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The Medical Vanguard Diabetes Management Project was designed to deploy an Internet based diabetes management system, MyCareTeam, into a number of existing diverse clinical environments and evaluate how such a stand-alone clinical information system can be integrated into diabetes management program. The diverse environments include the High-Risk Pregnancy Clinic at the National Naval Medical Center and 8 Native American Communities throughout the United States. The GAO Report *Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89)* will be used as the basis for the evaluation of the technology implementations. While the implementation of MyCareTeam has been shown to be clinically effective in some environments (KE Smith, et al, 2004, PR Conlin, et al, 2004) the processes required to implement this technology into diverse communities has not been studied. This project has two primary specific aims: clinical deployment and deployment evaluation.

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Introduction:

The Medical Vanguard Diabetes Management Project was designed to deploy an Internet based diabetes management system, MyCareTeam™, into a number of existing diverse clinical environments and evaluate how such a stand-alone clinical information system can be integrated into multiple diabetes management program. The diverse environments include the High-Risk Pregnancy Clinic at the National Naval Medical Center and 8 Native American communities throughout the United States. The GAO Report *Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89)* will be used as the basis for the evaluation of the technology implementations. While the implementation of MyCareTeam™ has been shown to be clinically effective in some environments (KE Smith, et al 2004, PR Conlin, et al, 2004) the processes required to implement this technology into diverse communities has not been studied. This project has two primary specific aims: clinical deployment and deployment evaluation.

Body:

Statement of Work:

The approved Statement of Work for this project has two primary aims – *clinical deployment* and *deployment evaluation*. During this first year, much time has been spent on clinical deployment of MyCareTeam™ at multiple sites. The administrative processes of setting up subcontracts, working through the Human Subjects Review Processes for each institution, and coordinating with the multiple sites have been challenging. This report will present the challenges and successes of deploying this technology into diverse clinical environments and then identify the next steps once deployment is complete and enrollment and operations can begin.

Clinical Deployment:

As we prepare to deploy MyCareTeam™ in multiple Department of Defense (DOD) and Native American healthcare environments, we approach this technology insertion from a global perspective that includes concerns of the enterprise (DOD or Native American facility), existing diabetes management programs, healthcare units, clinical staff, and patients. The goal of the deployment of MyCareTeam™ is to improve the effectiveness of various existing diabetes management programs for the medical beneficiaries in the DOD as well as Native American Communities as measured by improved health outcomes and clinical care delivery.

The clinical deployment portion of this project focuses on determining the most efficient and effective way to identify and organize the roles and responsibilities of individuals within the healthcare enterprise and the insertion of MyCareTeam™ within the healthcare delivery system. A comprehensive systems approach to the integration of MyCareTeam™ into the different clinical environments will be undertaken.

All clinical deployments need to go through many stages before MyCareTeam™ can be used effectively. Program setup and recruitment are two critical components of deploying MyCareTeam™ into an existing clinical environment. We have identified the stages of (A) program setup and (B) recruitment that are critical to a successful deployment of MyCareTeam™.

(A) Program Setup

1. **secure subcontract for each group**
   Prior to implementing MyCareTeam™ at any of the Native American Communities, a subcontract must be formalized between Georgetown University and the Community. This process takes place in cooperation with the Georgetown University Office of Research and Technology Development Services. The subcontract, which includes a detailed budget and a comprehensive statement of work, is written with input from each project site. Before signing the subcontract, the budgets are reviewed by a member of the National Congress of American Indians President's Taskforce on Healthcare Technology to ensure that the monies allocated and distributed to the Native Communities are done so fairly. Native Communities are ask to submit quarterly reports outlining progress on their activities and present an invoice for expenses related to the project. Thus far, we have subcontracts in place with two of the seven American Indian groups and also with the Native Hawaiian group. These subcontracts were originally created for one year, however, they are being extended to a two-year agreement, now that the second year of funding has come through and the extension to this program was received from the United States Army Medical Research Acquisition Activity. In stead of a subcontract, Georgetown University entered into a Cooperative Research and Development Agreement (CRADA) with the National Naval Medical Center. This document guides the use of personnel, resources, and equipment between the Navy and Georgetown University during the course of this project.

2. **create a local project team including clinical and project management personnel**
   At all sites with which a subcontract has been established, a team of clinical, administrative, and project management personnel has been identified. Some sites have identified a physician as a member of the team, but most often a nurse or diabetes educator has primary responsibility for interacting with the patients using MyCareTeam™. Within each community, an advocate within the health clinic, an administrator or a provider with diabetes knowledge and experience, needs to be identified. This person drives the program from within the clinic. Their job is to coordinate the clinical personnel that will work on the project, identify patients for recruitment, deal with contractual and human subjects' issues, and direct the adjustments that need to be made to the MyCareTeam™ application. A team of individuals will be involved from the start – but having an advocate makes coordination between the clinical and technical teams run smoother.

   At two of our currently active sites (Poarch Band of Creek Indians, Atmore Alabama and the Hawaiian Health Clinics) the advocate for the project is the clinic administrator. At our other active site, a newly hired program manager without any real connection to the clinical department is the advocate. He is well connected within the community and can hopefully engage the clinic personnel to move the project forward. Having different types of personnel as the project advocate will allow us to evaluate how each type succeeds in garnering support for the project. At the National Naval Medical Center, our advocate is a clinical nurse dealing directly with the high risk patient population.

   Another important role of the project team is to help us understand the statistics and services that define their health clinic, their diabetes program, and the available technology resources.

3. **define the existing health services at each site**
The National Naval Medical Center (NNMC) is a full service medical institution providing primary and specialty care to all members of the armed services and their families. National Naval Medical Center has the facilities to perform lab tests, surgery, rehabilitation, and other services of a full service in – and out-patient medical institution – including a pharmacy system. The Native communities with which we have established subcontracts or are currently negotiating the subcontracts tend to be more single clinics focusing on primary care with some specialty services provided. Most do not have surgery departments, rehabilitation, or therapy (PT, OT, or radiation). They do provide pharmacy services, some provide laboratory services, and most have a nurse practitioner or family medicine doctor that visits the clinic regularly but is not on full time staff at the clinic. Some patients in the Native Communities need to travel many hours to the nearest hospital or specialty clinic (like dialysis) and thus access to care for these populations is limited and difficult.

4. **define the existing diabetes services at each site**
National Naval Medical Center has two clinics that focus on the treatment of pregnant women with diabetes. They have a gestational diabetes mellitus (GDM) clinic that focuses on women who are pregnant that develop diabetes during their pregnancy but can control their blood sugar levels through diet and exercise. Most of these women do not take medication for their GDM. The other clinic is the Complex Obstetrics (COB) clinic that focuses on pregnant women with pre-existing diabetes or pregnant women who developed GDM but need insulin or oral medications to control their diabetes. Patients from both of these clinics will be enrolled in the study as long as they use a glucose meter to track their blood sugar readings.

Most of the Native Communities have implemented diabetes clinics within their primary medicine clinics. Some of the communities have endocrinologists as consultants that visit their patients periodically, all have glucose meters and supplies available to their patients at no cost, and all of the clinics provide educational classes to their patients on diabetes. One of the clinics provides a monthly foot clinic where patients can get appointments to have their feet examined and cared for. (Foot ulcers leading to amputation is a very serious and common complication of diabetes). One of the sites we are currently working with was using a standalone software application to read their patients' glucose meters when the patients came in for their regularly scheduled visits. All are excited about using our technology.

The table below shows the statistics about the clinics we have begun working with. It identifies some of the baseline information we have gathered regarding the clinic and existing diabetes programs

	Number of members	Number of diabetics	Number of clinics	Glucose meter
National Naval Medical Center		15-30 at a time	2 GDM and COB	AccuChek Advantage
MHA	12000	10800	5	AccuChek Advantage
PBCI	2260	300	1	Precision Xtra
Tlingit & Haida	6000	160-180	1	AccuChek Advantage
Nez Perce	5000	406	2	OneTouch Ultra
Wampanoag	898	16	1	OneTouch Ultra
Hawaiian Natives Na Puuwai Ke Ola Mamo	65	18	4	 OneTouch Ultra OneTouch Ultra
Rosebud	24500			Precision Xtra

5. define the technology resources available

The implementation of MyCareTeam™ requires some home monitoring technology. Patients connect their glucose meter to a vital signs modem device which connects directly to a phone line. The modem reads the data from the glucose meter and transmits the readings. Initially, we had concerns about the availability of telephone lines, computers, and Internet access within some of the more remote Native communities. However, initial discussions at all the sites have assured us that access to telephone lines will not be a problem for most patients. Therefore, there should not be any technical barriers to transmitting their blood glucose readings to the MyCareTeam™ database.

Access to computers and knowledge of the Internet may be more difficult. Most sites, excluding National Naval Medical Center, felt that a small percentage of their mostly adult patients with type 2 diabetes would have access to a computer and even smaller amount with Internet knowledge. Therefore, most of the sites have decided to place public access computers with Internet access in key locations that make them accessible to patients. The sites also recognize that it may be necessary to provide individuals that can train patients on using the computer to access MyCareTeam™ and also to help patients review their data.

High speed access to the Internet from the public use machines should be available for most sites. Most patients with a computer in their home or a family member's home would use dial-up access to the Internet. A toll-free number will be setup at the ISIS Center in Washington, DC to receive the glucose readings from the patients modem devices. The modem devices will be pre-programmed to send data to this number before distributing them to the patients.

As patients are enrolled in the study, we will ask the individual sites to please collect some basic information regarding their access to a PC, the Internet and their prior use and comfort level of both.

6. define the clinical protocol to be carried out

Each site determines for itself the best way to implement MyCareTeam™ into their existing diabetes management program. The protocols for the Mandan, Hidatsa, and Arikara Nation,

the Poarch Band of Creek Indians, and the National Naval Medical Center have been defined. They are summarized here.

Mandan, Hidatsa and Arikara Nation. Patients will be recruited initially from the Parshall and White Shield Health Facilities. Five to ten patients will be identified first to act as a focus group and provide directed feedback to the project team focusing around accessibility, understandability, and usefulness of the MyCareTeam™ technology. Participants will be selected based on those who are compliant with medications and monitoring regimens but who still have poorly controlled diabetes. They will also be selected based on their willingness to access MyCareTeam™ via the Internet. Once selected, these patients will be followed by an RN or LPN from the Parshall or White Shield Health Facilities. After the initial focus group has provided some feedback, modifications will be made based on that feedback and the study will be opened to a larger patient population and more patients will be recruited. Patients will be selected based on the following criteria: A1C greater than 8 in the last two months; currently uses a standard glucose meter; over 18 years of age; have access to a standard telephone line; can read and write English; and can read a computer screen.

Patients will be asked to transfer their glucose meter data weekly to the MyCareTeam™ secured database. Once the data is available via MyCareTeam™ patients and providers will review the data and communicate via the site. Changes in medication regimen and suggestions for diet and exercise adjustments can be made through MyCareTeam™. MyCareTeam™ will be used as part of routine care by health facility staff in managing the recruited diabetic patients during this evaluation project.

Poarch Band of Creek Indians. Like the Mandan, Hidatsa, and Arikara Nation, the Poarch Band of Creek Indians will start with a focus group and expand after receiving feedback from the group. Their inclusion criteria are also the same. For the Poarch Band of Creek Indians, they will perform the study at their one health clinic. All providers involved will be employees of the health clinic. The nurses will review the data via MyCareTeam™ and communicate information back to the patient's physician if necessary or the physician will have permission to access the data on MyCareTeam™ if desired.

National Naval Medical Center. Patients will be recruited from the Prenatal Assessment Center at the National Naval Medical Center in Bethesda Maryland. Subjects for the study will come from a population of pregnant women who have either preexisting diabetes or who have been diagnosed with gestational diabetes. Patients will be eligible for the study if they meet the following criteria: pregnancy is complicated by either type 1 or 2 diabetes or patient is diagnosed with gestational diabetes; they regularly test blood glucose levels using a standard glucose meter; they have access to a standard telephone line; can read and write English; and are over 18 years of age.

Patients will transfer their blood glucose readings twice a week to the MyCareTeam™ secured database using the AccuLink Modem. The providers will then examine the information either online or from a printed copy of the data inserted into the patient's paper record. If the physician orders a change to the patient's regimen, the information will be messaged back to the patient via MyCareTeam™. Patients will also be instructed to review

their own data on MyCareTeam™ and to look for and send messages to their providers using the system. Patients will be directed to online educational information that is available at the MyCareTeam™ web site and they will be encouraged to review the information when they have questions or concerns. Patients will be asked to fill out a survey (see Appendix A) two-four weeks after enrollment and again towards the end of their pregnancy. The survey will help us to understand their reaction to the technology implemented through MyCareTeam™, how they felt about communicating with their care provider over the Internet, and their feelings towards the educational materials.

7. **determine where the database and web servers will be hosted and managed**
Due to monetary constraints and technical expertise, all sites have opted to have the ISIS Center at Georgetown University host the web and database servers and to setup a toll-free telephone number to facilitate the transfer of data directly from the glucose meters to the MyCareTeam™ database. The computer facility at the ISIS Center is a locked room in a secured facility. It is protected by electronic firewalls and VPNs as need to ensure the safety and integrity of the clinical data.

8. **secure human subjects approval from all necessary institutions**
Human subjects' protections are a large piece of getting this program underway. Before recruitment of study participants can begin, authorization must be received from three separate human subjects approval agencies or institutional review boards (IRB). The first agency is Georgetown University. We first received expedited review approval from the Georgetown University IRB on August 21, 2003 with continuing approval granted on July 15, 2004. Our next approval renewal date is July 15, 2005. The second human subjects' approval comes from the regional IRB for each of the American Indian, Alaskan Native and Native Hawaiian communities and the National Naval Medical Center and is referred to as the primary IRB approval. Each study site submits a protocol and consent form adapted to their individual needs. The Native American and Alaskan Native communities plan to seek approval from the Indian Health Service (IHS) IRB committees. For those IHS sites where there currently is no active IRB, authorization will come through IHS Headquarters in Bethesda, Maryland. These IHS area IRB committees are located in: Alaska; Aberdeen, North Dakota; Albuquerque, New Mexico; and Portland, Oregon; Primary approval for the Native Hawaiian study will come from Papa Ola Lokahi, a Native Hawaiian Healthcare System providing human subjects approval on projects related to Native Hawaiian Healthcare. The National Naval Medical Center has its own IRB committee. The third and final authorization comes from the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command. This is referred to as secondary approval.

IRB approval took on average four months for the two sites, National Naval Medical Center and Mandan Hidatsa, and Arikara Nation, that have received primary approval. These IRB committees had set schedules that were well defined and a well stated process to assist us and the sites in preparing and submitting the proposals. Secondary approval has been more difficult to obtain and the communication process for getting feedback from the committee or IRB reviewer at the United States Army Medical Research and Materiel Command has been long in coming. Secondary IRB approval was submitted in June 2004. As of submission of

this annual report, comment on the human subjects' proposal submitted to the HSRRB office of the United States Army Medical Research and Materiel Command has not been received by the principals and therefore implementation of the project or recruitment of patients can not begin.

9. **review the MyCareTeam™ site for modifications, setting defaults, creating accounts**
At each site, a demonstration of the technology is given to the clinical and project team members and they are asked to identify areas of the technology that would need adjustment to make it more acceptable to their clinical providers as well as to potential patients. Determining features within MyCareTeam™ that would be used by the clinical team, the graphics, colors, and other GUI features that may not be culturally appropriate to the patient population, and most importantly, the educational materials that are presented to the patients. All of these items, along with some configurable options are identified by the clinical team and the adjustments are made by the technical team. Wherever possible, we try to identify areas that can be used by more than one project site. (Appendix B contains screen shots from the MyCareTeam™ application)

Treating pregnancy complicated by diabetes or gestational diabetes is different than treating adult diabetic patients and therefore changes to the features of MyCareTeam™ were required. Fasting blood sugar levels are very important to identify and track for pregnant women with diabetes and therefore special attention is paid to the first reading of the day in the blood glucose log book page and the associated graphs. Medications taken by pregnant women with diabetes are also different than those prescribed to non-pregnant adults. The lab tests ordered for pregnant women are different than those ordered for adult diabetics and the surrogate marker of long-term glycemic control, hemoglobin A1C, is not as important for a woman with gestational diabetes. Individual glucose readings are more critical and therefore patients at National Naval Medical Center are asked to transmit their glucose readings twice a week where as sites treating adults with diabetes request their patients send their glucose readings once a week. Many sites request some change in the patient registration screen. Each site has added or removed some information to make it more relevant to the way they currently manage their clinic. Some of the changes have been incorporated for all sites and others only for the site that requested it.

The educational materials were revamped for all the active sites. National Naval Medical Center provided us with their paper-based pregnancy and diabetes materials and with the help of our diabetes educator we built an online educational site describing all aspects of diabetes and pregnancy, both gestational diabetes and pregnancy complicated by existing diabetes. Some of the Native communities currently use the Indian Health Service diabetes curriculum to educate their patients about diabetes. With permission of the Indian Health Service, we have taken their materials and put them up on our web site. We have added culturally appropriate graphics and images to break up the information on the pages. Where appropriate we have placed links to other sites recommended or approved by the Indian Health Service. We anticipate that most of the Native Communities will use this as the educational materials that are presented to their patients from the MyCareTeam™ site.

There are many configurable options within the MyCareTeam™ site. Each clinic can decide on the list of alert values to focus on, the upper and lower limits of the normal range for blood sugar levels, whether to track blood pressure as well as blood sugar levels, the medications they prescribe, the lab tests that are performed, and whether to provide reminders to patients for clinic visits, lab tests, or other items. MyCareTeam™ is then configured to include each of these options. The look of the opening page has been modified to be more appropriate for different sites.

An initial user account is created for a single provider at each site that allows them to register new patients as well as other care providers. There are multiple options that are set for each new provider registered into MyCareTeam™. These options include whether a provider can register new patients or other providers, enter medications, message patients, and mark patients records as having been reviewed. This access control is for the privacy and security of the information within the MyCareTeam™ site.

10. procure technology including blood glucose meters, modem technologies, cables, computers, install communications lines, setup telephone numbers

Once the glucose meters and other possible vital signs monitoring equipment have been identified, the appropriate technology to facilitate the transfer of the data from the glucose meters to the MyCareTeam™ database is determined. Two technology vendors have been identified that can read data from the glucose meters being used and transfer the data via telephone line to the MyCareTeam™ database. These devices by Roche and AeroTel (See Appendix C for pictures of modem technologies) allow patients to use three different vendors' glucose meters and potentially electronic blood pressure cuff without requiring a patient have a computer at home. Engineers from the ISIS Center have written software that facilitates the acceptance of the data from these devices and transfers that data to the secured MyCareTeam™ database.

All sites are responsible for purchasing their own glucose meters and strips for their patients, which is how they operated before the start of this project. All sites use a single manufacturer's meter with all their patients. We have identified modem technology as described above that works with the manufacturer's glucose meters being used by all sites to permit easy transmission of glucose readings from the glucose meter itself directly to the secured MyCareTeam™ database. Each site is responsible for purchasing the modem devices and respective cables for their patients, except for National Naval Medical Center. Our budget purchases the required modems and cables for the National Naval Medical Center.

There are three glucose meters being used by all active sites, Accu-Chek Advantage, OneTouch Ultra, and Precision Xtra. The Accu-Chek Advantage works with the AccuLink modem, both by Roche Diagnostics, to transmit the data out of the connected glucose meter over standard telephone lines to the secured database. The OneTouch Ultra, by Johnson & Johnson, and the Precision Xtra, by MediSense, work with the TeleCliniQ, by AeroTel Inc., to transmit the data out of the connected glucose meter over standard telephone lines to the secured MyCareTeam™ database. Software was provided by both Roche and AeroTel to receive the data files from their respective modems. Secure File Transfer Protocol (FTP) is

used to transmit the data inside our firewall and then software developed at the ISIS Center is used to parse the files, match the data files to the correct patient and insert the data into the secured MyCareTeam™ database.

Some of the sites have identified public areas in which they will place community computers with Internet access for the patients to use to review their clinical data. At the National Naval Medical Center two PCs were purchased to be placed in a private room identified for pregnant women with diabetes to use. They will have private access to their clinical data and a printer to print out any of the information, as desired. Even women not enrolled in the study will be able to review the educational materials developed for this project using those computers. Some of the Native Communities are identifying locations for public computers where they will be most accessible and therefore used by patients enrolled in the study. If Internet access does not exist at these locations it is the responsibility of the site to secure it.

A toll-free telephone number will be installed at the ISIS Center to accept the data transmitted from the AccuLink and TeleCliniQ devices from all of the sites, regardless of location. Internet access will not be available through this toll-free phone number.

11. train clinical personnel

Initial training sessions of key clinical personnel were held at each of the three sites that currently have subcontracts in place. However, since the human subjects' process is taking longer than expected, retraining will be required once the sites are permitted to begin recruitment. The ISIS Center personnel train the clinical staff, however, it is the responsibility of the clinical staff or the administrative personnel at each location to train the patients. We recommend training patients when they are given their AccuLink or TeleCliniQ modems. The training process for the providers is usually about 1-3 hours and for the patients 30 minutes to 1 hour. The outline of the provider training course and the user manuals distributed at the course are included in Appendix D.

(B) Recruitment

1. define inclusion and exclusion criteria for patient participation

Each Native Community defines its own criteria for patient inclusion as does the National Naval Medical Center. Since this is not a randomized, control trial and pure clinical outcomes are not our major focus of the study, they can be more lenient about who is included in the study. Most sites have decided to look for patients whose blood sugars are not under good control, usually these patients have an A1C value above 8, and that can read and write English. Technical ability is not a criterion for inclusion and neither is comfort with computers or the Internet. However, patients must be willing to use the computer as a means for communicating with their care providers and to review their own clinical data. These patients must be willing to use a public access computer if they do not have direct access to a computer with Internet access.

2. identify recruitment procedures

Each site will determine the best way to recruit their patients. Since we are working directly with personnel at the different clinics, the clinical personnel will be familiar with the patients

and will be able to talk with them directly about participation. Whether to use public announcements, brochures, or flyers for recruitment will be decided by each site individually.

3. **identify incentives, if any, that will be used**
   Most of the sites feel that some small incentives, tokens, and rewards will be necessary to keep patients interested and using the MyCareTeam™ system and checking their blood sugars regularly. The tokens may be things as simple as movie tickets, coffee mugs, t-shirts, etc. Patients will be given the modem devices that some may see as an incentive. Lastly, as a project, we will see about receiving some gifts from corporations like Nike that can be used as incentives to patients that are compliant with the programs.

4. **gain consent**
   Once each site is ready to begin, they will need to enroll patients into the trial and get informed consent for their participation. Each site's consent form will be reviewed by the primary and secondary IRB committees before being given to the patients. The Principal Investigator or a co-investigator will talk with the patient and make sure that they understand the project and know what they are signing before the patient is fully enrolled into the project. Consents forms from the Mandan, Hidatsa, and Arikara Nation in North Dakota and the National Naval Medical Center in Maryland have received primary approval and are included in Appendix E.

	MHA	PBCI	Papa	Tlingit and Haida	Gay Head	Nez Perce	Rosebud	Mescalero	National Naval Med Center
(A) Program Setup									
Subcontract/CRADA	X	X	X	Ongoing		Ongoing			X
Project Team	X	X	X	X					X
Health Services	X	X	X	X	X	X			X
Diabetes Services	X	X	X	X	X	X			X
Technology Resources	X	X	X						X
Clinical Protocol	X	X	X						X
Host Servers	X	X	X	X	X	X			X
Human Subjects	Primary	Ongoing	Ongoing						Primary
Modify MyCareTeam™	X	X	Ongoing						X
Procure Technology									X
Training	X - retrain	X - retrain	X - retrain						X - retrain
(B) Recruitment									
Criteria									
Procedures									
Incentives									
Gain Consent									

X - completed

Deployment evaluation

Introduction

This section focuses on evaluating whether the insertion of MyCareTeam™ into routine delivery of healthcare services and specifically chronic disease management was effective.

The earlier indications of the effectiveness of MyCareTeam™ as a stand-alone specialty disease management e-health system are encouraging. However, insertion of MyCareTeam™ into multiple diverse clinical environments presents new technical, clinical, management, and cultural challenges.

Many of these items are required for chain of events analysis and are categorized into the Program Setup Group and are bureaucratic or technical in nature, but are still critical to the clinical deployment and the clinical outcomes. The combination of bureaucratic, technical and clinical events is required to facilitate and thus evaluate a successful clinical deployment.

Since we have not been able to begin recruitment yet, this section will focus on how we are preparing for the analyses once we have received Human Subjects Approval and our projects have begun. We will detail the types of information we will gather and how it will be collected. We will also talk about how it will be used and applied to the performance measures and techniques outlined below.

Evaluation Measures

The evaluation component of this project is based on the protocol outlined in the GAO Report, *Executive Guide: Measuring Performance and Demonstrating Results of Information Technology Investments (GAO/AIMD-98-89).* This IT Performance Management Approach makes use of measures designed to create and facilitate action to improve performance. Information produced by this approach delivers the following benefits: (1) early warning indicators of problems and the effectiveness of corrective action, (2) input to resource allocation and planning, and (3) periodic feedback to clinical personnel, patients, and healthcare management about the quality, cost, and timelines of MyCareTeam™. The GAO report recommends a Chain of Events Analysis to evaluate the implementation of the standalone technology. In preparation for performing this type of analysis, we have identified the items that need to be considered and categorized them into the following 5 areas:

(A) Program Setup
(B) Recruitment
(C) Operations
(D) Support
(E) Analysis.

The areas of Program setup and recruitment relate much more to the clinical deployment, rather than the evaluation of the deployment. They were discussed in detail in the preceding section. In this section, we will focus more on assessing the areas of (C) Operations, (D) Support, and (E) Analysis.

The proposed performance management approach requires partnerships between the ISIS Center at Georgetown University and the various DOD and Native American clinical sites. The ISIS team will work with members of the clinical sites to jointly identify the goals, objectives, and assessment tools described in the following sections.

To measure the success of the clinical deployment of MyCareTeam™ in the different clinical environments (DOD facility and Native American communities) we look at individual measures related to recruitment, clinical monitoring, treatment, and clinical outcomes. Different items of measurement have been identified for each of these areas and we will gather the data for each of these measurements directly from the clinical database.

Evaluating Recruitment
To determine if the recruitment procedures were successful, the following information will be collected throughout the recruitment period:

- number of possible participants
- number of patients approached about participating
- number of patients agreeing to participate

The number of patients with diabetes seen at each clinic was estimated by clinic personnel at the start of the project. Once recruitment is ready to begin, this number will be updated and using their enrollment criteria to determine eligibility to participate, each clinic will begin recruitment. Each clinic will be asked to track the number of patients contacted about participation in the study, thus counting the number of possible participants who were approached about participating, regardless of whether they chose to participate or not. This includes tracking how many people were asked directly, attended meetings about the project, or estimating numbers based on more group activities – like health fairs, flyers, etc. The clinics will also be asked to track the patients that agree to participate and are actually enrolled. From these numbers, we can determine the percentage of patients that were reached and the percentage that chose to participate and apply similar numbers to future implementations. It will help us understand how many patients can be reached and the time and effort required to recruit these patient populations.

Evaluating Compliance with Clinical Monitoring

- frequency of blood sugar testing
- frequency of sending in BG values
- frequency of reviewing BG data and other clinical info by patient
- frequency of reviewing BG data and other clinical info by provider
- frequency of sending comments or messages

The frequently with which patients check their blood sugar levels, transfer their blood sugar readings to the secured database, or communicate with their provider via MyCareTeam™ have been shown in previous studies to correlate positively with clinical outcomes. The MyCareTeam™ database allows us to track these measures within the MyCareTeam™ database. Each blood sugar reading sent to MyCareTeam™ is stamped with the date and time the reading was taken. From these values, we can calculate the frequency with which the patients are testing their blood sugar, daily. Similarly, each transfer of blood sugar readings from the glucose meter

to the database is time stamped with the date and time the reading was sent to the database, so we can calculate the frequency with which they transfer their data. All logins to MyCareTeam™ are recorded so we can easily calculate the frequency with which patient and providers log into MyCareTeam™. And lastly, the messages sent between patients and providers are also time stamped, so we can determine the frequency and time interval with which they get sent. Patient and provider compliance can and will be checked using these measures.

The compliance with clinical monitoring parameters will allow for analysis to determine if clinical outcomes are improved among the groups of individuals that use these features more than those individuals that chose not to use them. It will also tells us something about how successful we were with implementing MyCareTeam™ into the different cultural environments (DOD, Native American) and also into the new area for us of diabetes and pregnancy.

Treatment Changes

- number of changes in medications by care provider
- Suggested diet or exercise changes by care provider
- Number of messages sent to patient with clinical content, suggestions, or advise

There are certain treatment measures that can be gathered from the MyCareTeam™ database and thus allow us to determine the types of interactions occurring using MyCareTeam™ and the level of treatment being provided. The medications page allows us to determine the number of adjustments made to patients' diabetes, blood pressure, or pregnancy (for National Naval Medical Center) medications and determine the frequency of those changes. This may help to explain changes in clinical outcomes. Similarly, analyzing the messages sent between patients and providers may help to explain the types of interventions occurring and may explain changes in clinical outcomes and lead us to identify new features (e.g., goal setting behavior tracking) that would be a benefit if added to MyCareTeam™.

Assessment of Clinical Outcomes

- Change in A1c
- Change in Cholesterol measures
- Change in BMI
- Change in numbers of hypo- and hyperglycemic events
- Weight of baby at birth (for National Naval Medical Center)

Diabetes outcomes are measured by the above clinical parameters. Previous studies of MyCareTeam™ have shown improvements in A1C, cholesterol and BP while showing a decline in BMI. It is expected that this study will show similar results, however, a stronger focus will be placed on maintaining or improving BMI as well. Providers will concentrate on educating patients about the link between glycemic control and weight gain, especially for type 2 diabetic patients. Patients will have regular lab tests and those values will be entered in the MyCareTeam™ secured database. We can then use the data from the MyCareTeam™ database to analyze the clinical outcomes of the patients enrolled. As stated above, we will look at the groups of individuals that showed the largest improvement in clinical parameters and determine the characteristics of the population as well as the actions of those patients to determine the most effective use of MyCareTeam™.

Other process parameters that we will track and analyze include those associated with inserting and maintaining and supporting the technology. These include the Use of the MyCareTeam™ technologies, Training users on the system, and the Support that was required and provided.

Use of Technology

- Frequency of use
- Ease of use
- Most used features

The frequency of use of MyCareTeam™ by patients will be collected as stated earlier – by reviewing the audit trails maintained within the MyCareTeam™ application. These audit trails track when users log into and out of the system and thus how long they are engaged can be calculated. We track how often the patients engage in some of the features of MyCareTeam™ like exercise tracking, communicating with their providers, and maintaining their "other medications" list. These values plus a short survey on their perceptions regarding ease of use, features they like, and those they say they use most will be used to evaluate the acceptance of the technology by the patients. A short survey to the providers will help us understand their preferences for features in MyCareTeam™ as well as their perception of ease of use. We also track how frequently providers use the system – however, they may be more likely to use the system even if they don't find it intuitive or easy to use simply because their patients are using it. Therefore, we expect to place greater emphasis on the survey responses than on the data gathered from the audit trail which tracks how frequently patients and providers log in or use some features of MyCareTeam™.

Training

- How long did initial training take
- How many technical questions were raised

We will keep complete records during the training sessions to determine how long it takes to train the providers and the types of questions they have during the training. It is our goal to streamline the training sessions so that it does not take the providers more than 1-2 hours to be trained and feel comfortable to use the system and to train their patients in its use.

Support

- Number of support calls received
- Number of bugs reported
- Number of fixes made
- Amount of time MyCareTeam™ was down

Support logs will be kept to track the numbers and types of support questions that are raised, how they were fixed, and the length of time between the support request being filed and the resolution of the problem. E-mail, telephone, and messages from within MyCareTeam™ are all available for providers to register technical problems or questions. A log will be kept that details all support messages regardless of how they are conveyed. The log will include a date and time of reporting, a description of the problem, who reported the problem or raised the question, the

resolution, date and time of resolution, date and time of notification of resolution, how notification of resolution was given, and who handled the issue.

From this log, we can determine how many small fixes were required, how many changes to the application were requested and completed, and how many larger technical issues were reported. We will also track if the MyCareTeam™ Web Server, database Server, modem servers for receiving glucose meter data, or Internet access to the ISIS Center are unavailable and thus making MyCareTeam™ unavailable. We will keep logs of frequency and duration of each outage.

Chain of Events Analysis

An example of a chain of events analysis is given below. It identifies the different steps that are essential to achieving the end result of implementing a successful IT program, MyCareTeam™, at each identified health clinic. The chain of evidence, that is a necessary component of a chain of events analysis, includes indicators of whether the steps are occurring and identifies some of the measures that will be used. The IT support chain shows the items that directly affect the achievement of the program outcome. Finally, measuring how well IT is supporting these intermediate steps is critical to demonstrating how well it is performing.

Chain of Events Health clinic participants	Identify existing diabetes programs at each site	Adjustment to diabetes management at sites	Patients more compliant with self-monitoring of their diabetes	Patients HbA1c is reduced and more patients cared for
Chain of Evidence	National Naval Medical Center, Mandan Hidats & Arikara, Poarch Band of Creek Indians, Nez Perce, Tlingit & Haida, Wampanoag, Rosebud, Hawaii clinics	Number of participants Provider participation	Frequency of: BG testing; BG transmit; BG and clinical data review; Provider BG and clinical data review; Sending comments or messages	Collection of A1C, BMI, & cholesterol in range; counts of hypo- & hyper-glycemic events; recording baby birth weight
	Intermediate Outcomes			End Outcomes
IT Support Chain	Timely, helpful implementation strategies provided	Insertion of home technologies and access to MyCareTeam™	Training; support calls received; software problems reported and fixed; System down time	Analysis of use statistics identified in chain of evidence
IT Measures	Development of project plan for insertion of MyCareTeam™	Numbers of patients and provider using MyCareTeam™ to communicate and manage their diabetes	Analyze all measures listed above	Evaluate use statistics vs. health outcomes vs. satisfaction and ease of use

Key Research Accomplishments:

Mandan, Hidatsa, and Arikara Nation (MHA):

1. Sub-contract is in place - contract extension is pending;
2. Key personnel at the MHA clinics have been identified. Bruce Hall, the project manager, will oversee implementation of MyCareTeam™;
3. MyCareTeam™ will be implemented at 2 health clinics, Parshall and New Town, on the MHA reservation;
4. Aberdeen Area Indian Health Service Institutional Review Board approval (primary IRB) has been granted for MHA Nation; waiting on comment from the Human Subjects Research Review Board (HSRRB)/Office of Regulatory Compliance and Quality (RCQ), United States Army Medical Research and Materiel Command (approval request was submitted in early June 2004);
5. Areas of adjustment to MyCareTeam™ have been identified by MHA nation and the changes put in place by ISIS Center; some outstanding pieces need to be provided by MHA before the site can be made publicly available;
6. Some clinical personnel have been trained, however, retraining and training of additional persons will be necessary;
7. Technology to be used has been identified - patients will use Roche Accu-Chek Advantage glucose meters and Roche AccuLink modems; a reduced purchase price has been negotiated with Roche for purchase of the modems; and
8. An Internet version of the Indian Health Service Diabetes Curriculum has been implemented and was offered to the clinical personnel for use by their patients.

Poarch Band of Creek Indians (PBCI):

1. Sub-contract is in place - contract extension is pending;
2. Key personnel have been identified - Annette Hicks, the clinic administrator, will head up the implementation and Donna Johnson is the certified diabetes nurse who will work directly with the patients;
3. MyCareTeam™ will be implemented in one health clinic located on the reservation;
4. Demonstrated the site to some of the clinical and administrative personnel at PBCI Health Clinic; all comments, suggestions, and requests for changes have been implemented;
5. Precision Xtra glucose meters will be used with the AeroTel TeleCliniQ modem to transmit the blood glucose readings directly from the meter to the MyCareTeam™ database; a reduced purchase price has been negotiated with AeroTel.; software has been developed to read data directly from the Precision Xtra meter connected to a PC, in case it is required for a community PC;
6. Clinical personnel have been trained, however, retraining will be necessary;
7. Poarch Band of Creek Indians and Georgetown University personnel submitted the Primary IRB approval request to the IHS Central IRB office – including consent form and protocol. Still waiting on comment; and
8. An Internet version of the IHS Diabetes Curriculum has been implemented and will be used by the clinical personnel for use by their patients.

Papa Ola Lokahi

1. Sub-contract is in place and the contract extension is pending;

2. Papa Ola Lokahi is the key group overseeing the implementation of the project at two health clinics; a short proposal outlining the project at the two clinics has been prepared;
3. Ke Ola Mamo on Oahu and Na Pu'uwai on Molokai have been identified as the clinical sites for the project;
4. An intensive meeting was held to identify the areas of the site that require modification to be appropriate for their clientele – final decisions still need to be made by the clinical sites and communicated to Georgetown University;
5. Papa Ola Lokahi's Institutional Review Board is determining whether an IRB is necessary; primary IRB approval has not been submitted.
6. Intensive training will be done once most of the modifications are in place and the IRB is approved;
7. OneTouch Ultra glucose meters will be used with the AeroTel TeleCliniQ modem to transmit the blood glucose readings directly from the meter to the MyCareTeam™ database; a reduced purchase price has been negotiated with AeroTel.; software developed by Georgetown University is available to read data directly from the OneTouch Ultra meter connected to a PC in case it is required for a community PC; and
8. Educational materials have not been identified

Tlingit and Haida

1. Tlingit and Haida tribes have replaced the Chilkoot tribe at the request of the National Congress of American Indians Presidents Task Force on Health Information Technology;
2. An initial meeting took place in Alaska in late April with the Tlingit tribe and their contracted healthcare provider, SEARHC; a followed-up meeting took place in August with SEARHC and they are very excited to participate on behalf of the Tlingit/Haida tribes; final agreement to participate should come from SEARHC's Board of Directors shortly; and
3. IRB items (sample consent form and sample protocol) and information needed to start the sub-contracting process (request for budget and sample SOW) were sent to a tribal POC and given to a SEARHC representative - we are waiting for a response.

Wampanoag Tribe of Gay Head

1. Started sub contract procedure, waiting for a budget and statement of work;
2. No key personnel have been identified as yet and the clinical team that will participate has not been identified either; and
3. Met with Wampanoag tribe twice to discuss the project, however, there is only a small number of diabetic patients on island and limited clinical resources; the tribe is still determining the best way to follow-up and implement the project.

Nez Perce

1. A site visit took place in April 2004 with tribal health clinic personnel; and
2. IRB items (sample consent form and sample protocol) and information needed to start the sub-contracting process (request for budget and sample SOW) were sent to a tribal POC and we are waiting on a response

Rosebud Sioux

1. No further progress.

Mescalero

1. No further progress. They have chosen not to participate at this time.

National Naval Medical Center

1. Have had multiple meetings with clinical personnel to identify the needs of pregnant women with diabetes – both gestational diabetes and women with existing diabetes who become pregnant;
2. The IRB was granted by the National Naval Medical Center and the CRADA established between National Naval Medical Center and Georgetown University;
3. A diabetes educator working with the development team from Georgetown University has worked closely with the nurses at National Naval Medical Center to identify and develop the educational piece for the web site – it is now ready to launch;
4. More meetings are planned to determine if other operational items need changing in order to handle the unique needs of managing pregnant women with diabetes - many changes have already been implemented;
5. The clinical team is in place and ready to start; training has been completed but a refresher may be needed; and
6. The Roche Accu-Chek Advantage glucose meters with the Roche AccuLink modems will be used; twenty modems have been ordered and received; PCs were ordered and received to use as public access machines for the patients and laptops for the clinical staff.

Advisory Board

1. An eleven member advisory board comprised of a diverse group of individuals has been formed; members of the board have clinical backgrounds, belong to Native Communities, are diabetes advocates, are academics, or work in the private corporate sector;
2. The Board has been tasked to provide guidance on the implementation of MyCareTeam™, but more importantly on helping design a sustainability plan;
3. The first meeting was held in Washington DC and the board agreed to meet twice a year; and
4. The second meeting, originally scheduled for October 2004, was postponed until MyCareTeam™ is implemented in at least one native Community.

Reportable Outcomes:

- Presentations
    a. "Using Internet Technology to Treat Diabetes in Pregnancy", P Angelus, BA Levine, C Christian, TMJ Hu, F Fang, SK Mun, D Bloom, S Stone, C Macedonia, accepted for presentation at the 2nd Annual Forum on Remote Monitoring & Home Telehealth: Integrating Process with Outcome, American Telemedicine Association, Boston MA, Sep 2004
    b. "Home Monitoring for Diabetes and End Stage Renal Disease", BA Levine, presented to TeleHealth New Hampshire, Bartlett, New Hampshire, June 2004
- Funding applied for based on work supported by this award
    a. AHRQ: "Diabetes Management in Poarch Band Indian Community". Submitted April 2004, not funded

b. NIH TRP: "Technology Empowered Nurse-Directed Diabetes Study". Submitted June 2004, no decision made yet
c. Letter of Intent submitted to RWJ Foundation in answer to the Health eTechnologies Initiative with the University of Florida. Submitted April 2004; not accepted
d. NSF ITR: "Embedding Human Value in Sociotechnical Systems: Social Networks to Manage Teen's Chronic Diseases". Submitted Feb 2004; not funded

Conclusions:

This first year of the Medical Vanguard Diabetes Management Project has been a frustrating and educational year. It has taught us not to take the administrative tasks of beginning a large evaluation project for granted. The human subjects' requirements and subcontracting and contracting tasks have cost us much time and money to get them in place. As we move forward with the other American Indian sites, we hope to get through the human subjects' process more quickly and trust that the time required by the Medical Research and Material Command to review the proposal will be shorter since a modification will be requested and not a new application review.

If recruitment and enrollment of patients do not begin early in this year of the project, it will be difficult to complete a full evaluation of the technology insertion and thus measuring whether the individual sites benefit from the technology as predicted will be quite difficult.

Invaluable comments and feedback have been received from the clinical personnel at each site as MyCareTeam™ is modified to fit their specific user needs. The addition of patient registration fields, expansion of online diabetes educational materials (the Indian Health System Diabetes Curriculum and the National Naval Medical Center diabetes and pregnancy materials), look and feel of the home page of the site, and other features that have been activated or deactivated based on site preferences have been implemented. Sites have been created for the National Naval Medical Center, Mandan, Hidatsa, and Arikara Nation, and the Poarch band of Creek Indians that will allow their patients and providers to feel comfortable using them as soon as the human subjects' approval is granted.

At this point, there are no research results to speak of and the collection of data is minimal. Most of the information gathered to date is subjective in nature and is gathered through the multiple meetings we have held with each site as we work with them to prepare MyCareTeam™ so it is most useful for them.

References:

1. "Impact of MyCareTeamTM for Poorly Controlled DM", KE Smith, B Levine, SC Clement, MJ Hu, A Alaoui, SK Mun. Diabetes technology and Therapeutics, 2004, Vol 6. Issue 6. (to be published Dec 2004)
2. "A Clinical Trial of Web-based Care Management in Patients with Poorly Controlled Diabetes Mellitus", PR Conlin, GT McMahon, HE Gomes, SH Hohne, TMJ Hu, BA Levine, submitted to JAMA, (in review August 2004)

Appendices:

The following are the appendices included in this report:
Appendix A – Patient Satisfaction with Telemedicine Survey
Appendix B – Screen shots of MyCareTeam™ application
Appendix C – Pictures of the modem devices used in the study
Appendix D – Outline of MyCareTeam™ Training Session and user's manuals
Appendix E – Consent Forms from Mandan, Hidatsa, and Arikara Nations and from National Naval Medical Center

Appendix A

Patient Satisfaction with Telemedicine Survey

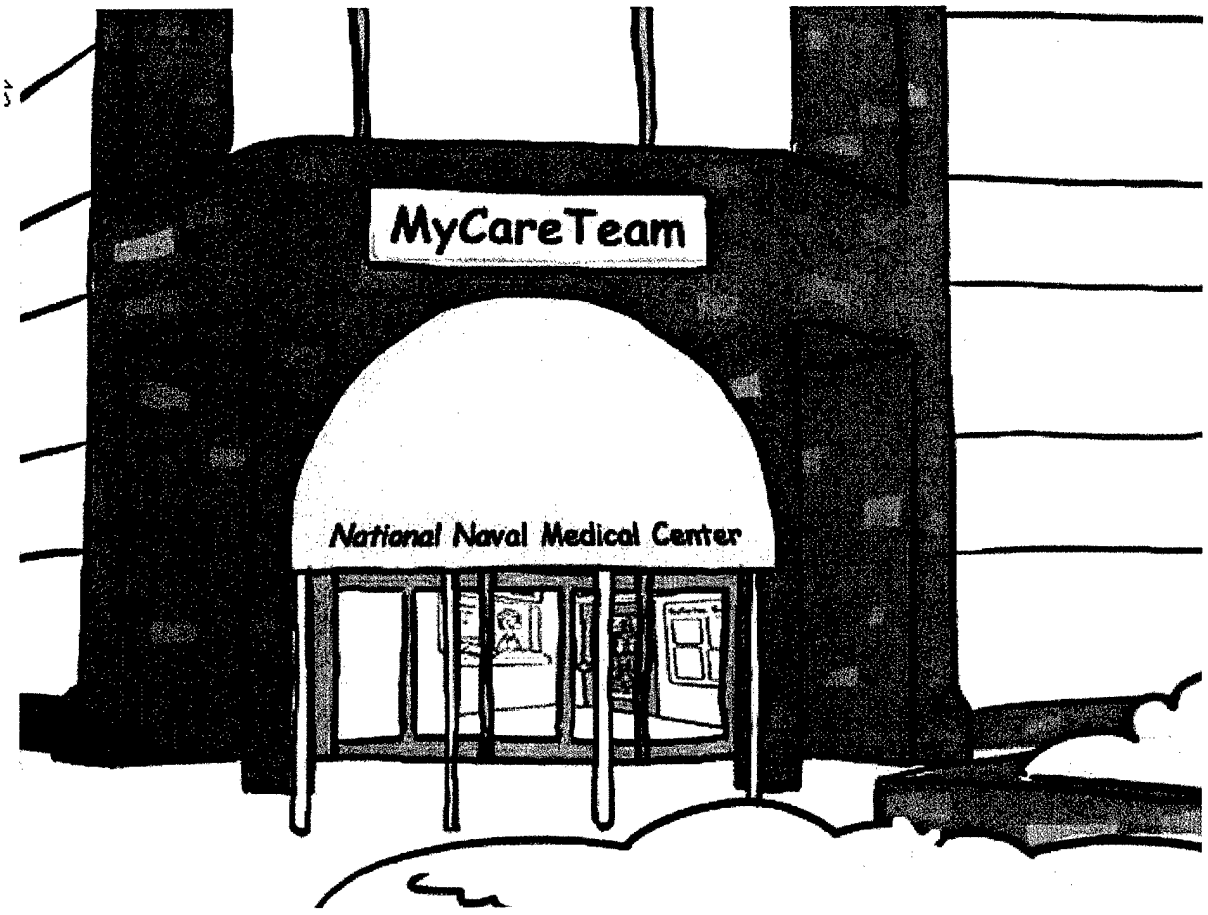
Use of Technology	**5** ☺	**4**	**3** 😐	**2**	**1** ☹
1. I find the MyCareTeam program easy to use.					
2. MyCareTeam pages are displayed quickly					
3. MyCareTeam is available whenever I need it					
4. My current blood glucose readings are available on MyCareTeam whenever I check for them					
5. The graphics on MyCareTeam are friendly and					

Method of Education	**5** ☺	**4**	**3** 😐	**2**	**1** ☹
1. I learn a lot form the MyCareTeam education pages					
2. The information I seek is available at MyCareTeam or they direct me to the correct pages					
3. I have learned a lot about my disease from reviewing the analysis of my blood sugar values on MyCareTeam.					

Method of Communication with care provider	**5** ☺	**4**	**3** 😐	**2**	**1** ☹
1. I communicate with my provider using MyCareTeam frequently					
2. I find it difficult to discuss issues with my care provider using MyCareTeam					
3. I like communicating with my care provider over MyCareTeam					

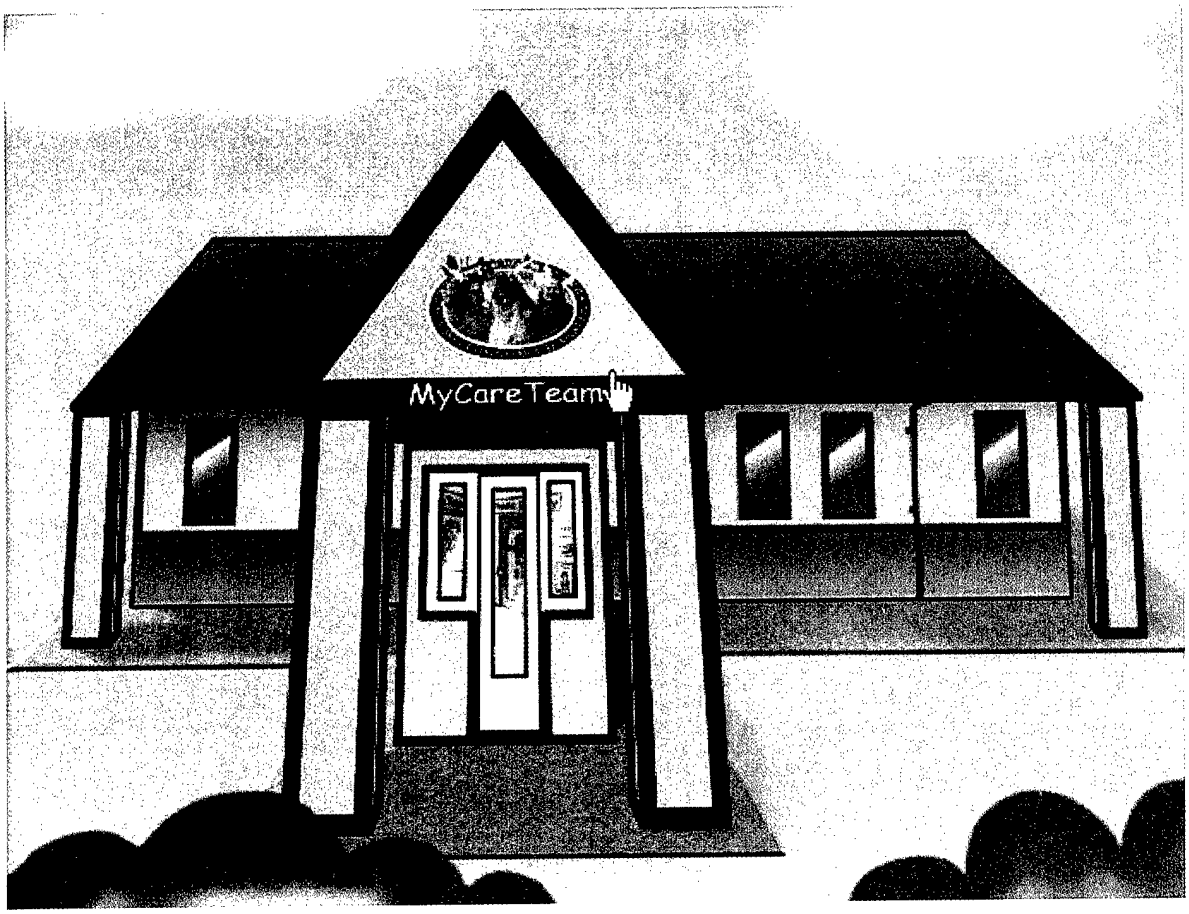
Appendix B

Screen Shots of MyCareTeam™ Application



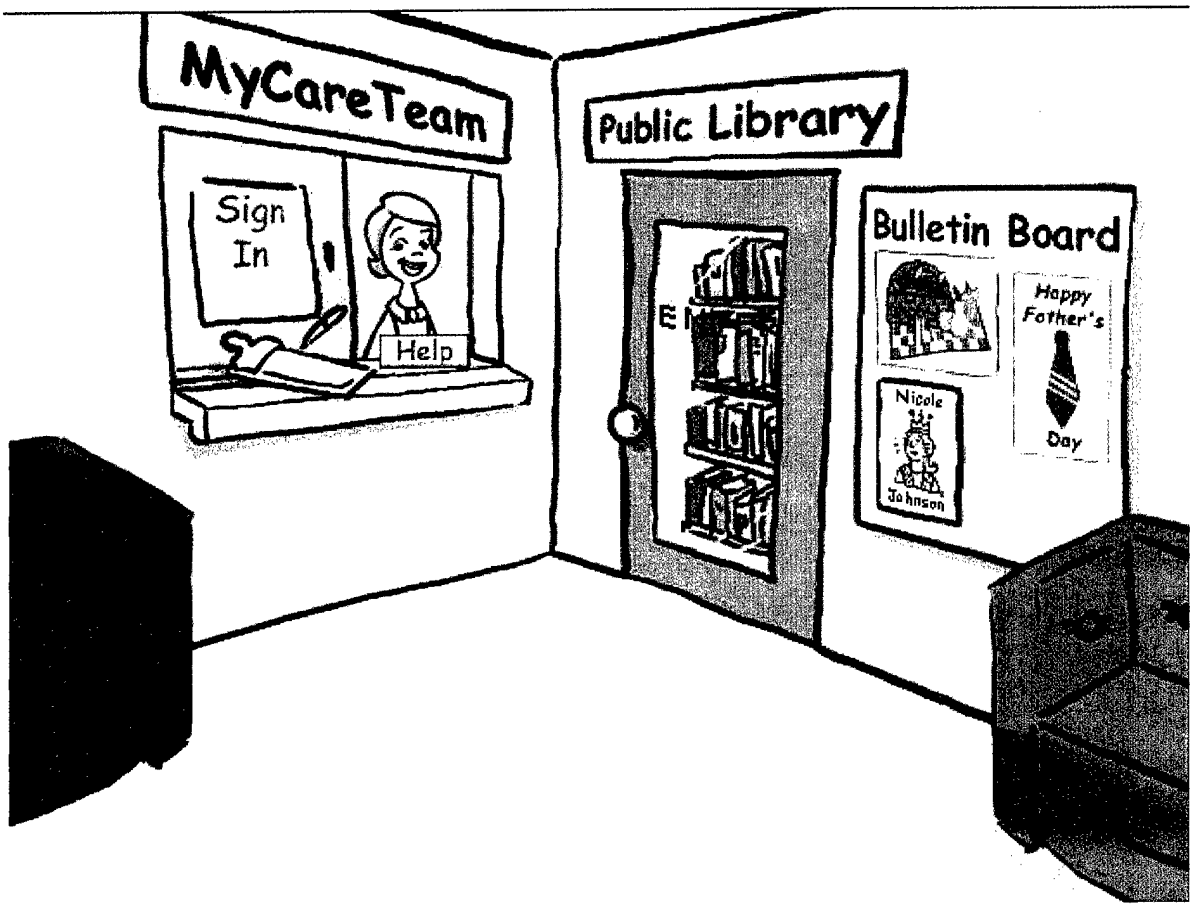
Contact us

MyCareTeam™ splash page for National Naval Medical Center

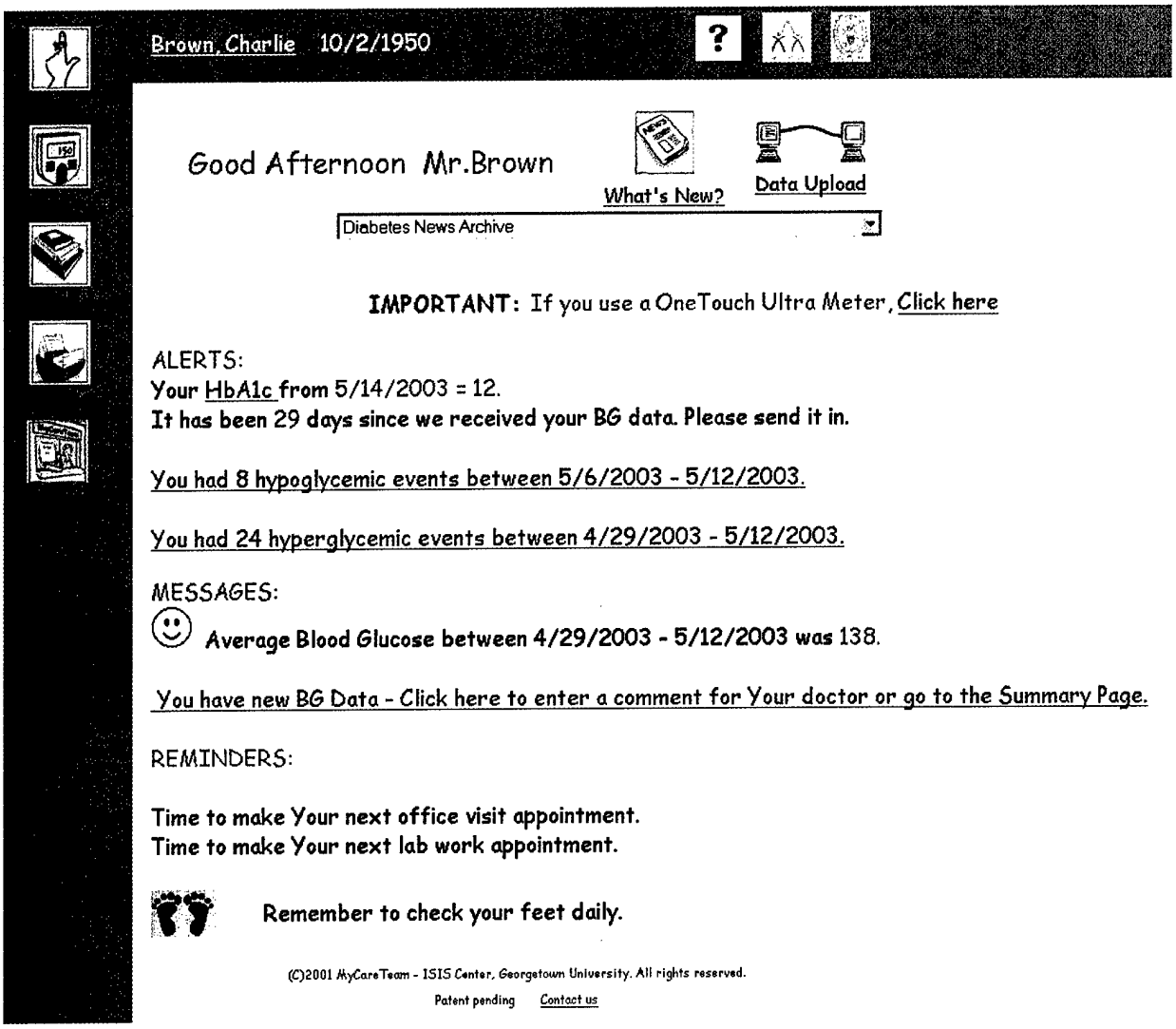


Contact us

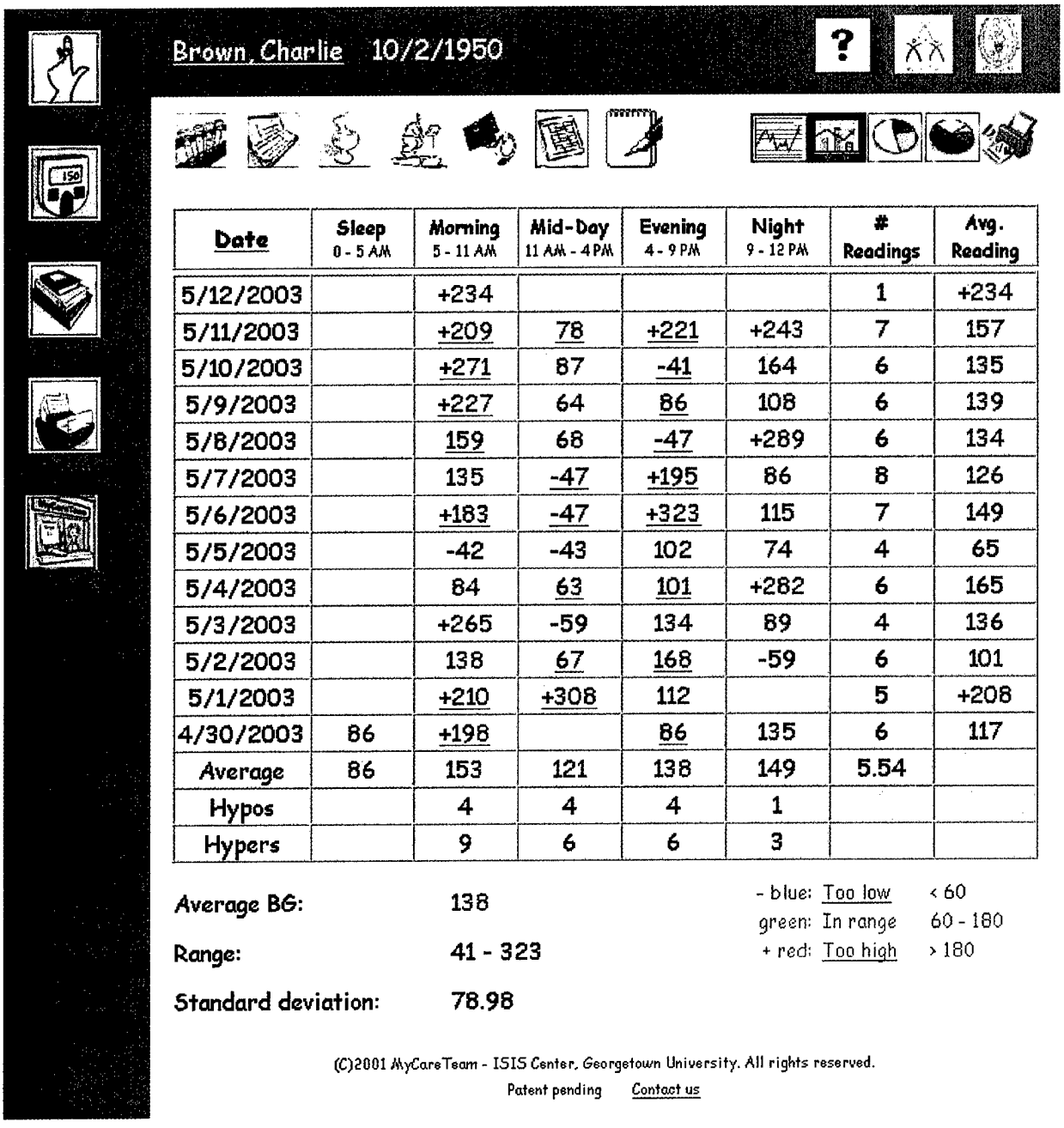
MyCareTeam™ splash page for Mandan, Hidatsa, and Arikara Nation



Lobby area –access to public education materials, news items, and secure sign-in



Patient screen showing automated analysis of data after sign-in



Brown, Charlie 10/2/1950

Date	Sleep 0 - 5 AM	Morning 5 - 11 AM	Mid-Day 11 AM - 4 PM	Evening 4 - 9 PM	Night 9 - 12 PM	# Readings	Avg. Reading
5/12/2003		+234				1	+234
5/11/2003		+209	78	+221	+243	7	157
5/10/2003		+271	87	-41	164	6	135
5/9/2003		+227	64	86	108	6	139
5/8/2003		159	68	-47	+289	6	134
5/7/2003		135	-47	+195	86	8	126
5/6/2003		+183	-47	+323	115	7	149
5/5/2003		-42	-43	102	74	4	65
5/4/2003		84	63	101	+282	6	165
5/3/2003		+265	-59	134	89	4	136
5/2/2003		138	67	168	-59	6	101
5/1/2003		+210	+308	112		5	+208
4/30/2003	86	+198		86	135	6	117
Average	86	153	121	138	149	5.54	
Hypos		4	4	4	1		
Hypers		9	6	6	3		

Average BG: 138

Range: 41 - 323

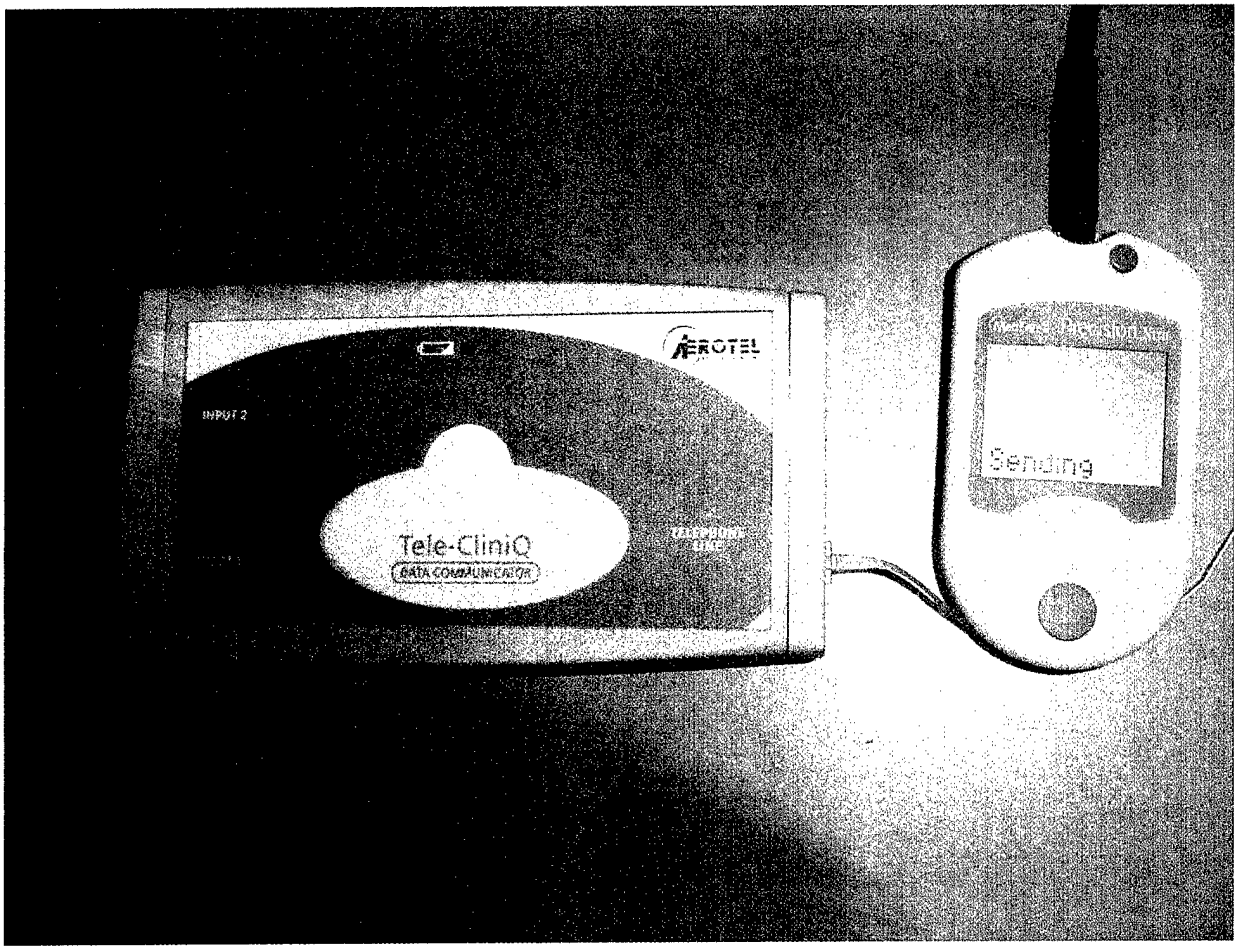
Standard deviation: 78.98

- blue: Too low < 60
green: In range 60 - 180
+ red: Too high > 180

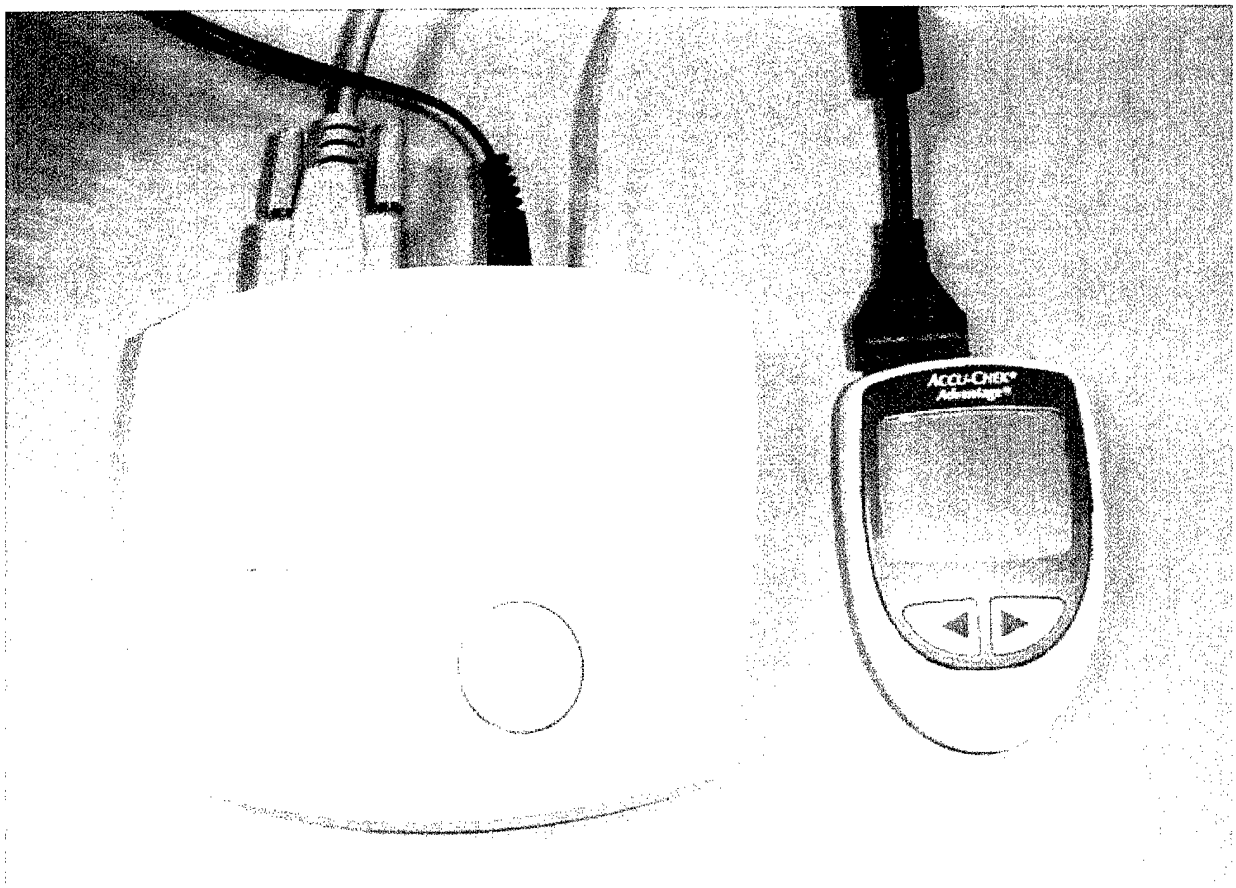
Patient blood glucose log book

Appendix C

Aerotel TeleCliniQ Modem Device
Roche Diagnostics AccuLink Modem



AeroTel TeleCliniQ modem device with Precision Ultra glucose meter



Roche Diagnostics' AccuLink modem device with Roche Accu-Chek Advantage glucose meter

Appendix D

Training Outline
User's Manuals

MyCareTeam Training Schedule

1. Overview of Applications
   a. Blood Glucose and Blood Pressure reading program
      i. Retrieving data from the meters
      ii. Entering a comment for the BG data
      iii. Location of final data file
      iv. Format of final data file
   b. MCT Web Application
      i. Patients side
      ii. Practitioners side
      iii. General Public Access
2. Blood Glucose and Blood Pressure reading program
   a. Installation
   b. Patient Use – connections, running application
   c. Creation of data file – format and location
   d. AccuLink and TeleCliniQ Devices
3. MyCareTeam Web Site
   a. Connectivity - How will patients connect to the Internet and therefore have access to MyCareTeam?
   b. Logging in
   c. Practitioner Use
      i. Creation of new patients
      ii. Entering lab values
      iii. Use of reminders page
      iv. Selecting patient's data to view from:
         1. Alert List
         2. New Data List
         3. All Patient List
      v. Review of Patient Data
         1. Difference of selecting from Alert or New Data lists and all patients list
         2. Explanation of Patient Alert Page (Alert or New Data selection)
            a. Alerts
            b. Messages
            c. Reminders
            d. Clinical Data Icons
         3. Log Book Page
            a. Categorization of received data
            b. Date Range (default and how to change)
            c. Graph options – line, histogram, pie charts
            d. Multiple readings for a time slot
            e. Averages by TOD or Date
            f. Overall average, range, Standard Deviation
            g. Recognizing Hypo- & hyper- glycemic events & counts
         4. Lab Values

a. 12 month schedule
b. Message and clapping for HbA1C < 7
c. Pop-up definitions

5. Medications
   a. Ability to enter insulin, pump, and oral med prescriptions
   b. Blood Pressure/Hypertension medications
   c. Current and Previous prescriptions available
   d. View other medications that the patient enters
6. Exercise Log
   a. View current 14 day log
   b. Change date range
7. Blood Pressure Log
   a. View current 14 day log
   b. Change date range
8. Summary Page
   a. How it is created
   b. Each field
   c. Practitioner comments
   d. Date range selectable
   e. Graphing functions for current data view
   f. Highlighted entry
9. Individual patient messaging
   a. Messages order by date
   b. Contain message sent to/from given patient by given user
   c. Date selection from within messaging
   d. New message preceded by red *
   e. Viewing a message
   f. Creating/Adding a message
   g. Sending a message
   h. Replying to a message

vi. Checking for new messages – All patient messaging
   1. Message Count
   2. Date selection from within messaging
   3. Viewing a message
   4. Creating a message
   5. Sending a message
   6. Replying to a message

vii. Education Piece
   1. Georgetown educational material

viii. Contacts
   1. View bios
   2. Send messages
   3. Emergency and general phone numbers

d. Patient Use
   i. Alerts and messages page
      1. Alerts

2. Messages
3. Reminders
4. Data Upload
5. News articles – new and archive
6. Drill-down into hypo- and hyper- glycemic events
7. Enter comments
8. Pop-up definitions
9. Link to external web site (Need to identify what site this would be)

ii. Clinical Data
1. Log Book Page
   a. Categorization of received data
   b. Date Range (default and how to change)
   c. Graph options – line, histogram, pie charts
   d. Multiple readings for a time slot
   e. Averages by TOD or Date
   f. Overall average, range, Standard Deviation
   g. Recognizing Hypo- & hyper- glycemic events & counts
2. Lab Values
   a. 12 month schedule
   b. Message and clapping for HbA1C < 7
   c. Pop-up definitions
3. Medications
   a. View current and previous prescriptions available for insulin, oral meds, or pump prescription
   b. View current and previous blood pressure/hypertension medications
   c. Allow patient to enter other medications they may be taking
4. Exercise Log
   a. Enter new data into the exercise log
   b. View current 14 day log
   c. Change date range
5. Blood Pressure Log
   a. View current 14 day log
   b. Change date range
6. Summary Page
   a. Explain how it is created
   b. Each field
   c. Practitioner comments
   d. Entering comments (with data, from alert page, or here)
   e. Date range selectable
   f. Graphing functions for current data view
7. Individual patient messaging
   a. Messages order by date
   b. Messages sent to/from patient by all MCT members assigned to the patient
   c. Date selection from within messaging
   d. New message preceded by red *

e. Viewing a message
f. Creating/Adding a message
g. Sending a message
h. Replying to a message

iii. Education
1. Georgetown educational material

iv. Contacts
1. View bios
2. Send messages
3. Emergency and general phone numbers

e. Logging out
i. Track usage log in and out times noted per user
ii. Return to lobby
iii. Access to education and news articles once the patient has logged out

MyCareTeam
Instructions for Using the MyCareTeam Internet Site
Patients

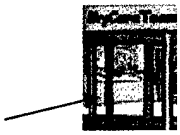
General Directions

1. Internet Program: You should be using Internet Explorer version 4.0 or higher or Netscape Navigator version 4.0 or higher.
2. Computer: An IBM compatible machine is required. Display resolution of your computer should be set to a minimum of 800x600 pixels.
3. Internet Connection and Modem Speed: You need a general Internet connection, and a modem - modem speed of 56 kilobits per second or higher will work best.

Steps You Need to Take to Visit the MyCareTeam Web Site

1. **Type in this Web address or url:**
   http:/mycareteam.georgetown.edu

2. **Enter the Virtual MyCareTeam clinic.**

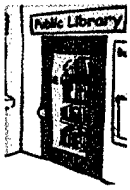


Move the mouse over the front door and click to enter the Virtual MyCareTeam clinic.

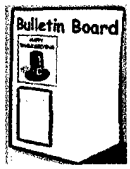
3. **Clinic Options**

There are 5 options:

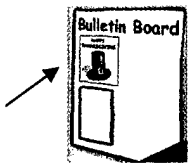
1. Click on the clipboard under the "Sign in " sign to get access to the Members Only portion of the site. Here, you can view your personal information, the education and information pages, and the latest news items in the world of diabetes patient care services and delivery.



2. Click on the "Public Library Door" for access to diabetes education and information materials.



3. Click on the "News" icon or anywhere on the bulletin board for access to the latest and archived news items related to diabetes.



4. Click on the "Holiday" sign on the bulletin board - sometimes we will have special information for you related to the specific time of the year or holiday.

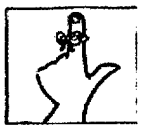
5. To get help at this screen, click on the receptionist or the HELP sign. You will see help on what you can do at this screen, or scroll through the document for help on the entire site.

More detail you need about using this site: Let's access your personal information

When you want to review your personal information, click on the clipboard to enter the **Member's Only** portion of the site. Enter your personal username and password and then click on submit. If you forget either your user name or password, please contact a MyCareTeam member and he/she will help you. (**Note:** There is a chance that the login window may not close after logging in. If this occurs, click on the x in the upper right-hand corner of the login window to close it.)

If you want to change your password, click on the words Change Password. You will be prompted to enter your current Username and Password then enter your New Password twice - this is to make sure you type it correctly. Then click submit. It you made a mistake click reset to clear all fields. If you don't want to change your password after all, click cancel.

What you can find after you've entered... for Members Only



Now you are at your Personal Information page-- also called the **Alerts & Messages** page. Here you have many choices and lots of information that may be presented to you, including items in your diabetes clinical information or vital sign readings that are of concern.

Alerts

- If a message appears under the Alerts heading, you may want to contact a MyCareTeam member for further clarification. You will be alerted to items such as:

  a. A current HbA1c value that is greater than or equal to 9.

b. More than 3 hypoglycemic events (blood sugar level below 60) in the last week for which we have your blood sugar readings. Clicking on this line will bring up a window that shows your hypoglycemic events by day of the week and time of the day.

c. More than 6 hyperglycemic events (blood sugar level above 180) in the last two weeks for which we have your blood sugar readings. Clicking on this line will bring up a window that shows your hyperglycemic events by day of the week and time of the day.

d. You have not sent in new blood sugar data for more than two weeks.

e. An average blood sugar level that is greater than 180 over the last two weeks for which we have your blood sugar readings.

Messages

- If a message appears under the Messages heading, then we have some positive news for you. It will be one of the following:

  a. A reduction of at least 1 point in your HbA1c value since you entered the program.

  b. An average blood sugar level that is less than or equal to 150 for the last 2 weeks for which we have your blood sugar readings.

  c. You have new blood sugar data and have an opportunity to enter a comment to your MyCareTeam members regarding these readings. (You will have another opportunity to enter a comment at a later time if you prefer.)

Reminders

- If a message appears under the **Reminders** heading, then you should be aware that one of the following periodic events is due or past due:

  a. Annual eye exam

  b. Quarterly HbA1c test

  c. Periodic office or clinic visit

  Also, if you have new messages waiting to be read, a message will appear here. You can then either go directly to your messages or get there through the clinical data icon.

Your options from within the Members Only section are:

a. Click to view your personal information-- also called **Alerts & Messages** page. (This is the default page when entering the Member's Only area and was described above.)

b. Click here to access to your Clinical Data including blood sugar data, lab data, medications, exercise log, and blood pressure log.

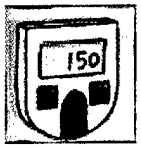
c. Click on the newspaper icon to see the latest news story from MyCareTeam members. The pull-down list below the icon is the Diabetes News Archive that provides access to the older stories.

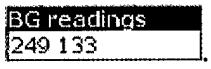
d. Click on the books icon to view the Diabetes Education pages, and other important and fun information.

e. Click here to leave a message for or view biographical information about a MyCareTeam member.

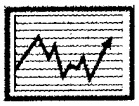
f. Click on this icon to log out and return to the MyCareTeam registration area.

Your Clinical Data



1. On the Member's Only page, under "Clinical Data," you will see your blood sugar logbook, which contains your latest two weeks' worth of blood sugar readings. The default time frame for displaying the information is two weeks, but by clicking on the word Date in the table heading you can change this time frame. Each reading is presented in a table by date and time slot. Multiple readings for a given date and time slot are identified by the underlining of a value in the table (for example +249). Placing your cursor over one of these underlined values displays all the readings for that date and time slot 

. Averages of blood sugar readings by day, time slot, and entire period are given along with counts of hypoglycemic and hyperglycemic events and number of readings taken. Hypoglycemic events (blood sugar below 60) are displayed in the logbook as a blue value preceded by a minus sign (e.g. -55), and hyperglycemic events (blood sugar above 180) are displayed as a red value preceded by a plus sign (e.g. +205). The average, standard deviation, and overall range for all blood sugar readings over the date range are also presented.



1.a Click on this icon to display a line graph of all blood sugar readings for the date range selected in the logbook (two weeks by default). The red or upper line on the chart identifies the upper limit (180) of the acceptable range for blood sugar levels; the blue or lower line marks the lower limit (60).

1.b Click on the Histogram icon to display two histograms for the date range selected in the logbook. The first histogram is for the average blood sugar readings by day of the week and the second for the average blood sugar readings by time slot. Again, the red or upper line on the histogram identifies the upper limit (180) of the acceptable range for blood sugar levels; the blue or lower line marks the lower limit (60).

1.c Click here to display a pie chart that shows the percentage of the time your blood sugar readings were within the target range (60 - 180), above the target range (greater than 180), and below the target range (less than 60) for the date range selected in the logbook.

1.d Click here to display 5 pie charts that represent the percentage of the time your blood sugar readings were within the target range (60 - 180), above the target range (greater than 180), and below the target range (less than 60) for each of the 5 time slots for the date range selected in the logbook.

2. Click here, on the Logbook icon, to bring you back to the blood sugar logbook described above in **Your Clinical Data** section.

3. Click here, on the Laboratory icon, to view the laboratory values that have been acquired from your blood work over the last 12 months. You will see information on your HbA1c, Cholesterol, HDL, LDL, Triglycerides, and Body Mass Index.

4. Click here, on the Prescription icon, to view your latest insulin or basal prescription, plus any oral medications for your diabetes that have been prescribed for you. Click on the left and right arrows, ⇦ ⇨, to toggle between your older and current prescriptions.

5. Click here to add other medications that you may be taking that your MyCareTeam may not know about. These can include prescription or over-the-counter medications

6. Click here, on the Exercise icon, to view or enter information into your exercise log. You can select and enter a date, the type of exercise, and the duration of the exercise. You may also enter a comment about the exercise, if you choose. The previous two weeks' worth of the log is displayed automatically. You can change the exercise date range by selecting **Date** in the table heading. And remember:

If you have chest pains, shortness of breath, or unusual fatigue stop all activity and call your physician or 911 immediately

7. Click here on the Data Summary and Physicians Comments icon, to view a "snapshot" or summary of your blood sugar reading uploads. A 30-day summary is displayed by default, but you can change that by selecting **Date** in the table heading. This summary chart displays the date of the upload, the average of all the blood sugar readings for that upload, the number of hypoglycemic and hyperglycemic events within the data, the percentage of time the blood sugar readings were within target, an average number of readings taken per day, and the total number of days worth of data. Also, if you entered a comment with your data it is displayed here. If you didn't, you can now enter a comment to your MyCareTeam member and they can leave one for you. **Note**: these messages should be related to your blood sugar upload and not general comments. General comments should be sent in the Message pad section described below.

8. Click here on the Message Pad icon, to leave a message for a MyCareTeam member or to view new and old messages sent to you. The number on the icon shows the number of your unread messages. A 14-day summary is displayed by default, but you can change that by selecting **Date** in the table heading. All message either sent to you or that you have sent are shown in the list. It is ordered by date and shows the person the message was sent to, who sent the message, and the subject of the message (what the message is about). A red star (*) preceding the date indicates that the message has not been viewed. Clicking on the underlined **text** in the subject field will display the message. If you are viewing a message someone sent to you, then you can click the reply button to send a reply to that person.

Education and Information

The Education and Information page is accessible by clicking on the Education and Information icon. Here you can learn about 8 areas related to your health and care of your diabetes. Here you can learn about diabetes, blood sugar control, possible complications and related problems, nutrition and exercise guidelines, on-going clinical trials and some fun-facts. You can also access the latest diabetes news item and the archive of previous news items from this page.

Contact Information

Click here to leave a message for a MyCareTeam member. Click on the MyCareTeam member's name to leave them a message. All messages will be filtered through the nurse for the project. See the description of the Message Pad icon above for more details on leaving a message. By clicking on a MyCareTeam member, you can see information about that provider. Emergency and non-emergency phone numbers are presented here along with a technical support number.

Technical Support: 800-555-1212

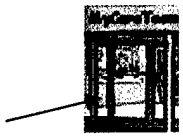
MyCareTeam
Instructions for Using the MyCareTeam Internet Site
Practitioners

General Directions

1. Internet Program: You should be using Internet Explorer version 4.0 or higher or Netscape Navigator version 4.0 or higher.
2. Computer: Display resolution of your computer should be set to a minimum of 800x600 pixels.
3. Internet Connection and Modem Speed: You need a general Internet connection, and a modem - modem speed of 56 kilobits per second or higher will work best.

Steps You Need to Take to Visit the MyCareTeam Web Site:

4. **Type in this Web address or url:**
   http://mycareteam.georgetown.edu
5. **Enter the Virtual MyCareTeam clinic.**

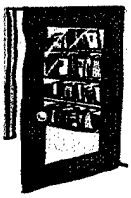


Move the mouse over the front door and click to enter the Virtual MyCareTeam clinic.

6. **Clinic Options**

Once you enter the Clinic Lobby, there are 5 options:

1. Click on the clipboard under the "Sign in " sign to get access to the Members Only portion of the site. Here, you can view your patient's information, the education and information pages, and the latest news items in the world of diabetes patient care services and delivery. You can also add new patients, add lab values, add prescriptions, and create messages for patients.



2. Click on the "Public Library Door" for access to diabetes education and information materials.

3. Click on the "News" icon or anywhere on the bulletin board for access to the latest and archived news items related to diabetes.

4. Click on the "Holiday" sign on the bulletin board - sometimes we will have special information for you related to the specific time of the year or holiday.

5. Click on the receptionist to view an online version of instructions for patient use of the MyCareTeam site.

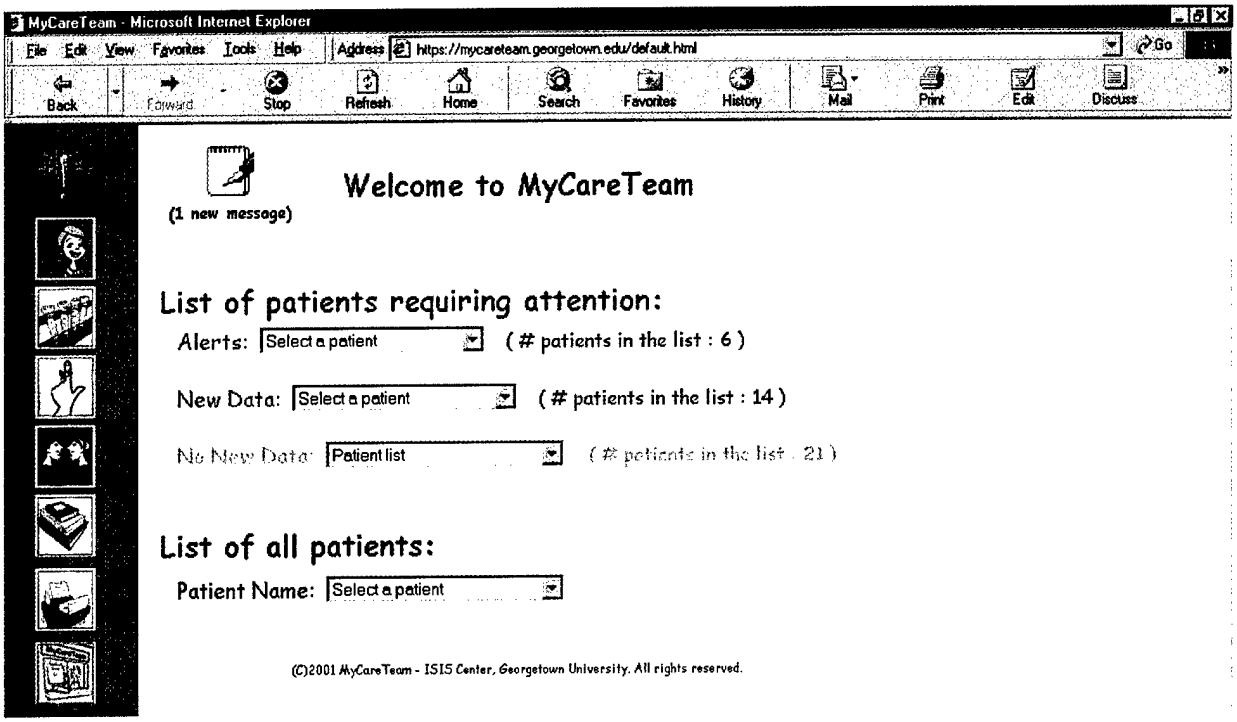
Let us access your patients' information:

When you want to review your patient's information or add new data for patients, click on the clipboard to enter the **Member's Only** portion of the site. Enter your personal username and password and then click to submit. If you forget either your user name or password, please contact a MyCareTeam member and he/she will help you. (**Note:** There is a chance that the login window may not close after logging in. If this occurs, click on the x in the upper right-hand corner of the login window to close it.)

If you want to change your password, click on the words Change Password. You will be prompted to enter your current Username and Password then enter your New Password twice - this is to make sure you type it correctly. Then click submit. It you made a mistake click reset to clear all fields. If you do not want to change your password after all, click cancel.

What you can find after you have signed in ... for Members Only

When you login as a practitioner, the first page you will see looks like the following:



As a practitioner, when you enter the site you will be presented with a page listing all of the patients assigned to you:

1. that have an alert value associated with their current data. In the sample above: (# of patients in the list: 6)
2. that have new data you that have not seen. In the sample above: (# of patients in the list: 14)
3. that have not sent new blood glucose data for more than 2weeks. In the sample above: (# patients in the list: 21)
4. and an alphabetical list of all your patients.

Selecting a patient from either the alert list or the new data list will bring you to the patient's Personal Information page--also called the Alerts & Messages page (See Alerts & Messages Section below). Here you have many options and information presented, including their diabetes clinical information or vital sign readings that are of concern.

The "no new data" list merely presents you a list of patients that are remiss at sending current blood glucose data in.

Selecting a patient from the all-patient list will bring you directly to their clinical data page also called blood glucose

logbook. (See Patient's Clinical Data Section later in the manual for information on that page.)

From this first page, the practitioner also has the ability to see all new messages that have been sent to you from any of your patients. The number of new messages you have is shown next to the message pad icon  (1 new message).

To see all your new messages or to send a message to any of your patients, click on the message pad icon in the upper left-hand corner of the screen. At this point, you will be presented with the ability to enter a message for any of your assigned patients. You will also have a list of messages that you have not read. See the Message Pad section below about creating, viewing, and replying to messages.

Alerts & Messages Page

Alerts

If a message appears under the Alerts heading, there is at least one item in the patient's data that was outside the acceptable range. The items that patients are alerted to include:

a. A current HbA1c value greater than or equal to the predetermined upper limit target.

b. More than 3 hypoglycemic events (blood glucose level below 60) in the last week for which their blood sugar readings are in the database. Clicking on this line brings up a window that shows the hypoglycemic events by day of the week and time of the day.

c. More than 6 hyperglycemic events (blood glucose level above 180) in the last two weeks for which their blood sugar readings are in the database. Clicking on this line will bring up a window that shows the hyperglycemic events by day of the week and time of the day.

d. They have not sent in new blood sugar data for more than two weeks.

e. An average blood sugar level that is greater than the predetermined upper limit of the target range over the last two weeks for which their blood sugar readings are in the database.

f. The patient has a new comment in the Summary page from

you or another practitioner treating the patient and the patient has not reviewed that comment yet.

Messages

- If a message appears under the Messages heading, then the patient had some positive news. It will be one of the following:
  d. A reduction of at least 1 point in their HbA1c value since they entered the program.
  e. An average blood sugar level less than or equal to 150 for the last 2 weeks for which their blood sugar readings are in the database.

Reminders

- If a message appears under the **Reminders** heading, then you should be aware that one of the following periodic events is due or past due for the patient:
  d. Annual eye exam
  e. Quarterly HbA1c test
  f. Complete lab workup
  g. Periodic office or clinic visit

a. Click on the registration clerk icon to perform administrative functions such as adding new practitioners or patients into MyCareTeam.

b. Click on the lab icon to enter lab results for all of your patients.

c. Click on the finger with string icon to keep the reminder fields up-to-date for all your patients.

d. Click on the books icon to view the Diabetes Education pages, and other important and fun information.

e. Click here to leave a message for or view biographical information about a MyCareTeam clinical member.

f. Click on this icon to log out and return to the MyCareTeam registration area.

Patient's Clinical Data

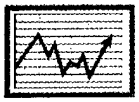
After selecting a patient from the all-patient list or selecting their **blood sugar logbook** icon from the **Alerts & Messages** page, you gain access to their blood sugar logbook. The

icons for all clinical information related to the patient are presented along the top of the page, just under the patient name. The icons that are outlined in red are ones that contain new information that has not been checked by an authorizing practitioner. As an authorizing practitioner views these pages, the red outlining will disappear. If an un-authorizing practitioner views the page - the red outlining will remain until cleared by an authorizing practitioner. (Authorizing practitioners mark that patient's data has been reviewed whereas unauthorizing practitioners can view patient's data but it remains marked as unseen.)

1. Within the patient "Clinical Data" page you will see their **blood sugar logbook**, which contains their latest two weeks' worth of blood sugar readings. The default time frame for displaying the information is two weeks, but by clicking on the word Date in the table heading you can change this time frame.

   Each reading is presented in a table by date and time slot. Multiple readings for a given date and time slot are identified by the underlining of a value in the table (for example +249). Placing your cursor over one of these underlined values displays all the readings for that date and time slot 

   . Averages of blood sugar readings by day, time slot, and entire period are given along with counts of hypoglycemic and hyperglycemic events and number of readings taken. Hypoglycemic events are displayed in the logbook as a blue value preceded by a minus sign (e.g. -55), and hyperglycemic events are displayed as a red value preceded by a plus sign (e.g. +195). The average, standard deviation, and overall range for all blood sugar readings over the date range are also presented.



1.a Click on the Line icon to display a line graph of all blood sugar readings for the date range selected in the logbook (two weeks by default). The red or upper line on the chart identifies the hyperglycemic or upper limit (180) of the acceptable range for blood sugar levels; the blue or lower line marks the hypoglycemic or lower limit (60).

1.b Click on the Histogram icon to display two histograms for the date range selected in the logbook. The first histogram is for the average blood sugar readings by day of the week and the second for the average blood sugar readings by time slot. Again, the red or upper line on the

histogram identifies the hyperglycemic or upper limit (180) of the acceptable range for blood sugar levels; the blue or lower line marks the hypoglycemic or lower limit (60).

1.c Click on the Pie Chart icon to display a pie chart that shows the percentage of the time your blood sugar readings were within the target range (60 - 180), above the target range or hyperglycemic (greater than 180), and below the target range or hypoglycemic (less than 60) for the date range selected in the logbook.

1.d Click on the other Pie Chart icon to display 5 pie charts that represent the percentage of the time your blood sugar readings were within the target range (60 - 180), above the target range or hyperglycemic (greater than 180), and below the target range or hypoglycemic (less than 60) for each of the 5 time slots for the date range selected in the logbook.

2. Click on the Laboratory icon to view the laboratory values that have been entered for the patient over the last 12 months. You will see their HbA1c, Cholesterol, HDL, LDL, Triglycerides, and Body Mass Index.

3. Click on the Prescription icon to view or change the insulin, basal prescription, blood pressure or oral medications prescribed for the patient. Click on the left and right arrows,  , to toggle between older and the current prescriptions.

3.a Clicking on the Insulin/basal Medications icon will allow you to view or change the insulin or basal prescription that your patient should be taking.

3.b Clicking on the Oral Medications icon will allow you to view or change the oral medications that your patient should be taking.

3.c Clicking on the Blood Pressure Medications icon will allow you to view or change the blood pressure medications that your patient should be taking.

3.d Clicking on the Other Medications icon will show you any other medications that the patient is

taking that you and other members of MyCareTeam may not know about. These can include prescription or over-the-counter medications

4. Click on the Exercise icon to view the patient's exercise log. You can change the exercise date range by selecting **Date** in the table heading

5. Click on the Data Summary and Physicians Comments icon to view a "snapshot" or summary of the patient's blood sugar reading uploads. A 30-day summary is displayed by default, but you can change that by selecting **Date** in the table heading. This summary chart displays the date of the upload, the average and standard deviation of all the readings for that upload, the number of hypoglycemic and hyperglycemic events within the data, the percentage of time the blood sugar readings were within target, an average number of readings taken per day, and the total number of days worth of data. Also, you can see any comments that the patient has entered for you and you can enter a comment to that patient.

6. Click on the notepad icon to check on messages from the given patient or to leave a message for the given patient. To leave a message for the patient, you only need to enter the reason for the message as a subject heading. This should be a short descriptive of what the message is about. Then select the **Add Message** button to include the entire message. The date of the message, who it is to, and who it is from are automatically filled in when you select **Add Message**. After typing in your message select **Submit** to submit your message, **Reset** to wipe out the message and type in a new one, or **Cancel** to forget about adding a message altogether. If you **Submit** the message, a confirmation window pops-up temporarily to tell you that the message has been sent. If you **Cancel** the message, you will be brought back to the message list screen.

   The list of messages that have been sent to the patient or the patient has sent is shown below the area to add a new message. Any message preceded by a red * means that the message has not been viewed. To view a previously read or unread message, select the individual message subject. This will open a new window containing the message and offering the option to respond to the message. You will have he option to **Respond** to the message or to **Close** the window without responding. If you chose to reply, you can enter the response and **Submit** it, **Reset** the text window, or **Cancel** without responding.

Administrative Functions

There are many administrative functions to allow you to update your personal information, register new patients and practitioners, reassign patients or practitioners, add files to the site, view patients information and remove patients or practitioners form the site. Clicking on the Administrative icon can access them.

a)  Update personal info	b)  Register a practitioner	c)  Register a patient
d)  Upload a file	e)  Reassign practitioners	f)  Reassign patients
g)  View patient's info	h)  Remove practitioners	i)  Remove patients

Click here to change or add your address or phone numbers. You will not be allowed to change your name, specialty or social security number.

Click here to register a new practitioner into the site. You will need to know their name, social security number, address, phone numbers, and specialty. You will also assign them a role such as physician, nurse, engineer, etc. Note: fields in red are required fields.

Click here to register a new patient into the site. You will need to know their name, medical record number, height, weight, attending practitioners, primary disease, and treatment. Other demographic information may be entered but is not required. Note: fields in red are required fields.

Click here to upload a picture of a patient or a News article to the site. If uploading a picture of a patient you will need to know the patient name and the path and filename of the picture. If uploading a News article, you will need to provide a title of the article and the

path and filename of the article. For both types of files, you can browse the file system to find the file to upload. Simply click on the browse button.

Click here to change the care providers assigned to a selected patient. Click on the [redacted] to select one or more practitioners to be add to the list of those caring for the selected patient. Click on the [redacted] to remove one or more practitioners from caring for the selected patient.

Click here to change patient patients assigned to a selected practitioner. Click on the [redacted] to select one or more patients to be added to the list of patients cared for by the selected practitioner. Click on the [redacted] to remove one or more patients from the selected practitioners care.

Click here to view the patient's demographics information and other related data. You cannot make any changes to that information here. Select the patient whose information you wish to view from the drop-down menu.

Click here to remove a practitioner from accessing the site. This will automatically remove the practitioner from caring for any patients. Multiple practitioners can be selected for removal at this point. **Note**: Use this feature carefully. Be sure you want to remove the practitioner completely before continuing.

Click here to remove a patient from accessing the site. This will automatically remove the patient from their practitioners' list of patients for which they provide care. Multiple practitioners can be selected at this point. Multiple patients can be selected for removal at this point. **Note**: Use this feature carefully. Be sure you want to remove the patient completely before continuing.

Lab Entry

To enter lab values for your patients, click on the lab entry icon on the left side of the screen. You will be asked to enter a date for the lab screening or recent weight and then pick the patient you want to enter the data for. Then you can enter any of the lab data for the selected patient. If you realized you selected the wrong patient or entered the wrong date, you can select the Back button to go back and change the date or select another patient. If the selected patient and date are correct but you entered the wrong values, hit the Reset button to clear the lab fields and reenter the data. If everything is correct, hit the Submit button. You will be given one last chance to confirm what you entered with an option to back-up and make any changes that are required.

Reminders

For each patient, you can setup a reminder list to tell them when their next clinic visit, lab workup, HbA1c test, and eye exam are. To use this feature, you simply insert when the most recent exam is/was and then how long until the next item is due. For example, if they had an HbA1c on June 1, 2001, you would enter this date as the current date and select 90 days for the next test.

Education and Information

The Education and Information page is accessible by clicking on the Education and Information icon. Here you can learn about diabetes, blood sugar control, possible complications and related problems, nutrition and exercise guidelines, ongoing clinical trials, and some fun facts. You can also access the latest diabetes news items and the library of previous news items from this page.

Contact Information

Click here to leave a message for a MyCareTeam member. All messages will be filtered through the nurse. Information about your MyCareTeam members is presented on this page, along with an emergency phone number, a non-emergency contact number and an 800 technical support number.

Technical Support: 800-555-1212

Appendix E

Consent Forms
Mandan, Hidatsa, and Arikara Nation
National Naval Medical Center

AAIRB #: 03-R-22AA

Consent to Participate in Research

Project Name: Medical Vanguard Diabetes Management Project

Project Director: Deborah Thompson

Principal Investigator: Deborah Thompson **Telephone: 701-627-4781, ext. 8053**

Sponsor: Georgetown University under contract to Telemedicine and Advanced Technology Research Center at Fort Detrick, Maryland.

Introduction

You are invited to consider participating in this research study. We will be evaluating the insertion of diabetes management software into the existing diabetes program within the MHA nation. This form will describe the purpose and nature of the study, its possible risks and benefits, other options available to you, and your rights as a participant in the study. Please take whatever time you need to discuss the study with your physicians, hospital personnel and your family and friends. The decision to participate or not is yours. If you decide to participate, please sign and date the last line of this form.

Background and purpose of the study

We will be testing how easily we can introduce an existing Internet based diabetes management program into the standard of care for people with diabetes. This will involve the electronic transmission of blood sugar readings from a standard glucose meter to a secured database accessible over the Internet and the use of an Internet based application to review your blood sugar readings. We are investigating what is involved with the introduction of this technology into the Native American community of the MHA Nation.

Total number of subjects

About 50 people will take part in this study. Participants in the study are referred to as "subjects." 50 subjects will be participating from MHA Nation.

How your treatment will be determined in this study

If you meet the criteria to participate and agree to participate you will be assigned to the treatment group and we will identify you as a "subject" in the study. In the event of an emergency, you should contact your physician immediately. Participation in this study will not affect how you obtain emergency care.

AAIRB #: 03-R-22AA

Length of the study for each subject

We expect that you will be in the study for 6 months.

Possible benefits of participating in the study

You might find that participating in this study makes you more aware of managing and controlling your diabetes. However, we cannot guarantee that you will experience medical benefits from participating in this study. Others may benefit in the future from the information we obtain while you are in this study.

Possible side effects and other risks of participating in the study

You should not experience any side effects as a result of participating in this study.

Who can participate

This study is designed for adults with either type 1 or type 2 diabetes mellitus that have been diagnosed for at least 6 months. You should be under regular care by a physician or nurse practitioner at one of the tribal clinics. You should be currently using a glucose meter to measure your blood sugar levels regularly and controlling your diabetes through oral medications, insulin, or diet and exercise. Your suitability for this study will be determined by medical tests and by your ability and willingness to access a computer and comply with the requirements of the study.

Who cannot participate [when applicable]

The computer applications used in this study require one be comfortable reading English.

Other treatment options

If you do not participate in this study, the following options are available to treat your illness/condition: Standard care as provided by the medical clinics on the reservation.

Confidentiality of the data collected during the study

Every effort will be made to keep your medical records confidential as well as other personal information that is gathered during the study.

We cannot guarantee absolute confidentiality. Whenever data from this study are published, your name will not be used.

Individuals from the MHA Nation health clinics, Georgetown University Medical Center, the Indian Health Service and U.S. Army Medical Research and Materiel Command may look at

medical and research records related to this study, both to assure quality control and to analyze data. We will disclose personal information about you to others as required by law.

Data security

Information about your participation in this study will be stored in a computer. We will take the following precautions to protect it from unauthorized disclosure, tampering, or damage:

1. Only authorized users will have access to your data – this includes yourself, your care providers, and researchers involved in this study.
2. The data will be stored in a database that exists on a computer that is behind a firewall located at Georgetown University in Washington, DC. A firewall is a computer device that restricts access to the computers that are protected by it.
3. Whenever your data is presented to you or your care provider over the Internet through an application like Internet Explorer, it is encrypted before being transferred and decrypted at your computer. Encryption means that the information transferred will be scrambled while it is being transferred over the Internet and put back together once it reaches your computer so that it is readable again. The type of encryption used is called 128-bit Secure Socket Layer (SSL) and is one of the most secure forms of data encryption available.

New findings

Throughout the study, we will tell you about new information we receive about treatments that may be appropriate for you, about the treatments under research in this study, and any information that may affect your interest in remaining in the study.

Costs to you for participating

Qualified study subjects will **not** have to pay to participate in this study.

Payments to you for participating

Qualified study subjects will not be paid for participating in this study. However you will receive the following benefits:
You will receive a glucose meter.
You will receive glucose testing strips.
You will be eligible for small gifts like a t-shirt, coffee mug, or other token gift if you meet the requirements of the study.
You will receive a device called a modem that will allow you to connect your glucose meter to your telephone line and transfer the glucose readings to the secured database.

Commercial Interest

AAIRB #: 03-R-22AA

For your information, the MHA Nation and Indian Health Service do not hold a patent for this device and has no potential financial interest in the outcome of this study. (Institution or individual investigator)

Your rights as a participant in the study

Participation in this study is entirely voluntary. You have the right to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Should you decide to leave the study, contact your care provider and inform him/her that you no longer care to participate in the study. You will need to return the device that connects the glucose meter to the telephone line.

Should you decide not to participate or to withdraw, your medical care will not be affected nor will your relations with your physicians, and other personnel within the MHA Nation or the IHS. Your care, however, may subsequently be managed by different researchers or physicians.

Problems and questions

Call Deborah Thompson at 701-627-4781 ext. 8053 day or night if you have questions about the study, any problems, unexpected physical or psychological discomforts, any injuries, or think that something unusual or unexpected is happening.

Call Dr. Elaine Miller at 605-226-7341 or Dr. Dewey Ertz at 605-341-8647 or toll free at 866-331-5794 of the Institutional Review Board office of the Indian Health Service with any questions about your rights as a research subject.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

Investigator's statement

I have fully explained this study to the subject. I have discussed the procedures and treatments, the possible risks and benefits, the standard and research aspects of the study, and have answered all of the questions that the subject and the subject's family members have asked.

Signature of investigator _____ Date _____

AAIRB #: 03-R-22AA

Subject's consent

I have read the information provided in this Informed Consent Form (or it was read to me by _____). All my questions were answered to my satisfaction. I voluntarily agree to participate in this study.

Signature of subject or Legally Authorized Representative_____

DATE

Permanent Address of the Subject_____

[Upon signing, you will receive a copy of this form, and the original will become part of your medical record.]

Witness

Printed Name of Witness _____

Signature of Witness _____

DATE

NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MARYLAND

This consent form is valid only if it contains the IRB stamped date

Consent for Voluntary Participation in a Clinical Investigation Study

1. You are invited to participate in a research project entitled, Medical Vanguard Diabetes Management Project being conducted at the National Naval Medical Center (NNMC), Bethesda, Maryland and eight other clinics across the United States. You have been invited to participate in this project because you are pregnant and have been diagnosed with type 1, type 2 or gestational diabetes. Your participation is voluntary. You should read the information below and ask questions about anything you do not understand, before deciding whether or not to participate.

2. The purpose of this research project is to study how well a diabetes management system works in different diabetes clinics and the impact the system has on patients and care providers. For women with diabetes, good blood sugar control during pregnancy is very important both to the mother and her baby. Patient education, in combination with close monitoring by health care providers, can help diabetic women control blood sugar levels and achieve a healthy pregnancy. Non-pregnant diabetic patients who used this system in earlier studies showed an improvement in their blood sugar levels.

During this project, we will be testing a system called MyCareTeam (MCT). MCT is an interactive Internet-based diabetes management system. We plan to have as many doctors, nurses and patients as possible work with the MCT system and then ask them to tell us what they think about the system and if it helped them manage diabetes. The system was built by the Imaging Science and Information Systems (ISIS) Center at Georgetown University Medical Center. The Prenatal Assessment Center here at the NNMC is one of nine clinics participating in this study. The entire Medical Vanguard Diabetes Management Project will take about one year to complete.

3. Your participation in this research project will start when you sign the consent form and will continue for the duration of your pregnancy.

4. The procedure for this project involves being trained by the study nurse (a nurse with special training about the project) on how to use the MCT system and also on how to use another piece of equipment called an AccuLink Modem. This training will take about one hour and will take place in the Stitt Medical Library. Normally, when pregnant diabetic women are followed in the Prenatal Assessment Center they receive diet and blood sugar testing instructions when they first visit the clinic. Thereafter, patients are asked to telephone the diabetes nurse twice a week and report the results of their blood sugar tests. After seeing the results of the tests, the doctor may decide to make changes in a patient's diet, activities or in the type or amount of medicine the patient is taking. This is called diabetes management. A doctor or nurse from the Prenatal Center would then contact the patient by telephone to give them this information.

If you agree to enter this study, you will be asked to electronically send your blood sugar information twice a week to the diabetes nurse instead of talking to the nurse over the telephone. The nurses and the doctors in the Prenatal Center will then look at your information using the MCT system. If a change needs to be made in your diabetes management, they will message that information back to you over the MCT system.

If you do not have a personal computer (PC) in your home, you will still be able to send your blood sugar information to the diabetes nurse using the modem and the doctors and nurses will continue to telephone you with any changes to your diabetes management. They will also send the same information to you through the MCT system. We will ask you to view this information as often as possible as well as to send messages back to your care providers using either the PC in the Stitt Library, or any other computer available to you, e.g., family member or friend, at work, or local libraries.

Learning materials about diabetes during pregnancy will also be available on the MCT system. You will be asked to look at this information as often as you can. If you have questions or need additional materials during your pregnancy, we asked that you message the study nurse with this request.

As part of this study, you will also be asked to fill out a survey 2-4 weeks after you are enrolled in the study and at one other time before you have your baby. All of the messages to and from your care providers and your blood sugar levels will be stored on a protected database at the ISIS Center while you are enrolled in the study and then after the study is complete.

5. Specifically, the experimental part of this research is that a study nurse will teach you how to use the MCT system and the AccuLink Modem. Twice a week you will electronically send your blood sugar levels to the Prenatal Assessment Center nurse. You will receive messages from your care providers. You will also be asked to view your information and to send messages to your providers using the MCT system. These messages and your blood sugar levels will be stored on a protected database at the ISIS Center during the study and then after the study has ended. At 2-4 weeks after starting the study, and again toward the end of your pregnancy you will be ask to fill out a survey about your experience using the MCT system.

6. A total of 60 subjects are expected to participate in this project at NNMC and approximately 320 subjects from the other eight sites in the Medical Vanguard Diabetes Management Project. The study at NNMC is expected to take approximately one year to complete.

7. The possible risks and discomforts, associated with your participation in this research project include:

- Using a PC, a study nurse will teach you how to use the MCT system and how to use the AccuLink Modem. You could possibly become frustrated with this change in your procedure and when technical difficulties with the MCT occur.

- Twice a week you will electronically send your blood sugar levels to the Prenatal Assessment Center nurse. You will receive messages from your care providers. These messages and

your blood sugar levels will be stored on a protected database at the ISIS Center at Georgetown University Medical Center during the study and then after the study has ended. While your information is being sent from the glucose meter to this protected database, your name is not on the information. Only after the data is put in the protected database is your name reconnected to either your blood sugar levels or messages. MCT will allow only you, your care providers, and employees of the ISIS Center who work on maintaining the database to see your blood sugar and personal health data. When you or a care provider requests your data over the Internet using MCT, the data will be sent scrambled (encrypted) preventing anyone from snooping around on the Internet to gain access to it, look at it, or change it. We use a method called 128-bit Secure Socket Layer (SSL) encryption to protect your information as it travels across the Internet. 128-bit SSL encryption is the industry standard and one of the most protected ways to send information across the Internet. The MCT database is located inside a locked room at the ISIS Center to protect it physically from unauthorized access. Firewall technology is used to block the data stored on the database from being hacked into.

- You will also be asked to view your information as often as possible and to send messages, from your own PC or from an alternative site, to your provider using the MCT system. You should not experience any side effects as a result of participating in this activity.

- At 2-4 weeks after starting the study, and again towards the end of your pregnancy you will fill out a survey about your experience using the MCT system. You should not experience any side effects as a result of participating in this activity.

While all risks at this time have been discussed above, other unforeseen risks may occur or be revealed during future studies. In the event that the investigators in this study find in the future that there was a potential risk to you unknown at the time of your participation in the Study, and such risk is other than insignificant and might have some bearing on your health status, you will be informed.

8. This research may or may not help you personally but the results may help the investigator learn about how well this type of diabetes management system works in different diabetic clinics and the impact the system has on patients and care providers

We cannot guarantee that you will experience medical benefits from participating in this study. However, you might find that participating in this study makes you more aware of managing and controlling your diabetes.

9. The alternative treatment, should you decline enrollment into this study, has been explained as follows: Twice a week you would telephone the diabetes nurse and report the results of your blood sugar tests. If after seeing these tests, your doctor decided to make any changes to your diet, activities or in the type or amount of medicine your are taking, you would be contacted by telephone with this information.

10. In all publications and presentations resulting from this research project, your anonymity will be protected to the maximum extent possible; although, authorized Navy Medical Department

personnel and personnel from the sponsor, Georgetown University Medical Center and U.S. Army Medical Research and Materiel Command may have access to your research file in order to verify that your rights as a subject in this study have been safeguarded.

11. The investigators may terminate your participation in this project for the following reasons: If your physician determines that further participation is this study is not in your best interest or if you do not comply with the study the principal investigator may take you out of the study without your consent. The investigators or sponsors may also stop the study for various administrative reasons without your consent.

12. You may withdraw from this study at any time without prejudice to your future care. Your withdrawal from this project will not cause you to lose any benefits to which you are otherwise entitled.

13. Any new significant findings either good or bad, developed during the course of the research, which may affect your willingness to participate further, will be explained to you.

14. If you suffer physical injury or if you should require hospitalization as a result of your participation in this project, immediate medical treatment will be available at the National Naval Medical Center. However, if you require inpatient hospitalization, you will be required to pay the customary fees for subsistence (hospital meals) to the National Naval Medical Center in accordance with standard regulations. It has been explained to you that your entitlement to medical and dental care is governed by federal laws and regulations. Any injury resulting from your participation in this research project will be evaluated and treated in accordance with the benefits to care to which you are entitled under these regulations. You will not be entitled to compensation for injuries or to future medical care as a result of your participation in this project except as may be provided for through these regulations or other remedies available under federal law.

15. Your participation in this project is voluntary and your refusal to participate will involve no penalty or loss of benefits to which you are entitled under applicable regulations. If you are active duty military, you should not be influenced by a higher ranking official and you are not being given an order to participate. Your election, whether to participate or not, will not affect your military career. If you choose to participate, you are free to ask questions or to withdraw from the project at any time. Dr. Farzaneh Sabi or the institution may also terminate your participation.
If you should decide to withdraw from the research project, we request you notify Dianne Bloom at *(301)-319-5038* to ensure an orderly termination process. Your withdrawal will involve no loss of benefits to which you are entitled.

16. If you have any questions regarding this research project, you may contact ***Dr. Farzaneh Sabi at (301) 319-5058, Dianne Bloom at (301) 319-5038 or Cherrel Christian (301) 336-8752.*** If you have any questions regarding your rights as an individual while participating in a research project at the National Naval Medical Center, Bethesda, you can contact one of the Research Administrators, Clinical Investigation Department, at *(301) 295-2275*. They will answer your questions or refer you to a member of the Institutional Review Board (IRB) for

further information. If you believe, you have been injured as a result of this project you may call the legal office at *(301) 295-2215.*

SIGNATURE OF RESEARCH SUBJECT OR LEGAL RESPRESENTATIVE

You certify that you have received a copy of this consent form.

_____

Subject/Patients Initials Date

You have read (or someone has read to you) the information provided above. You have been given an opportunity to ask questions and all of your questions have been answered to your satisfaction.

BY SIGNING THIS FORM, YOU WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

_____

Patient/Subject Signature Date

_____

Typed Name, Grade or Rank, SSN

SIGNATURE OF INVESTIGATOR

You have explained the research to the subject or his/her legal representative, and answered all of his/her questions. You believe that he/she understands the information described in this document and freely consents to participate.

_____ _____

Investigator Signature Date (must be the same as subject's)

_____

Investigator typed Name, Grade or Rank

SIGNATURE OF WITNESS

Your signature as witness is intended to attest that the information in the consent document and any other information was explained to and apparently understood by the

subject or the subject's legal representative, that questions and concerns were addressed and that informed consent was freely given.

_____ _____

Witness' Signature Date (Must be the same as subject's)

_____

Witness' Typed Name, Grade or Rank

PRIVACY ACT STATEMENT

1. Authority. 5 USC 301

2. Purpose. Medical research information will be collected to enhance basic medical knowledge, or to develop tests, procedures, and equipment to improve the diagnosis, treatment, or prevention of illness, injury or performance impairment.

3. Use. Medical research information will be used for statistical analysis and reports by the Departments of the Navy and Defense, and other U.S. Government agencies, provided this use is compatible with the purpose for which the information was collected. Use of the information may be granted to non-Government agencies or individuals by the Chief, Bureau of Medicine and Surgery in accordance with the provisions of the Freedom of Information Act.

4. Disclosure. All information contained in this Consent Statement or derived from the experiment described herein will be retained permanently at National Naval Medical Center, Bethesda, Maryland and salient portions thereof may be entered into my health record. I voluntarily agree to its disclosure to agencies or individuals identified in the preceding paragraph and I have been informed that failure to agree to such disclosure may negate the purposes for which the experiment was conducted.

_____

Patient/Subject Signature Date

_____

Typed Name, Grade or Rank, SSN

_____

Investigator Signature Date (must be the same as subject's)

_____

Investigator typed Name, Grade or Rank

_____

Witness' Signature Date (Must be the same as subject)

_____

Witness' Typed Name, Grade or Rank