nutritionist and staff member 3 is a part-time Diabetic Nurse Educator.

The Best Centre staff had difficulty in completing the timesheets due to the constant changing of tasks throughout the day. At times, staff multitasked numerous activities during a half-hour period. Documenting this number of activities proved to be too demanding for a two-week period, but the staff was able to record their activity over the course of approximately one week. Although not all tasks were collected, enough information was available to make some general approximations. An example of a data collection sheet is shown in Appendix E-3. Staff member 1, 2, and 3 recorded 8, 7, and 3 days of data respectively (see Appendix E-4, E-5, and E-6). A regular work week for staff members 1, 2, and 3 are 7, 5, and 2 days respectively.

On the summary sheets of the time data (Appendix E-7 and E-8), the tasks related to data collection and data formatting are highlighted. The time spent on these data collection tasks is totaled in the "Data collection" column to give an estimate of the amount of time that could be saved through use of the PDA/Web technology. These tasks include:

P1 – Consulting with patient on the phone;
I2 – Information Retrieval via fax;
I3 – Information Retrieval via phone dictation;
I4 – Information Retrieval via pager/phone dictation;
I5 – Information Retrieval via making copies of patient diary;
D1 – Copying information into another format.
Through discussions with the staff, a large percentage of time indicated as P1: "consulting with patient on the phone" was spent transcribing dictated blood sugar and insulin doses. It was estimated that roughly 90% of the time indicated as P1 for staff member 1 was data collection, 25% for staff member 2, and 50% for staff member 3. If patients' data were already available through PDAWeb technology, the time spent dictating and transcribing data over the phone would decrease dramatically.

Information retrieval through various means could be eliminated by use of PDAWeb technology. Information would no longer need to be received by fax and then put in the patient chart (Time code I2). The large amount of time spent transcribing data while listening to a patient or parent dictate them on the phone would be completely done away with (Time codes P1, and I3). Time code I4 was used to indicate calls to the pager that lead to calling the patient back, only to transcribe blood sugar and insulin doses over the telephone. Also, since data would already be available at the Best Centre via the WWW, clinicians would no longer need to make copies of patient diaries (Time code I5). Finally, patient data available through PDAWeb technology would be standardized in pre-designed format, eliminating the need to copy data into another format (Time code D1).

The time associated with the above tasks could be eliminated using the technology. Of all the data collected, the total time associated with these tasks was 1115 minutes out of a total of 7707 collected minutes for the three staff members (18.6 out of 118.0 hours). The time spent on these activities represented 15.8% of the total recorded time for the staff.

The number of days collected for each of the staff members was inconsistent, so the data was then adjusted to represent a normal work week based on the number of days that a staff member typically worked per week. This data showed similar results with these tasks representing 907.2 minutes out of a total of 5813 (15.1 out of 96.9 hours). This represents 16.7% of the estimated weekly activity of the Best Centre staff. For a staff of only 2 full time and one part time employee, the savings of 15.1 hours is significant, being almost half of a full time employee's time. This time could be dedicated to consulting with patients and performing other patient care activities.
12.4 Patient Feedback

The patient interviews were conducted after the patients had the opportunity to use the PDAs for a period of approximately one-month. These interviews were conducted over the telephone with the child, his/her parents, or both. Feedback from each of these interviews is in Appendix G. The main issues obtained from this feedback are summarized in Table 6 below. With this feedback tabulated, it made it easier to work with the PDA/Web programmers to suggest solutions and decide on which changes were most important. This is discussed in Section 13.1.

Table 6 - Patient Identified Problems

<table>
<thead>
<tr>
<th>Problem</th>
<th>Participant</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Takes a long time to enter time if data entry done retrospectively at the end of the day.</td>
<td>110, 109, 112</td>
</tr>
<tr>
<td>2. Late night measurements (11pm) cannot be entered the next morning. Also, overnight measurements (3am) must be associated with the same day (i.e. a day starts at breakfast and ends at the next day's breakfast)</td>
<td>110, 109</td>
</tr>
<tr>
<td>3. Reporting screens on PDA (&quot;Full report&quot;) is hard to understand</td>
<td>109, 111</td>
</tr>
<tr>
<td>4. Symptom severity: Lengths of time should go by 5's instead of 15</td>
<td>111</td>
</tr>
<tr>
<td>5. Simple Sugars need to go by 5's, instead of 10's</td>
<td>110, 111</td>
</tr>
<tr>
<td>6. Insulin and Blood sugar values take too long to enter (i.e. insulin level of 27)</td>
<td>112</td>
</tr>
<tr>
<td>7. In episodes, if &quot;No symptom&quot; is selected a severity is still required for &quot;Next&quot; to show up</td>
<td>110</td>
</tr>
<tr>
<td>8. High Blood Sugar: Actions - should allow for more than one action to be selected</td>
<td>109, 112</td>
</tr>
<tr>
<td>9. Causes: Should allow for more than one cause</td>
<td>Designer</td>
</tr>
<tr>
<td>10. Would like ability to write more notes</td>
<td>101, 111, 104</td>
</tr>
</tbody>
</table>
13 Discussion

13.1 Summary of Problems & Changes to specifications

13.1.1 Blood sugar and Insulin Input screens

Problems 1 and 2 from Table 6 are related to blood sugar and insulin input screens.

![Blood Sugar/Insulin Input Screen]

The first problem has to do with it taking a great deal of time for patients to enter data into the PDA if it is done retrospectively at the end of the day. Since the time on the “Set to match time of test and/or dose” field (as shown in Figure 12 above), defaults as the current time, if data for a whole day is entered all at once at 7:30pm, the user would have to hold down the backwards arrow for a long time before the time would get back to the morning data, for example to 7:00am. This long time period is sometimes compounded by the fact that there are sometimes two insulin doses taken in the morning. The reason for this problem was that the first specifications for the PDA were designed with the expectation that patients would most of the time enter the data into the PDA at the time of the blood sugar test or insulin dose. However, some patients and their families were very concerned about losing the PDA and always left it at home, entering all the day’s data in at once in the evening.

The second problem was that overnight measurements such as at 3am have in the past been reported with the previous calendar day. In diabetes management, a reporting day begins at breakfast and ends at the next day’s breakfast. Since the PDA was developed based on only allowing retrospective data entry for the current calendar day, overnight measurements past 12:00am could not be associated with the previous day’s data. A similar problem was that patients would only have one hour to enter data for a
measurement taken at 11pm. If a patient woke up in the middle of the night, they would generally take the blood sugar and not record the value until the morning as some of the glucometers have their own memory. This would not be allowed by the PDA because it would not allow data entry for the previous day.

The suggested solution for these two problems was to re-design the screen, taking off the entry of time of measurement or dose and allowing the patient to select the date to either the current day or the previous day. This is shown in Figure 13 below.

Although the time could be valuable information for analysis, the clinicians do not normally ask for the time of measurement or dose to be recorded. It was built into the original specifications because there are some patients who are on intensified programs where the time data is more important. However, this is a small percentage of patients and it was decided that the time data was causing patients to not enter data because it was taking too long. Without the time data, a before or after selection was also added to give patients opportunity to enter more data than the standard meal time and bedtime data generally taken before the meal. Patients would need to be trained to know that an extra measurement or dose between breakfast and lunch should be recorded as an "After Breakfast". Likewise, an extra measurement or dose between lunch and dinner should be recorded as an "After Lunch" and so on. This is the current practice for recording extra measurements and doses in paper diaries.

An overnight event was also added to allow patients to enter in late night measurements and/or doses. Since the time was taken off and retrospective data entry was allowed for
the previous day, overnight (3am) measurements could then be associated with the correct day.

13.1.2 PDA Reporting Capability

As mentioned in Section 5.1, screen size was a limiting factor in designing the reporting screens for the patients to view their own data. There was enough of a difference between the designed screens shown in Figure 14 below and the paper diaries (example in Appendix B-4) that patients rarely attempted to view the data on the screens and preferred reading it out of their paper diaries. If the paper diary is to be eliminated by this technology, the viewing capabilities of the PDA must be easily usable by the patient.

Feedback from the patients indicated that the Blood Sugars screen was useful but the Full Report screen was hard to understand and much different from the paper diary. This was due to the fact that patients were accustomed to viewing breakfast, lunch, and dinner in columns as opposed to rows. It was also indicated that the number of low and high blood sugar episodes was not used by the patient. This would free up some screen space for another viewing format. The following re-designed screens (Figure 15) show the suggested solution.

Figure 14 - PDA Reporting Screens

Feedback from the patients indicated that the Blood Sugars screen was useful but the Full Report screen was hard to understand and much different from the paper diary. This was due to the fact that patients were accustomed to viewing breakfast, lunch, and dinner in columns as opposed to rows. It was also indicated that the number of low and high blood sugar episodes was not used by the patient. This would free up some screen space for another viewing format. The following re-designed screens (Figure 15) show the suggested solution.
The reporting screens are comprised of three separate screens. The blood sugar screens are divided into two screens for before and after measurements. The insulin screen shows the insulin values by allowing the user to select a particular meal or event. This is required because there is not enough room to display all the insulin values on one screen. The toggle buttons on the bottom of the screen allow the user to toggle back and forth between screens. It is expected that this interface will provide the patient with "paper diary" like viewing of data.

13.1.3 Accuracy and speed of data entry

Problems 4 through 6 were all related to being able to enter data accurately and at the same time enter it quickly. For example, problem 6 indicated that insulin values required too much time to enter because using the arrows only increased or decreased the value by 0.5 units. With an upper limit of 70, it took a long time to reach high values. To balance the need to quickly enter data and the need to have finite enough divisions (ex. 0.5 units for insulin), the suggested solution was to design the PDA so that single touches to the arrows increased the values by a small increment, while holding down the arrow increased it by a greater value. For the insulin values, single touches would increase or decrease the values by 0.5 units, while holding down the arrows would increase the value by 2 units. Similar solutions were suggested for both problems 4 and 5.
13.1.4 Multiple selections of boxes

As discussed in Section 5.2, there are high blood sugar and low blood sugar episode screens that lead the patient through a series of questions that attempt to get some information about why the patient had a blood sugar value out of their normal range. Problems 7 through 9 identify suggested changes to these screens. The four diagrams shown below in Figure 16 are the screens associated with reporting a high blood sugar episode. There are four similar screens for a low blood sugar episode.

Figure 16 - High Blood Sugar Episode Screens

Problem 7 indicated that if “None” was selected on the first “Symptoms” screen, then the second screen should be skipped because there would be no severity or time period. However, the third and fourth screens should still be completed because of the high blood sugar measurement. Problem 8 indicated that on the “Actions” screen, more than one selection should be allowed, since more than one could be performed. The suggestion was to allow multiple selections (except for the “Did nothing” selection). Problem 9 was similar, suggesting to allow more than one selection for the “Causes” screen. These suggested changes apply to the low blood sugar episode screens as well.
13.1.5 Notes function

During patient interviews, many patients commented on the inability to write notes on the PDA. The intent of introducing the Low blood sugar episode, High blood sugar episode, and Activity screens were to allow patients to enter these notes by checking off boxes. However, patients felt that these screens were not sufficient to replace a notes function. As discussed, writing text into a PDA is not an easy task and should be avoided if possible. There was no suggested change to the specification, but future research should attempt to properly emulate the notes function on the PDA.

13.2 Other contributing factors

There are other factors unrelated to the technology that might have or may in the future cause the technology to have less than optimum benefit. If patients are unwilling to enter data into the PDA at the time of measurement, it will necessitate the continued need to maintain a paper diary. As shown by this study, with the paper diary continuing to be the primary data collection point, entry into the PDA might be of secondary priority resulting in potential missing data.

Another issue is that although data is transferred in the PDA/Web solution, clinicians have to view the data in order for it to be useful. One benefit that can be easily realized is that a clinician can access the patient data when a patient requests advice either during an appointment or emergency situation. However, another benefit could be that the clinician could review the data even before the patient requests advice, thus monitoring a patient’s condition or compliance to a treatment regimen. In this way, a clinician might be able to see an unhealthy pattern in the data that the patients themselves would not be able to deduce. However, this monitoring would place much more workload on the staff, as someone would need to be analyzing all incoming patient data. If patients were to assume that this type of monitoring was occurring, it would give them a false sense of security that a clinician is monitoring their health. A solution in the future could be to automate some of this monitoring by setting up alarm conditions to alert the clinician of any data that might be of concern. An example of an alarm condition might be to notify the clinician if a patient is out of their normal range of blood sugars more than ten times during a week.
Another problem with diabetes management is that some patients purposely do not want data to be transferred to a clinician. Reasons for this behavior might be that they are ashamed of their poor control of diabetes or do not want to hear from the clinician how they have to change their lifestyle to improve their diabetic control. In the past, this type of behavior has been demonstrated by patients “forgetting” or “losing” their paper diaries that they are supposed to bring to appointments with clinicians. This technology may have the ability to depersonalize the data transfer and provide the clinician more data to analyze. However, this behavior should be recognized as some patients might resist the technology for the above mentioned reasons.
14 Conclusions

This study has shown that PDA/Web technology is a tool that has the potential to assist clinicians to more efficiently provide intensive therapy for diabetic patients.

14.1 Hypothesis 1

The use of PDAs with Web-based technology by the 10 study patients will increase the amount of patient data accessible by the clinician.

Of the ten patients in the fifty-day study, two patients dropped out, four patients recorded 31 to 35 days of data, two patients recorded 36 to 45 days of data, and two patients collected 48 days of data. With the two patients who dropped out removed from the sample, the mean number of days of data collected was 39.1 with a standard deviation of 6.5.

There are many reasons for missing days of data. These included delayed downloading of data, inability to enter data retrospectively, not receiving feedback from clinicians, duplicated data entry, and various programming problems in the prototype.

The PDA/Web system produced fewer days of data than available in the paper diary. The difference was less than 20 days in all cases, with four of those below 10 days difference. The calculated mean difference was 5.9 days with a standard deviation of 13.54. The difference is not statistically significant with a confidence level of 95%.

The PDA/Web system produced more days of data for the clinician than what was in the patient's data at the Best Centre during the fifty days prior to the beginning of the study. Six of the eight patients who completed the study had greater than 21 days more through the PDA/Web system than what was available at the Best Centre. The calculated mean difference was 26.4 days with a standard deviation of 16.72. This mean difference is statistically significant with 95% confidence.

The PDA did not increase the number of blood sugars taken by any patient. This was due to the fact that the patients in the study were already very good in terms of compliance to taking between four and six blood sugar measurements per day.
14.2 Hypothesis 2

The use of PDAs with Web-based technology by the 10 study patients will increase the number of clinical interventions.

Problems with programming prevented the display of patient data to the clinicians at the Best Centre. Unfortunately, programming resources were unavailable at that time to make suggested changes, resulting in no clinical interventions being attributable to usage of the technology. The programming changes were finally made with only seven days the study for clinicians to utilize the technology.

There were also some difficulties in measuring the number of clinical interventions. The study was designed to count the number of clinical interventions noted in patient charts so that a comparison between the number of clinical interventions made before and after implementation of the technology could be made. However, from reviewing patients' old paper diaries, it was also found to be difficult to distinguish a clinical intervention from a patient controlled change in insulin dosing.

14.3 Hypothesis 3

A time study will indicate that an inordinate amount of staff time is spent collecting patient data.

Through the data collected in the time study, it was estimated that data collection tasks required 15.1 hours of staff time per week. These tasks could be eliminated if the PDA/Web technology was implemented for all patients at the Best Centre. This amount of time represents 16.7% of the estimated weekly activity of 96.9 work hours. At almost half of a full time employee's time, the time could be reallocated to consulting with patients and performing other patient care activities.
14.4 Important Patient Suggested Changes

Patient feedback indicated that the time of blood sugar measurement and insulin dose was too time consuming in the current setup. Clinicians did not feel that time data was valuable enough to sacrifice patient usability so it was suggested that the time request be taken off.

Patient feedback indicated that there was enough of a difference between the PDA reporting screens and the paper diaries that patients rarely attempted to view the data on the screens and preferred reading it out of their paper diaries. If the paper diary is to be eliminated by this technology, the viewing capabilities of the PDA must be easily usable by the patient. A few screen design changes were suggested.
15 Recommendations

15.1 Future PDA/Web Diabetes Clinical Trials

In subsequent studies, some attempt should be made to have a clearer understanding of how to measure the number of clinical interventions before and after implementation of the technology. One way to do this might be to choose a subset of the patients who are known not to make their own insulin dose adjustments. Therefore, every change in insulin dosing could be counted as a clinical intervention.

As mentioned in this study, the set of patients chosen was an exceptional group whose compliance was between four and six blood sugar measurements a day. This prevented any measurement of whether the PDA/Web system might have an effect on a patient increasing the number of blood sugar measurements taken per day. However, this was a good set of patients for this prototype stage because patients who are less compliant to between four and six blood sugar measurements per day tend to spend less time on their diabetes management and might have easily given up on problematic technology during this stage. Once the technology is stabilized, it is recommended that a set of non-compliant patients (do not take enough blood sugar measurements) is chosen to measure whether the technology can increase a patient’s compliance to the DCCT recommended four to six blood sugar measurements per day.

It is recommended that some more research be conducted into how to fully emulate the writing of notes on a PDA. This is a necessary function in order for patients to entirely discontinue use of paper diaries and use the PDA/Web system for their diabetes documentation.

Once the technology is error free, fully functional, and reliable, the study should be conducted without the backup use of paper diaries. This is necessary to accurate test whether patients can use the PDAs and will uncover any other functionality that is necessary for diabetes documentation. It is also necessary to measure the full benefits of the technology both in increased data capture and in patient satisfaction.
When a larger patient study is possible, it is recommended that the study be longer in time period so that an attempt can be made to measure the technology's impact on improved patient outcomes. A good indicator for better patient outcomes in diabetes care is the HbA₁c measurement that is taken at the Best Centre every three months. This HbA₁c value indicates how in control a patient's blood sugar levels have been in the preceding months.

### 15.2 Other research

In this study, it was indicated that if the PDAWeb system was implemented for a large patient population, there would be an enormous amount of data that would need to be analyzed. The benefit of being able to monitor this data would improve the care of patients by being able to alert them of unhealthy patterns in their blood sugar levels. However, it would be extremely time consuming to manually monitor this data. It is recommended that some research be conducted into creating some logic for automation of this monitoring function. An example could be automating the process to notify the clinician if a patient is out of their normal range of blood sugars more than ten times during a week.

Through this study, it was also found that some patients purposely do not want their data to be transferred to a clinician. Reasons for this behavior might be that they are ashamed of their poor control of diabetes or do not want to hear from the clinician how they have to change their lifestyle to improve their diabetic control. It is recommended that some behavioral research studies be conducted to analyze the ability of the technology to depersonalize the data transfer. Another interesting behavioral study would be to analyze the ability of technology to induce interest in better diabetes control.

Although the technology is available and beneficial for the health of diabetic Canadians, it is still unknown as to who would fund this technology in Canada. It is recommended that all the business scenarios be investigated and studied to see how such a technology could be implemented in Canada's health care system.
Diabetes is only one data intensive disease where PDA/Web technology can be applied. Any disease that requires data transfer from patients to clinicians can utilize this technology. It is recommended that some research be conducted into the application of PDA/Web technology in other disease management models.
16 Resources


Joslin Diabetes Center (1999) Research Update Pamphlet


http://www.who.int/ncd/dia/dia_est.htm
# Diabetes Estimates 1995-2025

**Diabetes mellitus number of cases**  
(in thousands)  
1995 | 1997 | 2000 | 2025
---|---|---|---

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Benin | 26 | 28 | 31 | 75  
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Burkina Faso | 50 | 52 | 57 | 126  
Burundi | 27 | 28 | 31 | 75  
Cameroon | 72 | 77 | 85 | 210  
Cape Verde | 1.9 | 2.2 | 2.5 | 6.8  
Central African Republic | 19 | 21 | 22 | 47  
Chad | 36 | 38 | 42 | 92  
Comoros | 2.9 | 3.1 | 3.4 | 9.8  
Congo | 13 | 14 | 15 | 35  
Côte d'Ivoire | 67 | 71 | 77 | 195  
Equatorial Guinea | 2.2 | 2.3 | 2.4 | 5.2  
Eritrea | 16 | 17 | 19 | 45  
Ethiopia | 244 | 260 | 283 | 685  
Gabon | 9.6 | 10 | 11 | 19  
Gambia | 6.1 | 6.5 | 7.2 | 16  
Ghana | 89 | 96 | 106 | 269  
Guinea | 31 | 33 | 36 | 89  
Guinea-Bissau | 6.1 | 6.5 | 6.9 | 14  
Kenya | 123 | 132 | 146 | 442  
Lesotho | 11 | 12 | 13 | 31  
Liberia | 17 | 18 | 19 | 48  
Madagascar | 69 | 74 | 83 | 221  
Malawi | 48 | 50 | 53 | 114  
Mali | 48 | 51 | 56 | 144  
Mauritania | 13 | 14 | 16 | 35  
Mauritius | 9.3 | 9.8 | 11 | 19  
Mozambique | 79 | 87 | 99 | 228  
Namibia | 8.7 | 9.3 | 10 | 24  
Niger | 37 | 40 | 44 | 112  
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http://www.who.int/ncd/dia/dia_est.htm  
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http://www.who.int/ncd/dia/dia_est.htm 30/08/99
Appendix B- Best Centre Forms

1. Physician Referral Form __________ 74
2. Initial Assessment Form __________ 75
3. Diet History/Dietitian Worksheet Form ______ 76
4. Example of a paper diary ______________ 78
5. Appointment Record Form __________ 79
| **Patient Name:** |  |
| **Address:** |  |
| **Mother:** | **Father:** |  |
| **Telephone Numbers:** | (complete only sections which apply) |  |
| **Mother Residence:** | **Father Residence:** |  |
| **Mother Business:** | **Father Business:** |  |
| **Patient's Age:** | **Date of Birth:** | **Age at onset of Diabetes:** |  |
| **Diabetes Medication:** |  |
| a.m. | Noon | p.m. | HS |  |
| N | N | N | N |  |
| R | R | R | R |  |
| H | H | H | H |  |
| **Previous Diabetes Date:** | **Location:** |  |
| **Education:** |  |
| **History of Hospital Re-admission:** | **DKA Date:** |  |
| **Severe hypo:** | **Date:** |  |
| **Ophthalmologist:** | **Date of Previous Appointment:** |  |
| **Prescribed Diet:** | **OR According to Dietitian:** |  |
| **Recent Laboratory Results:** | **Date:** | **Blood:** |  |
| **FBS:** | **2 HRPC:** | **RBS:** | **HgbA1c:** | **Normal Range:** |  |
| **Chol:** | **Tng:** | **HDL:** | **LDL:** | **TSH:** |  |
| **Urea:** | **Creatinine:** | **OTHER:** |  |
| **Urine G:** | **K:** | **Microalbuminuria:** | **Protein:** |  |
| **Specific Comments or Instructions:** |  |
| **Date of Referral:** | **Signature of Referring Physician:** |  |

Authorization given for insulin/diet adjustments to be made by qualified staff at the Charles H. Best Diabetes Centre for Children and Youth.  

Signature of Physician
<table>
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<tr>
<th>Name:</th>
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<td>P.H.N.</td>
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**Lab work done**
- CHOL
- TRIG
- HDL
- LDL
- HgAlc
- UREA
- CREATININE

**Previous Diabetes Education**
- Year:  
- Place:  

**Family History Of Diabetes**

**Patient Reaction To Diagnosis**

**Presenting Symptoms**
- Polydipsia
- Polyuria
- Polyphagia
- Fatigue
- Weakness
- Wt. Gain
- Wt. Loss
- Vision Change
- Other

**Diabetes Medication**
- Insulin
  - Name:  
  - Dosage:  
- Name:  
  - Dosage:  

**Date Started**

**Injection Site Rotation**
- Sites Used: Abd.  
- Legs  
- Arms  
- Hips  

**Site Problems**

**Other Health Problems**

**Other Medication**

**Medic Alert Identification**
- Necklet  
- Bracelet  
- Wallet

**Exercise**
- Type & Amount

**Urine Test**
- Method
- Test times

**Blood Test**
- Method
- Test Times
- Meter Certification Date

**Signed**
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**EXERCISE:**

**PATIENT INSTRUCTED ON:**

- **EXERCISE**
- **READING FOOD LABELS**
- **LOW FAT EATING**
- **INTENSIFIED MANAGEMENT**
- **LOW PROTEIN DIET**
- **MEAL PLAN ALTERATIONS**
- **SICK DAYS**
- **ALCOHOL**

**COMMENTS:**

---
**DIETITIAN'S WORKSHEET AND ASSESSMENT FORM**

**DATE**

**CALORIE LEVEL**

**NUTRITIONAL ASSESSMENT**
- **AGE**
- **Grade**
- **HEIGHT**
  - % ile
- **WEIGHT**
  - % ile
- **IBW**
  - % IBW
- **BMI**

**RECENT WEIGHT CHANGE**

**RECOMMENDED NUTRIENT INTAKE**
- **Energy**
- **Protein**

**CURRENT INSULIN DOSE**

**HgBAIC**

**Other lab values**

**MEAL PATTERN**

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**KCAL.**

**KJ.**

**PRO**

**%**

**CHO**

**%**

**FAT**

**%**

**Carbohydrate Distribution**
- **AM**
- **PM**
- **HS**
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**AVERAGE**

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Summary:

Every 3 months

Charles H. Best Diabetes Centre

Contact (Face to Face)

Appointment Record
Appendix C – Functional Specifications

1. Original Functional Specifications 81
2. Changes to Functional Specifications 100
LogPad Screen Content & Operation
Control Screen for Patient Use

Screen 1.0 Patient Gateway
Purpose: Acts as gateway to other screens, orientation to tasks. Appears when LogPad is switched ON, and is used by patient to enter data each day, to adjust for travel to different time zone. All native PalmPilot applications and all panel buttons are inoperative except for the ON/OFF switch. LogPad switches OFF automatically 1 minute after last touch.

Detailed Functionality and Tests
1. LogPad version number for this project matches build number.
2. Patient name appears as entered via Screen 9.1 during assignment.
3. Date: is bold, synchronized to server UMT at each upload.
4. Time: time displayed is server UMT plus offset to match local time. It is corrected if necessary at each upload. Touching on the time field pops up Screen 1.0PU for adjustment of the offset (hour) to local time in case the patient travels across time zones or a daylight/standard time transition occurs.
5. "Blood Sugar/Insulin" brings up Screen 2.0 for entry of blood sugar measurements and insulin administration.
6. "Low Blood Sugar Episode" brings up Screen 3.0 for reporting an episode after it has occurred. In later versions Screen 3.0 may also be activated automatically when the patient enters a value that is below a "targeted blood sugar range" unique to each patient.
7. "High Blood Sugar Episode" brings up Screen 3.3 for report of an episode after it has occurred. In later versions Screen 3.3 may also activated automatically when the patient enters a value that is above the targeted blood sugar range.
8. "Exercise Period" brings up Screen 10.0.
9. "Message to Best Center" brings up Screen 5.0 allowing the user to pose non-emergency questions which can be viewed by Best Center staff.

LogPad screen matches above diagram

Diabetes Project
LogPad Screen Content & Operation  Diabetes Project
Control Screen for Patient Use (Continued)

Screen 1.0 Patient Gateway

(Screen Diagram Repeated)

Detailed Functionality and Tests

10. "View Data" brings up Screen 11.0.

11. "Send Stored Reports" shows the number, n, of stored reports (n). Touching
button brings up Screen 6.0: Send Information. If no reports are stored for later
sending, the action button does not appear and the statement “Last report sent
DateTime” appears instead. DateTime displays the date and time last report was sent.

12. “Centre Use” brings up Screen 8.0.

13. LogPad turns OFF automatically 1 minute after last touch.

30/08/99

Verified against implementation by __________ Date _____
LogPad Screen Content & Operation
Popup Screen from Patient Gateway

Screen 1.0PU  Time Adjust
Purpose: Adjust hour to match local time so that all patient data is timestamped for the patient’s local time.

Detailed Functionality and Tests
1. Up arrow sets the hour ahead each time it is touched. Down arrow sets the hour back. Minutes cannot be changed. Am and pm change appropriately as the hour is adjusted.
2. “Cancel” returns to Screen 1.0 without change to set time.
3. “OK” sets the adjusted time to be the LogPad current time and returns to Screen 1.0.

Verified against implementation by ___________ Date ____
30/08/99 

Version 1.8 
Page 4
Diabetes Project

LogPad Screen Content & Operation

Diary Questions

Screen 2.0 Current Blood Sugar/Insulin

Purpose: This is the primary data capture screen for tracking blood sugar levels and insulin administration. This screen is an example of a diary where current measures are recorded.

Detailed Functionality and Tests

1. Patients select time category related to current measurement or insulin dose by touching proper word. The selection highlights on touching. Highlighting remains until report is filed.

2. When selection is chosen, “Set time of measurement/dose” appears allowing the patient to indicate when the blood sugar was taken. The default time is the current time.


4. “Insulin” has a box around it. When touched, a screen pops up for the patient to select among types of insulin (R, N, H). The Insulin spinner increments by steps of 0.5 with a hard range of 0-70.

5. “Back” returns to prior screen (1.0) without storing any data entered.

6. “Next” appears after the Blood sugar spinner, Measurement category, and Time of measurement fields are touched OR after the Insulin Dose field is touched.

7. “Next” goes to Screen 3.0.
LogPad Screen Content & Operation

Diabetes Project

Diary Questions: Low Blood Sugar: Symptoms Report

Screen 3.0 Low Blood Sugar Episode: Symptoms Report

Purpose: Data capture screen for reporting presence and severity of a collection of symptoms associated with an episode of low blood sugar.

Set time symptoms ended:

< 04:32 pm >

Check symptoms you experienced:

☐ None
☐ Trembly
☐ Sweaty
☐ Dizzy
☐ Pale
☐ Blurry vision
☐ Headache
☐ Hungry
☐ Tired
☐ Moody
☐ Other

Back Next

LogPad screen matches above diagram

Detailed Functionality and Tests

1. Patient indicates the time that the symptom(s) ended. Touching on the left arrow retards the time setting by 5 min increments from the present time, which appears by default in the box. Touching right arrow advances time. Time cannot be advanced beyond the present.

2. Patient touches checkboxes for any symptom that was experienced in the episode.

3. “Back” returns to prior screen (1.0)

4. “Next” appears after the end time has been set and at least one symptom has been checked; goes to Screen 3.1.

Verified against implementation by _____________ Date____

30/08/99 Version 1.8 Page 6
Diabetes Project
Diary Questions: Low Blood Sugar: Severity Report

Screen 3.1 Low Blood Sugar Episode: Severity Report
Purpose: Data capture screen to get severity and duration for the symptoms experienced in this episode of low blood sugar.

LogPad screen matches above diagram

Detailed Functionality and Tests
1. Patient touches VAS to set marker proportionately between almost unnoticeably mild (Mild) and as severe as they can imagine (Severe). The number will be reported as a single integer between 0 and 100. 20 is mild, 40-60 is moderate.
2. The duration is set by adjusting the duration spinner, which is initially blank. Touching the up arrow increments the spinner by 15 min increments (4 to the whole hour). Touching the down arrow produces similar decrements.
3. “Back” returns to prior Screen 3.0
4. “Next” goes to Screen 3.2.

Verified against implementation by ______________ Date____
30/08/99 Version 1.8 Page 7
Screen 3.2 Low Blood Sugar Episode: Causes Report

Purpose: Data capture screen for reporting the user's perception of the cause of the episode.

What was the main cause of the low blood sugar (check one below)?

- [ ] Too much insulin
- [ ] Too little food
- [ ] Extra exercise
- [ ] Delayed meal times
- [ ] Stress/Excitement
- [ ] Illness
- [ ] Don't know

LogPad screen matches above diagram

Detailed Functionality and Tests

1. Patient touches the check box corresponding to the main cause for the low blood sugar level. Checking another box deletes the mark from the first and places it in the second box such that only one box can be checked at a time.

2. "Back" returns to Screen 3.2

3. "Next" appears after the single cause is selected; goes to Screen 3.3
LogPad Screen Content & Operation  Diabetes Project
Diary Questions: Low Blood Sugar: Actions Report

Screen 3.3  Low Blood Sugar Episode:
Actions Taken Report
Purpose: Data capture screen for reporting the actions taken by the user in reaction to the episode of low blood sugar.

How did you respond to the low blood sugar level?

☐ Took simple sugars:
   40 grams

☐ Did nothing
Did you have a follow up snack or meal?
   Yes  No

Back  Next

LogPad screen matches above diagram ☐

Detailed Functionality and Tests
1. Patient can check either or both boxes. If "Took simple sugars" is checked, the spinner is enabled so the patient can enter the number of 10 gram units taken. The Spinner increments by steps of 10 with a range of 10-50.
2. Patient must answer Yes or No to the snack/meal question. Touching highlights the selection, which remains highlighted until the report is sent.
3. "Back" returns to prior Screen 3.2
4. "Next" appears after both questions are answered; goes to Screen 5.0

Verified against implementation by _____________  Date____
30/08/99  Version 1.8  Page 9
LogPad Screen Content & Operation  Diabetes Project
Diary Questions: High Blood Sugar: Symptoms Report

Screen 3.5  High Blood Sugar Episode - Symptoms Report

Purpose: Data capture screen for reporting presence and severity of a collection of symptoms associated with an episode of high blood sugar.

<table>
<thead>
<tr>
<th>Set time symptoms ended:</th>
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<tbody>
<tr>
<td>04:32 pm</td>
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</tbody>
</table>

Check symptoms you experienced:
- Thirsty
- Dry mouth
- Drowsy
- Frequent urination
- Bedwetting
- Stomach pain
- Other

LogPad screen matches above diagram

Detailed Functionality and Tests

1. Patient indicates the time that the symptom(s) ended. Touching on the left arrow retards the time setting by 5 min increments from the present time, which appears by default in the box. Touching right arrow advances time. Time cannot be advanced beyond the present.

2. Patient touches checkboxes for any symptom that was experienced in the episode.

3. “Back” returns to prior screen (1.0)

4. “Next” appears after the end time has been set and at least one symptom has been checked; goes to Screen 3.6.

5. “Back” returns to prior Screen 1.0

Verified against implementation by _______________ Date____

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LogPad Screen Content & Operation  Diabetes Project
Diary Questions: High Blood Sugar: Severity Report

Screen 3.6  High Blood Sugar Episode: Severity Report
Purpose: Data capture screen to get severity and duration for the symptoms experienced in this episode of low blood sugar.

Rate the severity of the symptoms in this episode

Mild    Severe

How long did the symptom(s) last?

5:15     Hours:Min

LogPad screen matches above diagram

Detailed Functionality and Tests
1. Patient touches VAS to set marker proportionately between almost unnoticeably mild (Mild) and as severe as they can imagine (Severe). The number will be reported as a single integer between 0 and 100. 20 is mild, 40-60 is moderate.

2. The duration is set by adjusting the duration spinner, which is initially blank. Touching the up arrow increments the spinner by 15 min increments (4 to the whole hour). Touching the down arrow produces similar decrements.

3. “Back” returns to prior Screen 3.5

7. “Next” appears after the Symptom Severity, and Duration fields are touched

8. “Next” goes to Screen 3.2.

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LogPad Screen Content & Operation Diabetes Project
Diary Questions: High Blood Sugar: Causes Report

Screen 3.7 High Blood Sugar Episode -
Causes Report
Purpose: Data capture screen for
reporting the user's perception of the
cause of the episode.

Detailed Functionality and Tests
1. Patient touches the check box corresponding to the main cause for the high blood
sugar level. Checking another box deletes the mark from the first and places it in the
second box such that only one box can be checked at a time.

2. “Back” returns to Screen 3.6

3. “Next” appears after the single cause is selected; goes to Screen 3.8

LogPad screen matches above diagram □
LogPad Screen Content & Operation  
Diabetes Project 
Diary Questions: High Blood Sugar: Actions Report

Screen 3.8  High Blood Sugar Episode: Actions Taken Report
Purpose: Data capture screen for reporting the actions taken by the user in reaction to the episode of low blood sugar.

Detailed Functionality and Tests
1. Patient indicates each action taken in response to the high blood sugar level and/or episode. If “Extra dose of insulin” is selected, the spinner is enabled to allow the patient to enter the number of units taken. The Spinner increments by 0.5 steps from 0 to 70.
2. If “Measured ketones” is selected then the patient must select one among the alternatives for the values of the Ketone test. The selection will be highlighted and remain highlighted until the report is stored or sent.
3. “Back” returns to prior Screen 3.7
4. “Next” appears after any one of the check boxes is checked. “Next” goes to Screen 5.0

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Version 1.8  Page 13
LogPad Screen Content & Operation
Diabetes Project

Diary Questions: Exercise Information

**Screen 10 Exercise Period**

Purpose: Data capture screen for reporting time, intensity, and duration of a period of greater than usual physical activity as in an exercise period.

- LogPad screen matches above diagram

**Detailed Functionality and Tests**

1. Patient indicates the time that the period of exercise ended. Touching on the left arrow retards the time setting by 5 min increments from the present time, which appears by default in the box. Touching right arrow advances time. Time cannot be advanced beyond the present.

2. Patient indicates intensity of activity as either light, moderate, or vigorous by touching on the VAS Scale. Touching moves the marker to the point touched.

3. The duration of the exercise period is set in the duration spinner, which is initially blank. Touching the up arrow increments the spinner by 15 min increments (4 to the whole hour). Touching the down arrow produces similar decrements.

4. “Done” appears after an entry has been made for each section of the page. “Done” goes to **Screen 5.0 Message From Patient**

5. “Back” goes to prior screen (1.0)

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LogPad Patient Use Screens

Data Review for Self-Management

Screen 11.0 Data review: Blood sugar results & Symptoms
This screen shows blood sugar measurements and number of Hi and Lo blood sugar levels (out of range) per day. (These are triggered by number of episodes recorded)

Rows appear by descending date (newest data on top).
Scrolling (by use of scroll buttons) shows all collected data (up to 4 weeks).

"Full Report" toggles to Screen 11.1
"Done" returns to Screen 1.0

Screen 11.1 Data review: Full Report
This screen shows Glucose measurements, Insulin doses, and number of Hi and Lo blood sugar levels per day. (These are triggered by number of episodes recorded)

* Ideally, the actual time values of "Other" data entry points will be shown, but the word "Other" will suffice if sorted in the correct order.

Rows appear by descending date and time (newest data on top).
Scrolling shows all collected data (up to 4 weeks).

"Blood Sugar" toggles to Screen 11.0
"Done" returns to Screen 1.0
Screen 5.0 Message from Patient

Purpose: To allow patients to communicate regularly with caregivers at the center. Screen includes both structured and free text.

Detailed Functionality and Tests

1. Patient uses stylus to write onto the screen area designated by the box. Writing outside the box will not show onscreen nor will it be transferred to the database.

2. The Checkbox triggers a request to the patient's primary caregiver at the Centre to return a telephone call.

3. "Clear Message" deletes all marks from the message box and allows new marks to be made.

4. "Back" returns to prior screen (1.0, 3.3, 3.7). Any marks made in the box remain until either "Clear Message" or "Done" is touched.

4. "Done" is always available since sending a message is optional. "Done" goes to Screen 1.0, and stores all data in the report. The number of stored reports is incremented by 1.
LogPad Screen Content & Operation
Data Transmission Screens

Screen 6.0 Send Information
Purpose: All patient transmissions begin with this screen. Patients are encouraged to send reports regularly (once a day) at a preferred time.

Phone# 1 877 657 1747

Please make sure the LogPad is connected to the phone; then touch Send NOW.

Send later Send NOW

LogPad screen matches above diagram

Detailed Functionality and Tests
1. "Phone #" is the toll-free number that the LogPad will dial automatically.
2. "Send later" returns to Screen 1.0, with the number of stored reports unchanged.
3. "Send NOW" is emphasized, and goes to Screen 6.1.
4. There is no "Back" button. The report is final and cannot be edited or reviewed after the patient touches "Done".

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30/08/99 Version 1.8
LogPad Screen Content & Operation
Diabetes Project
Transmission Status Screens

Screens 6.1 - 6.6 Transmission Status
Purpose: These screens proceed automatically and are useful for the patient if they are interested in confirming that the transmission is successful. Once data is uploaded from the LogPad it is deleted. This deletion is not done until the LogPad confirms that an archival back-up of the server database has been completed after a successful transmission.

LogPad screen matches above diagram

Detailed Functionality and Tests
1. Screen 6.1: Once a LogPad connects to the server we display “BEGINNING SESSION”.
2. Screen 6.2: When we send the Signon/RegSignon, we display “AUTHENTICATING”.
3. Screen 6.3: When beginning to send the Nth block (report or action), we display “SENDING REPORT [N]”.
4. Screen 6.4: When we get the MarkBlockSent command, we display “SIGNING REPORT [N]”, decrement N and return to Screen 5.3 until all blocks are sent.
5. Screen 6.5: When we get the ReceiveUpdate command, we display “RECEIVING UPDATE”.
6. Screen 6.6: If the connection breaks or server is down, we display “Not able to read from PHT server” and exit the transmission session (and return so the main screen, 1.0)
7. Successful transmission leads to an automatically generated message via the PHT messaging utility as shown on Screen 7.0.

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LogPad Screen Content & Operation

Diabetes Project

Successful Transmission Message

Screen 7.0  Successful Transmission
Purpose: This screen appears at the end of each successful transmission to assure the patient that everything is OK.

Your report was transmitted and received successfully.

Thank you!

LogPad screen matches above diagram

Detailed Functionality and Tests

1. The message appears at the end of a transmission and remains until the LogPad is turned off, either actively or automatically, or until the “OK” action button is touched. It continues to appear when the unit is again switched ON until the “OK” button is touched.

2. The message is authored via the CRMS application using LinkManager and is to be generated automatically for each transmission.

3. “OK” brings up the next message, if any, or goes to Screen 1.0.

Verified against implementation by ________________ Date____

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Message to Patient

Purpose: Messages are authored by Centre personnel using the web CRMS application. They appear at the end of the first transmission session that occurs after they are posted.

Hi, Kris
Your next appointment at the Centre is at 2 pm next Wednesday. Can you make it? Bring your LogPad with you, please.
--Cindy

LogPad screen matches above diagram □

Detailed Functionality and Tests

1. The message appears after the automated message on Screen 7.0 and remains until the LogPad is turned off, either actively or automatically, or until the "OK" action button is touched. It continues to appear when the unit is again switched ON until the "OK" button is touched. □

2. The message is authored via the CRMS application using LinkManager, which allows separate messages to be sent to each patient or a single message to be sent to all patients. Author name appears automatically on the message to patient screen. □

3. "OK" brings up next message, if any. After last message "OK" returns to Screen 1.0. □
### Patient Suggested Changes to LogPad Design

<table>
<thead>
<tr>
<th>Problem</th>
<th>Participant</th>
<th>Suggested Solution</th>
<th>Implication</th>
</tr>
</thead>
</table>
| 1. Takes a long time to enter time if data entry done at the end of the day. | 110, 109, 112 | Take time off of blood sugar and insulin data entry screen. Each record will be associated with a specific meal/event and also either be before or after that event. (see Figure 1 below) | • How will "Other" times be handled  
• Mariene will ask patients to enter between meal data as "After" the last meal. |
<p>| 2. Late night measurements (11pm) cannot be entered the next morning. Also, Overnight measurements (3am) must be associated with the same day (i.e. a day starts at breakfast and ends at the next day's breakfast) | 110, 109    | Allow retrospective data entry for present and previous day. i.e. date defaults at present day and allows a decrement of one day only. (see Figure 1 below) | Must select the correct date. |
| 3. Full report hard to figure out                                       | 109, 111    | Change report screens to Figure 2, 3, &amp; 4.                                          | Hard to design?                                                                                      |
| 4. Severity: Lengths of time should go by 5's                          | 111         | Change to                                                                            |                                                                                                       |
| - Single touch: increment by 5                                          |             |                                                                                                                                                   |
| - Hold down: increment by 10                                            |             |                                                                                                                                                   |
| 5. Simple Sugars need to go by 5's                                      | 110, 111    | Change to                                                                            |                                                                                                       |
| - Single touch: increment by 5                                          |             |                                                                                                                                                   |
| 6. Insulin and Blood Sugar values take too long to enter (i.e. insulin level of 27) | 112         | Blood Sugar                                                                          |                                                                                                       |
| - Single touch: increment by 0.1                                       |             |                                                                                                                                                   |
| - Hold down: increment by 1                                             |             |                                                                                                                                                   |
| Insulin                                                                |             |                                                                                                                                                   |
| - Single touch: increment by 0.5                                        |             |                                                                                                                                                   |
| - Hold down: increment by 2                                              |             |                                                                                                                                                   |
| 7. In episodes, if &quot;No symptom&quot; is selected a severity is still required for &quot;Next&quot; to show up | 110         | &quot;No symptom&quot; should skip severity and time screen                                      |                                                                                                       |</p>
<table>
<thead>
<tr>
<th>8. High Blood Sugar: Actions - should allow for more than one action to be selected</th>
<th>109, 112</th>
<th>Allow either selection of &quot;Did Nothing&quot; box or multiple selections of other boxes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Causes: Should allow for more than one cause</td>
<td>Albert</td>
<td>Allow multiple boxes to be checked</td>
</tr>
</tbody>
</table>

---

Blood Sugar/Insulin Screen
Figure 1

**Blood Sugar/Insulin**

<table>
<thead>
<tr>
<th>Date of test or dose</th>
<th>Breakfast</th>
<th>Dinner</th>
<th>Bedtime</th>
<th>Overnight</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/22</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test or dose was:**

<table>
<thead>
<tr>
<th>before</th>
<th>after</th>
</tr>
</thead>
</table>

**Set to match blood sugar value**

| 17 | | |

**Select TYPE of Insulin Dose**

<table>
<thead>
<tr>
<th>N</th>
<th>H</th>
<th>R</th>
</tr>
</thead>
</table>

| Back | Done |

---

Insulin Report (to replace Full Report)
Figure 2

**Data: Blood Sugar (Before)**

<table>
<thead>
<tr>
<th>Date</th>
<th>B</th>
<th>L</th>
<th>D</th>
<th>E</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/22</td>
<td>13</td>
<td>17</td>
<td>12</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>09/21</td>
<td>11</td>
<td>20</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>09/20</td>
<td>6</td>
<td>15</td>
<td>1</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>09/19</td>
<td>11</td>
<td>19</td>
<td>14</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>09/18</td>
<td>9</td>
<td>17</td>
<td>12</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>09/17</td>
<td>4</td>
<td>13</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Data: Insulin**

<table>
<thead>
<tr>
<th>Date</th>
<th>Insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/22</td>
<td>12.5</td>
</tr>
<tr>
<td>09/21</td>
<td>12.5</td>
</tr>
<tr>
<td>09/20</td>
<td>12.5</td>
</tr>
<tr>
<td>09/19</td>
<td>12.5</td>
</tr>
<tr>
<td>09/18</td>
<td>12.5</td>
</tr>
<tr>
<td>09/17</td>
<td>12.5</td>
</tr>
</tbody>
</table>

**Breakfast**

<table>
<thead>
<tr>
<th>BS Before</th>
<th>BS After</th>
<th>Done</th>
</tr>
</thead>
</table>

---

**Data: Blood Sugar (After)**

<table>
<thead>
<tr>
<th>Date</th>
<th>B</th>
<th>L</th>
<th>D</th>
<th>E</th>
<th>V</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/22</td>
<td>13</td>
<td>17</td>
<td>12</td>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>09/21</td>
<td>11</td>
<td>20</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>09/20</td>
<td>6</td>
<td>15</td>
<td>1</td>
<td>11</td>
<td>2</td>
</tr>
<tr>
<td>09/19</td>
<td>11</td>
<td>19</td>
<td>14</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>09/18</td>
<td>9</td>
<td>17</td>
<td>12</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>09/17</td>
<td>4</td>
<td>13</td>
<td>10</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

**Breakfast**

<table>
<thead>
<tr>
<th>BS Before</th>
<th>BS After</th>
<th>Done</th>
</tr>
</thead>
</table>

---

- Switching back and forth must show the same dates i.e. if I move the blood sugar (before) screen to show data beginning with 09/20, switching to the other screens will show the same range of dates.

- If more than one data point was entered into that category (i.e. a second Breakfast After value), the most recent value will overwrite the past data (the occurrence of this will be very rare).
Appendix D – Training Manual
Training Manual for LogPad

Charles H. Best Diabetes Center Data Collection Project

August 30, 1999

Albert Tseng
University of Toronto
Institute of Biomedical Engineering
(416) 410-3601
albert.tseng@utoronto.ca
LogPad Operation
Control Screen for Patient Use

Welcome! This is your new LogPad!

The first thing you need to know is that the LogPad is not a toy. It is a tool to help you become more healthy by storing all your diabetes information. Remember to be gentle with the LogPad as it can easily break if dropped.

Let’s start by learning what the buttons on the LogPad do. The most important button is the green button on the bottom left side the LogPad. This is the POWER button and turns the LogPad on. The other buttons on the front of the LogPad only work when the LogPad is used for other purposes. To use the LogPad for your diabetes information, these extra buttons aren’t needed.

Try turning the LogPad on by pushing the POWER button!
LogPad Screen Content & Operation
Control Screen for Patient Use

Screen 1.0  Start Screen
This is the first screen that you will see when you turn on your LogPad. This screen allows you to select what you want to do with the Log Pad.

The LogPad shows your name, the date, and the time on this screen. The tab at the top right of the screen is only to be used by the staff at the Best Center.

Whenever you enter information into the LogPad, you do it by using the plastic pen that is kept in the holder on the upper right side of the LogPad.

The first tab (Blood Sugar/Insulin) lets you enter your blood sugar levels and insulin doses. Touch this tab with the pen whenever you do a blood sugar test or take an insulin dose. (Read more on Screen 2.0.)

A touch on the second tab (Low Blood Sugar Episode) lets you enter in your symptoms when you had a low blood sugar. (Read more on Screen 3.0.)
Screen 1.0  Start Screen
(Continued from last page)

A pen touch on the third tab (High Blood Sugar Episode) lets you enter in your symptoms when you had a high blood sugar. (Read more on Screen 3.5)

The fourth tab (Exercise Period) lets you record when you exercised. (Read more on Screen 4.0)

The fifth tab (Message to Best Center) allows you to send a message to the staff at the Best Centre. (Read more on Screen 5.0)

The sixth tab (View Data) allows you to see your old blood sugar and insulin data.

The last tab (Send Stored Reports) allows you to send your information to the Best Centre through the phone line. The number beside the tab tells you how many reports need to be sent to the Best Center. The information should be sent over the phone line every night before you go to sleep. (Read more on Screen 6.0)
LogPad Screen Content & Operation

Diary Questions

Screen 2.0 Current Blood Sugar/Insulin
This screen is for entering in your blood sugar and/or insulin doses. If you are taking a measurement and a dose at the same time, they can be entered at the same time. If not, you can also enter them individually.

The first thing that needs to be done is to select the period that the test or dose is for. This can be done by touching Breakfast, Lunch, Dinner, Bedtime or Other. When you touch the word, it will be highlighted.

After you have selected the meal, use the time box to enter the time that you did the test and/or the time that you took your insulin dose. Change the time by using the arrows beside the time box.

The third step is to enter in the blood sugar value using the arrows beside the box. If you didn’t take a measurement, don’t touch those arrows and the box will remain blank.

For entering Insulin dose, first touch the box that has INSULIN and select which type of insulin you used. Then, a box will appear allowing you to use arrows to select the dose of insulin. If you didn’t take insulin, don’t select a type of insulin.

If you need to make a correction, click BACK. If you are finished, click NEXT to return to the Start screen.
LogPad Screen Content & Operation Diabetes Project
Diary Questions: Low Blood Sugar: Symptoms Report

Screen 3.0 Low Blood Sugar Episode: Symptoms Report
This screen lets you record your symptoms due to low blood sugar.

The first thing is to record the time that the symptoms ended by using the arrows beside the time.

Next, check off the boxes beside the symptoms you experienced. If you had no symptoms, check the NONE box.

When you are finished, touch NEXT to continue or BACK to make a correction.
Diary Questions: Low Blood Sugar: Severity Report

Screen 3.1 Low Blood Sugar Episode: Severity Report
This screen lets you record how severe the symptoms were. Touch the position on the scale which best describes how severe the symptoms were. The left side of the scale indicates mild while the right side indicates severe.

Next, indicate how long the symptoms lasted by touching the arrows beside the time. These are recorded in hours and minutes.

When you are finished, touch NEXT to continue or BACK to make a correction.
Screen 3.2  Low Blood Sugar Episode: Causes Report

This screen lets you record what you think the reason for the low blood sugar was. Check one of the boxes which best describes why you think you had a low blood sugar.

When you are finished, touch NEXT to continue or BACK to make a correction.
Screen 3.3  Low Blood Sugar Episode: Actions Taken Report
This screen lets you record what you did to correct the low blood sugar. If you took simple sugars, check the box and indicate how many grams of sugar you took by touching the arrow keys beside the box.

If you did nothing, check the “Did Nothing” box.

Also, indicate whether you had a follow up snack or meal by touching YES or NO.

When you are finished, touch NEXT to continue or BACK to make a correction.
LogPad Screen Content & Operation
Message From Patient

Screen 5.0 Message from Patient
This screen lets you write messages to the Best Center if you have any questions or comments that you might have.

First write the message in the text box. Then check off the “Call me as soon as possible” box if you would like the Best Center staff to call you back.

If you would like to clear off the text box, touch the “Clear Message” tab. If you would like to go back to the previous screen, touch “Back”.

If you are finished, touch the DONE tab and you will get back to the Start screen.
LogPad Screen Content & Operation Diabetes Project
Diary Questions: High Blood Sugar: Symptoms Report

Screen 3.5 High Blood Sugar Episode - Symptoms Report
This screen lets you record your symptoms due to high blood sugar.

The first thing is to record the time that the symptoms ended by using the arrows beside the time.

Next, check off the boxes beside the symptoms you experienced. If you had no symptoms, check the NONE box.

When you are finished, touch NEXT to continue or BACK to make a correction.
Screen 3.6  High Blood Sugar Episode: Severity Report

This screen lets you record how severe the symptoms were. Touch the position on the scale which best describes how severe the symptoms were. The left side of the scale indicates mild while the right side indicates severe.

Next, indicate how long the symptoms lasted by touching the arrows beside the time. These are recorded in hours and minutes.

When you are finished, touch NEXT to continue or BACK to make a correction.
Screen 3.7 High Blood Sugar Episode - Causes Report

This screen lets you record what you think the reason for the high blood sugar was. Check one of the boxes which best describes why you think you had a low blood sugar.

When you are finished, touch NEXT to continue or BACK to make a correction.

Blood Sugar: Causes

What was the main cause of the high blood sugar (check one below)?

- [ ] Forgot to take insulin
- [x] Not enough insulin
- [ ] Increase food
- [ ] Decrease exercise
- [ ] Illness
- [ ] Stress/Excitement
- [ ] Other medication
- [ ] Rebound from low blood sugar
- [ ] Don't know

(Back) (Next)
LogPad Screen Content & Operation  Diabetes Project
Diary Questions: High Blood Sugar: Actions Report

Screen 3.8  High Blood Sugar Episode:
Actions Taken Report
This screen lets you record what you did
to correct the high blood sugar.

If you did nothing, check the "Did Nothing" box.

If you took extra fast acting insulin, check
that box and indicate how many units you
took by touching the arrows beside the box.

If you plan to adjust your next dose, check
that box.

If you plan to check your blood sugar
again later check that box.

If you measured ketones, check that box
and indicate what the measurement was
by touching the appropriate box.

When you are finished, touch NEXT to
continue or BACK to make a correction.
LogPad Screen Content & Operation
Message From Patient

Screen 5.0 Message from Patient
This screen lets you write messages to the Best Center if you have any questions or comments that you might have.

First write the message in the text box. Then check off the “Call me as soon as possible” box if you would like the Best Center staff to call you back.

If you would like to clear off the text box, touch the “Clear Message” tab. If you would like to go back to the previous screen, touch “Back”.

If you are finished, touch the DONE tab and you will get back to the Start screen.
Screen 4.0 Exercise Period
This screen lets you record your exercise activity.

The first step is to enter the time when the exercise ended by touching the arrows beside the time box. The current time will show up first.

Next, indicate how hard you exercised by touching the scale. If you had a light exercise, touch the left side of the scale. If you had a heavy exercise, touch the right side of the scale. If you had a moderate exercise, touch the middle part of the scale.

The last thing you need to do is enter the amount of time you exercised by touching the arrows beside the box. This time is recorded in hours and minutes.

When you are finished, touch Next or BACK to make a correction.
LogPad Screen Content & Operation

Message From Patient

Screen 5.0 Message from Patient
This screen lets you write messages to the Best Center if you have any questions or comments that you might have.

First write the message in the text box. Then check off the “Call me as soon as possible” box if you would like the Best Center staff to call you back.

If you would like to clear off the text box, touch the “Clear Message” tab. If you would like to go back to the previous screen, touch “Back”.

If you are finished, touch the DONE tab and you will get back to the Start screen.

I am thirsty.
LogPad *Patient Use* Screens

**Data Review for Self-Management**

---

**Screen 11.0 Data review: Blood sugar results & Symptoms**

This screen shows you your blood sugar measurements and the number of Hi and Lo blood sugar levels (out of range) you had per day.

Rows appear with the most recent date at the top and you can scroll through the data by using the scroll buttons. You can see up to 4 weeks of your blood sugar and insulin levels.

The “Full Report” button switches to **Screen 11.1**. When you are finished viewing your data, press “Done” to return to the Start screen.

---

**Screen 11.1 Data review: Full Report**

This screen shows you your blood sugar measurements, insulin doses, and number of Hi and Lo blood sugar levels per day.

Rows appear with the most recent date at the top and you can scroll through the data by using the scroll buttons. You can see up to 4 weeks of your blood sugar and insulin levels.

The “Blood Sugar” button switches to **Screen 11.0**. When you are finished viewing your data, press “Done” to return to the Start screen.

---

<table>
<thead>
<tr>
<th>Date 1998</th>
<th>Blood Sugar</th>
<th></th>
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<td>2</td>
<td>7</td>
</tr>
</tbody>
</table>

---

30/08/99      Version 1.0     Page 18
Screen 6.0 Send Information
This screen lets you send your recorded information to the Best Center. You should make it a habit to send the information to the Best Center every night before you go to bed. This will ensure that the Center has the most up to date information.

When you see this screen, make sure that the LogPad is connected to the phone by using the supplied cord and connecting one end to the bottom of the LogPad, and the other in your home’s phone jack.

If there is a number that you have to dial directly before the phone number, select Dial Prefix and enter the number. If your house has Call Waiting, select the Disable Call Waiting box. If you do not have touch tone dialing at your house, select Use pulse dialing.

If you wish to send the information, touch the “Send NOW” tab. If not, touch the “Send later” tab.

Do not touch or disconnect the LogPad until you see the “Your report was transmitted and received successfully” message.

Touch the OK tab to get back to the Start screen.
LogPad Screen Content & Operation
Message to Patient

Screen 7.1 Message to Patient
After transmission of your information, you may get some messages from the Best Centre. These will automatically show up on the LogPad after you transmit your information.

Touch the OK tab when you are finished reading.

Diabetes Project

Hi, Kris
Your next appointment at the Centre is at 2 pm next Wednesday. Can you make it? Bring your LogPad with you, please.
--Cindy

OK
Appendix E – Time Study

1. Task List ____________________________ 124
2. Timesheet ____________________________ 125
3. Example of a data collection sheet ________ 126
4. Time Study Data - Staff Member 1 ________ 127
5. Time Study Data - Staff Member 2 ________ 128
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7. Summary of Time Study Data (Collected) ___ 130
8. Summary of Time Study Data (Work Week) __ 131
Task List

Patient Care Activities
P1 Consulting with patient on the phone
P2 Patient appointment at the center
P3 On-site: New patient visit and education
P4 Off-site: New patient visit and education
P5 Team Conferences regarding patients
P6 Planning Care
P7 Charting
P8 Patient appointment - offsite

Information Retrieval
I1 From On-site Charts
I2 Via fax
I3 Via phone dictation
I4 Via other method: Specify
I5 Making copies of patient diary

Data Analysis
D1 Copying information into another format
D2 Analyzing information
D3 Graphing patient information

Education
E1 Education at a school or group home

Administration
A1 Answering Telephone
A2 Program Development (organization level)
A3 Booking patients
A4 Staff Training /Orientation

Other
O1 Travelling
O2 Fundraising
O3 Marketing
O4 Finances
O5 Purchasing
O6 Cleaning
O7 Public Relations
O8 Email
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Figure 4: Task Timesheet
Name: MARLENE GRASS
Date: MON MAY 17/99

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### Staff Member 3

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<th>Total T</th>
<th>Percentage</th>
<th>Data Collected</th>
<th>Average Work Week</th>
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<td>0</td>
<td>0.0%</td>
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<tr>
<td>Team Conferences regarding patients</td>
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<td>0.0%</td>
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<td>0</td>
<td>0</td>
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### Information Retrieval

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<th>Average Work Week</th>
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<td>15</td>
<td>5.0</td>
<td>1.3%</td>
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<tr>
<td>Via fax</td>
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<td>50</td>
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<td>4.3%</td>
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<td>33.3</td>
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<td>Graphing patient information</td>
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### Education

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<th>Total T</th>
<th>Percentage</th>
<th>Data Collected</th>
<th>Average Work Week</th>
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<td>0</td>
<td>0</td>
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### Administration

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<th>28/06/99</th>
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<th>Total T</th>
<th>Percentage</th>
<th>Data Collected</th>
<th>Average Work Week</th>
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<td>0</td>
<td>0</td>
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<td>0.0%</td>
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<td>0.0</td>
</tr>
<tr>
<td>Program Development (organization level)</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td></td>
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<td>Booking patients</td>
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<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td>Staff Training /Orientation</td>
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<td>0</td>
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### Other

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<th>28/06/99</th>
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<th>Total T</th>
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<tr>
<td>Finances</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td>Purchasing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td>Cleaning</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td>Public Relations</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
<tr>
<td>Email</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0%</td>
<td></td>
<td>0.0</td>
</tr>
</tbody>
</table>

### Total Minutes

<table>
<thead>
<tr>
<th>Total Minutes</th>
<th>10/05/99</th>
<th>22/06/99</th>
<th>28/06/99</th>
<th>Total M</th>
<th>Total T</th>
<th>Percentage</th>
<th>Data Collected</th>
<th>Average Work Week</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>410</td>
<td>420</td>
<td>330</td>
<td>1160</td>
<td>220</td>
<td>773</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Hours</td>
<td>6</td>
<td>8</td>
<td>7</td>
<td>5</td>
<td>19.3</td>
<td>3.7</td>
<td></td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td>19.0%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Summary (All recorded time)

<table>
<thead>
<tr>
<th>Patient Care Activities</th>
<th>All Recorded Time</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Percent-Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>P1 Consulting with patient on the phone</td>
<td>491</td>
<td>330</td>
<td>340</td>
<td>1761</td>
<td>19.4</td>
<td>16.4%</td>
</tr>
<tr>
<td>P2 Patient appointment at the center</td>
<td>155</td>
<td>1410</td>
<td>250</td>
<td>1815</td>
<td>30.3</td>
<td>25.6%</td>
</tr>
<tr>
<td>P3 On-site New patient visit and education</td>
<td>15</td>
<td>170</td>
<td>350</td>
<td>535</td>
<td>8.9</td>
<td>7.6%</td>
</tr>
<tr>
<td>P4 Off-site New patient visit and education</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.0</td>
<td>0.0%</td>
</tr>
<tr>
<td>P5 Team Conferences regarding patients</td>
<td>0</td>
<td>45</td>
<td>0</td>
<td>45</td>
<td>0.8</td>
<td>0.6%</td>
</tr>
<tr>
<td>P6 Planning Care</td>
<td>0</td>
<td>60</td>
<td>0</td>
<td>60</td>
<td>1.0</td>
<td>0.8%</td>
</tr>
<tr>
<td>P7 Charting</td>
<td>15</td>
<td>330</td>
<td>105</td>
<td>450</td>
<td>7.5</td>
<td>6.4%</td>
</tr>
<tr>
<td>P8 Patient appointment - offsite</td>
<td>0</td>
<td>390</td>
<td>0</td>
<td>390</td>
<td>6.5</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

### Information Retrieval

| I1 From On-site Charts                                   | 10                | 0   | 15 | 25   | 0.4  | 0.4%                    |
| I2 Via fax                                               | 20                | 0   | 0  | 20   | 0.3  | 0.3%                    |
| I3 Via phone dictation                                   | 20                | 0   | 0  | 20   | 0.3  | 0.3%                    |
| I4 Via other method: Specify                             | 240               | 0   | 0  | 240  | 4.0  | 3.4%                    |
| I5 Making copies of patient diary                        | 18                | 30  | 0  | 48   | 0.8  | 0.7%                    |

### Data Analysis

| D1 Copying information into another format                | 13                | 30  | 50 | 93   | 1.8  | 1.3%                    |
| D2 Analyzing information                                 | 40                | 60  | 50 | 150  | 2.5  | 2.1%                    |
| D3 Graphing patient information                          | 0                 | 0   | 0  | 0    | 0.0  | 0.0%                    |

### Education

| E1 Education at a school or group home                   | 0                 | 0   | 0  | 0    | 0.0  | 0.0%                    |

### Administration

| A1 Answering Telephone                                   | 230               | 120 | 0  | 350  | 5.8  | 4.9%                    |
| A2 Program Development (organization level)             | 0                 | 300 | 0  | 300  | 5.0  | 4.2%                    |
| A3 Booking patients                                      | 120               | 0   | 0  | 120  | 2.0  | 1.7%                    |
| A4 Staff Training /Orientation                           | 15                | 0   | 0  | 15   | 0.3  | 0.2%                    |

### Other

| O1 Travelling                                           | 30                | 30  | 0  | 60   | 1.0  | 0.8%                    |
| O2 Fundraising                                          | 645               | 30  | 0  | 675  | 11.3 | 9.5%                    |
| O3 Marketing                                            | 45                | 0   | 0  | 45   | 0.8  | 0.6%                    |
| O4 Finances                                             | 20                | 0   | 0  | 20   | 0.3  | 0.3%                    |
| O5 Purchasing                                           | 0                 | 0   | 0  | 0    | 0.0  | 0.0%                    |
| O6 Cleaning                                             | 240               | 0   | 0  | 240  | 4.0  | 3.4%                    |
| O7 Public Relations                                     | 140               | 0   | 0  | 140  | 2.3  | 2.0%                    |
| O8 Email                                                | 60                | 0   | 0  | 60   | 1.0  | 0.8%                    |

| Total                                                   | 2582              | 3335| 1760| 7077 | 118.0| 115.4                   |
|                                                       |                  |    |    |    |    | 15.8%                   |
## Summary (Work Week)

<table>
<thead>
<tr>
<th>Patient Care Activities</th>
<th>Work Week</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
<th>Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Consulting with patient on the phone</strong></td>
<td>Marlene 429.6, Karyn 255.7, Irma 226.7</td>
<td>892.0</td>
<td>14.9</td>
<td>16.4%</td>
<td>558.9</td>
</tr>
<tr>
<td><strong>Patient appointment at the center</strong></td>
<td>Marlene 135.6, Karyn 1007.1, Irma 166.7</td>
<td>1309.4</td>
<td>21.8</td>
<td>24.1%</td>
<td></td>
</tr>
<tr>
<td><strong>On-site New patient visit and education</strong></td>
<td>Marlene 13.1, Karyn 121.4, Irma 233.3</td>
<td>367.9</td>
<td>6.1</td>
<td>6.6%</td>
<td></td>
</tr>
<tr>
<td><strong>Off-site New patient visit and education</strong></td>
<td>Marlene 0.0, Karyn 0.0, Irma 0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td><strong>Team Conferences regarding patients</strong></td>
<td>Marlene 0.0, Karyn 32.1, Irma 0.0</td>
<td>32.1</td>
<td>0.5</td>
<td>0.5%</td>
<td></td>
</tr>
<tr>
<td><strong>Planning Care</strong></td>
<td>Marlene 0.0, Karyn 42.9, Irma 0.0</td>
<td>42.9</td>
<td>0.7</td>
<td>0.8%</td>
<td></td>
</tr>
<tr>
<td><strong>Charting</strong></td>
<td>Marlene 13.1, Karyn 235.7, Irma 70.0</td>
<td>318.8</td>
<td>5.3</td>
<td>5.9%</td>
<td></td>
</tr>
<tr>
<td><strong>Patient appointment - offsite</strong></td>
<td>Marlene 0.0, Karyn 278.6, Irma 0.0</td>
<td>278.6</td>
<td>4.6</td>
<td>5.1%</td>
<td></td>
</tr>
</tbody>
</table>

**Information Retrieval**

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Marlene</th>
<th>Karyn</th>
<th>Irma</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>From On-site Charts</strong></td>
<td>8.8</td>
<td>0.0</td>
<td>10.0</td>
<td>18.8</td>
<td>0.3</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Via fax</strong></td>
<td>17.5</td>
<td>0.0</td>
<td>0.0</td>
<td>17.5</td>
<td>0.3</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Via phone dictation</strong></td>
<td>17.5</td>
<td>0.0</td>
<td>0.0</td>
<td>17.5</td>
<td>0.3</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Via other method: Specify</strong></td>
<td>210.0</td>
<td>0.0</td>
<td>0.0</td>
<td>210.0</td>
<td>3.5</td>
<td>3.9%</td>
</tr>
<tr>
<td><strong>Making copies of patient diary</strong></td>
<td>15.8</td>
<td>21.4</td>
<td>0.0</td>
<td>37.2</td>
<td>0.6</td>
<td>0.7%</td>
</tr>
</tbody>
</table>

**Data Analysis**

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Marlene</th>
<th>Karyn</th>
<th>Irma</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Copying information into another format</strong></td>
<td>11.4</td>
<td>21.4</td>
<td>33.3</td>
<td>66.1</td>
<td>1.1</td>
<td>1.2%</td>
</tr>
<tr>
<td><strong>Analyzing information</strong></td>
<td>35.0</td>
<td>42.9</td>
<td>33.3</td>
<td>111.2</td>
<td>1.9</td>
<td>2.0%</td>
</tr>
<tr>
<td><strong>Graphing patient information</strong></td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Education**

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Marlene</th>
<th>Karyn</th>
<th>Irma</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Education at a school or group home</strong></td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

**Administration**

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Marlene</th>
<th>Karyn</th>
<th>Irma</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Answering Telephone</strong></td>
<td>201.3</td>
<td>85.7</td>
<td>0.0</td>
<td>287.0</td>
<td>4.8</td>
<td>5.3%</td>
</tr>
<tr>
<td><strong>Program Development (organization level)</strong></td>
<td>0.0</td>
<td>214.3</td>
<td>0.0</td>
<td>214.3</td>
<td>3.6</td>
<td>3.9%</td>
</tr>
<tr>
<td><strong>Booking patients</strong></td>
<td>105.0</td>
<td>0.0</td>
<td>0.0</td>
<td>105.0</td>
<td>1.8</td>
<td>1.9%</td>
</tr>
<tr>
<td><strong>Staff Training /Orientation</strong></td>
<td>13.1</td>
<td>0.0</td>
<td>0.0</td>
<td>13.1</td>
<td>0.2</td>
<td>0.2%</td>
</tr>
</tbody>
</table>

**Other**

<table>
<thead>
<tr>
<th><strong>Activity</strong></th>
<th>Marlene</th>
<th>Karyn</th>
<th>Irma</th>
<th>Total mins</th>
<th>Total hrs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Travelling</strong></td>
<td>26.3</td>
<td>21.4</td>
<td>0.0</td>
<td>47.7</td>
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<tr>
<td><strong>Fundraising</strong></td>
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<td>21.4</td>
<td>0.0</td>
<td>585.8</td>
<td>9.8</td>
<td>10.9%</td>
</tr>
<tr>
<td><strong>Marketing</strong></td>
<td>39.4</td>
<td>0.0</td>
<td>0.0</td>
<td>39.4</td>
<td>0.7</td>
<td>0.7%</td>
</tr>
<tr>
<td><strong>Finances</strong></td>
<td>17.5</td>
<td>0.0</td>
<td>0.0</td>
<td>17.5</td>
<td>0.3</td>
<td>0.3%</td>
</tr>
<tr>
<td><strong>Purchasing</strong></td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0%</td>
</tr>
<tr>
<td><strong>Cleaning</strong></td>
<td>210.0</td>
<td>0.0</td>
<td>0.0</td>
<td>210.0</td>
<td>3.5</td>
<td>3.9%</td>
</tr>
<tr>
<td><strong>Public Relations</strong></td>
<td>122.5</td>
<td>0.0</td>
<td>0.0</td>
<td>122.5</td>
<td>2.0</td>
<td>2.3%</td>
</tr>
<tr>
<td><strong>Email</strong></td>
<td>52.5</td>
<td>0.0</td>
<td>0.0</td>
<td>52.5</td>
<td>0.9</td>
<td>1.0%</td>
</tr>
</tbody>
</table>

**Total** | 2266.3 | 2387.1 | 773.3 | 5426.7 | 90.4 | 907.2 | 16.7% | 151.7 |
Appendix F – Patient consent form
Protocol Title: Pilot Study for use of PDA in Diabetes Self-Management Network

Principal/Overall Investigator: Albert Tseng

Site-Responsible Investigator(s)/Institution: Charles H. Best Center

Co-Investigator(s)/Study Staff: Marlene Grass, RN, Nick Zamora, OPTIUM Health Solutions

Description of Subject Population: Diabetic Pediatric Patients

PURPOSE

We would like permission to enroll you as a participant in a research study. The purpose of the study is to examine the benefits of using Personal Digital Assistants (PDA) and Web-based technology to improve the health management of diabetic patients. Personal Digital Assistants are small digital organizers (such as Palm Pilots) which are used to store various types of data. In this application, the PDAs will be used to store key patient data such as glucose and insulin levels. This information will be available through a secure Web-based computer network where clinicians can have constant access to up to date information.

Clinical studies have shown that continuous and proper management of diabetes can decrease the number of complications experienced and increase the quality of life of patients. The proposed technology attempts to provide a method for the consistent and frequent monitoring necessary for proper diabetes management.

PROCEDURES

If you agree to participate in this study, your medical records for a two-month period prior to the start of the study will be collected and analyzed. You will then be issued a PDA to take the place of your traditional paper diary. You will be trained on the use of the PDA and will have the opportunity to ask questions about the device. This device will serve as your patient data diary for glucose, insulin, exercise, and episode data for a two-month period.

STUDY CONTACTS

Principal Investigator: Albert Tseng, University of Toronto (617) 834-8264
Coordinator: Marlene Grass, Charles H. Best Diabetes Centre (905) 434-6291
Industry Sponsor: Nick Zamora, OPTIUM Health Solutions (416) 410-3601 ext.2
COSTS

There will be no additional costs to the patient

RISKS AND DISCOMFORTS

There are no risks or discomforts associated with the use of this device.

BENEFITS

The benefits of participating in the study include the free use of a high tech device that makes it easier to store and collect your diabetes related information. Another benefit would be to participate in a study that may help to improve the health care of all diabetic patients.

ALTERNATIVES

The alternative would be to continue on your current diabetes management plan.
THE FOLLOWING PARAGRAPHS CONTAIN STANDARD INFORMATION WHICH GENERALLY APPLIES TO PERSONS INVOLVED IN A RESEARCH STUDY AND ARE REQUIRED ON ALL CONSENT FORMS.

CONFIDENTIALITY
Medical information produced by this study will become part of your medical record, unless specifically stated otherwise in this consent form. Information that does not become part of your medical record will be stored electronically in the investigator's computer files and will be identified by a code number only. The code key connecting your name to specific information about you will be kept in a separate, secure location. Your medical record is available to health care professionals at the Charles H. Best Diabetes Centre, and may be reviewed by appropriate staff members in the course of carrying out their duties; however, they are required to maintain confidentiality in accordance with applicable laws and the policies of the Charles H. Best Centre. Information contained in your records may not be given to anyone unaffiliated with the Charles H. Best Centre in a form that could identify you without your written consent, except as described in this consent form or as required by law.

It is possible that your medical and research record, including sensitive information and/or identifying information, may be inspected and/or copied by the study sponsor (and/or its agents), and/or the federal or provincial government agencies, in the course of carrying out their duties. If your record is inspected or copied by the study sponsor (and/or its agents), or by any of these agencies, the Charles H. Best Centre will use reasonable efforts to protect your privacy and the confidentiality of your medical information.

The results of this study may be published in a medical book or journal or used for teaching purposes. However, your name or other identifiers will not be used in any publication or teaching materials without your specific permission. In addition, if photographs, audiotapes or videotapes were taken during the study that could identify you, then you must give special written permission for their use. In that case, you will be given the opportunity to view or listen, as applicable, to the photographs, audiotapes or videotapes before you give your permission for their use if you so request.

REQUEST FOR MORE INFORMATION
You may ask more questions about the study at any time. The investigator(s) will provide their telephone number so that they are available to answer your questions or concerns about the study. You will be informed of any significant new findings discovered during the course of this study that might influence your continued participation.

If during the study or later, you wish to discuss your rights as a research subject, your participation in the study and/or concerns about the study, a research-related injury with someone not directly involved in the study, or if you feel under any pressure to enroll in this study or to continue to participate in this study, you are asked to contact the Ethical Review Officer at the University of Toronto Research Services Office at (416) 978-5585. A copy of this consent form will be given to you to keep.
REFUSAL OR WITHDRAWAL OF PARTICIPATION
Participation in this study is voluntary. You do not have to participate in this study. Your present or future care will not be affected should you choose not to participate. If you decide to participate, you can change your mind and drop out of the study at any time without affecting your present or future care at the Charles H. Best Centre. In addition, the clinician in charge of this study may decide to end your participation in this study at any time after he/she has explained the reasons for doing so and has helped arrange for your continued care by your own doctor if needed.

INJURY STATEMENT
If you are injured during the course of the study and as a direct result of this study, you should contact the investigator at the number provided. You will be offered the necessary care to treat that injury. This care does not imply any fault or wrong-doing on the part of the Charles H. Best Centre or the investigator(s) involved.

SIGNATURE
I confirm that the purpose of the research, the study procedures and the possible risks and discomforts as well as potential benefits that I may experience have been explained to me. Alternatives to my participation in the study also have been discussed. All my questions have been answered. I have read this consent form. My signature below indicates my willingness to participate in this study.

Subject Patient _______________________________ Date _________________
Witness/Advocate/Minor/Legal Guardian (if required) _______________________________ Date _________________
Additional Signature (if required) (identify relationship to subject) _________________ Date _________________

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts as well as potential benefits and have answered any questions regarding the study to the best of my ability.

Study Representative _______________________________ Date _________________
Appendix G – Patient Interviews
Participant 101 – Age 10
Previous Method: Submits at visit

Who enters the data?
- Child and mother
- Enters data at time of measurement

Does the child carry the device everywhere with them?
- Travels in insulin kit with him everywhere
- Summertime at the boat

How easily is it to enter information?
- Really easy

How easy is it to read the information displayed on the screen?
- Child says it is not too bad to see screen
- Mother says that the small print and glare make it difficult to read

How do you like the format the glucose and insulin data is displayed in?
- Pretty different (from paper diary) but can figure it out - Child
- Not hard to understand - Mother

How satisfied are you with the amount of time it takes to enter data?
- 15 secs per entry – Mother
- Doesn’t take long to enter – Child

Does it take more time or less time than keeping a paper diary?
- Better than paper!

What do you like about the device?
- Don’t lose it like a paper diary - Child
- A lot quicker to record data - Child
- Great for viewing on the screen – Mother

What don’t you like about the device
- Keeps a lot of notes because of honeymooning
- Flip off cover falls off a lot

What would you like to see on the device?
- Notes
- Reminders for school and other things, scheduler, phone book

Is it better than paper?
- Paper is not easier than computer

Computer Access?
- Yes

Internet Access?
- Yes

Specific Problems
- Modem Errors
Participant 103 – Age 10

Previous Method - Dictates over phone

- Didn't go to the second training meeting

Who enters the data?
- Mother wanted to enter the data so child didn't have to worry about it.

Does the child carry the device everywhere with them?
- No
- During first week, child was with the mother so data was collected
- After the first week the child left home for a two week period and no data was collected

How easily is it to enter information?
- Didn't like having to go into the first sheet twice for N and R
- High blood sugars takes a long time to reach using half units.
- Novelty wore off
- Child is not interested in using the device because it is not a fun thing and she would rather be outside playing

How do you like the format the glucose and insulin data is displayed in?
- Viewing the data doesn't show the data

Specific Problems
- Couldn't send data over the phone line because they didn't have a telephone cord to transfer data with.
Participant 104 – Age 16

Previous Method: Submits at visit but sometimes dictates over phone when problems
• Usually entering data at time of test
• Entering it into the LogPad first, then writing it in the paper diary

Who enters the data?
• Teenager

Does the child carry the device everywhere with them?
• Brings it to work in the kit

How easily is it to enter information?
• Pretty easy

How easy is it to read the information displayed on the screen?
• Fine

How do you like the format the glucose and insulin data is displayed in?
• Reviewing data at night
• Didn’t notice the difference between the LogPad and the breakfast readings

How satisfied are you with the amount of time it takes to enter data?
• Within a few seconds
• (Tedious retrospective data entry is) your own fault for not entering at the time

Does it take more time or less time than keeping a paper diary?
• About the same

What do you like about the device?
• Easy and straight forward
• “All laid out for you”
• “When you get a high low episode, it does a lot of the thinking for you because it’s all laid out”

What don’t you like about the device
• There are no comments
• Comments are sometimes not associated with High’s or Lows? i.e. when you are proactive and take extra insulin for higher food intake before you get a high.

What would you like to see on the device?
• Different food items = how much insulin
• Calculator
• Memos
• Planners

Is it better than paper?
• Like it better than paper
• Less likely to be lost

Specific Problems
• Could not download data because she was trying to connect through the headset. (Now instructed to do it directly with wall jack)
**Participant 105 – Age 19**

*Previous Method: Keeps data private but has very good HbA1c*

Who enters the data?
- Teenager is entering data

Does the child carry the device everywhere with them?
- Doesn’t take it to work because she doesn’t want it to get damaged or stolen
- When she goes to a restaurant or to visit grandparents, she brings it with her
- Doesn’t bring it to work so data is entered at night time by referencing the paper diary
- On weekends, data entry is done at time of measurement

How easily is it to enter information?
- Straight forward

How easy is it to read the information displayed on the screen?
- Easy, fine

How do you like the format the glucose and insulin data is displayed in?
- Fine, the paper diary is a little better, but LogPad is okay

How satisfied are you with the amount of time it takes to enter data?
- 10 mins for the whole day’s data
- On the weekends when she enters at the time of measurement, it only takes a few seconds.

What do you like about the device?
- Convenient, and can send messages to the Best Centre

What would you like to see on the device?
- Calendar, phone book, scheduler and reminders

Is it better than paper?

*Computer Access?*
- Yes

*Internet Access?*
- Yes

**Specific Problems**
- Breakfast blood sugar shows up in yesterday’s place but goes to the correct date after you enter in the lunch blood sugar. This only happens with blood sugar, not with insulin
Participant 107 – Age 10
Previous Method: Submit at visits

Who enters the data?
- Child is able to do it on his own but usually has the help of parents.

Does the child carry the device everywhere with them?
- Afraid to lose it so it is left at home and data is entered at night.
- During school, he might leave it at home
- They realize it is time consuming for retrospective data entry

How easily is it to enter information?
- Pretty straightforward

How easy is it to read the information displayed on the screen?
- Okay, light contrast sometimes makes it difficult
- “Indiglo” back lighting might help

How do you like the format the glucose and insulin data is displayed in?
- The family is only using the Blood Sugar report but not the full report

How satisfied are you with the amount of time it takes to enter data?
- Takes 5 minutes for entry of a day’s data.

Does it take more time or less time than keeping a paper diary?
- More

What do you like about the device?
- Like the size
- Like passing information on the Best Centre because it is comforting to know that someone is monitoring.
- No faxing.
- If patient is sick, then the Best Centre already has all the information

What don’t you like about the device?
- Too much work to add Activity data
- Was using low and high blood sugar episodes at the beginning but stopped
- Because they were using the paper diary at the same time, they were not entering all the data into the PDA.

What would you like to see on the device?
- Ability to record that activity eliminated the need for insulin. i.e. after Activity screen, it asks whether any changes to insulin requirements was made.
- An average blood sugar so that they would know between 3 month appointments what their estimated HbA1c would be.

Computer Access?
- Yes

Internet Access?
- Yes
Participant 109 – Age 33
Previous Method: Faxes data (every week or more)
Who enters the data?
- records own data (sometimes husband enters data)

Does the child carry the device everywhere with them?
- leaves LogPad at home and records off the memory of the glucometer

How easily is it to enter information?
- Very Easy
- Hard to enter past data
- Can't enter data for last day
- If she has a low in the middle of the night, she would usually record the data the next morning out of the glucometer memory. The LogPad does not allow this.

How easy is it to read the information displayed on the screen?
- Finding it difficult to read due to eye problems
- Better in some lighting (backlighting and contrast issue)
- Characters are large enough

How do you like the format the glucose and insulin data is displayed in?
- Sometimes hard to figure out
- Don't use the LogPad for viewing data, still using the paper diary as reference

How satisfied are you with the amount of time it takes to enter data?
- Without Hi or Low data it takes about 15 to 25 seconds to enter one record
- With Hi or Low it takes 1 to 1.5 mins for one record
- Retrospective data entry – 3 to 4 mins each record

Does it take more time or less time than keeping a paper diary?
- More Time

What do you like about the device?
- Like that it's clean (no more blood on the paper)
- Neat (instead of scratchy writing with paper)
- Compact and small

What don't you like about the device
- Screens are set up for someone who is right handed, arrows (on the wrong angle, it is hard to touch correctly)

What would you like to see on the device?
- Only allows one selection option for Treating of High Blood Sugars
- Need to take into account Menstrual Cycle

Specific Problems
- On Full Report, if you skip Lunch data, then it will show previous days lunch measurements.
Patient Feedback for PDA's in Diabetes Management
Participant Interviews, August 1999

Participant 110 - Age 5
Previous Method: Faxes data

Who enters the data?
- High volume of data entry: Blood Sugars 6 times a day, two snacks
- Grandmother takes glucose during the day. Mother records data all at once at night by reading off the memory of the glucometer (which has no date or time)
- Data entry at night time (10pm) takes a long time (15 - 20mins) because the time has to be entered backwards (i.e. entering 7:30am time starting at default of 10pm)
- Does not enter data when middle of the night glucose level is taken because some concentration is required. Measurement is written down in the morning from the memory. LogPad does not allow entry of retrospective information from previous day.

How easily is it to enter information?
- Fairly easy to enter information

How easy is it to read the information displayed on the screen?
- Easier to read in the night than in the day

Does it take more time or less time than keeping a paper diary?
- Currently takes much more time than entering data into paper diary.

What do you like about the device?
- Entered data and downloaded data even from the cottage.
- Straight forward, when child gets older (7 or 8) he could probably do it himself
- Like the idea behind the system

What don’t you like about the device?
- Time of Entry
- Hard to enter retrospective data, can’t enter yesterday’s information

Specific Problems
- Viewing Data screens showed “Others” in wrong order. i.e. Snack at 2:30pm, Dinner at 6:00pm, then Snack at 8:00pm potentially showed up in wrong order. (no time as a reference)
- Simple Sugar entries are usually 15 or 25, which is not accommodated by the 10 gram increments
- With “No symptom”, still required to enter severity for “Next” to show up.
- Occasional modem errors which are fixed by reseating modem with Palm.
Participant 111 – Age 13

Previous Method: Dictates over phone (Best Centre insists on getting all data)

Who enters the data?
• Child and Mother together

Does the child carry the device everywhere with them?
• Carries it everywhere
• Measurements entered mostly at the time of measurement
• Sometimes at the end of the day

How easily is it to enter information?
• At first it was confusing, now they are becoming more familiar

How easy is it to read the information displayed on the screen?
• No problems
• In the full report, to read breakfast readings, you have to skip

How do you like the format the glucose and insulin data is displayed in?
• Real problems, confusing
• Don’t like the way the Full report is in rows (Can’t look for pattern in a column)
• Can’t see the time of when the low or high happens (only the number of lows and highs). In paper, it can be written between measurements

How satisfied are you with the amount of time it takes to enter data?
• Fast if you do it right away
• Takes longer if you are entering a high blood sugar because you have to start from zero

Does it take more time or less time than keeping a paper diary?
• Pen and paper is faster
• Have to go to an other screen to see the data

What don’t you like about the device
• Can’t correct the value after Done is pressed (Would like to be able to edit)
• Not reviewing data with the device. all they are really doing is entering data and sending it – Child
• Screen to small – would sacrifice small screen to be able to see more - Child

What would you like to see on the device?
• Comments section “i.e. swimming”
• Spot for HbA1c – Child

Is it better than paper?
• “Do I ever love my pen and paper”, “Frustrated with device” – Mother

Specific Problems
• LogPad enters yesterday’s data into the current data, and once the data is entered for each meal, that meal overwrites
• Modem errors: after a few retries it goes through
  • Error: Modem
  • Command Error: Check Modem Properties
    • Failure Reason: 4357
• Grams should go by 5’s
• Lengths of times should go by 5’s
Participant 112 – Age 11

Previous Method: Not sending data
- Records own data

From speaking with her mother
- Not into gadgets
- Parents have to tell her to use it.
- Doesn’t like entering data because she does it all at once
- Parents are trying to get her to enter data at the time of test

Who enters the data?
- Child herself

Does the child carry the device everywhere with them?
- Didn’t bring the device to camp with her for fear of losing it
- Parents fear of losing the device at school

How easily is it to enter information?
- Pretty easy, only a couple of minutes to enter

How easy is it to read the information displayed on the screen?
- Child says it is pretty easy
- Says her father is having harder time to see it due to contrast

How do you like the format the glucose and insulin data is displayed in?
- Use the book instead because on the LogPad you have to go to different screens

How satisfied are you with the amount of time it takes to enter data?

Does it take more time or less time than keeping a paper diary?
- Takes a bit longer than paper diary

What do you like about the device?
- Like high blood sugar episode screens better than writing notes.

What don’t you like about the device
- Retrospective data entry

What would you like to see on the device?
- Best Centre phone numbers
- Games

Is it better than paper?
- Would like to use it instead of paper

Specific Problems
- High Blood Sugar Episode – allows only one choice of reaction to high blood sugar
- Modem Error – often autodials and then it works.
  - 9 times out of 10 it doesn’t work the first time
Appendix H – Statistical Significance Tests

1. Statistical Significance Test 148
2. Reference Method 149

Statistical Significance: Testing for a difference in mean between two samples

The Null Hypothesis states that there are no effects. That is, if the experiment was conducted with an infinite number of subjects, the average difference in number of days of data between the PDA/Web solution and the current means would be zero.

The Alternative hypothesis is that if the experiment were conducted with an infinite number of subjects, there would be an average difference in number of days of data.

**PDA/Web - Best Centre**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Best Centre</th>
<th>PDA/Web</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>101</td>
<td>26</td>
<td>35</td>
<td>-9</td>
</tr>
<tr>
<td>104</td>
<td>0</td>
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<tr>
<td>105</td>
<td>0</td>
<td>32</td>
<td>-32</td>
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<tr>
<td>107</td>
<td>0</td>
<td>43</td>
<td>-43</td>
</tr>
<tr>
<td>109</td>
<td>50</td>
<td>48</td>
<td>2</td>
</tr>
<tr>
<td>110</td>
<td>10</td>
<td>34</td>
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<tr>
<td>111</td>
<td>16</td>
<td>39</td>
<td>-23</td>
</tr>
<tr>
<td>112</td>
<td>0</td>
<td>34</td>
<td>-34</td>
</tr>
<tr>
<td>Mean</td>
<td>12.8</td>
<td>39.1</td>
<td>-26.4</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>17.85</td>
<td>6.47</td>
<td>16.72</td>
</tr>
</tbody>
</table>

| Standard Error | 5.91 | Standard Deviation / Sqrt(N) |
| t(observed)    | 4.46 | Mean / Standard Error |
| degrees of freedom | 7 | N-1 |
| t(critical)    | 2.365 | from T-Distribution Table, the critical value of $t$ using 7 degrees of freedom, a two-tailed test, and the 0.05 level of significance |

**Result of Test (PDA/Web - Best Centre)**

Since the observed value of $t$ (observed) = 4.46 is greater than the critical value (2.365), the model under the Null Hypothesis is rejected and the Alternate hypothesis is accepted. The mean difference is significant with 95% confidence.

![t-distribution](image)

**PDA/Web - Paper Diary**

<table>
<thead>
<tr>
<th>Patient</th>
<th>Paper Diary</th>
<th>PDA/Web</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
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<td>50</td>
<td>35</td>
<td>15</td>
</tr>
<tr>
<td>104</td>
<td>50</td>
<td>48</td>
<td>2</td>
</tr>
<tr>
<td>105</td>
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<td>32</td>
<td>18</td>
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<td>107</td>
<td>50</td>
<td>43</td>
<td>7</td>
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<td>11</td>
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<td>112</td>
<td>50</td>
<td>34</td>
<td>18</td>
</tr>
<tr>
<td>Mean</td>
<td>45.0</td>
<td>39.1</td>
<td>5.9</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>14.14</td>
<td>6.47</td>
<td>13.54</td>
</tr>
</tbody>
</table>

| Standard Error | 4.79 | Standard Deviation / Sqrt(N) |
| t(observed)    | 1.23 | Mean / Standard Error |
| degrees of freedom | 7 | N-1 |
| t(critical)    | 2.365 | from T-Distribution Table, the critical value of $t$ using 7 degrees of freedom, a two-tailed test, and the 0.05 level of significance |

**Result of Test (PDA/Web - Paper Diary)**

Since the observed value of $t$ (observed) = 1.23 is less than the critical value (2.365), the model under the Null Hypothesis is accepted and the Alternate Hypothesis is rejected. The mean difference is not significant with 95% confidence level.

**Resources**
ANALYSIS OF CROSSED DESIGNS

CROSSED DESIGNS

As discussed earlier, a crossed design occurs when each subject sees each treatment level, that is, when there is more than one score per subject. The purpose of the analysis is to determine if the effects of the treatment are real or greater than expected by chance alone.

EXAMPLE DESIGN

An experimenter is interested in the difference of finger-tapping speed by the right and left hands. She believes that if a difference is found, it will confirm a theory about hemispheric differences (left vs. right) in the brain.

A sample of thirteen subjects (N=13) is taken from a population of adults. Six subjects tap for fifteen seconds with their right-hand ring finger. Seven subjects tapped with their left hand. After the number of taps have been recorded, the subjects tap again, but with the opposite hand. Thus each subject taps with both the right hand and the left hand. They appeared in each level of the treatment condition.

RAW SCORES

After the data is collected, it is usually arranged in a table like the following:

<table>
<thead>
<tr>
<th>Subject</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Hand</td>
<td>63</td>
<td>68</td>
<td>49</td>
<td>51</td>
<td>54</td>
<td>32</td>
<td>43</td>
<td>48</td>
<td>55</td>
<td>50</td>
<td>62</td>
<td>38</td>
<td>41</td>
</tr>
<tr>
<td>Left Hand</td>
<td>65</td>
<td>63</td>
<td>42</td>
<td>31</td>
<td>57</td>
<td>33</td>
<td>38</td>
<td>37</td>
<td>49</td>
<td>51</td>
<td>48</td>
<td>42</td>
<td>37</td>
</tr>
</tbody>
</table>

Note that the two scores for each subject are written in the same column.

STEP ONE - FIND THE DIFFERENCE SCORES

In analysis of crossed designs, first calculate the difference scores for each subject. These scores become the basic unit of analysis. For example, finding difference scores from the
data presented above would result in the following table:

<table>
<thead>
<tr>
<th>Subject</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
<th>11</th>
<th>12</th>
<th>13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Hand</td>
<td>63</td>
<td>68</td>
<td>49</td>
<td>51</td>
<td>54</td>
<td>32</td>
<td>43</td>
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<tr>
<td>Left Hand</td>
<td>65</td>
<td>63</td>
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<td>37</td>
</tr>
<tr>
<td>Difference</td>
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<td>5</td>
<td>7</td>
<td>20</td>
<td>-3</td>
<td>-1</td>
<td>5</td>
<td>11</td>
<td>6</td>
<td>-1</td>
<td>14</td>
<td>-4</td>
<td>4</td>
</tr>
</tbody>
</table>

The difference scores will be symbolized by \( D_i \) to differentiate them from raw scores, symbolized by \( X_i \).

**STEP TWO - FIND THE MEAN AND STANDARD DEVIATION OF \( D_i \)**

The next step is to enter the difference scores into the calculator and calculate the mean and standard deviation. For example, the mean and standard deviation of the difference scores presented above are:

Difference

\[-2\] \[5\] \[7\] \[20\] \[-3\] \[-1\] \[5\] \[11\] \[6\] \[-1\] \[14\] \[-4\] \[4\]

Mean = \( \bar{D} = 4.69 \)

Standard Deviation = \( s_D = 7.146 \)

The mean and standard deviation of the difference scores will be represented by \( \bar{D} \) and \( s_D \) respectively.

**THE MODEL UNDER THE NULL HYPOTHESIS**

The Null Hypothesis states that there are no effects. That is, if the experiment was conducted with an infinite number of subjects, the average difference between the right and left hand would be zero (\( \mu_D = 0 \)).

If the experiment using thirteen subjects was repeated an infinite number of times assuming the Null Hypothesis was true, then a model could be created of the means of these experiments. This model would be the sampling distribution of the mean difference scores. The central limit theorem states that the sampling distribution of the mean would have a mean equal to the mean of the population model. In this case the mean would equal 0.0, and
a standard error represented by $\sigma_D$. The standard error could be computed by the following formula.

$$\sigma_D = \frac{s_D}{\sqrt{N}}$$

The only difficulty in this case is that the standard deviation of the population model, $\sigma_D$, is not known.

The standard deviation of the population model can be estimated, however, using the sample standard deviation, $S_D$. This estimation adds error to the procedure and requires the use of the t-distribution rather than the normal curve. The t-distribution will be discussed in greater detail in a later chapter.

**STEP THREE - ESTIMATE THE STANDARD ERROR**

The standard error of the mean difference score, $\sigma_D$, is estimated by $s_D$, which is calculated by the following formula:

$$s_D = \frac{s_D}{\sqrt{N}}$$

Using this formula on the example data yields:

$$s_D = \frac{s_D}{\sqrt{N}} = \frac{7.146}{\sqrt{3}} = 1.982$$

**STEP FOUR - CALCULATE $t_{OBS}$**

The obtained mean difference is transformed into a z-score relative to the model under the Null Hypothesis using the following formula:

$$t_{obs} = \frac{\bar{D}}{s_D}$$

In the example data the preceding equation produces the following:

$$t_{obs} = \frac{\bar{D}}{s_D} = \frac{4.69}{1.982} = 2.366$$
STEP FIVE - FIND $t_{\text{CRIT}}$

The critical value for $t_{\text{H0}}$, called $t_{\text{CRIT}}$, is found in the t tables. The degrees of freedom must first be calculated using the following formula:

$$df = N - 1$$

In this case, it results in the following:

$$df = N - 1 = 13 - 1 = 12$$

Finding the critical value of $t$ using 12 degrees of freedom, a two-tailed test, and the .05 level of significance yields:

$$t_{\text{crit}} = \pm 2.179$$

Since the observed value of $t_{\text{obs}} = 2.366$ is greater than the critical value (2.179), the model under the Null Hypothesis is rejected and the hypothesis of real effects accepted. The mean difference is significant. In this case the conclusion would be made that the right hand taps faster than the left hand. This is because the mean difference is greater than zero, meaning that the top number is larger.

USING SPSS TO COMPUTE A CROSSED T-TEST

The data is entered into an SPSS data file with each subject as a row and the two variables for each subject as a column. In the example data, there would be thirteen rows and two columns, one each for the right and left hand data. The data file appears as follows: