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Telecommunications and Diabetes

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by

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Abstract:

This project investigates the impact of telecommunications and computer technology on diabetes care and management. HumaLink is an experimental medical device confronted with the normal considerations impeding widespread use, including cost analysis and patient and doctor opinions or confidence levels. Using published literature, consultations with experienced professionals, and feedback gathered from patient surveys, recommendations based on the current status will be constructed to improve on the acceptance of the system.

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1.0 Introduction

Since the first cases of diabetes were diagnosed, continuous improvements in the level of care available to patients have been sought. Research into the behavior of the disease and methods of control, including the Diabetic Complications and Control Trial (DCCT)[6] study, have provided the direction for future research and necessary medical improvements. Currently patients have at their disposal a range of testing and treatment options, from blood glucose (BG) test strips and prescribed insulin syringes, to surgically installed insulin pumps, to help maintain the normal baseline BG levels. Relatively standard methods to monitor BG at home have been established, allowing patients with some experience to self-treat the disease and therefore prevent the associated complications. Reactionary treatment measures for high or low BG levels are established and commonplace but are not always reliable.

The role of prevention has become increasingly important. Frequent BG monitoring, up to seven times each day, has been shown to greatly reduce the risks of severe complications resulting from deviant or abnormal concentrations. Increased monitoring produces greater amounts of data for each patient, all of which should be stored in medical files and reviewed by doctors for trends and opportunities for treatment modifications. Adjusting the treatments will ultimately result in higher quality of life (QOL) for each patient.

The onset of the information age has begun to ease the burden of data handling for the medical community. Computers manage and store files rapidly and with greater ease compared to traditional methods. Still, the number of patients far out-weighs the number of qualified medical professionals in the field who can provide specialized care. Inexpensive and reliable ways to improve the patient's everyday life and assist the doctors providing those improvements are being explored. The HumaLink system, developed by Dr. Albisser, is a solution to issues regarding data processing, doctor to patient ratios, lack in pro-active forms of care, and cost concerns facing the diabetic community. HumaLink is a mini-computer system that both collects/files data from patients and interacts with them to suggest accurate doses of medication based on personal history.

Three distinct groups of individuals contribute to understanding these complicated issues: patients, physicians, and insurance providers. All new medical devices must satisfy these three groups in addition to passing Food and Drug Association (FDA) testing before such technology becomes widely used. Skepticism and lack of confidence with new devices on the part of just one group can easily halt the progress towards establishment. Each group considers the associated risks differently; they have unique concerns surrounding the same overall goal of improved QOL at a low cost.

Patients may not initially trust the device to operate consistently and safely, a concern that may be overcome by the confidence of the medical community. The physician may not be sure of how to incorporate the device into an existing practice and cannot determine whether the change is going to be worthwhile for both he/she and his/her patients. Both groups rely on insurance providers for assistance in financing the new treatment offered by the device. The insurance companies may be unwilling to risk the investment for any number of reasons, including the fact that the device is not yet in general practice and that long-term results are not yet available. They may not realize that the initial investment to assist in establishing the care provided by the device might be cost effective. The savings are the direct result of consistent avoidance of major side effects associated with diabetes mellitus. Each side must be persuaded simultaneously since each step toward acceptance in one group relies on the level of acceptance in the other two. Another factor to address is the setting and scale on which to implement the device to gain the best results. The effects of using the device may be projected and might look promising but cannot be proven, leaving only optimistic predictions plus the task of justifying the risks to each group.

A closer look into each area of individual concern is required before any recommendations can be made. This research included: 1) querying the three groups (patients, doctors, and insurance providers) to uncover the primary concerns and 2) making recommendations based on the current observed status and on feedback received from a complex and dynamic healthcare system.

2.0 Background

The research conducted on this project included learning the pathology and effects of diabetes, the causes and the risk factors behind both late-onset and juvenile diabetes, and the physiological differences causing the behaviors of each particular type. With an understanding of the disease, the next step involved exposure to HumaLink, thereby reaching a level of familiarity with it and the impact of its operation and applications in the diabetic community. Further research was conducted to access established studies that formed the foundation for the evolution of devices like HumaLink as the need for increased levels of care was noticed.

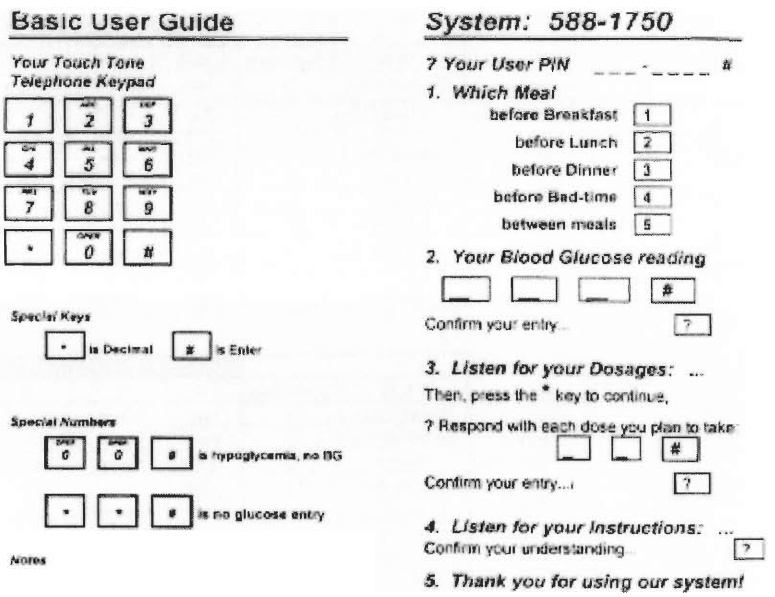
2.1 Overview of the HumaLink System

One of the main focuses of HumaLink and other diabetes management programs, is to motivate the patient to take an active role in controlling and managing his or her disease. Education must be provided to patients so their understanding of the disease improves the effectiveness of self-treatment and management. It is the premise of HumaLink that knowledge of self-management techniques and the increasing availability of technology should lower the frequency of long-term complications due to diabetes.

Patient self-management begins by accessing HumaLink via a touch-tone telephone. Patients dial the phone number for the system, which connects them directly to a computer utilizing interactive voice software. The computer prompts the patient to enter his or her personal identification number (PIN), typically the patient's home phone number, allowing access to the patient's personal information files for data collections and algorithmic extrapolation based on newly entered data points.

The patient receives a verbal prompt to enter information such as the number that corresponds to their next meal (Figure 2.1: 1 for breakfast, 2 for lunch, etc). The patient continues by entering his or her present blood glucose level. As a safety function, the computer echoes all data entries made allowing for the patient's verification and providing an opportunity for possible corrections. The newly collected data is combined with the blood glucose and insulin history, and the appropriate insulin dosage is calculated. The computer then relays verbal instructions for the exact insulin dosage. Finally, the patient is prompted to confirm the recommended medication.

Figure 2.1 – Basic User Guide for the HumaLink system



In addition to the basic interactions HumaLink is capable of handling, patients have the option to utilize special features. These features offered to the patient go beyond receiving and processing health information and prescribing recommended medication dosages. These special features take management of the disease to a more personal level accounting for an increased number of details and allowing even greater control. Patients can enter pertinent information concerning their lifestyle including recent or planned

physical activities or specify conditions such as noticed signs of hypoglycemia. Patients can also communicate changes in their diet, or detail any additional medications, which could affect the computer's recommendation.

The instructions for the special features are given in the Advanced User's Guide (Figure 2.2). The patient enters additional data and explanations using a series of number and asterisk entries. For example, a patient wishing to enter a blood glucose level of 52 mg per deciliter due to less food and more activity would use the keystrokes: 52**11**23. The sections starting with the asterisks are details related to the first value. Shown below is a sample of some of the commands available to the patient.

(a)

		suffix codes		
Factor	prefix code	1	2	3
Hypoglycemia	**0_	mild	typical	strong
Carbohydrates	**1_	less	typical	more
Activity	**2_	less	typical	more
Stress, etc	**3_	less	usual	more
Fever	**4_	mild	moderate	high
Monthly	**5_	less	usual	more
Steroids	**6_	less	same	more
Appetite	**7_	less	usual	more
Nausea	**8_	mild	moderate	vomiting
Ketones	**9_	trace	moderate	large

(b)

		suffix codes		
Factor	prefix code	1	2	3
Hypoglycemia	**0_	mild	typical	strong
Carbohydrates	**1_	less	typica	more
Activity	**2_	less	typica	more
Stress, etc	**3_	less	usual	more
Fever	**4_	mild	moderate	high
Monthly	**5_	less	usual	more
Steroids	**6_	less	same	more
Medication	**7_	enter the supplemental dose		
Nausea	**8_	mild	moderate	vomiting
Ketones	**9_	trace	moderate	large

Figure 2.2 – Advanced User Guide for the HumaLink system

These advanced features allow the patient to take a more active role in their own treatment and self-management. A patient also has the ability to alter a computer recommended dosage of ten units to fifteen units anticipating a larger then expected meal. To do so, the patient would confirm the recommendation as 15**13# instead of simply entering 10#. Patients can override the computer based on their own experience with the disease and the system will take the new value into account.

Professional intervention is arguably the most essential part of HumaLink, accomplished by incorporating input from medical personnel on a regular basis. This step takes physician time and should be compensated for in some manner. Patients in the same region are grouped together under the supervision of a case manager who oversees

their interactions with HumaLink. Reports of individual patient activity are generated weekly and monthly for each registered patient, depending on the frequency of interactions. HumaLink's reports for each patient contain the data entered, any special feature messages, and the dosage prescribed by the system during each interaction. Any abnormal data entries or crisis values that indicate dangerous situations including incidents of hypoglycemia or hyperglycemia are flagged for immediate professional review.

Physicians review the reports of patient activity and communicate with their patients via HumaLink by leaving voice-mail messages recommending possible changes in medication or activity, or if necessary suggest scheduling an appointment. The patient is notified of any messages the next time they access the system and can listen to them at any time during the call.

2.2 The Diabetes Complications and Control Trial

For years, diabetics and health professionals have attempted to create a standard, effective, diabetes patient management policy. Until the publication of the Diabetes Complications and Control Trial (DCCT), patients and physicians were unaware of the full potential benefits resulting from strict control of the disease using proper management techniques. The DCCT was a four-phase test sponsored by the National Institute of Diabetes, Digestive, and Kidney Diseases. The study attempted to determine the effects of two separate management plans on the progression of microvascular complications in subjects with insulin dependent diabetes mellitus (IDDM). Concurrently, a comparative study was conducted in the United Kingdom, the United Kingdom Prospective Diabetes Study (UKPDS).

Phases I through IV of the trial included the preparation and planning of a ten-year long study. By 1982, phase I had concluded and the first selection of patients with Type I diabetes took place; a total of 1441 IDDM patients were selected to participate in the study. A feasibility study was included in the first four phases limiting the patients who could participate. Applicants were first interviewed and judged on their ability to follow the hypothesized management regime because the study called on participants' willingness and a relatively high amount of skill and knowledge gained from experience.

For these reasons adolescents were not included in the feasibility study. The DCCT was not designed to test experimental therapy on the whole population, rather on a selected group of diabetics who were willing to make significant changes in their daily routine and lifestyle.

The DCCT study incorporated a control group and an experimental group, each with specific goals. The goal for the control group was general freedom from common diabetic symptoms whereas the experimental group focused on maintenance of baseline blood glucose concentrations. Control group therapy incorporated insulin injections twice daily and regular monitoring of blood glucose levels two to three times daily (Metabolic Control Matters, pg. 12). Experimental therapy embodied a definition of a range of specific glucose concentrations as a target.

Comprehensive education and training seminars were provided in both groups for individual patients and their immediate families. In addition to nutritional training, the experimental group participated in behavioral counseling to assist with lifestyle modifications that resulted from intense glucose monitoring, up to six times per day and multiple insulin injections. The experimental group delivered smaller, more frequent insulin dosages to adjust for day-to-day activities that would affect BG concentrations including expected caloric intake, exercise, emotional state, and various infections. In addition to increased blood glucose monitoring, the patient was expected to maintain closer contact with their health care professional on a weekly, or even daily, basis.

The DCCT relied on a number of different symptoms for measuring effectiveness. The existing knowledge of retinopathy, neuropathy, nephropathy, quality of life, patient safety, and risk for macrovascular disease were all taken into account. By counting the frequency of medical complications related to diabetes in each of the two groups, conclusions were drawn to define the required level of care for improved quality of life among patients.

Juvenile cataracts or retinopathy (Figure 2.3) is often a complication of diabetes and is due to a disruption of the lens structure and severe refractory error. The appearance of retinopathy is shown by the figure below.

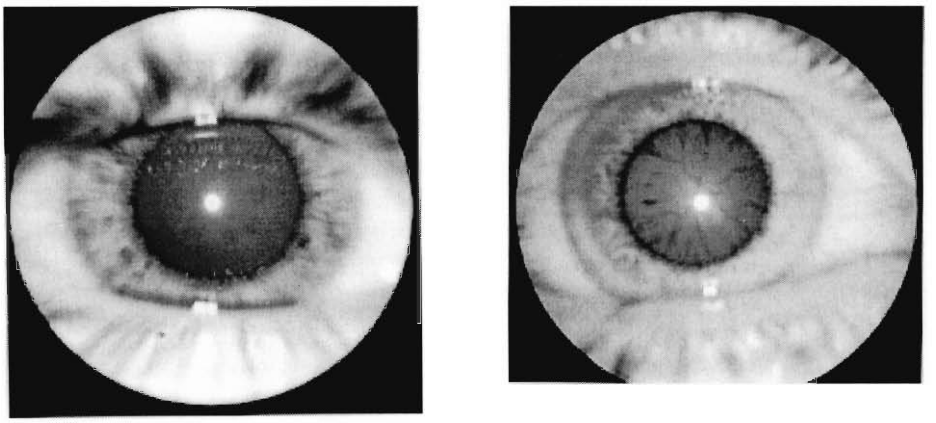


Figure 2.3 – Comparison of healthy eye (left) with an eye damaged from retinopathy (right)

Neuropathy is also a common problem for diabetics. Patients may suffer from diabetic foot (Figure 2.4) or even death as a result of nerve functions that are crippled by hyperglycemia.

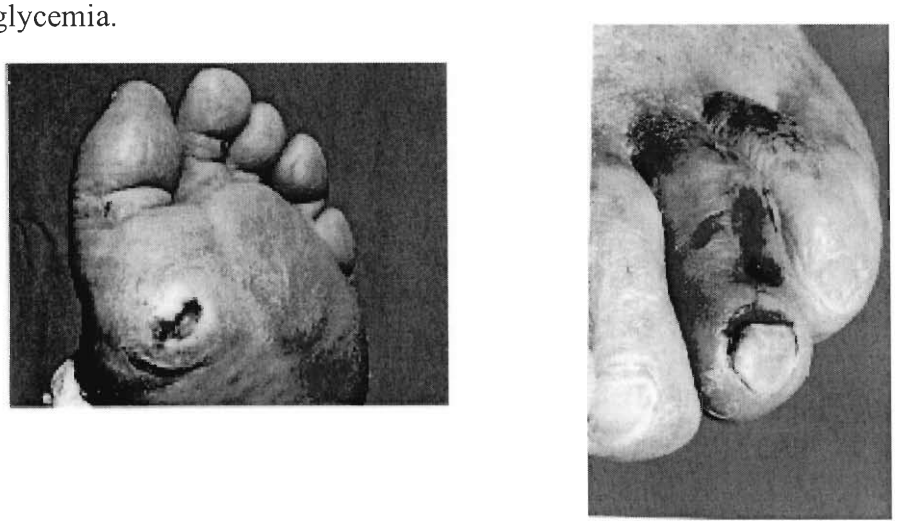


Figure 2.4 – Figure showing severe cases of diabetic foot. Damage is due mostly to loss of feeling and poor circulation.

Renal failure (not shown) is attributed to damaged blood vessels in the kidneys as a direct result of blood glucose imbalances associated with Type I diabetes, and is a serious health risk associated to diabetes.

Quality of life and psychiatric symptoms were monitored by surveys given to the patients and any cases of heart disease were recorded in both the control and experimental groups. A third party, Data, Safety, and Quality Review Group (DSQ), maintained results to ensure unbiased conclusion to the trial.

Testing was stopped by the DSQ in June of 1993, a year earlier than expected, due to conclusive data. The data for the tight control group showed a 76% decrease in retinopathy, a 60% decrease in neuropathy, and a 35-56% decrease in nephropathy, compared to the control group (Gatling, pg. 14).

Results favoring the experimental group provided a large set of conclusions. Improving the standards for diabetes management, including patient education, is reinforced by the results. The importance of metabolic control, demonstrated by the DCCT, was reflected by the improvements accomplished in the experimental group over those achieved in the control group. Second, health professionals, patients, and the general public should understand and appreciate the seriousness of diabetes and that optimal metabolic control prevents or delays the onset of secondary complications. In order that the positive results of the tight control in the experimental group are realized, patients are evaluated to assess their potential management capabilities and individualized regimens are designed to provide the greatest blood glucose control.

Results also showed the necessity for educated health care professionals trained to incorporate their knowledge and expertise into better patient self-management. Not only is it important that the doctors are trained, but patient education and counseling is fundamental to a healthier diabetic lifestyle.

The DCCT study recommendations will only be effective if national, multimedia, and public information campaigns are utilized to improve general public awareness of the DCCT results. Equally important from the DCCT study is the establishment of standards of care for both Type I and Type II diabetes.

The complexity of non-insulin dependent diabetes mellitus (NIDDM) leads to a pathogenesis that is less understood. Although never actually tested, it is argued that improving glycemic status in NIDDM leads to possible hyperinsulinemia, which in turn causes increasing cardiovascular risks. Possible NIDDM curricula may be increased education and counseling for changed lifestyles, exercise, and drug therapy. A heavier emphasis on nutritional management, negotiation of individual metabolic goals, and frequent contact with health care professionals, in addition to the DCCT recommendations, should be applied to Type II diabetics.

3.0 Methodology

The following section describes the methods we used to evaluate the situation surrounding HumaLink. In all cases we used the IQP handbook[9] for guidance and assistance in executing the research. We used different techniques to get the information we needed from each group.

3.1 Patients

In evaluating a medical device from the patient's view, care must be taken to properly gather the information to correctly evaluate the effectiveness of the device. A ready source of patient information and normally the most reliable source of direct feedback can be accessed using anonymous patient questionnaires. This questionnaire needs to be administered to all patients exposed to HumaLink regardless of the experimental group to which they belong. Sampling from all groups of the study is the best way to get useful information concerning the system as a whole.

Another source of data used to determine the effectiveness of HumaLink is utilized by comparing recorded medical data (blood glucose averages, frequency of complications, etc) prior to the start of the experiments to data collected following its completion. This medical data provides experimental differences and numerical values that are interpreted to quantify the overall effect of the device. This data identifies changes in the patient's medical health but does not indicate the level of confidence exhibited by the patient towards use of the device. It cannot serve to accurately predict the likelihood of continued patient interactions following the experiment regardless of the medical outcome. Two types of data must be collected from the patients to fully assess the success of HumaLink, medical improvements and psychological impressions.

The most useful and convenient measurement of relative good health is through the testing of glycolysated hemoglobin concentration (Hb_{A1C}) since values can be used as an indicator of changes in the medical status over the long term. Lower concentrations, expressed as a percentage, are directly related to better overall health; therefore a marked drop in percentage of Hb_{A1C} represents positive medical progress. All patients participating in the study should have an initial baseline Hb_{A1C} measured, to provide a

starting point for the data analysis. Measuring the concentrations at various intervals throughout the testing of the medical device is useful in providing transient data for continuous evaluation.

Data from the patient questionnaire combined with medical testing should be accumulated and evaluated to draw conclusions about the effectiveness of the medical device from a patient's point of view. Once again, it is important to draw conclusions from the group as a whole, as individual results may vary and are largely inconclusive.

3.2 Physicians

To better understand the role of the physician and possible applications of HumaLink as an aid to their efforts, research into the disease and the current methods of care was conducted. The next step involved requesting an interview with the developer of HumaLink, Dr. Michael Albisser. Dr. Albisser provided contacts and experienced insight unavailable elsewhere. The information he shared directed the research to a group of experienced doctors who assisted in the initial development and trials of HumaLink.

Using a telephone conference as suggested in the IQP Handbook[9], the interviewer composed a series of questions in a flexible format aimed at retrieving the required details from each doctor. It was important to maintain the flow of the questions and keep a focus on the overall direction of the discussion. A second project partner transcribed the conversation for later review.

Following up the preliminary conversations served to clear up any misconceptions or misunderstandings communicated in the first conversation. Review of the transcribed conferences from each doctor provided the necessary insight to draw up a meaningful set of recommendations to address the concerns about HumaLink from the doctors' point of view.

3.3 Insurance Providers

The costs associated with HumaLink cause many patients' inability or unwillingness to pay the additional fees inherent in using it. Insurance coverage is sought to alleviate the expenses of medical treatments. Before any insurance company will pay

the physicians' fees accumulated by the patient from interactions with the device, they must establish a policy allowing them to provide coverage.

Methods similar to those used to research the doctor's point of view were used to contact insurance companies. Through telephone conferences information and details were sought concerning the process of policy creation and adaptation. By increasing the understanding of how an insurance company makes its decisions and what types of criteria are used to determine coverage options, suggestions for modifications to HumaLink intended to suit the identified requirements could be applied.

The insurance company was provided a brief description of HumaLink and a few important details about the history of its applications. Advantages of use for the diabetic patient, including tighter glycemic control and lower frequency of long term debilitating effects resulting from diabetes, were mentioned and discussed. After the brief description, the insurance company was queried to determine whether or not they presently offered any coverage for telemedicine technologies.

The representative was then questioned to determine the methods and decision-making processes that operate in the company. Data from private companies, federally funded programs like Medicare and Medicaid, and some state-funded counterparts were collected and compiled. Combination of the various responses provides improved insight into the issues that must be addressed concerning the third-party payers of medical expenses. Conclusions are based on the gathered insight and are designed to specifically address the concerns of the insurance companies so they will be more willing to provide coverage for widespread application of HumaLink.

4.0 Results and Discussion:

At the conclusion of the lengthy data-gathering phase, all the information collected was organized and interpreted to provide a set of results. The condition of the results varied from group to group depending on the facility of the collection technique and various other issues like patient confidentiality, company policy disclosure regulations, etc. It was more challenging to get feedback from the patients and insurance companies compared to the doctors. Relying on surveys conducted in the past to collect most of the data from the patients, and the general unwillingness of insurance companies to offer insight provided much of the resistance noticed in this phase.

4.1 Patients

At the start of the HumaLink study in Worcester, Massachusetts, 17 patients were randomly divided into three groups. Group (A), consisting of 5 patients, was given test strips for blood glucose testing free of charge, and were left to treat their diabetes as they saw fit. The second group (B), consisting of 7 people, was given the same glucose strips as group (A), but in addition was provided with education on the proper treatment of diabetes, and was shown techniques of lowering blood glucose levels effectively on their own. The third group (C), made up of 5 patients, was provided with the test strips, the education sessions, as well as access and training on HumaLink. Patients were provided with instructions on the use of the system, given a personal identification number, and allowed access to HumaLink as needed.

Patients in all groups underwent a medical evaluation prior to the start of the study to provide an initial assessment of their current medical conditions related to diabetes. Specifically, their Hb_{A1C} was measured and recorded in their medical files for comparisons later in the study. As the study continued, the same medical evaluation was conducted to determine any change in their medical condition. Their final Hb_{A1C} and overall health condition was compared to that at the inception of the study.

In a previously conducted study (Bisette, 1999) there was an improvement of 0.75% in the Hb_{A1c} levels at the three-month mark compared to the patients' initial values at the beginning of the study which can be seen in Figure 4.1.

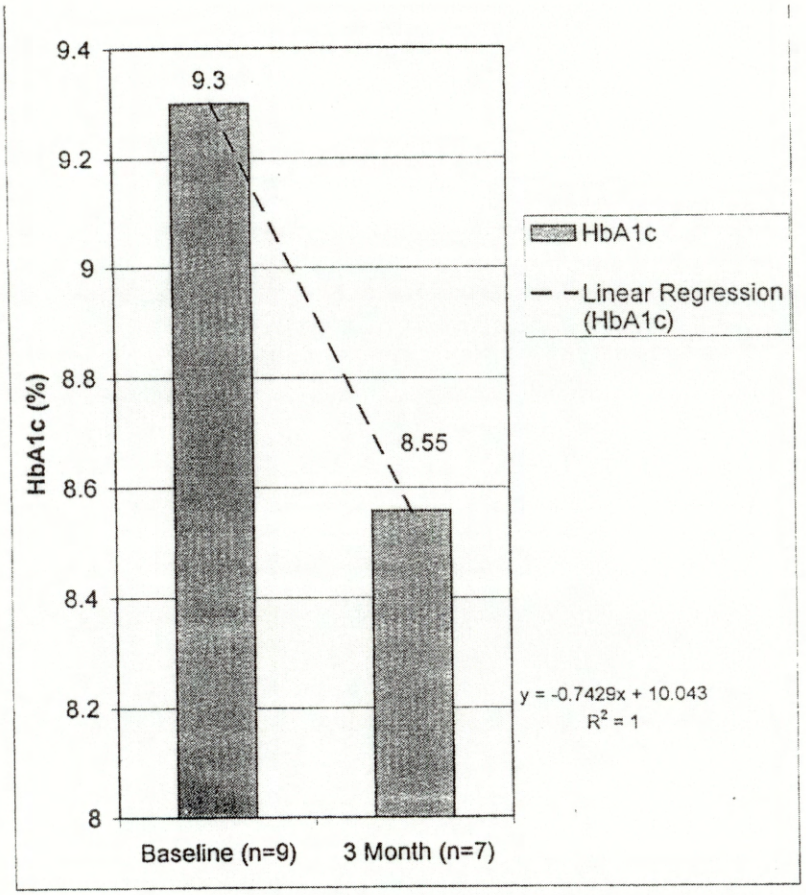


Figure 4.1 – Chart of average HbA1c levels at start of study (left) compared with average levels three months later (right)

Patients from group (A) and group (B) were asked to record their blood glucose levels for at least three consecutive days per week. These glucose readings were recorded by the patients themselves, and mailed into the doctors' office. The readings from group C went directly to the doctor's office via HumaLink. Weekly and monthly reports were compiled on a per-patient basis, for evaluation by health professionals.

Identical anonymous surveys were distributed to all study patients (Appendix H). The surveys asked the patients to rate their overall health and inquired about possible degradation in physical abilities or pain and discomfort associated with their diabetes. The questions were posed to determine if the patients were noticing any improvement in their diabetes and their quality of life in general.

Not all the patients assigned to each group completed and returned the survey to the doctor's office, making accurate analysis of their condition and perceptions difficult.

Limited conclusions can be drawn from this small patient response group. Patients' responses were entered into a spreadsheet to compile the feedback data and draw conclusions (Appendix I).

The patients from group (C) seem to trust HumaLink and its accuracy due to their improved understanding and its help in managing diabetes. No group of patients experienced a decline in the level of health over the course of the study. The most improvement in medical condition and the best results concerning patient satisfaction were noted in the group that had access to HumaLink. These results show extra attention and care provided concerning the patient's disease, purely through management education or by direct involvement with HumaLink helps to improve the patient's medical condition.

4.2 Physicians

Physicians and diabetologists, those specializing in the treatment of diabetes, represent another major portion of the diabetic community that will potentially be impacted by HumaLink. The system is designed for establishment on location with medical professionals to assist in the collection and recording of data in the form of patients' daily blood glucose self-measurements. Doctors can provide the essential medical input to oversee the efficient operation and application of HumaLink to the greatest benefit to the patients in their care. It is important to discover why doctors would be reluctant to endorse HumaLink and to gather their feedback on the system to make any required improvements. By addressing the issues from the doctors' point of view, HumaLink will come one step closer to widespread acceptance in the diabetes care community. Support from the medical sector is essential to promote the system from the patient's standpoint by increasing their level of trust.

Recognizing the concerns of the medical professional who will ultimately provide HumaLink for his or her patients as a hurdle for the system, feedback from practitioners in a variety of medical care settings was collected. These settings include a hospital or outpatient clinic (Case 1), and a managed care HMO (Case 2). In both cases the physician feedback was collected during a telephone interview in a series of separate calls, as well as a follow up conversation.

Case 1

The physician in case 1 is a specialist in the field of endocrinology and diabetes care, employed by a Health Management Organization (HMO). Since the release of the Diabetes Complications and Control Trial (DCCT), patients exhibited an increase in concern over their blood glucose concentrations. As a direct result, the frequency of phone calls to the doctor's office to report self-test values measured at home increased. This increased frequency of phone calls, mainly concerning the care of diabetic patients influenced the physician to seek an alternative method of handling the data flow. The doctor discovered HumaLink (then called Teledoc) through the introduction of a continuing education course in computer applications for diabetes management offered by HumaLink's developer.

Doctor 1 maintained contact with the developer ultimately leading to the doctor's introduction to HumaLink. The design of the machine appeared tailored to address the current issues in data handling and doctor/patient interactions. Doctor 1 recalls viewing HumaLink as "a salvation" because the automatic data collection capability facilitated tracking blood glucose concentrations of each patient. The first unit assisted monitoring 10 patients over six months, operated manually, and generated a considerable amount of work. Switching to automatic operation allowed a large increase in the number of patients (90) in the registry. Automatic operation is a mode built into the device in which the data is stored as usual but there is less frequent intervention on the part of the health care provider. The device only flags crisis situations for immediate consultation by the physician.

The senior leadership of the HMO resisted applying HumaLink as a standard practice. Despite the preliminary collected data, HumaLink was considered an experimental device, causing significant doubts in the generally conservative medical community. FDA approval would serve to alleviate these doubts and concerns bridging an essential gap towards general practice application. Currently the FDA has not approved HumaLink for general practice.

HumaLink and the concepts behind the development and creation provided the inspiration for an educational health care training and management method for diabetes: the G System (GS). Just as the purpose of HumaLink supports the implementation of the

DCCT recommendations, the GS continued the same reasoning but removed the computer aspect (HumaLink) by being willing to afford the costs of hiring additional staff to replace it with human counterparts. The US Diabetes Model was published as a discussion about the need for a foundation of care for diabetes. Using the US Diabetes Model for further impetus, physician 1 appealed to his senior leadership and introduced them to the idea for GS in 1995.

After receiving permission to implement the GS, and following the subsequent application of the principles therein, the development team received praise from the Hospital Association of Pennsylvania. The GS team won an award for Quality of Improvement generating a surge of interest from a number of health care plans for statewide establishment.

Early signs of success for GS included 55 clinics operating statewide caring for 4500 patients. The GS precipitated significant improvement in patient's quality of life recording an average Hemoglobin$_{A1C}$ (Hb_{A1C}) decrease from 8.9% to 7.5% (lower Hb_{A1C} has been directly related to improved general health and to decreasing the frequency of major medical complications due to diabetes) (Ref B). In addition, the GS produced an average blood pressure decrease of 35%, an average mean weight decrease of three pounds, and a 97% satisfaction rate.

An economic study conducted by the GS indicated that insurance companies saved a substantial amount of money after the application of the new policies. The results of the study were handled by the American Diabetes Association (ADA) and were unavailable for reproduction under the rules governing patient confidentiality.

Another factor that influenced the dramatic success of the GS included a nutritional education program for patients. Goal establishment and scheduling methods were created for the patients. Nurses use an algorithm that depends on measured blood pressure to establish targets for patients. These nurses form the backbone of the disease management in the primary care offices. A continuing medical education (CME) program was established at a state college and was essential to the success of the GS for both patients and clinicians. While not actively applied in the implementation of the GS, HumaLink has the potential to realize the same effects.

Physician 1 summarized the refusal to adopt HumaLink as an integral part of GS by indicating three sources. HumaLink's experimental status is the first of these; this status will continue to interfere with possible applications while it remains in that category. Possible application in organized medical care settings, especially primary care, are unknown and largely unexplored. Physician 1 indicated that in his experience, no drive for continued application of HumaLink in the current health care environment has been demonstrated. Twenty of the one-hundred and twenty active patients who were using the system during peak operation maintain regular interactions.

According to Physician 1, HumaLink appears very expensive, and the possible value it offers as a part of established health care offices (Diabetes Treatment Centers of America) or similar models using nurses and guidelines in addition to primary care has not been demonstrated. In fact, actual data detailing the economic ramifications of using HumaLink is unavailable to us. By making the patient registry a more compatible database and allowing network access will assist in integration of the system with current technology being used in the medical community. While HumaLink is an added resource for the 20 patients that continue to interactions, it is important to consider the populations of patients that would benefit the most from general application. Doctor 1 believes from his experience that patients with a relatively high Hb_{A1C}, exceeding 10 percent, will form the largest portion of potential users. Maintaining the number of patients and their level of involvement with the HumaLink over an extended time period has not been accomplished. Doctor 1 summarized by indicating that HumaLink has more potential as a data collector than an interactive device citing it is subject to inaccuracy in prescribing insulin doses due to its assumption of patient conformity to its strict regimes. Physician 1 believes over the long term, however, this type of device (HumaLink) will eventually be adopted, especially as technology becomes cheaper and additional research demonstrates proved value to overcome the doubts.

Case 2

The physician in Case 2 has extensive experience with HumaLink, having been one of the original evaluators. His experience is over a period of approximately three years. He has published an article in Diabetes Care detailing the initial results from using

the system. The article includes data collected and patient health results. The transcript of the telephone conference provided valuable insight on which to base our conclusions.

In 1993 and 1994 physician 2 saw patients two days a week. He was approached by the developer of HumaLink and asked to assist by operating the system on a trial basis in the interest of development and marketing. At the time, there were currently two groups of patients (Case 1) using the system in another region. Increased participation was required to fully research the potential impact of HumaLink and gather the data necessary for future marketing.

HumaLink, then Teledoc, underwent modifications allowing it to output insulin dose recommendations calculated from the data entered by the patients multiple times over the course of a single day. Previously the HumaLink used by Physician 2 functioned primarily as a data collector. An internal operating algorithm was activated in the software and adjusted to compensate for differences between individual patients' past BG level histories. The program allowed the system to calculate the amount of insulin required to maintain a baseline blood glucose concentration. This and other modifications sufficiently changed the operating behavior of HumaLink to warrant renaming, providing the current product name.

Physician 2 recommended patients use HumaLink during a regular visit on a case by case basis. Provided the patient was willing to try the system, a nurse administrator conducted a brief training and orientation session to acquaint the patient to the normal operating procedures, including establishing the patient's account and instructions on how and how often to efficiently communicate with the system.

Initially, use of HumaLink increased rapidly; the preliminary introduction to the patients caused immediate interest. The number of patients registered grew quickly and steadily. The patients in the registry contacted the system on a regular basis while they were under the care of Physician 2. Since the location in this case was a hospital, turnover of patients was large due to the temporary nature of the operational setting. The total usage of the system was relatively constant however, due to the continued departure of registered patients and the equally rapid influx of new patients. Some patients simply opted to leave the system after a short period of care. The data published in the article

was collected during this time period. In 1997 funding for the continuing research into HumaLink ceased and the project halted.

After the research grant terminated eliminating the source of funds paying for the costs associated with the system, insurance companies were approached. The policies for insurance companies stated they were only willing to cover the costs of Durable Medical Equipment (DME) supplies that were used *in* the home, for example test strips and insulin prescriptions. This policy does not apply to HumaLink, a telecommunications based device located in the doctor's office. They would not offer insurance coverage to pay for the system claiming the interface was not in the home. The insurance companies were unwilling to reimburse the doctor for interactions that were not face to face.

By citing a *prolonged encounter* situation with the doctor while using the system, some insurance companies were eventually persuaded to offer coverage for the system. The exception stipulated strict minimum time constraints regarding the length of time patients spent interfacing the system (i.e. in contact with the doctor) each month. Physician 2 recalled an unreasonable amount of difficulty involved in the billing process, undermining the success of attaining the coverage in the first place.

The issue of payment represents a major source of concern for Physician 2. Continued application of HumaLink in the hospital setting became an expensive risk from the doctor's point of view. Complications associated with receiving payment through an insurance company for a patient using HumaLink compared to the simple and well established payment scheme for a walk-in visit resulted in an overall decrease in the perceived potential efficiency. The time saved in the office by handling the incoming reports of patient blood glucose was out-weighed by the amount of time and effort required getting reimbursed for the service. The time and cost effectiveness of HumaLink was further questioned when Physician 2 considered the additional salary for the case manager or nurse administrator and the entirely unbillable time required to properly review the data summaries produced during normal operation.

The experience of operating HumaLink for a short time generated specific operational issues and effects, which Physician 2 cited while summarizing the pros and cons inherent with its application. Some of the topics mentioned are specific; others depend entirely upon the viewpoints possessed by each individual patient. The following

is a brief synopsis of the points touched upon in the course of the discussion. The mode of operation (data collection or true interaction) affected efficiency and the amount of variation in costs for patients, depending on whether they are Type I or Type II diabetics. In addition, it is difficult to determine if the considerable troubleshooting and the additional staff person are balanced by the quality of the records HumaLink produces.

The first variable defined was the doctor's decision to operate HumaLink either to simply collect data, or to activate the option allowing it to prescribe insulin doses. The decision is influenced by the number and type of patients registered on the system, a parameter subject to continual change in the dynamic health care environment. The larger the number of registered patients thee is the more need there is to operate in automatic mode, while some Type I patients may need more intervention than Type II patients, and so forth. Assuming the group of patients using HumaLink is constant provides the opportunity for a snapshot view of the pros and cons. The current steps HumaLink uses to prompt the patient are monotonous and must be repeated multiple times each day. These steps are intended to increase the safety of the interaction, accomplished with continuous verification steps inserted into the process. Eliminating the verification steps would speed up the data entry at the risk of increasing the likelihood of misunderstandings and incorrect data entries, detracting from the safety features built into the system. Using a single access connection at the end of a time period (a week) may provide the same service and increases the efficiency of the data collecting by eliminating multiple interactions throughout the duration. A single interface would reduce the probability of errors in the data entry but consequently undermines a key feature of HumaLink. The system would loose its ability to immediately react to crisis values input by patients. This feature depends on progressive data entry to allow highlighting of abnormal blood glucose concentrations to inform the doctor in a timely fashion.

Operating HumaLink in an interactive mode entirely eliminates the possibility of a single interface. Factors affecting this mode of operation include the type of diabetic using HumaLink, recognition of the amount of additional effort required to properly tune the algorithm for each patient, and assume that patients will be willing to conform to the dietary and testing regime upon which the algorithm is based. The option to operate

HumaLink in the manual (case manager input) or automatic (no case manager input) mode further complicates the situation.

The strict diet and exercise regime assumed by the system (and recommended by the DCCT) when it is applied to Type I diabetics, limited the amount of enthusiasm from those patients, and thereby its overall success. Type II diabetics, on the other hand, benefited appreciably from this feature. Experience and common sense dictates that not every patient (Type I or Type II) is willing to conform to the desired regimes.

Discrepancies in the level of cooperation cause the system to suggest doses that are incorrect, since it assumes the patient fully conforms to the regime. To compensate for the eventuality of inaccurate suggested insulin doses a case manager is assigned to closely monitor HumaLink's algorithm to maintain the level of required accuracy. The accuracy of dosage changes improves when HumaLink operates under manual control since the doctor or case manager manipulates the values directly with the machine serving as an intermediate. The continued accuracy achieved is unbalanced by the inefficiency inherent in that level of control. The doctor could easily contact the patient directly instead of through HumaLink. The prescription process is made more cumbersome by imposing a middleman between doctor and patient. The consequences are magnified since using HumaLink imposes difficulty in receiving payment for the same (or more) effort.

Overall the most benefit is derived from HumaLink when it is employed for Type II diabetics who possess a limited understanding of the disease. While increased education is desirable for improving the overall quality of life for each patient, it would eliminate a portion of the system's usefulness in Physician 2's estimation.

Patient costs associated with diabetes depend on how often the patient tests for blood glucose concentrations. Testing supplies were determined to be the most expensive part of maintaining the level of glycemic control recommended by the DCCT. These costs are represented by test strips and other required supplies, durable medical equipment normally covered by insurance companies. The amount of test strips used will increase with the frequency of testing required to provide data to HumaLink. It is potentially less expensive for a Type II diabetic since fewer tests are usually required to maintain glycemic control.

Expenses of concern for the doctor include the initial investment required to install HumaLink in the office, the addition of multiple telephone lines to provide for a number of simultaneous interactions by different patients, the payment of additional staff required for effective operation and maintenance, and the possibility of increased amounts of unbillable time spent reviewing reports produced.

The follow up conversation with Physician 2 explored new topics including other comparable systems, recommendations for improving the acceptance of HumaLink in the medical community, and returned to further discussion of payment issues.

Other comparable systems are available for interested patients. These alternatives are not considered more user friendly than HumaLink and are limited by the types of data handled by the software. Some programs accept data in the form of blood sugars and carbohydrate intake, similar to HumaLink, but predict a resultant value for the patient's blood glucose level, instead of recommending a course of action in the form of insulin dosage required to maintain a baseline blood glucose level. The software provides an idea of what happens to the concentrations of blood glucose following a meal or snack, or possibly some form of exercise but gives no feedback concerning medication or treatment. It serves only as an educational alternative and does not offer any treatment or explanation for its output. A further limitation of the program is it ignores background or historical factors in the patient's past to assist in the accuracy of the output. This type of software could be useful in determining whether the patient should eat a given meal by producing a predicted post-prandial blood glucose concentration. The patient could adjust the meal or insulin dosage accordingly to stay within the desired ranges. The system is called AIDA and is offered by a British company over the Internet.

Another alternative is an educational/entertainment software package that focuses on Type I diabetics. Packy and Marlon offer this software citing education as an integral part of diabetes self-management. Inclusion of educational capability could greatly improve the HumaLink system from the patient's perspective; in this manner patient concerns are reflected in the doctor's concerns.

In summary, Physician 2 believes HumaLink would benefit from becoming integrated into general practice. The time intensive considerations are balanced by the increase in the control patients have over their blood glucose concentrations. Improved

control of the disease leads to better general health. Despite the negative requirement of more time (for patient and physician), HumaLink produces the positive benefits reported in the article published in Diabetes Care.

HumaLink needs to be properly and aggressively marketed to become a part of general practice. Commercializing with advertisements and brochures available in doctors' offices serves to passively disseminate information to a wide audience and increase the general level of interest in technological applications designed to assist persons with diabetes.

Establishing a universal payment method for HumaLink and the services provided by it represents another important step towards becoming general practice. The hurdles for HumaLink from the doctor's perspective originate in concerns about how the third party payers and insurance companies will handle billing and reimbursals. Insight into the working policy of insurance companies serves to clear up most of the doubts and concerns surrounding the payment issue. Determining whether they are interested in short term investments or in the long-term cost benefits of providing coverage will address the feasibility of approaching them successfully. Insurance companies are not familiar with the technology further supporting a need for continued spread of education. The lack of concrete factual analysis and prospective studies to address the economic burden of diabetes greatly inhibits the system. Clearly demonstrating the care provided by HumaLink as an improvement over the care currently provided is a pivotal step towards coverage and acceptance as general practice.

HumaLink keeps good quality medical records at the expense of increasing work time, increasing expenditure, and reducing ***billable*** hours for doctors. It requires a part-time case manager or technician to operate it correctly, considerable troubleshooting to maximize effectiveness, in addition to four or five unbillable hours to review the records produced to realize the potential benefits. Currently, HumaLink does not pay for itself and is not totally user-friendly for the physician or the patient.

Comparison

Other results from two additional medical care environments: the hospital based outpatient clinic, and the HMO closely resemble those discussed above. All of the queried sources evidenced similar concerns in regards to HumaLink.

Despite the promising improvements HumaLink can produce by urging patients to better health through intensive glycemic control, as prescribed by the DCCT, the inherent limitations make its application finite. HumaLink is subject to high attrition of registered patients for a variety of reasons: interface problems related to the Interactive Voice Response (IVR) and the operating system, and the lack of educational capabilities. Combined with concerns about additional labor and payment for the system, and the efficiency of application, a significant number of doubts contribute to the doctor's view of HumaLink.

The number of active registered patients using HumaLink is initially stimulated by interest in a new device, and willingness to test it compatibility from each individual patient. After a short time HumaLink is unable to continue to captivate the patients' interest. The numbers decrease dramatically making basic operation unfeasible. In these conditions it is unable to justify its expenses. This pattern could relate directly to the manner in which it is employed in the office or clinic or may also be the result of each patient's personal preference.

The doctor interface is not considered user-friendly, requiring continuous review of charts produced to make the correct algorithm adjustments ensuring the highest standard of care offered. HumaLink requires significant modification and installation adjustments at first followed by a regular number of manual mid-care modifications throughout operation. Each patient enrolled in the database has a personalized algorithm controlling HumaLink's output recommendations.

Marketing and advertisement are required if HumaLink has a future in general practice. This approach will offset the experimental status currently hindering progress by increasing the level of interest and leading to more research and further developments. Continued research is necessary to determine the specific population targets that can

extract the maximum benefits, and accurate quality of life data must be collected by careful survey of patients.

Provided HumaLink achieves general practice application, the likelihood of acquiring insurance coverage for the associated cost increases. Doctors are looking at HumaLink to become a service for which they can be reimbursed. Additional hours in review of medical records outside of appointments cannot be tracked or measured accurately placing them outside insurance company policies. HumaLink is not considered durable medical equipment/supplies negating possible coverage for the unit itself.

The efficiency of HumaLink is variable depending on its method of operation: data collection or interactive insulin prescription. Each mode was accounted as questionable in the best circumstances, highly dependent on the application environment. HumaLink requires a case manager to monitor its output and perform adjustments as needed. Extra staff needs training to be effective, further increasing expenses for the provider. A predictable decline in the number of patients using the system in all settings makes it difficult to determine if HumaLink will pay for itself in the long term.

The interconnectivity of the concerns and issues increase the difficulty and complexity overall. Fixing one problem may have both functional and dysfunctional effects throughout the community. A solution to the problems facing HumaLink is beyond the scope of doctors alone.

4.3 Insurance Providers

In the first series of telephone conversations to third party payers, an almost obvious response was made apparent, large insurance companies make decisions based primarily on financial implications.

A Cigna Healthsource employee was contacted and briefly introduced to HumaLink. She had not heard of the system and had no prior knowledge of the existence of any similar devices. She was familiar with telemedicine but was not aware of any devices currently covered under the policies of Cigna Healthsource. When queried about the coverage selection process, her response indicated her interpretation of the source of

the question was a vendor seeking coverage options. She responded by requesting financial statistics explaining that the decision of the company would be centered solely on the cost effectiveness of the new device. She specifically requested data for the rental cost of the unit, the increased number of blood glucose test strips, increased prescriptions, and other costs associated with using the unit for comparison to her own data detailing the average costs of supplies for a diabetic not using the system.

After researching this data, it was found that a physician named Dr. Sidorov in Florida, was the only person that had access to reliable financial data. Dr. Sidorov was contacted shortly thereafter and the financial data was requested. Since the data included patients' names and numerical data, Dr. Sidorov decided the reports were too confidential to be released; he was not able to help with the data that Cigna Healthsource requested. Cigna Healthsource was contacted a second time and the representative was informed that the type of data requested was currently unavailable.

Coverage selection process information was requested again and the representative explained that for this type of device, the financial data that was unavailable would be compared to the current insurance data, and a decision would be made on the basis of less costs incurred by the insurance company.

Surprisingly, the representative was not interested in the decrease in frequency of long-term health problems associated with the application of HumaLink. The advantages of HumaLink were described to the representative with stress placed on the high costs of paying for hospital stays directly related to serious medical complications resulting from poor glycemic control. The primary focus of the insurance company revolves around cutting costs. It appears that more emphasis is placed on short-term rather than long-term costs. Consideration of long-term advantages did not seem to come into play in the company's coverage plans.

To broaden the research a representative from Fallon Healthcare, a local HMO, was contacted. Noticeably more resistance was encountered from the representative employed by Fallon, severely limiting the progress of the interview and the further collection of data from this new source. The topic was introduced in the same manner as with the representative from Cigna, however, the Fallon representative was unwilling to divulge any information concerning the policies and decision making process of the

company. Specific inquiry based on the information about the policy of Cigna, a competing insurance company, did not elicit any further assistance. The Fallon representative was unwilling to comment on any factors or considerations that contribute to the determination of coverage policies in his company; he would not state whether the company focuses on cost analysis or overall patient health. Further inquiries about long-term and short-term goals for diabetic subscribers also remained unanswered at the conclusion of the interview.

The next sector in the insurance coverage was the Health Care Financing Administration (HCFA). HCFA is a subsidiary of Medicare, a federally funded healthcare program that pays certain medical expenses for the aged. Since a significant portion of the aged population of the United States has Non-Insulin Dependant Diabetes Mellitus (NIDDM), this was the most logical place to search for more detailed information. A possible connection between the coverage policies of federally funded organizations and private corporations prompted further research into this side of the issue. Perhaps a coercive force can be induced on private companies if the coverage is established in the federal arena.

The Medicare representative could not provide the detailed practices of the coverage selection process citing that the decision was made based on another outside influence. Medicare covers only those items related to healthcare that fall into a broad category defined as durable medical equipment (DME). Medicare regulates what products are covered under their policies, while DME suppliers establish the criteria for the product to be insured.

A durable medical equipment supplier was sought as the next step and was contacted in the same manner as the insurance companies. The representative was not familiar with HumaLink but agreed to answer questions concerning the coverage criteria. Despite authorizing coverage provided for materials used in the home of each patient including home glucose monitors and test strips, the representative explained that HumaLink, located in the physician's office, does not qualify as durable medical equipment. Furthermore, the DME representative indicated that it was unlikely they would make a policy exception for a particular device especially one still in testing

phases. The representative then offered to forward a copy of the written coverage policies of the DME supplier as a reference for the research.

The DMERC policies, dated 25 February 1999, state that a device must meet the following criteria to be considered for coverage as durable medical equipment:

1. The patient has diabetes, which is being treated by a physician.
2. The glucose monitor and related accessories and supplies have been ordered by physician who is treating the patient's diabetes.
3. The patient (or the patient's caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips, and lancets.
4. The patient (or the patient's caregiver) is capable of using the test results to assure the patient's appropriate glycemic control.
5. The device is designed for home use.

HumaLink does not meet all the criteria and is therefore denied coverage since it is not considered DME.

Finally, the representative at the DME supplier stated that for a medical device such as HumaLink to be approved for coverage in a federally funded program (Medicare or Medicaid), it should have the support and endorsement of a national organization such as the American Diabetes Association. Petitioning is required to effect changes in policy allowing HumaLink coverage or authority for coverage.

The last aspects of the research into insurance policies and coverage originated on the state level. A state-funded program, Serving Health Information of Elders (SHINE), was contacted in the same manner used in the other scenarios. After introduction to the basis of the project, the representative from SHINE was questioned about their particular coverage selection process. The agent responded by describing the purpose of his organization. SHINE is a medical counseling program for everyone (state residents) including the elderly. A person seeking insurance for a particular disability or medical need can contact SHINE and receive a recommendation concerning which insurance companies are likely to offer coverage plans desired by the patient. Asking the following question, "Which insurance company would be most likely to address the needs of a diabetic patient requesting who opted to take advantage of the benefits provided by

HumaLink," resulted in a reply stating there were currently no insurance carriers that would pay for the service.

After contacting other state programs including the Civil Rights Office, and the Massachusetts State Insurance Commission, we determined that it is the decision of each particular insurance company to create policies for medical coverage.

5.0 Conclusions and Recommendations

A single set of recommendations based on a definite list of conclusions directly derived from the data gathered through feedback is nearly impossible to compile due to the complex nature of the socio-medical system studied in this research. The human factors and perceptions involved are challenging to quantify and lead to generalizations that may, in some cases, not reflect the actual outcomes of the system. The human factors are what serve as measurements of overall acceptance and are influenced by a staggering number of conditions and perceptions. The major areas of concern for this research were to explore these human factors and evaluate the connections that should be utilized to improve perceptions of HumaLink. The most significant of these issues are centered on the cost of HumaLink and how associated costs will be addressed.

Goal

The goal of this paper is to make recommendations that are going to assist HumaLink towards greater acceptance. The changes are to be implemented both in the environment of intended application and to the device itself. Changes to the device will influence the socio-medical system, and changes in the system will affect the device. We are attempting to make HumaLink the normal standard of care.

Human Factors

To address the environment in which HumaLink is intended to be implemented the first step is to increase the level of general public awareness. Most diabetics are not aware of the outcome of major recent research on the affects and importance of glycemic control, as discussed in the DCCT. The more people, both patients and the general public, who are aware of the research and the technology which is being developed in reaction, the more likely it will be subject to critical attention. An increase in the amount of attention received by HumaLink is a step in the right direction towards advancements and improvements. If a larger number of people are aware of the existence of technological care options and the personal medical benefits thereof, that will provide the

impetus for involvement from major organizations like the American Diabetes Association (ADA) and other national organizations. This involvement is needed to assist in gathering the encompassing data about costs and Quality of Life (QOL) for comparison to the current standards of care.

Patients should be assisted by their physicians in becoming more familiar with the DCCT, what it means to them, and the technology that is available to assist them in complying to the recommendations in the DCCT.

Physicians should be encouraged to remain current and aware of the results of the DCCT and how the information can be used to benefit the entire population of patients. They also need to be aware of options available to them in the field of telemedicine and telecommunications that are specifically designed to address the issues inherent in realizing the recommendations contained in the DCCT.

Education: Diabetes and Technology

Providing clinical education to the patients in the form of seminars and patient resource groups will make them more aware and active in the glycemic control needs, especially those specifically provided for by HumaLink. Patients need to be offered education covering the results of the DCCT and the care options available through the use of telemedicine. Many patients do not know how technology can assist them in the self-management of their disease, so by introducing them to the technology they are made more effective in controlling the disease and preventing complications.

Physicians should be encouraged to explore the applications of telemedicine in the care of their patients. They should be offered professional academic courses geared to inform them of the latest advances in technology so they can better care for their patients and handle the immense amount of data associated with tracking this type of disease. Physicians should be educated on the results of the DCCT and what it means for their patients, and how telecommunication applications can be applied to self-management of diabetes.

Marketing HumaLink to both doctors and patients implies both increased education and increased awareness. Providing pamphlets and teasers about the

technology available in telecommunications and the benefit to each group generates interest and inserts the idea into the environment. By generating a marketing campaign the demand will increase which may cause a positive active pursuit of the topics due to curiosity alone. There are many possible marketing approaches, commercials, magazines, pamphlets for the medical office, telemarketing, etc. Any of these can be geared to focus on a certain population within the diabetic community, such as elderly or juvenile patients. Creating demand in the public arena will provide a push for established organizations to conduct further research into the subject of telemedicine applications in general, and specifically into the effects of HumaLink on the quality of life of patients.

By letting patients and physicians get exposure to the system, more feedback can be collected suggesting physical improvements to HumaLink. These could include the method of access, the design of the software operating the algorithm, etc. Improved access options could be to network the device and make its service available over the growing Internet. By making the algorithm less mysterious, patients may be more inclined to trust its suggestions.

Costs

One of the questions associated with costs for the use of a new device is: "Who is responsible for paying for its use and application? Is it the physician who provides the service or the patient who benefits from the availability?" Depending on who you ask, the responsibility lies in different places: patients think insurance companies should handle the costs and fees associated with the system, doctors see providing HumaLink as a service to be reimbursed for as opposed to paying for the costs themselves, and insurance companies are not aware enough of it to decide whether they will include HumaLink as a covered medical device. Trends show that new technology tends to decrease in cost as the cost of hardware drops during the application period. Among the three, patients, physicians, and insurance companies, the costs of installing and operating the system and the expense of hiring and educating new employees need to be met.

Cost is a significant concern since it involves the relationship between patient and doctor and since it includes, for the first time, insurance providers in the equation. The

most significant issue facing HumaLink is the question of payment for the system and its services.

Physicians would like to be compensated for providing the additional service to the patients and for the cost of hiring and paying new employees and giving them training. In addition, the physician is seeking payment for the additional hours in review of medical records produced by the device. They are not willing to pay for the installation of the system and the maintenance costs by themselves.

Patients will not elect to pay unless they are convinced the device will realize the promised benefits, which takes time, patience, and trust. Regardless, they will still look towards insurance companies to at least partially cover the expense. Presently, patients do not entirely trust HumaLink therefore they are reluctant to pay extra fees for it and they demonstrate a tendency to wander away from the regular interactions the design calls for to produce the best results.

The lack of comparable data that relates to the actual short and long term economic effects of using the device seriously limit the willingness of insurance companies to offer payment or coverage for it. Most companies are not even aware of the device yet and they will not cover an unknown device for which there is no concrete data. Insurance companies will only agree to reimburse physicians for the use of HumaLink if they determine that it saves money as compared to the current coverage policies. Insurance companies require the development of a convenient and accurate method to track additional billing hours due to operating HumaLink.

Acquiring cost data analysis and distributing it to insurance companies is a required step so they can compare old policy options to newly created policies that include devices like HumaLink. The increase in daily expenses due to more frequent usage of BG test strips to maintain tight control is far offset by the savings noticed from fewer occurrences of major complications requiring hospitalization and prolonged intensive care. If this can be proven with data directly associated to the device, the cost-centered policies active in insurance companies will push them to cover HumaLink.

In addition, another consideration is the rapid turnover rate of an insurance subscriber from one provider to another. Constant occupation and job changes coupled with the option for any employed individual to change their health insurance provider on

a yearly basis, results in a very varied group of subscribers from year to year. The insurance companies may concentrate on figures detailing the turnover rates and may decide to concentrate on the short term rather than the long-term costs of each subscriber.

The system must address these human factors: awareness, education, and marketing if it is to be more widely accepted by all groups. Aside from human factors there are hardware improvements that can be applied to improve the overall attractiveness of the device: interface, media of availability (Internet access for example), and the characteristics of the software handling the data files. The characteristics of the device and the rest of the environment influence the human factors in general. The concerns all connect to each other, therefore it is difficult to solve one problem without affecting the other areas. A simultaneous solution to the problems facing the system goes beyond the scope of each individual group, consequently, a collaboration of all three, patients, physicians, and insurance providers, may ultimately lead to the widespread use and acceptance of HumaLink.

Recommendations

Physical Changes

HumaLink should focus on reducing the start-up costs to an amount that is comparable to care currently available. For short-term focused companies it is not justifiable to risk the investment for start up, by decreasing the size of this investment it will be more justifiable. The unit requires multiple users, all of whom may have different insurance carriers. To pay for HumaLink, each insurance company covers respective associated costs for each patient with an active plan, a portion of the total expense.

The doctor interface built into HumaLink has similar convenience issues from a user's/provider's point of view. The production of reports, in convenient medical format, still requires physicians to review them and make adjustments to the program algorithm in the interest of providing the highest level of care. Each registered patient has a personalized algorithm controlling recommendations supplied by HumaLink, the case manager or the physician implements each adjustment manually.

External Changes

Devising a plan to address the amount of distrust for the device involves a dramatic increase in education and awareness in diabetes in general, and in the technological applications that are becoming available with greater frequency and more dependability.

Successful support and backing from a major organization like the ADA will prompt the required increase in education and marketing. In addition it also to supports the idea of the creation of new policies, allowing either eventual classification as DME, or alternately, as a new classification of medical device that will qualify for coverage by federal insurance providers. This national coverage will set the example for private companies.

Focusing on the long-term benefits of strict glycemic control, one feasible change to insurance company policy that could assist HumaLink towards general acceptance might be to provide coverage for patients on the stipulation that they must follow guidelines set by the DCCT. This option would make the average long-term costs decrease overall since the frequency of major complications (neuropathy, retinopathy, heart conditions) would be reduced. Patients would seek methods to keep them eligible for coverage; HumaLink is one easy and convenient solution to that problem. Through the encouragement of patients to enroll in HumaLink and using registration as proof of eligibility for coverage, the insurance providers could create new policies that will facilitate physician compensation for providing the required service to the patients. HumaLink would become the norm, the standard of care provided by the medical community to diabetes patients.

Stiff policies make HumaLink difficult to accommodate federally funded programs like Medicare. The American Diabetes Association must be persuaded to petition the government committees seeking authorization for coverage.

Further Research

More statistical research is necessary to determine the specific population HumaLink should target (elderly experienced diabetics, newly diagnosed diabetics, or

juvenile diabetics). The device has yet to prove its efficiency for the entire population of diabetes patients. Limited application for some patients greatly reduces it marketability, especially since one physician indicated only a small fraction of the population would benefit. Quality of life data must be collected to ensure the diabetic community receives the maximum benefits.

Vitally important cost information must be collected and made readily available. A detailed cost analysis has to be conducted over a longer period of time and cover a wider variety of patients. The long-term approach and a short-term approach need to be addressed separately since the cost comparison for each scenario is drastically different. This analysis should include the cost of the system itself (set-up and maintenance), telephone compatibility, test strips and other required DME that will be used by patients and in the number suggested by the DCCT. This data needs to be made available to insurance companies so they can compare it with figures currently available on the cost of diabetes over both short and long term time periods.

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Appendix A:

Function of the pancreas in the body

In the human body, the pancreas is located behind the stomach and liver, next to the gall bladder. Areas of the pancreas, known as the islets of Langerhans are made up of three different types of cells, alpha, beta and delta cells. Alpha cells store and secrete Glucagon, Beta cells store and secrete Insulin, and Delta cells store and secrete digestive enzymes.

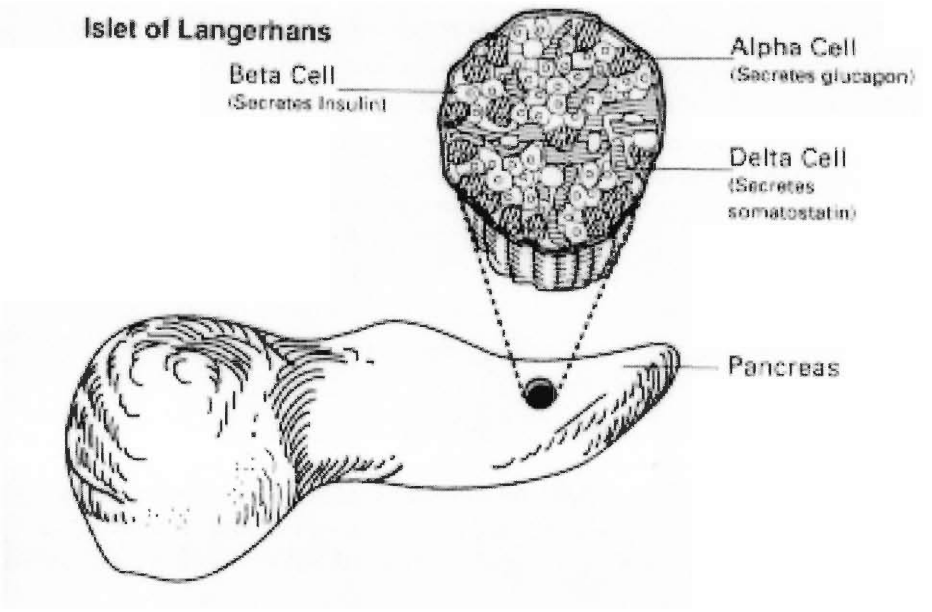

Figure A.1 – Diagram of the Human Pancreas

Beta cells produce insulin in the human body. Insulin is a hormone, or long chain of amino acids made up of the A-chain and the B-chain. The A-chain has twenty-one amino acids and the B-chain has thirty. Both the A and B chains are linked by two disulfide bridges as shown in figure A.2. Insulin attaches to the receptor sites of most

body cells and acts to allow the glucose in the blood stream to enter the cells to be metabolized as energy, allowing the cells to function and grow.

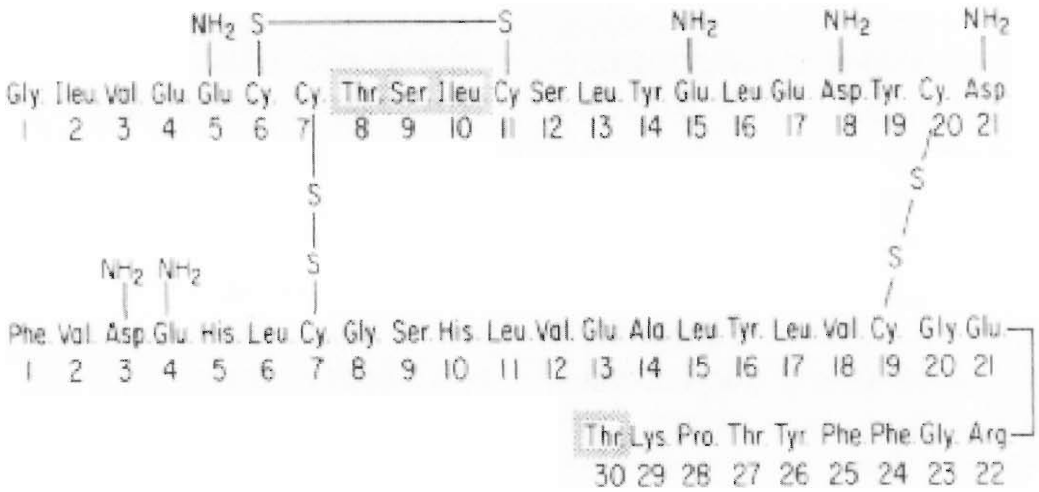

Figure A.2 – Diagram of an Insulin Molecule

More specifically, energy comes from the metabolizing process and the breaking of the bonds of glucose. Glucose enters the blood through digestion from the consumption of nutrients in the form of proteins, fats, and carbohydrates. These are then broken down and converted into crude base products. Proteins break down into amino acids which are the building blocks of cells. Fats are broken down into fatty acids, which store energy in fat cells throughout the body, and complex carbohydrates splinter into the less complex glucose molecules. Normal blood glucose (BG) levels are between 60-140 mg of glucose per deciliter of blood. Through natural digestion, the BG levels rise, increasing the amount of glucose in the blood leading to corresponding increases in the level of insulin secreted to utilize it.

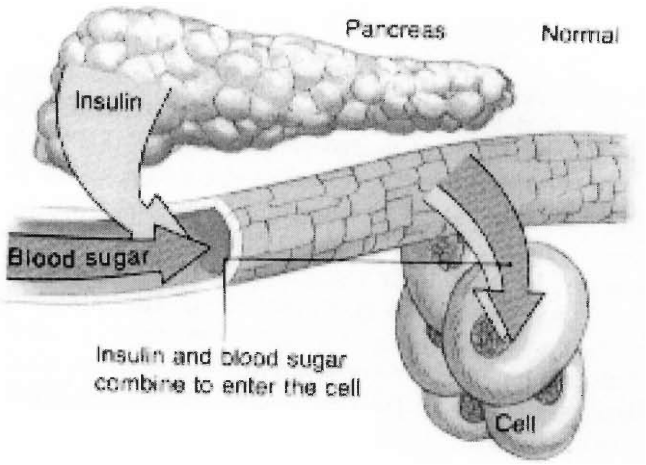

Figure A.3 – Figure of a Normal Functioning Pancreas

In deviation from normal functions of the body, there are two possible scenarios, one case is where the body has trouble producing insulin or is totally incapable for one reason or another, and the second is in the case where the body cannot use the insulin it is already producing. These are known as Type I and Type II diabetes respectively.

Appendix B:

Type I Diabetes

In examining the pancreas, one malfunction may be the lack of insulin produced. The source of the insulin in a normally functioning pancreas is the beta cells. In the case of Type I diabetes, the beta cells do not produce any insulin. The beta cells have either been destroyed by the body's auto-immune response of insulin antibodies, or they are missing from the structure of the pancreas. As a result of the malfunctioning pancreas, the glucose stays in the bloodstream and can reach far above normal limits. The body can no longer regulate the level of glucose in the blood, and the diabetic can suffer from hyperglycemia which leads to ketoacidosis. As a result of this hyperglycemic state, high levels of glucose in the blood may lead to a "spill-over" effect into the urine and other bodily fluids. Toxic levels of glucose can lead to tissue damage of the kidneys and eventually renal failure.

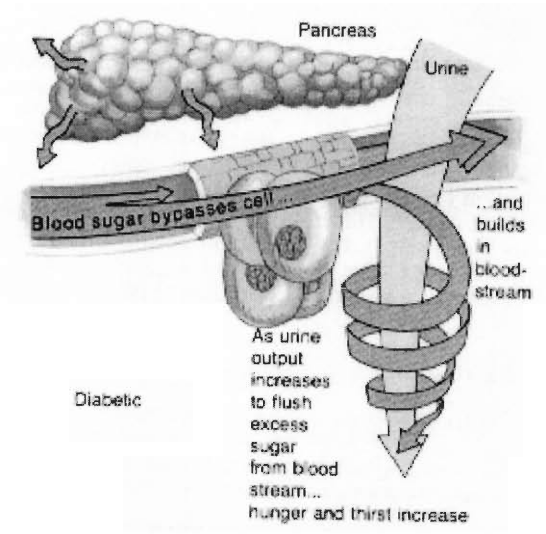

Figure B.1 – Diagram of a Diabetic Pancreas

Type I, also known as juvenile onset diabetes, is most often found in children, teens, and young adults. This condition is believed to be at least partly hereditary, having a link with a currently unknown gene. It is estimated that 1.4 million Americans suffer from Type I diabetes, approximately 5-10 % of the total American diabetic population (Haire-Joshu pg.3).

Symptoms of Type I diabetes include thirst, weight loss, irritability, frequent or excessive urination, and dehydration. These symptoms result from the body's attempt to dilute urine and other bodily fluids as a result of high glucose levels. Fatigue, another major symptom, results from a lack of energy due to glucose not entering the cells. Other adverse affects on the body may include diabetic foot, diabetic eye, disorders of the nervous system, or cardiovascular damage.

Diagnosis of Type I diabetes is based on the excess levels of glucose present in the bloodstream. Diagnosis of the disease may be made through a simple blood test, or a measurement of glucose in the urine. The goal of managing this disease is to maintain blood glucose levels in a "safe zone". Diabetes is best kept under control by diligent home monitoring of blood glucose levels, with daily insulin injections, exercise and dieting.

Appendix C:

Type II Diabetes

Type II, also known as adult onset diabetes is different than Type I. Instead of arising from some form of damage to the pancreas resulting in no insulin production, Type II is mainly the result of unbalanced hormones in the body. Excess insulinase serves to convert the insulin to an inert form before it can function at the receptor sites of cells. Insulin antibodies, from the body's immune system, attack and destroy the insulin produced and as a result, excess glucagon in the liver causes high glucose levels in the blood.

Major differences from Type I diabetes include, excess insulin in the blood and weight gain. Other symptoms may include blurred vision, tingling in extremities, weight gain, slow healing of infections, and recurrent infections are all symptoms yet they can be easily confused with other natural signs of aging.

Diagnosis is accomplished through oral glucose tolerance tests, and a c-pep urine test. Because c-pep and insulin are both produced in the pancreas in equimolar amounts, high levels of c-pep along with a high glucose in the blood indicate that the insulin produced is not being used effectively.

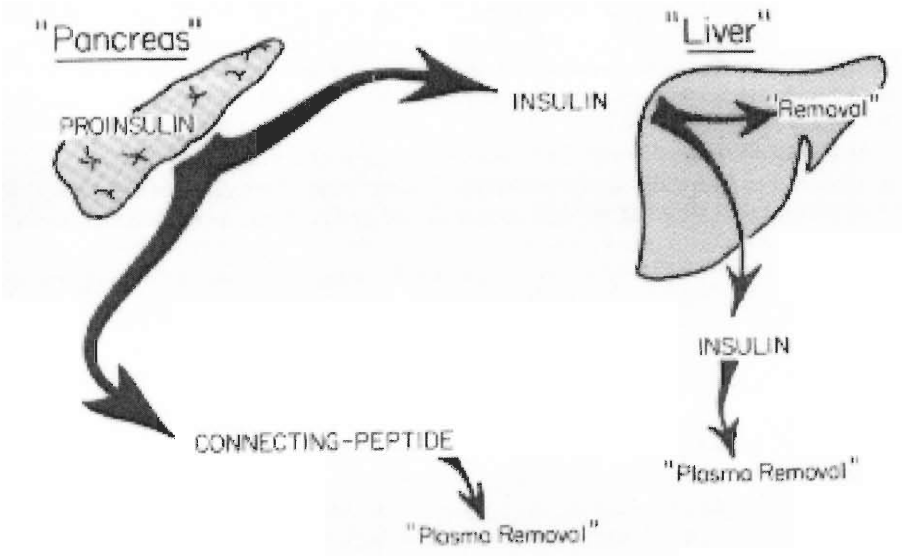

Figure C.1 – Picture of C PEP and liver/insulin relationship

Genetics of the disease is not totally understood and it is believed that the disease is preventable to a certain extent. The subject may be predisposed to the disease, but lifestyle factors may increase or decrease actual risk. Factors include, weight control, exercise regime, and increased chromium intake, which increases activity at interface sites on cells.

Managing Type II is similar to Type I. There is usually no need to administer insulin shots, since there is no shortage of available insulin in this case. Redistribution of caloric intake, monitoring of the BG levels, oral hypoglycemic agents, combinations of insulin therapy and oral agents, and exercise will all improve the condition and health of a diabetic patient. Notably, it may become necessary to alter treatment of Type II diabetics after a certain time period. It has been recorded that initial treatment with oral agent may become ineffective as the disease ages, and supplementary methods including insulin injections may be required.

Appendix D:

Insulin

Insulin is a naturally occurring hormone manufactured by the beta cells of the pancreas. Its major function is the breakdown of glucose in the bloodstream. Insulin production may be hindered if not absent altogether in diabetic persons. Many Type II diabetics and all Type I diabetics require exogenous insulin administered by injection. Other alternative forms of insulin intake are discussed later in this section. Diet, exercise, and oral medication may play a large role in determining whether the patient needs to augment his or her insulin levels through insulin injections. If a Type II patient can maintain moderate glucose levels in the blood by the three previously mentioned regimes, then the insulin produced by the body may suffice even if at lower than normal levels.

Exogenous insulin is acquired by one of two means of production. The insulin is either synthesized in a laboratory or obtained directly from animals. Human insulin is engineered genetically using one of two host cells. Scientist have been able to manufacture insulin with the help of e.coli bacteria (Humulin) and yeast cells (Novolin) by altering the cell's hormone and enzyme production so that insulin hormone is produced. Animal insulin can be made from either beef or pork or a combination of the two. It is not clear which insulin is suitable for all purposes, but studies have proven that human and pure pork insulin tend to lower blood glucose more effectively than beef or the combination of beef and pork.

All insulin, whether animal of human can be classified as either short, fast, or intermediate acting. Making up these three categories are seven types of insulin: Regular, Semi-Lente, NPH, Lente, Ultralente, Insulin Lispro, and 70/30. Insulin can be

used in prescribed combinations to accommodate the needs of virtually every Type I and II diabetic. Regular insulin may be produced from any of the four sources (human, pork, beef, or pork and beef combination). It is classified as fast acting because its effect is short-lived in the body. Regular insulin is mainly used before meals to control post meal glucose elevation, as well as other immediate correction of blood sugar levels.

Semi-lente insulin is also used with post meal glucose elevations and its duration is short but twice that of regular insulin. Originating from the beef and pork combination, this type is usually prescribed along with Lente insulin, an intermediate acting insulin. Lente is manufactured from beef, pork, or human synthesis and contains added zinc for slower absorption. Two daily injections of Lente insulin provide the body with a basal amount, or normal healthy dose of insulin for the average diabetic. Combining these two injections with semi-lente before meals is not an uncommon prescription.

Similar to Lente, and often an alternative to, is NPH. Derived from beef, pork, human, or the beef and pork combination, it has the same intermediate acting time as Lente and provides the same basal amount. Both Lente and NPH are simply regular insulin with added zinc to delay insulin absorption from under the skin. The only major difference between the two is that NPH has added modifying protein to make it more insoluble whereas Lente is relatively insoluble without the need for the modifying protamine.

Ultralente , a member of the longer acting insulin category, is made by human synthesis or beef. Also containing zinc, this insulin has the longest acting effect of any of the insulin types, and provides the steadiest basal amount. One injection per day of

Ultralente coupled with regular insulin before meals suffices many patient's needs. Since Regular insulin is such a common component in many diabetic's regimes, a human mixture of 70% NPH and 30% Regular is manufactured. Two injections per day of 70/30 used in conjunction with the regular insulin, may allow for post meal injections to be omitted by keeping glucose levels in a safe range. The most recently discovered human engineered insulin is known commercially as Lispro. It has the most rapid onset of any insulin and is taken fifteen minutes before a meal in combination with longer acting insulin such as Ultra Lente (Galloway pgs. 37-48).

It has been shown that in certain situations, a steady basal dosage of insulin can be administered to keep a patient at normal blood glucose levels. Sometimes, however, this is not always the case. Changes in exercise or activity level may alter the metabolism of the body and blood glucose levels can fluctuate. Snacks during the day may be added or omitted having the same effect as rising or falling activity levels. Delayed meals or changes in the amount of food eaten, and alcohol consumption can also have an effect on the blood glucose levels. Probably the most obvious in their role in glucose variance is over treatment of incorrect insulin injections, skipped injections, or insulin injected into lumpy area of arm or leg causing a much slower absorption of insulin into blood. Because blood glucose levels are directly related to the amount of insulin in the body, it is clearly apparent why late dosages or slow absorbing shots can lead to a serious glucose fluctuation.

Although insulin injections provide suitable levels of insulin, many users now seek new alternatives to avoid the pain and inconvenience of needles. Research has begun in the area of nasal inhalants , skin patches, and pulmonary inhalants

(www.inhale.com). Nasal inhalants currently being studied in New Zealand, are designed to deliver human insulin in the powdered form. Some disadvantages already observed are the expensive apparatus that is required to propel the powder. Cost effectiveness in combination with erratic insulin absorption rates, play a major role in its inability to be accepted as a viable insulin delivery alternative. Environmental humidity and mucosal skin inflammations such as the common cold can alter one's own absorption through the capillaries in the nose and sinus area. Add to the fact that more concentrated insulin is required for nasal absorption and this method begins to lose its feasibility.

Another form of insulin delivery currently under development, is a skin patch similar to nicotine patches for habitual tobacco smokers. In this method small monomeric forms of insulin are transdermally delivered via iontophoresis. Aided through the lipophillic layer of the skin by a small electric current, the insulin has been successfully delivered to the bloodstream in animals. Setbacks to this method include polymerization of the insulin monomers, and the weak ionization of the human dermal layer, both hindering insulin absorption. Despite these hurdles, researchers are still attempting to perfect the method.

An additional method being studied is a pulmonary insulin inhalant. This is a powdered aerosol containing either human or animal insulin taken orally by the patient similar to an asthma inhaler. Heading up research is Inhale Therapeutic Systems Incorporated in collaboration with Pfizer. The effort has shown Type II diabetics to improve glycemic control with inhalants such as sulfonylurea and metformin. Glucose levels have stayed at more normal levels than diabetics using oral agents and placebos. In a study of 33 patients, 32 opted to continue usage of the inhaler (source). There is

still no means of insulin administration that is as effective as the injection method. Until an alternative is accepted, diabetics will continue their current treatment techniques.

Appendix E:

Hyperglycemia

Hyperglycemia effects both Type I and Type II diabetics, and is defined as an abnormally high blood glucose level. These high blood glucose levels are usually a consequence of two situations. In one case, which is usually seen in Type I diabetics, the body may have too little or not enough insulin. Usually in the case of Type II diabetics, the body cannot properly use the insulin it has. In both cases, blood glucose levels become abnormally high, and can approach dangerous levels if left untreated. Hyperglycemia can also occur in diabetics as a result of changes in activities such as eating more than planned, exercising less than planned, or from a shock to the system such as a cold or flu. Symptoms of hyperglycemia are identified as high blood sugar, high levels of glucose in bodily fluids, frequent urination, increased thirst, blurred vision, headaches, and fatigue. One way to prevent hyperglycemia is to stay in a safe glucose target range. This may be achieved by consistent self-administered blood tests. It is recommended that blood glucose levels be tested as often as four times a day, according to the Diabetes Control and Complications Trial. By measuring blood glucose levels diligently, and properly treating and the hyperglycemic levels, diabetics can manage their disease so as to avoid any serious complications.

Appendix F:

Hypoglycemia:

Hypoglycemia, a common occurrence in diabetics, is a result of a low blood glucose level. Three main causes of this condition can be identified as: deficient food supply, excess insulin supply, or hepatic disorders, otherwise know as excess exercise without energy intake. Excess insulin in the body can serve to rapidly move all the glucose from the blood to the cells. This could be the result of too much insulin administered, incorrect timing on the insulin dosage, incorrect type of insulin administered, or a deficiency of the natural insulin anti-bodies in the patients system. As a result, insulin remains in the bloodstream for an extended period of time.

TABLE 10–1. SYMPTOMS AND SIGNS OF DIFFERENT PHASES OF HYPOGLYCEMIA*

PHASES†	A-V O_2 DIFF.	SYMPTOMS AND SIGNS
Cortical	6.8	Somnolence, perspiration, hypotonia, tremor
Subcortico-diencephalic		Loss of consciousness, primitive movements (sucking, grasping, grimacing), twitches, restlessness, clonic spasms, hyperresponsiveness to pain, sympathicotonia (tachycardia, erythema, perspiration, mydriasis).
Mesencephalic	2.6	Tonic spasms, inconjugate ocular deviation, Babinski sign
Premyencephalic		Extensor spasms. Rotation of head causes extensor spasm of extremities on the side toward which the chin points and flexor spasm on the opposite side
Myencephalic	1.8	Deep coma, shallow respiration, bradycardia, miosis, no pupillary reaction to light, hypothermia, atonia, hyporeflexia, absent corneal reflex.

Figure F.1 – Symptoms and signs of Hypoglycemia

Some symptoms of hypoglycemia may include fatigue, sweating, and serious cases can lead to coma, or even death. A patient can avoid hypoglycemia by ensuring that he or she remains in a stable blood glucose range.

Appendix G:

Diabetic Ketoacidosis:

When cells cannot use the energy of glucose due to lack of insulin, they turn to the next best form of energy, stored fat. The cells begin to digest the fat, releasing toxins known as ketones into the bloodstream, leading to a condition known as Diabetic Ketoacidosis, otherwise known as DKA. This condition only occurs in Type I diabetics and is seen most often in persons with unrecognized and untreated diabetes.

One of the many symptoms of Diabetic Ketoacidosis is extreme thirst. This is the body's attempt to dilute the high levels of glucose in the blood and consequently in the urine. With this thirst comes frequent urination. The patient is drinking more, and the body is trying to rid itself of excess glucose. The diabetic will experience sudden weight loss due to the breakdown of the stored fat in the body. This breakdown of fats is what causes the release of ketones into the bloodstream, and the body attempts to rid itself of these through the urine. The diabetic may experience what is described as "fruity" breath. This fruity breath is a result of one constituent part of a ketone, known as acetone.

Ketones are a group of chemicals that include acetone, betahydroxybutyric acid, and acetoacetic acid. Ketones can be very dangerous if their level is left unchecked. The ketones lower the pH level of the blood, and often result in cellular damage. Severe ketoacidosis may lead to hospitalization and possible renal failure.

Appendix I:

Anonymous Patient Survey

1. In general, would you say your health is (circle one)

Group	A. Excellent	B. Very Good	C. Good	D. Fair	E. Poor
A.		1		1	
B.			5	1	
C.			3	1	
?		2	1	1	

2. Compared to one year ago, how would you rate your health in geneal now? (check one)

etter than one year ago

Group
A.
B.
C. 1
?

somewhat better now than one year ago

Group
A. 1
B. 3
C. 1
?

about the same as one year ago

Group
A. 1
B. 1
C. 3
? 3

somewhat worse now than one year ago

Group
A.
B. 2 circulation problems
C.
? 1

much worse than one year ago

Group
A.
B.
C.
?

3. The following items are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

A. Vigorous activities, such as running, lifting heavy objects, paticipating in strenuous sports. If yes how much?

Group	Yes	No	Comments
A.	1	1	back pain
B.	2	4	completely
C.	2	3	
?	1	3	considerably

B. Moderate activities, such as moving a table, pushing a vaccuum cleaner, bowling, or

playing golf. If yes how much?

Group	Yes	No		
A.		2		
B.	1	5	once a month	golf-no long walking
C.	1	4		once a day
?	1	3	2-3 times/day	

C. Lifting or carrying groceries. If yes, how much?

Group	Yes	No		
A.	1	1		
B.	1	5	twice a week	
C.	1	4		once a week
?	1	3	4-5 times/day	

D. Climbing one flight of stairs. If yes, how much?

Group	Yes	No		
A.	1	1		
B.	1	5	cramping from poor circulation	
C.	3	2	out of breath	4-5 times/day
?	2	1		a little

E. Walking several blocks. If yes, how much?

Group	Yes	No		
A.	2		back pain	
B.	2	4	3 times a week	cramping from poor circulation
C.	3	1	daily	
?		4		

F. Walking one block. If yes, how much?

Group	Yes	No	
A.		2	
B.	1	5	cramping from poor circulation
C.		4	
?		4	

G. Bathing or dressing yourself. If yes, how much?

Group	Yes	No		
A.		2		
B.	1	5	daily	
C.	1	4		2-3 times/day
?	1	3	daily	

4. During the past 4 weeks, have you had any of the following problems with your work or any other regular daily activities as a result of your physical health?

ı the amount of time you spent on work or other activities

Group	Yes	No
A.		2
B.	1	4
C.	1	4
?		4

Accomplished less than you like

Group	Yes	No
A.	1	1
B.	2	4
C.	2	3
?	2	2

Were limited in the kind of work or other activities

Group	Yes	No
A.		2
B.	1	5
C.	1	4
?	1	3

had difficulty performing the work or other activities.

Group	Yes	No
A.	1	1
B.	1	5
C.	1	4
?	1	3

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)? (Yes, No)

on the amount of time you spend on work or other activities

Group	Yes	No
A.		2
B.	1	5
C.	1	4
?	1	3

Accomplished less than you like

Group	Yes	No
A.	1	1
B.	2	4
C.	2	3
?	2	4

didn't do work or other activities as carefully as usual

Group	Yes	No
A.	1	1
B.	2	4
C.	2	3
?	1	3

6. During the past four weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups? (Circle One)

Group	Not at all	Slightly	Moderately	Quite a bit	Extemely
A.	1		1		
B.	3	3			
C.	1	2	1	1	
?	4				

7. How much bodily pain have you had in the past 4 weeks? (circle one)

Group	None	Very Mild	Moderate	Severe	Very severe
A.			1	1	
B.		3	2	1	
C.	1	2	1	1	
?	1		3		

8. During the past four weeks, how much did pain interfere with your normal work (including both

work outside the home and housework)? (circle one)

Group	Not at all	A little bit	Moderately	Quite a bit	Extremely
A.		1	1		
B.	2	3		1	
C.	2	1	2		
?	2	1	1		

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past four weeks:

Do you feel full of pep?

Group	All	Most	A good bit	Some	A little	None
A.				1	1	
B.			3	1	1	1
C.			1	3		
?		1		3		

Have you been a very nervous person?

Group	All	Most	A good bit	Some	A little	None
A.						2
B.				2	1	3
C.		1			2	2
?			1	1		2

elt so down in the dumps that nothing could cheer you up?

Group	All	Most	A good bit	Some	A little	None
A.						1
B.				1	2	3
C.						5
?					2	2

Have you felt calm and peaceful?

Group	All	Most	A good bit	Some	A little	None
A.	1					
B.		2	1	2	1	
C.		2	2	1		
?		1	1	2		

Did you have a lot of energy?

Group	All	Most	A good bit	Some	A little	None
A.				1		1
B.		1	2	1		2
C.			1	2	1	1
?		1		2	1	

Have you felt downhearted and blue?

Group	All	Most	A good bit	Some	A little	None
A.						1
B.				1	3	2
C.					2	3
?					1	3

Did you feel worn out?

Group	All	Most	A good bit	Some	A little	None
A.					1	
B.		1		2	2	1
C.		2		1	2	
?			1	2		1

Have you been a happy person?

Group	All	Most	A good bit	Some	A little	None

A.	1					
B.	3		1	1	1	
C.		2	1	1	1	
?		2	2			

Did you feel tired?

Group	All	Most	A good bit	Some	A little	None
A.				1	1	
B.		1		2	3	
C.		2		1	2	
?			1	2		1

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)? (circle one)

Group	All of the time	Most of the time	Some of the time	A little of the time	None of the time
A.			1		1
B.			1	2	2
C.		1		1	3
?					4

11. How true of false is each of the following statements for you?

seem to get sick a little easier than other people?

Group	Definitely true	Mostly true	Don't know	Mostly False	Definitely false
A.		1	1		
B.	1	1	1		2
C.	2				3
?				1	3

I am as healthy as anybody I know.

Group	Definitely true	Mostly true	Don't know	Mostly False	Definitely false
A.				1	
B.		2	1		2
C.		1	1		3
?		2		1	1

I expect my health to get worse.

Group	Definitely true	Mostly true	Don't know	Mostly False	Definitely false
A.				1	
B.		1	4		
C.	3				2
?			3	1	

My health is excellent.

Group	Definitely true	Mostly true	Don't know	Mostly False	Definitely false
A.				1	
B.		1	1	1	2
C.		1			4
?	1	2		1	

12. How do you feel about being part of a scientific research study?

Group	Great	Good	Indifferent	Uneasy	Very bad
A.		2			
B.	2	4			
C.	1	2			
?		3	1		

13. Before entering this study, how often did you visit your clinical physician?

Group	> once a month	once a month	every 3 months	every 6 months	once a year	never

A.	1	1		
B.	2	3	1	
C.	1	1	2	
?		2	1	

14. Before entering this study, did you ever call your doctors for advice or help?

Group	No	Yes	If yes, how often?		
A.	1	1			
B.	2	4	sporatically	1-2/mth	when needed
C.	1	2	once a month		
?	2	2	2-3 times/year	seldom (once a year)	

15. Do you feel that you have received adequate medical care over the past five years?

Group	Yes	No	Do not know
A.	2		
B.	3	3	
C.	2		1
?	3	1	

16. Do you feel that your doctor has enough time to adequately address all your medical needs?

Group	Yes	No	Do not know
A.		2	
B.	2	3	1
C.			3
?	1	2	1

17. Do you feel comfortable using your touch tone phone to transfer information to your doctor?

Group	Yes	No	Do not know
A.			2
B.	6		
C.	2		1
?	2	1	1

18. Do you feel comfortable receiving medical advice over the phone?

Group	Yes	No	Do not know
A.	2		
B.	5		1
C.	2	1	
?	4		

19. Do you feel comfortable listening to a recorded human voice give medical advice over the phone?

Group	Yes	No	Do not know
A.		2	
B.	5		1
C.	2		1
?	1	2	1

20. Do you feel that your health can improve with a little more effort on your part?

Group	Yes	No	Do not know
A.	2		
B.	6		
C.	3		
?	3		1

21. Do you have any comments, concerns, or questions about this study?

Group	Yes	No	
A.		2	
B.	2	4	More info on what the results are telling you just concern on how diabetes med is effecting my body
C.		3	
?		4	