iitCARES

IIT Creating Access to Remote Electronic Support

Final Report

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Executive Summary

The IPRO 345 team aims to develop a remote diabetes testing support center for Mount Sinai Hospital that would automatically sync a patient's home blood glucose monitor to a remote database that a qualified medical professional will be able to view remotely. This should decrease the amount of time spent of record keeping for clinicians and patients as well as limit clinical visits to when they are only necessary. This project will require multiple phases and semesters to properly research, test and implement the new technology.

As the first section, the summer 2011 IPRO team worked to create a strong foundation for the following IPRO teams to take off from. The team worked to clear the way for future teams by completing the required ethics procedures, writing the interview questions, and researching available technologies. Originally the team planned on completing interviews with the hospital staff this summer, but due to a staffing change at Mount Sinai Hospital we were unable to do so.

Purpose and Objectives

Diabetes is a chronic disease that affects roughly 25.8 million people in the United States alone and it is expected to drastically increase. It is metabolic disorder characterized by high levels of blood glucose that oftentimes leads to complications such as blindness, heart failure and kidney failure. It is a serious illness that usually leads to strict medication regimes and daily blood testing. Frequent clinical visits are also required to monitor glucose levels.

This leads to a very intimate relationship between clinician and patient in which the transfer of data is necessary. A large amount of time and money is dedicated to the transfer of patient data. According to the Center for Disease Control and Prevention, $174 billion dollars were spent purely on the care and treatment of diabetes in 2007 alone. Hopefully, by decreasing the amount of time and resources spent transferring records it can save money for clinicians and patients alike.

In conjunction with Mount Sinai Hospital the IPRO 345 team aims to introduce a remote data transfer center that would allow patients to automatically transmit their readings to the clinician. This will allow for fewer clinical visits, an increase in data transfer productivity, and minimize human error in the process. The Mount Sinai hospital patient community is largely comprised of people who depend on Medicare and who cannot afford the substantial money and time commitment proper diabetes treatment requires. Also many of the patients are elderly and have other health concerns that make data collection difficult and traveling daunting. Creating a remote testing system would greatly impact this community, allowing for a much higher quality of care and minimizing the inconveniences the patients encounter.

The goal of this IPRO is to find the best system for Mount Sinai's needs. Due to the complexity of the issue, the project has been devised into multiple phases. The planned three phases will be divided between 3-4 semesters of IPRO teams. The main objectives will include but would not be limited to:

1. Study the feasibility of the implementation of mobile technologies in the management of patients with diabetes through interviews and observations of the health care system.
2. Research recent technological developments in the monitoring of chronic diseases, specifically diabetes
3. Utilize all team member skills to maximize efficiency and gain valuable team work experience
4. Work as a team to improve Mount Sinai's current approach to treating diabetes and other chronic diseases

The summer 2011 IPRO team worked to accomplish the first phase of the program; studying the feasibility of implementation and developing guidelines for the subsequent phases. The immediate goals of first phase was to understand the hospital system, find and list the best diabetes management support devices and applications, and compare possible venders that would build the Support Center network.

Organization and Approach

At the beginning of the summer semester, the entire IPRO 345 team was involved in researching current telemedicine systems in use today and also recent technologies introduced in health care management. This research consisted of reviewing case studies and published scientific reports, providing a general background for the field. After two weeks of researching the general problem the team broke into three separate groups to work on specific details of the project.

The first research team formed was to investigate existing mobile glucose monitors that could send patients' readings to a central database. The research team consisted of Unubold Chinzorig, Hazel Michael, and Carolyn Kos. They utilized internet sources to find the most up to date technology possible.

Due to the size of the system needed to transmit patient data to a secure database, the group decided to split off and investigate the individual components of the data transmission system after the initial research was complete. Unubold investigated mobile phone applications approved for use that followed the established criteria. Carolyn investigated stand alone devices, including glucose monitors that automatically transmitted patient readings and supplementary devices that utilized other electronic devices, such as a phone or computer, to send patient glucose readings. Hazel investigated the online database that would allow doctors, patients, and family members to access patient information remotely. The online database will allow patients and doctors to monitor the patients' response to treatment by observing trends in the readings.

After investigating the clinical components of the problem, the group reformed and began to investigate the administrative needs. A basic outline of program functions was drafted by the team. Current supporting venders were also researched and reported.

The second research team consisting of Kendra Johnson investigated the ethical ramifications of conducting the primary interviews that were originally scheduled to take place this summer. She initiated contact with the ethics center of Illinois Institute of Technology, and brainstormed what ethical considerations the future IPRO team will need to be aware of when conducting interview and in testing the system as well as began the Institutional Review Board approval process. Her research was mainly conducted by meetings with the Illinois Institute of Technology IRB board chair and the Ethics librarian. She also utilized online sources to obtain greater detail about regulations and procedures. The team also participated in a group discussion with the ethics coordinator to discuss what ethical considerations are involved with this project.

The final team consisted of Nicole Valio, who edited and created interview questions that the future IPRO teams could use when conducting interviews with patients of Mount Sinai. She did so with careful consideration to the tone, directness, and verbiage of the questions so that they would not be leading or biased. She used intuition and general knowledge as a basis for her work.

Analysis and Findings

In order to properly lay the ground work for future IPRO 345 sessions, there were several separate hurdles were overcome. Firstly, an initial investigation of the expected needs of the users and the capabilities of current technologies was conducted. This will provide future teams with a simple basis to find solutions for the specific issues that Mount Sinai Hospital's diabetes treatment center faces. Secondly, appropriate interview questions were drafted that would successfully provide the data needed to understand the system currently in place. Finally, the ethical hurdles that would be encountered by interviewing human subjects were identified and reported.

Technological Investigation

Based on the population of the Mount Sinai hospital, the IPRO team decided upon appropriate criteria list to be used in evaluating blood glucose monitors. The device should be simple to use by all patients, with a user-friendly interface, and data transmission in under three clicks. It must be compact, allowing patients to easily transport the device. The device must be able to send the patients' blood glucose readings securely to a database accessible to Mount Sinai hospital. Also, any blood glucose monitor classified as a medical device must be approved by the FDA before use in this IPRO.

Based on the established criteria, two separate matrix charts comparing the available blood glucose monitors and mobile phone applications were created. Additional considerations not essential to the IPRO were listed for comparative purposes.

The matrix charts will allow for an easy reference for the fall 2011 IPRO team. Instead of researching existing medical technology again in the fall, the fall 2011 team can use the existing matrix tables to guide their selection of an appropriate mobile device.

Interview Methodology

As part of the preparation for IPRO 345 Fall Semester, the summer team along with Dr. Geisler devised a set of interview questions for the patients and clinicians at Mount Sinai Hospital. The main purpose of this questionnaire is to learn about the current system for the treatment of diabetes at the hospital by inquiring about the methods of diabetes data collection by patients and data analysis by clinicians.

The IPRO team aims to discover how patients record the data in the home setting along with how it is brought into the hospital. From there, it is believed that it will be useful to discover who becomes responsible for the patient data in the hospital, what they do with it, who has access to it. It is also desired to discover how the hospital presently deals with this information in regards to other hospital-wide databases in the administrative and financial offices. Furthermore, current and future budgets need to be discussed to discover the price range possible for this endeavor.

The questionnaire is divided into two main sections: the clinical path and the administrative path. The questions under the clinical genre are directed at patients, caregivers, as well as clinicians who directly deal Mount Sinai patients and their diabetes data. Conversely, the questions in the administrative section will be answered mostly by the managerial staff at Mount Sinai.

In writing and revising the questions, we were careful to choose wording appropriate for the different audiences. For example, in our verbiage for queries directed at patients, we made an effort to be direct and simple. Additionally, we did our best to phrase the questions in a way so as not to be lead the responses. This proved to be one of the most difficult tasks in creating the interview questions.

Overall, we strove to make the questions for patients, clinicians, and other hospital staff members as direct and to-the-point as possible. This will ensure the most reliable and useful information will be gathered as easily as possible for the students of IPRO 345 Fall Semester.

Ethics

In order to protect the rights of the future interviewee's, the ethical ramifications and requirements were investigated. It was found that an extensive review process is required whenever human subjects will be a source of research. A report detailing the procedures and requirements has been created for future teams.

The Institutional Review Board (IRB) requires two separate procedures to be completed before a single question has been asked. First each interviewer must complete a certification program that takes approximately two hours and is available via http://phrp.nihtraining.com/users/login.php [11]. Two members of the current IPRO team completed this certification process.

Secondly, an approval application needs to be submitted to the IRB board detailing the interviewing procedures and questions. The application for IRB approval for the IPRO 345 team cannot be completed until the specifics of the interview are decided. An ethics report was compiled explaining the procedures necessary to the future IPRO teams. The summer 2011 IPRO team underwent an ethics presentation to gain a better understanding of the problems that human interviews pose [8].

Finally, when conducting any human research all participants must submit a letter of written consent [11]. This has been written and provided for the following IPRO sections and is also attached as an appendix. Completed forms of written consent need to be stored in a secure location for at least six years post research completion.

Conclusions and Recommendations

Technological Recommendation

As a basis for following IPRO 345 semesters, guidelines of product specifications were drafted.

Diabetes Electronic Support Center

The clinical requirements for the support center are as follows:

1. Effective communication between patient and clinician
2. Medical information is communicated to the patient in simple and understandable terms
3. Secure web portal that can only be accessed by authorized individuals
4. User friendly web portal that is intuitive to work with
5. Ability to integrate with existing EMR databases for easy medical record information retrieval

Whatever database selected to use in Mount Sinai Hospital, it must allow for a variety of functions. Most importantly, the DESC must be able to retrieve information from the remote testing equipment used by the patients. It should also be able to analyze the glucose readings and compare it to standard thresholds. If glucose levels are hazardous, it should have an automatic alert to inform clinicians of the variability. An automatic feedback should be established to provide receipt of data transmission. Finally, it should be able to send reminders to patients to check their glucose levels regularly.

The following is a graphical representation of the desired diabetes electronic support center (DESC).

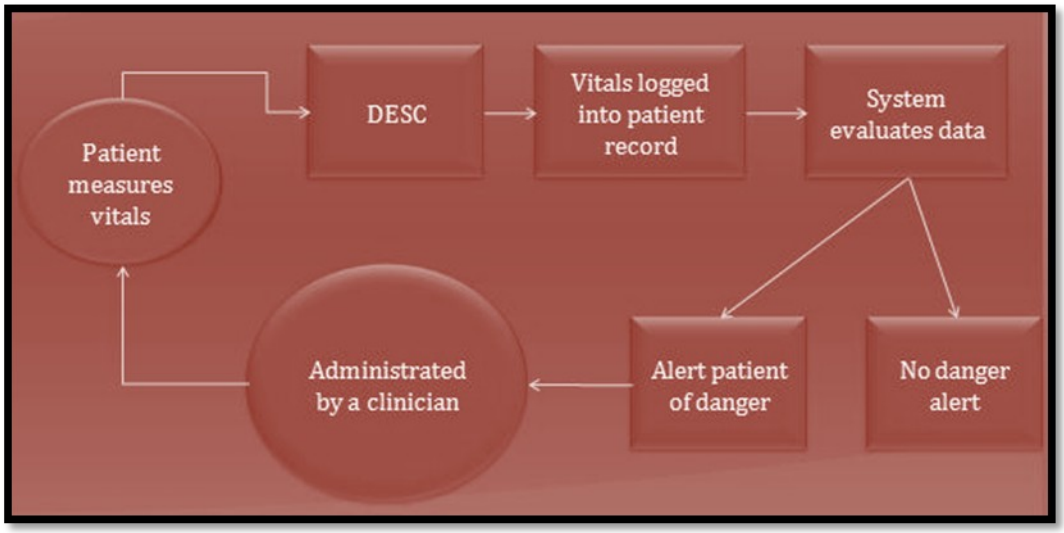

Figure 1: Desired DESC system

The DESC should have built in intelligence that will evaluate data and report to clinician and generate actions automatically. Once an action is taken by the software, a clinician will be referred examine the action and report it to the patient. This system will also enable routinely analysis of the data once the patient has sent it via a mobile device. Therefore, the DESC system is a tool allowing the clinicians to save time and to obtain an accurate, timely, and pattern of the patients' blood sugar profile.

A variety of businesses that provide similar products were investigated. It was found that the desired DESC went beyond what is normally provided by available products. The following is the matrix chart comparing known products.

	DESC	Google Health[1]	Cerner[2]	Atrius[3]	Versus[4]
Simplify & Manage Official Medical Records	✓	✗	✗	✗	✗
Simplify & Manage Medical Information	✓	✓	✗	✗	✗
Connect Patients to Clinicians	✓	✓	✗	✓	✗
Connect Clinicians to Clinicians	✓	✗	✓	✗	✓
Home Access of Medical Information	✓	✓	✗	✓	✗
Remote Patient data tracking	✓	✗	✗	✗	✗

Figure 2: Matrix chart of clinical diabetes databases [1], [3], [2]

The ideal goal of the DESC system project is to have excellent communication between patients and clinician as well as clinician to clinician. The DESC should provide easily accessible information by authorized personnel such as a clinician or patient, simplify and manage records in orderly form, eliminate communications barriers between clinicians to clinicians and clinicians to patients, and track data accumulation received by a remote electronic support such as mobile device.

Diabetes Testing Equipment

Since a large portion of the people who will be using the testing equipment will be medically hindered, ease of use was the largest consideration when comparing diabetes testing equipment. It was decided that any equipment chosen should have the following features:

1. Current FDA approval

2. Available online database
3. Alert system
4. Measures other vitals
5. Send data in less than three user inputs

It should also be fiscally conscience or covered by insurance. It also will need to be able to link to the DESC system supported by the hospital. With these considerations in mind, a matrix chart was developed comparing some of the most popular diabetes testing equipment currently available. It has been added as an attachment. The favored testing equipment is the HealthPal which is very easy to use and provides alerts and an online database available to patients and clinicians [10].

Interview Methodology

Next semester, it is the recommendation of IPRO 345 Summer Semester that future IPRO 345 team uses the questions complied for the interviews to be conducted at Mount Sinai Hospital. The verbiage used in each question was chosen very carefully to accommodate the audience. It is recommended that the interview questions are reviewed by the IPRO intern Jill May. The questions will likely also need to be reviewed by the board at Mount Sinai Hospital before they are administered to patients.

The questions have been divided into two categories for simplicity. The first set of questions is directed at patients, caregivers, and clinicians who deal directly with the data collected. The second set of questions are intended as administrative in nature and are more likely to be answered by directors and those in managerial positions at the hospital.

As long as the questionnaires are administered along with the consent form which we have composed, all the ethical considerations for surveys such as this have already been considered and discussed within multiple trained persons at IIT. Moving forward, IPRO 345 Fall Semester can distribute the questions, compile the results, and begin to analyze the current situation of diabetes care at Mount Sinai. It is our hope that these interview questions will provide the basis for which IPRO 345 can begin to devise a system that creates access to remote electronic support for the diabetic patients of Mount Sinai Hospital.

Ethics

In order to legally and ethically conduct any research, the following steps still need to be completed by the future IPRO sessions [8].

1. A detailed research plan needs to be developed including information on sample size and selection, location of interviews, information recording and procedures to protect confidentiality.
2. Interview questions need to be finalized
3. All investigators must complete the online training and print their certificates to accompany the I.R.B. approval form.
4. The I.R.B. approval form needs to be submitted to the contact information listed on the form

at least a month prior to the expected start of the interviews.

5. Any changes in the research procedure need to be submitted to the I.R.B. for re-approval.

Prior to interviewing anyone affiliated with the Mount Sinai Hospital, the future IPRO team will also need to check if there is a separate I.R.B. approval process through the hospital itself.

Appendix A: Team Roster

Unubold Chinzorig

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Appendix B: Final Budget

The IPRO 345 team required funds for transportation to and from the meetings located at the downtown campus, including the cost of street parking and gas. Printing costs were also incurred through the creation of the IPRO day poster and various informational packets. Finally, with the approval of the IPRO board, refreshments were purchased with IPRO funds. Listed below is the itemized table of all final expenditures:

Activity	Description		Cost
Transportation	Fuel	9 trips, 4 miles at 0.50$ per mile	$18.00
	Parking		$47.75
Refreshments			$45.85
Total			$111.60

Note: Budget with proof of purchases has been submitted to the IPRO office, sorted by purchaser.

Appendix C: Matrices of Diabetes Testing Equipment

DEVICES / FEATURES	HealthPal [10]	Glucotel	Telcare	Bayer Contour USB Blood Glucose meter
		BodyTel™	TELCARE®	Contour USB BLOOD GLUCOSE MONITORING SYSTEM
Dimensions	109 mm x 54 mm x 23 mm	140 mm x 32 mm x 17 mm	N/A	76 mm x 38mm
Battery type	Lithium polymer	2 AAA batteries	N/A	Rechargable Battery
Connection	Cable connection & Bluetooth	Bluetooth	GPRS enabled	Through computer with internet connection
Price	N/A	$140	N/A	$30
FDA approval	Yes	Yes	Pending	Yes
Online database	HealthCOM	BodyTel Center	MyTelecare.com	Glucofacts Deluxe
Data availability	Patients & Doctors	Patients & Doctors	Patients & Doctors	Patients
Alert type	Alerts for glucose tests & automated call system	Yes	Custom Alert	Manual alerts can be set
Measures other vitals	Yes	Yes	Yes	No
Under 3 clicks	Yes	Yes	Yes	No
Easer interface	Yes	Yes	Yes	Yes

APPS FEATURES	Glucool [5]	Log for Life [9]	Glucose Meter [6]	Glucose Buddy
Price	$ 7.99	Free (+++)	$2.82	Free
Platform	Android	iOS	Android	iOS
Syncs with Online Database	Google Health (+)	Log for Life online database	Google Health (+)	Glucose buddy online database: MyDiabetes
Syncs with BGM devices	No	No	Yes (++)	No
Other features(++++)	Yes	Yes	Yes	Yes
URL Link	http://www.glucool.com/	https://www.logforlife.com/	GlucoseMeter	GB

Appendix D: Letter of Written Consent

Dear interview participant:

In an attempt to bring remote diabetes testing equipment to Mount Sinai Hospital, we require information regarding individual patient's daily testing procedure as well as information about the patient's meetings with their doctor and the storage of their vitals readings. This will allow us to create a general system that will meet the patients of Mount Sinai's needs.

Involvement is voluntary. If you choose to participate, we will not be recording your identity, but we will need your age, gender and current medical condition. Your specific information will only be used to generalize the information and it will not be given to anyone outside of the researching team.

Your involvement will help us to create a diabetes testing program that will be automatically providing your doctor's with your daily readings. This should decrease the amount of time you will spend in a clinic, as well as increase the quality of care your physician will be able to provide.

There are not any foreseeable risks to your person; however if you feel uncomfortable at any point during the interview you have the right to withdraw without penalty. You also have a right to refuse participation. Current and future treatment will in no way be affected by your participation.

If you have any additional questions, please feel free to call or Professor Eliezer Geisler at 312.906.6532. Please note that we are not affiliated with Mount Sinai Hospital.

If you would like to participate in an interview, have read this letter fully and understand all its components please sign your name in the space provided.

Thank you for your time and consideration.

_____	_____	_____
Patient Name (Printed)	Signature	Date
_____	_____	_____

Caregiver Name (Printed) Signature Date

Appendix E: Proposed Interview Questions

Clinical Path

In the home:

1. What type of glucose meters are used by patients?
2. What daily readings are collected by patients? (glucose levels, blood pressure, weight, pluse, etc.)
3. How do patients record these readings? A written log? Typed into a computer?
4. Who records the daily readings? The patient? A nurse/ caregiver? A family member?
5. How often do patients go to the hospital with these readings? Do patients feel that this is too frequent, not frequent enough, or just right?

In transit:

1. In what format are the readings presented to the clinician at the hospital? Hard copy? Electronically?
2. Who transfers the data? The patients themselves? Caregivers?
3. How often is the data brought into the hospital? Daily? Weekly? Other?
4. To whom in the hospital is the data given to? Doctors? Nurses? Other?
5. What does the data consist of? Glucose readings? Vitals? Descriptions of conditions and symptoms? Additional medical information?
6. Are there any issues of privacy concerning transfer of the data from the home to hospital?

In the hospital:

1. Who in the hospital receives the data from home? Doctors? Nurses? Physicians' assistants? Other?
2. What is the next step taken by the clinician who receives the data? Where is the data sent? In what form?
3. How complete is the data brought in by patients? Is falsification ever a concern?
4. What clinical action is taken by the doctor/ nurse upon receiving the data?
5. Is the data analyzed and compared to previous readings from the same patient? Is the analysis performed on the data based on standards? If yes, which standards are used by clinicians?
6. Are there well-defined protocols regarding the receipt, analysis, and action required with the data thus received by clinicians? If yes, what are these protocols?
7. Who else at the hospital is involved with the analysis of the data and any medical actions to be taken? What is the level of their involvement?
8. Who has access to the data brought in by patients?
9. Who is responsible for communicating with the patient?
10. Who is responsible for linking the data and analysis with the administrative organs of the hospital (e.g. accounts, information systems)?
11. When a patient is admitted/ readmitted, how is the patient's clinical data collected at the hospital and then linked to the data previously received from the home? How do the two systems connect/ integrate?
12. How is such data used in the studies of diabetes and for statistical analyses?
13. Does the hospital have statistics on the relationship between modes of treatment of diabetes at

the hospital and the incidence and protocols of data received from the home?

Administrative Path

The Diabetes Database:

1. Is there currently a diabetes database at Sinai? If yes, what are its capabilities and limitations?
2. Who is in charge of the diabetes database? Who manages it? In what department/ unit is it housed?
3. What categories of data are stored in the database?
4. Is the diabetes database a dedicated database or is it shared with other chronic diseases?
5. How is the database linked to other administrative information systems, such as financial systems?
6. How is the database linked to other clinical databases?
7. What types of inputs go into the database? What kind of outputs/ reports does it generate? Who receives these reports? Who has access to these reports?
8. What is the current budget for this database?

The Sinai Information Systems:

1. How is this database linked to other Sinai clinical and managerial information systems?
2. How is the diabetes clinical data evaluated as a chargeable activity at Sinai?
3. What software and hardware technologies are used at Sinai to communicate with the home of a patient (telemedicine)?
4. How do these relate to the case of diabetes? Are there specialized technologies currently being used in the link between the home and the hospital? If yes, what are they?
5. Is telemedicine used in other diseases at Sinai? If yes, how are they similar to and different from their use in diabetes?
6. What is the range of funds available for development and implementation of the DESC (Diabetes Electronic Support Center)?
7. What type of alerts is the hospital interested in sending?

Appendix F: References

[1] “An Important Update about Google Health”. Google. http://www.google.com/intl/enUS/health/about/.

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