Patient-Focused

Wireless Messages for Diabetes

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Table of Contents

Abstract

Diabetes is a serious medical condition, affecting about 16 million Americans, and accounting for one out of every seven dollars spent related to health care each year. It is imperative to find new and innovative ways to help patients acknowledge, then manage, this condition. Aggressive management of blood sugars reduces future diabetes-related complications, but this is difficult to achieve. Studies suggest that about 50% of patients with diabetes have poor glycemic control. Recent interventions mainly target health care providers, including provider-based reminders to support the care plan. These reminders are limited by triggering only at clinic visits. Processes that work best provide continuing and ongoing support to patients, but continual monitoring systems in use today are not truly interactive (e.g. devices that transmit vital signs/blood glucose levels).

This paper describes a patient-centered, configurable messaging system and protocols for its use. This messaging system utilizes information from the electronic medical record to generate patient-specific messages concerning medications and laboratory results, and can send patient-specified messages as well. This technology allows patients to be surveyed on health issues, with their replies available for population analysis. These short conversations provide reinforcement of the patient-provider agreed care plan between office visits, and are collected and summarized for future office visits.

The pilot phase of this project is completed, with initial patient feedback ascertained through interviews and through instruments created to evaluate patient attitudes towards their health care team, towards diabetes, and towards technology. Using the messaging system has proven to be helpful, even enjoyable, for some patients.

Statement of Purpose

This study has three primary aims, which are to answer the questions: Are there clinical scenarios where patients can benefit from wireless messages reinforcing the patient-provider agreed care plan? Can a messaging system be developed to automate this process? Can this system, with specific protocols for its use, influence measurable patient outcomes, including glycemic control, blood pressure, and patient perceptions?

The messaging system and clinical protocols to be created have the requirements that they must be patient-focused (empowering patients to become the primary facilitators of their adherence to health maintenance tasks), they must require minimal additional time commitment and change to physician/health care team practice style, they must leverage existing electronic medical record (EMR) efforts, and they must be acceptable both to patients and to members of the health care team who would use them.

Introduction/Overview

Diabetes is a serious medical condition, in which complications can be reduced by aggressive glycemic control. In some patients, poor glycemic control is correlated with poor adherence to their diabetes care plan. This study involves introduction of a wireless technology based messaging system to provide ongoing reinforcement of the care plan, in the hope that this will lead to improved adherence and improved outcomes.

There are three areas reported in this paper: clinical scenarios where messages are beneficial, a description of the messaging system and how it is used, and a clinical trial to test the efficacy of the messaging system in an outcome-based manner.

I begin by identifying clinical scenarios where patients might benefit from the existence of a messaging system. These scenarios were determined through discussions with patients and with the health care team, looking for areas where increased clarity of or consistency of communication could lead to improved care.

When discussing the messaging system, I outline the design goals, provide an overview of the system and its requirements, and describe protocols for proper use of the system. These protocols have been developed with an eye towards minimizing the costs of adopting the messaging system.

Lastly, I describe the clinical trial, including a study overview, installation and use of the messaging system, and a discussion of our outcome measures. The pilot phase of the study is completed, and preliminary results concerning the usability and usefulness of the messaging system are reported.

Significance

Importance of Glycemic Control

Diabetes is a serious medical condition, affecting about 16 million Americans (with a mortality of 160,000) per year. It accounts for one out of every seven dollars spent related to health care each year (1, 2). With this significant an impact, it is imperative to find new and innovative ways to help patients acknowledge, then manage, this condition. Studies show that aggressive management of blood glucose levels reduces the incidence of complications from diabetes (3, 4, 5, 6, 7, 8); yet this control is difficult to obtain. Generalist physicians lack the time to perform thorough follow-up visits, seeing patients for less than 15 minutes, when it takes 20 minutes to perform a thorough screening and examination (9, 10); and patients will often come in with other acute complaints without specifically mentioning diabetes at the time of encounter. In addition, the management of chronic disease is time consuming, and treatments must be considered in a multifactorial context (8, 11, 12, 13). Even with aggressive targets and therapies in place, studies suggest that around 50% of patients with diabetes have poor glycemic control as measured by Hemoglobin A1c (HbA1c), and have a body mass index (BMI) greater than 26 (14).

Adherence

Part of the problem with glycemic control is due to adherence, which is as low as 10% in certain cohorts (15). This results from many factors, including complexity of treatment regimen (16), medication errors, and medication side effects (15, 17). The patient's support group is also important, with family support, peer support (18), positive

family climate, open relationships in family, and parental support in the case of children correlating with improved adherence (19, 20, 21).

Additional factors which influence adherence are values, attitudes, motivation, and self-discipline (18). The health care system is moving in the direction of patient autonomy, "where patients have the responsibility for independently managing their own illnesses and practitioner-patient relationships are often well-developed over time. (22)". Adherence is positively influenced by the quality of partnership between the patient and physician (19, 20, 23), by health education (18, 21), and by supportive, motivating relationships with health care providers (24). Encouragement and positive feedback from, and collaboration with, health care providers supports adherence (18, 19, 20, 24).

Current Solutions

It has been found that chronic disease management is most effective when adherence is improved through routine monitoring with continual adjustments (25). This has been achieved with two major classes of interventions: the advent of chronic disease management teams, and the use of technology to identify/organize patients with chronic medical conditions, to ensure appropriate routine care and health maintenance.

With chronic disease management teams, non-physicians have expanded roles with excellent results. These individuals review patient records, provide reminder services for preventative health and health maintenance tasks, and can provide suggestions toward treatment simplification while providing sustained follow-up (26). Most unselected, willing subjects with diabetes can achieve improved glycemic control with frequent, convenient support from a knowledgeable professional (27, 28), or even from trained community health workers (29). In one study, nurse case managers utilizing

a diabetes registry of patients within a health maintenance organization (HMO) setting provided a 12-month HbA1c decrease of 1.7% (vs 0.6% in the control group) with n = 545. This diabetes case manager managed 71 patients for the study, and felt that she could manage as many as 300 patients, consistent with studies estimating a case load of 250 patients (9). Other studies which use health care teams (including physicians, subspecialists, pharmacists, nurse counseling) have been successful in affecting glycemic control as measured by HbA1c (26, 30, 31). Continual contact with the health care team can also allow for management tailored to patient stage of ideation (32), leading to increased exercise, change in diet, and decrease in smoking. Continual patient contact allows for "early detection of problems, coordination of care, and timely physician visits" which promote increased effectiveness of medical interventions (29).

There have been a number of studies which have resulted in instruments developed specifically to gauge patient attitudes and perceptions. Some of these instruments have general applicability, including the Diabetes Attitude Scale (DAS) (33) and the diabetes care profile (DCP) (34). These studies suggest that improved attitudes correlate with improved glycemic control. There are other studies which have also surveyed patient attitudes with other instruments, including the Barriers to Adherence Checklist (BAC) (35).

The role of technology in chronic disease management has also allowed the health care team to focus on the essentials of treatment, saving time and cost while simultaneously improving patient care and outcomes. Most interventions to date have focused on two areas: monitoring and management support tools (tracking, monitoring, and plotting the course of chronic disease management), and communications tools

(improving interaction between patients and their health care team). Monitoring tools have included automated devices to transmit patient vital signs (36), and paper and electronic management support tools (database to track patient labs, medications, and preventative health tasks). Web-based versions of these systems have been proposed for private patient usages (37). Monitoring and management support tools appear to be cost-effective, in one study showing a savings of $27,000 per patient with a time weighted average HbA1c decrease of 1.7% (38). Communications tools for ongoing chronic disease management include two-way paging systems (39, 40), automated telephone conversation systems (41), video conferencing home visits (42), and other communications technologies. These tools are most effective for systematic follow up with patients form knowledgeable care teams (43), "especially when there is continuity between the patient and service provider (44)."

Attacking this problem with a two-pronged approach is likely to be more effective than attempting a single-focus intervention (45). This has been demonstrated with highly active antiretroviral therapy (HAART), which requires similarly rigid adherence – including regular meals, exercise goals, and adherence is limited by forgetfulness, regimen complexity, medication side effects, and inadequate patient knowledge (46). Alarm clocks, "routinizing", and two-way paging interventions with aggressive management with continuous follow-up are helpful in this patient population (40, 46).

Significance of Hypothesis

If a low-cost wireless messaging system for diabetes can be created where interactions with the system are acceptable to patients, and actual improvements in Hemoglobin A1c (HbA1c) are noted, then long-term complications of diabetes can be

postponed, leading to decreased overall health care expenditures. If improvements in adherence to the treatment plan due to this system should lead to improvements in certain secondary outcome measures (lipid panel, blood pressure), then this system could contribute to significantly decreased morbidity and mortality in patients with diabetes due to complications of strokes and heart disease.

Given the success of diabetes management through continual monitoring and close follow up, and the existence of pager-based messaging systems for management of Human Immunodeficiency Virus (HIV) infected patients, the hypothesis that a wireless technology based messaging system for diabetes can be created to automate this system, and which will be useful, appears to be very reasonable. If this system can demonstrably improve patient outcomes, then it will allow systems of this nature to be adopted more readily (through coverage by insurance, and through increased referrals by practitioners).

Methods

This project has three components: determination of clinical scenarios to be facilitated by the messaging system, the implementation of the messaging system including protocols for its use, and the clinical trial to determine efficacy of the messaging system.

Clinical Scenarios

Reminders and messages for patients were determined from multiple sources. Physicians were interviewed for 30 to 60 minutes, and asked about specific communications issues and scenarios which they had faced in clinical practice, and of scenarios where more timely communications might have led to better outcomes. Other

health care team members (diabetes nurse educator, doctors of pharmacy, nutritionist) were also asked about their non-clinic patient communications, and observations concerning questions which may be useful when surveying entire patient populations. A physician who had developed a messaging system for Human Immunodeficiency Virus Positive (HIV +) patients was surveyed. MEDLINE and MD Consult searches were performed on the key words "diabetes", "reminders," "pager," "compliance," and "adherence," with article bibliographies also examined.

Messaging System

Design Goals

Design goals were determined from the same informal interviews with members of the health care team, from discussions with Information Technology staff, from discussions with the Human Subjects Division, and from my personal experience from eight years of commercial software development.

Development Environment

Software was developed using tools from Microsoft Corporation, including Access 2000, FrontPage 2000, Visual C++ 6.0, and Visual InterDev 6.0. Web pages in the project are written mostly in VBScript, utilizing Active Server Pages (ASP) technology. The development platform was Microsoft Windows 2000 with Internet Information Services (IIS), Internet Explorer 5.5, and Outlook Express installed. Internet connectivity was provided by Speakeasy DSL service. Test e-mails from the system were sent from a Speakeasy Internet account utilizing Post-Office-Protocol (POP3). The main development computer was protected by a 2Wire HomePortal™ hardware firewall, and a

second notebook computer had only sources to Web pages, and would use the Internet via University of Washington provided dial-up access.

The software was co-developed by myself, and two Computer Science students (Wai Man Ip, Casey Hagen) according to my architectural specifications and software was synchronized weekly during the development cycle. Communications protocols for interactions between the messaging system, patients, and the health care team have been implemented in the software. During the pilot phase of the study, messages sent to patients were agreed upon between the study coordinator (myself) and the patients during the enrollment interview (please see "Clinical Trial: Enrollment Interview" below).

Clinical Trial

Technological solutions in health care have often been implemented, but many rely on user satisfaction surveys and do not utilize outcome-based research to quantify their efficacy. We have chosen to determine whether this messaging system actually has effects on patient outcomes by utilizing the strongest type of study available for this purpose: a randomized clinical trial.

Please see Figure 1, "Study Overview" in the Figures section for a diagram of the clinical trial as approved by the Institutional Review Board (IRB).

Recruitment

For this study, we identified patients within the University of Washington Physicians Network (UWPN) Clinic system with Hemoglobin A1c values between 8.0 and 9.4. This cohort was used for two reasons: because we performed analysis which showed that in this glycemic range, that we would need 48 patients enrolled in the study

to detect a 0.5% change in Hemoglobin A1c (HbA1c); and because there is another ongoing study at UWPN examining the patient population with HbA1c's of 9.5 and over. Since HbA1c's require at least 2 months to reflect any changes, and given restrictions on my own time, I decided to have patients enroll for a 3 to 6 month time interval (12 months would otherwise have been the most ideal for the patients with Type 2 diabetes, for whom exercise and diet are major components of therapy).

Letters were prepared for these patients, and physicians could choose the subset of their eligible patients that would receive the recruitment letters. Most of the patients were actually contacted, but reasons for provider refusal to include patients included: recent exacerbations of illness, participation in other studies, knowledge that patients were illiterate, non-English speaking, or had poor eyesight, feeling that patients specifically would not want to be included in studies, and that certain patients would not benefit from reminders. The letters were signed by the physicians, and were sent with a response card. Please see Appendix A, "Physician's Letter" and "Response Card" for the recruitment materials. Patients who responded positively or and patients who did not return response cards were contacted for possible inclusion in the study.

Randomization

Randomization was performed via a spreadsheet generated in Microsoft Excel 2000 (please see Appendix B, "Randomization Spreadsheet"). The spreadsheet was used to generate random values of 0 and 1 which were balanced in groups of 6. After generation of the spreadsheet, envelopes were created with "NO PAGER" or "PAGER" entered corresponding to 0 or 1 values in the spreadsheet. A randomly determined point in the middle of this stack of envelopes was selected, and the envelopes were "cut" like a

deck of cards at that point. The envelopes were then numbered from 1 through 60, and saved for use at the time of enrollment.

Enrollment Interview

During the study, we attempted to utilize a process similar to if this messaging system was deployed in practice, where physicians would make a referral to the diabetes nurse educator for more intensive diabetes follow up.

Patients who expressed interest in participating in the study were contacted by Kathy Gibbs, Nurse Practitioner to schedule an enrollment interview appointment. At the appointment, the patients were seen by Kathy to go through the consent process.[1] After the consent form was signed, I would present the screening instrument. If patients passed the screening (including no contraindications like having a pacemaker), we would screen blood pressure and administer the preliminary survey (please see Appendix C, "Preliminary Survey"). The randomization envelope would then be opened, and patients in the control ("NO PAGER") group would be offered a chance to hear more about the study before being sent to the laboratory for Hemoglobin A1c lab draw.

In the experimental ("PAGER") group, the participants were given a Motorola™ T-900 two-way pager (see Figure 2, "Motorola Talkabout™ Model T-900" in the Figures section), which is an alphanumeric pager with a small keyboard. Pager service was supplied by Metrocall. In addition, patients received an instruction sheet for basic pager use, an instruction manual, a AA battery, and the enrollment sheet (see Appendix D).

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[1] As per our institutional review board (IRB) approval, I was not allowed to consent patients given possible conflict of interest issues.

The messages were entered as described in the "Results: Messaging System: Usage Protocols" section below.

Messaging System Use

During the course of the study, the messaging system sends alerts for events throughout the course of the day, as agreed upon during the enrollment interview, as per fixed protocols as specified in the "Results: Clinical Trial: Messaging System: Usage Protocols" section below. Changes in messages could be requested by contacting the administrator by pager, by electronic mail (e-mail), or by replying to messages sent by the messaging system. Changes in configuration of the messaging system were typically made within 48 hours. The administrator pager also received messages from the messaging system every 4 hours to verify that it was running.

Exit Interview

All patients enrolled in the study will be contacted to schedule an exit interview appointment. At this appointment, we will screen blood pressure and administer the exit survey (please see Appendix C, "Exit Survey"). Blood pressure will be checked, and Hemoglobin A1c levels will drawn if not already obtained in the previous 30 days.

Outcome Measures

Follow up for the pilot phase of the study was by phone call asking about experiences. Specifically, three questions were asked: How's it going? Have you had any problems with the system? Are you still using your pager?

For the full clinical trial, we will use Hemoglobin A1c (HbA1c) as our primary outcome measure. We will also examine blood pressures, lipid panels, and vaccination

rates. Subjective outcomes will include assessments about patient attitudes towards the health care team, towards diabetes, and towards technology as per our preliminary and exit survey instruments (please see Appendix C). These surveys were developed from the Barriers to Adherence Checklist (BAC), the Diabetes Attitude Scale (DAS), instruments for evaluating adolescent compliance, and a survey instrument assessing patient comfort with the HIV-related paging system (19, 33, 35, 40).

Results

In this section, I will discuss the three areas examined by this study: clinical scenarios, the messaging system, and the clinical trial. I will begin by discussing the clinical scenarios where a messaging system may be useful. Next, I will discuss the architecture of the messaging system, including how the system supports generation, maintenance, and distribution of messages, and protocols for use of the messaging system to address the specified clinical scenarios. Finally, I will discuss the pilot phase of the study, including the subset of the messaging system which was in use, and the patient feedback from this phase.

Clinical Scenarios

Glycemic control is easiest to achieve in a controlled environments where patients have fixed mealtimes, with highly regimented intakes, and consistent activity and exercise levels from day to day. Unfortunately work, school, and other commitments make it increasingly difficult to maintain rigid daily schedules – it is easy to spend a few extra hours at work wrapping things up or having one's attention focused elsewhere during the day, causing ripples in glycemic management which may resulting in potential

hyper- and hypo-glycemia. It is also increasingly difficult for patients to manage complex health-focused regimens when in the context of daily variation in schedules (e.g. students with Monday-Wednesday-Thursday classes may find it difficult to keep the timing of their daily Insulin and meal-times consistent).

I have identified a number of scenarios which might be addressed by a messaging system. Many of these scenarios involve sending messages to encourage a consistent repetition of the health care plan, independent of the hectic and potentially chaotic schedule necessitated by today's busy lifestyles. These scenarios, and the types of messages to address them, include:

- Medication Reminders. These scenarios concern partial adherence to dosing regimens for medications. Clinical examples include the patient who becomes noncompliant because "no one told me to refill my medicines" so he stopped taking them when his prescriptions ran out, and patients who remember to take mealtime doses of their medications, but forget to take doses of their medicines not related to other fixed events in their day ("I always forget to take my nighttime Celexa and Evista."). Many pharmacies are offering services to patients via e-mail or pager devices whereby patients are reminded to get medication refills. There are also some systems (primarily one-way) which remind patients to take medications at certain times of the day.
- Medication Dosage Change Support. These scenarios concern patients who become nonadherent after recent changes in their medication regimen. One physician reported a patient who stopped taking a newly prescribed medicine, and did not notify the provider until their regularly scheduled follow up

appointment ("I stopped taking my medicine 3 months ago because it made me feel dizzy.") Patients do not always realize that they should communicate changes in medication regimen back to their health care team! Also, there is no process whereby patients can directly update their electronic chart (medication list) to ensure its accuracy. There is only provider-maintained charting which may not reflect current medication usage.

- Medication Dosage Clarification. There was a recently reported case of a Spanish speaking patient dying of a drug overdose because they understood "once a day" to be eleven tablets a day. Patients also may not space their medication doses appropriately through the day, leading to unpredictable effects (e.g. taking 2 insulin doses spaced inappropriately leading to roller-coaster effects on glycemic level, because their breakfast was at 9 am and their dinner was at 3 pm).
- Blood Glucose Testing Reinforcement. When titrating medications to try and optimize glycemic control, the health care provider may feel that patients have suboptimal control at various times of the day ("I think your blood sugar is going high in the afternoons, I'd like you to check your sugar at 3 pm."). With a busy schedule, it is easy to forget ("I wanted to check at 3 pm, but I forgot, and I checked at 7 pm. It was normal.").
- Exercise Reinforcement. One of the mainstays of treatment for Type 2 diabetes is exercise, but with today's busy lifestyles, it is easy to be consumed by the task at hand and not make time to exercise. It is also easy to forget scheduled exercise classes.

- Meal Time Reinforcement. Some patients have great difficulty remembering to have an afternoon snack, as they are busy with other obligations through that time period. Others fail to make time to eat lunch, resulting in lunch times which vary greatly from day to day.
- Dietary Reinforcement. Another mainstay of the treatment for Type 2 Diabetes is making dietary changes. There are systems already developed which reinforce good eating behaviors (ediets.com), but additionally, it has been noted that many patients consume large numbers of calories through soft drinks and juices, which they do not perceive as harmful.
- Appointment Reminders. Appointments and appointment-related events (pre-visit lab draws) are often missed by patients for various reasons, and patients are not always aware of preventative health appointments to be scheduled (yearly ophthamological referral, up to quarterly visits for diabetes).
- General Broadcast Messages. The health care team may have occasion to make general announcements to the patient population for preventative health issues like influenza vaccinations in the Autumn, medication recalls, or availability of new medications and/or devices for diabetes management.

Messaging System

I developed the messaging system and determined protocols to facilitate communications between the patient and the health care team to address these scenarios. In the next three sections, I will describe high-level software design goals, describe the messaging system architecture, and describe the protocols for messaging system use.

Design Goals

This intervention is designed to encourage patient feelings of empowerment by assisting them with adherence to their care plan, to foster physician-patient communication by making communications more structured, and to improve the office visit by providing pre-encounter patient information summaries which concisely summarize care plan compliance and ongoing patient issues.

To ease adoption of this system, we wanted to create communications protocols that utilized the system, yet would require minimal changes to the practice style of the health care team. We also wanted to be able to run the system from data already provided by the patient's electronic medical record-based (EMR-based) charting.

In more detail, our design objectives included:

- Increase Accessibility to Patients. It is sometimes difficult to contact patients who have busy schedules. Some patients supply a home phone number where messages cannot be left, some patients are homeless, and other patients may has jobs which require them to travel frequently. Often, office staff must make multiple phone calls to contact patients to distribute information, to communicate lab results, and to confirm appointments.
- Support Propagation of Patient Communications into Medical Records. We want to support processes to ensure that patient communications (electronic mail, phone calls, other non-office-visit patient contacts) are reflected back into their medical records. This may be important for billing reasons.
- Prototype Patient Accessibility to Medical Records. One of the primary attractions of patient-centered on-line medical records has been patient access to

laboratory results. Patients enjoy Internet access to these records, but also appreciate timely and direct communications of these results. It is also useful to patients to have an easily accessible checklist of preventative health items which they can address, and can access from home. Most systems today which do allow home access merely allow access to adaptations to the provider interface to the medical record systems, and not a patient interface, which makes it more difficult for patients to retrieve meaningful data. There is not consistently sufficient explanatory support (help functionality) implemented to allow patients on these systems to interpret their medical records.

- Increase Health Care Provider Capacity. In the context of chronic disease management teams, it would be ideal for systems developed to increase the capacity of the primary chronic disease manager (diabetes nurse educator, doctor of pharmacy) without presenting changes to physician practice style (referral to the chronic disease manager). It would be ideal for a record of patient communications to be accessible in a well understood format (note in chart, or in electronic medical record) so that they could be accessible by all members of the health care team at future office visits.
- Provide a Patient Customizable Solution. The system must be user customizable, and it's even better if the system can be customized in an automated manner (not requiring intervention from the health care provider team). This will allow for maximum flexibility, and minimize additional work for the health care team.
- Utilize Existing Electronic Medical Records (EMRs). Given the high cost of deployment of electronic medical record systems, the ideal system would leverage

data stored in existing systems, and help define data storage requirements to facilitate efficient storage for data lookup and utilization.

- Integrate with Existing Practices of Health Care Providers. Given the traditional reluctance of providers to change their practice style, the ideal system would have minimal impact on a typical office visit. This is because practitioners are typically resistant to electronic tools which require new training, a different practice style, or force the practice of medicine to guidelines to which the practitioner may not agree. A practical system would allow practitioners the freedom to continue to utilize their own clinical judgment when creating the patient care plan, and support reinforcement of this care plan.

Messaging System Architecture

The messaging system consists of multiple components – the web-based user interface, the message generator, the task scheduler, the message sender, and the response processor. Please see Figure 3: "Messaging System Conceptual Overview" in the Figures section for a high level architectural schematic of the messaging system.

- Diabetes Records Database. This is an Access 2000 database (DB1.MDB) which contains diabetes specific information from the patient's Electronic Medical Record (EMR), and also contains user-specified reminder preferences. The schema for the study database is available upon request.
- Web Based User Interface. This user interface allows access to diabetes specific information contained in the study database. All information in the database pertaining to a patient is displayed on different tabs (medication regimen, responses from the patient, etc). This interface also allows access to system

configuration, allowing various classes of messages to be enabled or disabled. Screens used during the pilot phase of the study can be found in Appendix F, "Web-Based Interface".

- Message Generator. This is an Windows application (DppManager.EXE) which examines the database, and determines whether new information present requires new messages to be sent to the user. If so, the new messages are generated and scheduled in the Windows 2000 Task Scheduler.
- Task Scheduler. We utilized the Windows 2000 Task Scheduling service, and the Task Scheduler Applet was used to enter reminders which were not daily reminders at a fixed time. Some of these more complicated reminders included appointments every other week, or reminders for only specific days of the week.
- Message Sender. This is an application (SendMail.EXE) which sends an e-mail message. This application takes as command line parameters the e-mail address of a two-way pager, the message to send, and up to 4 pre-programmed replies which can be returned easily by the patient.
- Response Processor. This is an application (GetNotes.EXE) which examines the administrator's electronic mailbox, and forwards critical pre-programmed replies (marked by (*)), or any non-pre-programmed reply, to the administrator's pager. All e-mail responses are also saved to the diabetes records database and filed under the study code corresponding to the pager which authored the reply.

For the purposes of the study, the services used were operating system supplied low level interfaces. The Database Access services were built using Active Data Objects

(ADO) technology, the Scheduling Service utilized was the ITaskScheduler interface, and the E-mail service utilized was the Mail Application Program Interface (MAPI).

Usage Protocols

This section contains usage protocols for the comprehensive messaging system. These protocols include the steps for configuring the messaging system for a new patient, a walkthrough of the generation and delivery of a message and processing of responses, and a description of how the messaging system supports the clinical scenarios defined above. In the "Clinical Trial: Messaging System" section, I discuss the subset of this system actually in use during the pilot phase of the study.

Messaging Configuration

To configure the messaging system, a member of the health care team meets with the patient (at the establishment of care, or at a follow up appointment) to discuss their current diabetes care plan. Together, they determine messages and the times at which they will be sent. These messages may be any combination of appointment reminders, new lab results (HbA1c), reminders to take medicines, reminders for meals and for bedtime, reminders to exercise, and reminders to check blood sugar. The desired messages are written on a sheet of paper. They then discuss issues related to current state of health (including vaccinations, smoking, exercise, diet, and level of understanding about what to do about hyperglycemia and hypoglycemia).

The pager is then tested to insure that it is working, and that the correct pager number is known. Patients are then sent a test message to which they must respond. If they are successful, the patient is allowed to leave with a pager.

The messaging system is configured to support the agreed upon messages within 48 hours through the administrator and patient user interfaces (see Appendix F, "Web-based Interface", Appointments and Options tabs). Patients start to receive messages after their personalized messages have been generated and scheduled.

Communications Flow

Please see Figure 3: "Messaging System Conceptual Overview" in the Figures section, which also illustrates the flow of information through the messaging system.

Message Generation and Scheduling

Messages are generated and scheduled in one of three ways, depending on type.

1. Messaging System-Supported Reminders. The Message Generator examines both the clinical information (entered and maintained through the web-based interface) and the messaging system configuration settings kept in the diabetes records database. Messages are then generated as outlined in "Results: Messaging System: Usage Protocols: Protocols for Clinical Scenarios" and scheduled at the appropriate times. For example: "It's time for breakfast!" to be sent at 8:00 am daily, or "It's time for your Insulin" to be sent nightly at 10:00 pm.
2. Patient-specified Custom Reminders. These messages are patient-specific, and are not generated automatically due to complexity. These include compound messages (since the message generator does not coalesce messages at this time), messages which are sent less often than once a week (e.g. appointments which occur every two weeks) or messages sent on just certain days of the week (reminders for actions on Monday-Wednesday-Thursday). These messages are

directly entered via the Administrator interface (Task Scheduler). This involves running the Task Scheduling wizard and providing the application to run (Message Sender), the patient's pager e-mail address, the message to be sent, any pre-programmed replies for the message, and providing a time, dates, and frequency for which the message will be sent.

3. General Broadcast Messages. This is for messages to be sent to all patients. These messages are entered via the Administrator interface (Microsoft Access 2000) directly into a table into the diabetes records database, and are scheduled by the Message Generator to be sent to every patient registered in the messaging system. Messages classified as questions are recorded in the patients' invidividual feedback logs in the diabetes records database, as well.

Outbound Messages

When the task scheduler executes the message sender at a specific point in time, the application runs and generates an electronic mail (e-mail) message which is delivered to the pager address specified in the command line. This message may contain pre-programmed replies (automatic responses which may be relevant to the message sent, which can easily be returned by the patient upon receipt of the message). This e-mail is generated using Outlook Express, and the system is configured to save a copy of the message in the Sent Items folder. These items can be reviewed at a later date by opening Outlook Express and perusing them.

Incoming Messages

Replies to messages sent from patients back to the messaging system can be retrieved and read using Outlook Express. In addition, messages in the local Inbox can be analyzed by the response processor. This application opens each unread message in the Inbox, and checks to see if the sender is a patient registered in the diabetes records database. If so, the message contents are examined. If the message contains a critical pre-programmed reply, or if it is free-form text, it is forwarded to the administrator pager. All messages from patients are then processed with information placed in the diabetes records database, and the message is marked as read.

Protocols for Clinical Scenarios

There are two components to the intervention: the web-based user interface to the diabetes records database, and a two-way pager utilizing wireless messaging system. Protocols to address the clinical scenarios identified in the "Clinical Scenarios" section may involve interactions with one or both of these components.

- Medication Reminders. Patient medications and the times at which they are taken are recorded at the time of preliminary interview. This information is entered into the diabetes records database through the Web-based Interface (see Appendix F: "Web-based Interface", Medicines tab, Change Medicines, and Find Medicine pages). Reminders are generated only for those doses which the patient has difficulty remembering, and have the form "It's time to take your <name of medication>". Patients who report excellent compliance are not set up with medication reminders. Medication refill reminders are programmed to trigger three days before the computed refill date, and

take the form "Your <medication name> needs refilling in 3 days." Free-form reminders can also be entered directly into the messaging system utilizing the Administrator interface. These are used when multiple medications are utilized at a specific time of day "Good evening, it's time to take your Celexa and Evista" or if the medication regimen varies daily "Please remember to take <dosage> of <medication name>" where the dosage may vary depending on day of week.

- Medication Dosage Changes. Software was implemented so that patients would be reminded about new doses of medicines daily for one week ("Remember to take <dose> of <medicine name>"), with a follow up in two weeks after starting a new medication dose asking if they were still taking this medication ("How are you doing on your new dose of <medicine name>?" – pre-programmed replies "Ok", "Not taking it (*)"). A critical response of "Not taking it" would generate a referral back to the care provider for further exploration. Both the question and any reply would be logged in the communication log (see Appendix E, "Communication Log").
- Medication Dosing Clarification. Medications can be entered and are displayed by name in a grid, which shows when they are to be taken (see Appendix F, "Web-based Interface" Medicines tab). Dosages are specified in medication reminders.

- Blood Glucose Testing Reinforcement. Reminders have been implemented for occasional scheduled blood glucose testing. They can be scheduled at a specific time of the day, to occur on selected days of the week, for a specified number of weeks. The reminders have the form "It's time to check your blood sugar."
- Exercise Reinforcement. Reminders for exercise are entered through the administrator interface, as patients have many different activities in which they will participate. Messages include "It's time to exercise", "Get ready for exercise", and "It's time for your walk," and would be sent up to one and a half hours before the desired exercise activity.
- Meal Time Reinforcement. The messaging system was implemented to support mealtime reminders for all meals, but patients desired reminders only for specific meals or snacks which were commonly forgotten. Reminders entered by the administrator included "It's time for a snack," and parts of compound reminders like "It's time for dinner, and your nighttime Insulin."
- Dietary Reinforcement. The messaging system does not directly support messages to reinforce dietary goals, however, it can support automated, scheduled surveying of the patient population (e.g. survey of daily beverage intake, number of servings of various food groups, etc), with automatic recording of patient responses in the patient's personal feedback log (see Appendix E, "Patient Feedback Log").

- Appointment Reminders. Reminders for appointments allowed the interval before appointment to be customized, as some patients preferred to be notified a few days before appointments to come in for lab work, and others preferred to be notified a few hours before their appointment on the day of the appointment. Appointment times are visible and modifiable in the Web-based interface (please see Appendix F, "Web-based Interface", Appointments tab).
- Patient-Specified Custom Reminders. Support for personal reminders was implemented in the messaging system through the administrator interface (Task Scheduler), but there was no support in the Web-based User Interface. These reminders can specify any message text. Messages for the study tended to be reminders to see other, non-diabetes related health care professionals for appointments every two weeks.
- General Broadcast Messages. The messaging system allows for broadcasting general announcements to all patients on a specific date, at the time that they individually choose for non-urgent messages.

The web-based interface can be configured by the patient to enable or disable receipt of each of the supported message types above (see Appendix F, "Web-based Interface", Options tab).

Clinical Trial

Recruitment

The clinical trial was delayed by six months to resolve issues with potential conflict of interest raised by the Office of Technology Transfer. We have just started the trial in earnest. To date, 62 patients have been contacted about possible inclusion in the study, including patients of Dr. Failor at UWPN Factoria clinic, and all eligible patients at the UWPN Belltown clinic. 15 patients responded positively by response card or during follow up phone call. 4 are enrolled (two with pagers and two without), for a total of two pilot phase users.[2]

Messaging System

Installation/Test Environment

All components of the messaging system for the study were copied onto a local hard drive of a desktop computer running Windows 2000, with Internet Information Services (IIS) and Internet Mail Application Protocol (IMAP) installed. The Task Scheduler was configured to allow access to an individual user account. The database db1.mdb was registered in a system namespace via the Control Panel to the name "Dpp".

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[2] 94 additional letters have already been prepared to be sent for the remainder of eligible patients at UWPN Factoria. We plan to include patients at the UWPN Des-Moines and Auburn clinics to allow us to reach a target n of 60 (to allow for 20% attrition). We will enroll patients through March, 2002.

The networking configuration was set to only accept connections from a UWPN mail server, and a UWPN administrator machine; and the machine is stored in a locked room at the UWPN Belltown clinic. E-mail is accessed using Outlook Express only, configured to deliver mail asynchronously every 5 minutes.

Since a minimal configuration of IMAP with Outlook Express was utilized, inbound messages were not able to be processed by the Response Processor without an additional step of manual transfer of messages between Server Inbox and Local Inbox. This resulted in the Response Processor being run weekly instead of running continuously; and made it so that we did not send out messages for which replies might have required immediate action.

Usage Protocols for the Pilot Study

For the pilot part of the study, we utilized the protocols for medication reminders, exercise reinforcement, meal time reinforcement, appointment reminders, and customized patient reminders. All reminder protocols utilized were as specified in the "Results: Messaging System: Usage Protocols: Protocols for Clinical Scenarios" section above; except for appointment reminders, which were entered manually by the administrator. Other reminder types were not utilized. While some messages were generated using the automated tools provided, the majority of messages were entered directly via the administrator interface. This was to allow reminders to be coalesced for patient convenience (e.g. "Good morning, time for your breakfast and insulin!" instead of separate reminders for "Time for breakfast" and "Time for your insulin!").

Outcomes

Patient Attitudes at Enrollment

Patients who declined the study did so because "I have enough beepers already", or "I don't need reminders. I need time and money. That would improve my health." Patients that were interested in the study felt that they wanted to do more for their diabetes, loved of technology, thought that pagers would be helpful in their daily life, or stated "why not?"

Metrics

Outcome measures collected include "Diabetes Vital Signs" (HbA1c, blood pressure, last lipid levels) and information about patient attitudes towards the health care team, and towards diabetes, as per the survey instruments constructed for Appendix C. As we have preliminary data for only 2 patients, and have not collected data for the end of the study period, we are not reporting them, but they are available upon request.

Pilot Study Feedback

The results of the two patient interviews at the end of the pilot part of the study follow. Patients were asked "How's it going? Have you had any problems with the system? Are you still using your pager?"

Patient 1

I'm doing OK. This system needs some fine tuning, otherwise it's working really well. When you are out of town, there needed to be better follow up for when I wanted to change my reminders.

The only problems I've had with the pager is that sometimes the messages are late, and sometimes it says they are (STORED), altogether less than 5% of the time. Also, I sometimes sleep through the night time reminder, and the pager beeping drives my dog crazy!

I'm really happy that I have the pager – it keeps me on track. Even if the messages are late, I don't forget because I'm expecting the pager to go off.

Patient 2

I'm doing OK. The pager messages are late over 50% of the time, I don't know if they are STORED or not. Just carrying around the pager reminds me that I have to exercise, or seeing it reminds me to go exercise, and I do exercise more! I found getting lab results and pre-appointment "go to the lab" reminders useful.

All Patients

Each patient requested a different set of reminders, and a total of one to four messages per day were requested. The reminders most used in the pilot phase were medication reminders and exercise reminders. Receiving lab results by pager was very popular, but even without the messaging system, these results appeared to be communicated in a timely manner as per existing UWPN clinic policies.

Discussion

I will discuss what's been learned in the three major areas of study: clinical scenarios, messaging system, and the pilot phase of the clinical trial.

Clinical Scenarios

Most of the protocols defined for management of the various clinical scenarios appeared to be both helpful and acceptable to patients. The patients that participated in the pilot part of the study preferred to receive no more than five messages in any given day. To achieve this, and to better support some of the clinical scenarios not utilized in the pilot, it seemed that a few of the protocols needed minor modifications. Some of the protocols that could use modifications include:

- Medication Dosage Changes. The protocol for medication dosage changes specifies a follow up question two weeks after new medication dose, which asks the open ended question "How are you doing on your new dose of <medicine name>?". If tied to a medication database, this question could be "The most common side effects of <medicine name> are <side effects of medicine>. Have you experienced any of these since starting this medicine?"
- Medication Dosing Clarification. In the Web-based interface, changing the pillbox presentation to make it graphical (depicting actual tablets where possible) along with the correct quantity and time sequence, would be a useful representation for patients.

- Blood Glucose Testing Reinforcement. We alternately considered having a message that read "Please check your blood sugar, and report the results," with pre-programmed replies including ranges (it's less than 70, 71-120, 121-180, greater than 180), with appropriate follow up message ("That blood sugar reading is out of the desired range, please contact ... if you don't know what to do"). It was felt that for the purposes of this study that it was best to provide instructions on what to do in the enrollment letter (see Appendix B, "Enrollment Letter") on who to call, and contact phone numbers, including 911 for emergencies; but certainly, if the response processor is working robustly, instantaneous assistance at time of hypo- or hyper-glycemic episode might prove to be very timely and educational.
- Dietary reinforcement. Surveys about beverage consumption (to estimate extra caloric intake) and dietary factors (number of servings of vegetables today) may allow the health care team to better assess nutritional status than information obtained during clinic visits. If this system is automated, and results can be charted over time, this type of feedback may lead motivated patients to weight loss and reductions in insulin resistance.
- Appointment reminders. The system also has hardcoded values to remind patients when appointments were due (reminder for diabetes care appointment if no future appointment and last appointment was 3 months prior, and reminder for opthamological appointment if no

future appointment and last appointment was 12 months prior). These intervals should be configurable on a per-provider basis, or perhaps even a per-patient basis; so that the system will request that patients return over the correct intervals.

Otherwise, the protocols in use during the pilot part of the study appeared to be well tolerated by patients, who uniformly found the pagers to be useful, even when messages were not being delivered! The messaging system's reinforcement of the care plan resulted in improved adherence to the care plan, as self-reported by the patients.

Messaging System

Design Goals

Many of the initial design goals of the messaging system were achieved by its implementation. Security, privacy, and tighter integration with existing electronic medical record systems (EMRs) will be important when trying to make this messaging system useful in real clinical scenarios. Comments on how the messaging system met the following initial design goal areas follow:

- Accessibility to Patients. Providing all patients in the experimental group with pagers has proven to be a way to improve accessibility to patients. It was easy to reach the patients in the pilot study for their follow up phone calls – I could text or numerically page them!
- Patient Accessibility to Medical Records. Communication of laboratory results by pager (specifically, preliminary HbA1c at the beginning of the study) was extremely popular. The Web Based

Interface contains lists of health maintenance and educational tasks to be seen and discussed with patients, and these issues were discussed during the preliminary interview with patients in the experimental group – and I did receive some questions about what to do in the event of hypoglycemia. I referred these patients to their health care team for ongoing educational support.

- Health Care Provider Support. The combination of a web-based registry and pagers to support the care plan did tend to result in moving the burden of diabetes management more towards the patient. It's not clear whether this system will allow more patients to be managed, because the system allows patients to see more axes of their diabetes care, resulting in more communication between the health care team and the patients. It does seem that the patient focus on their care plan (as per patient report) is more intense and involved than without the messaging system.
- Patient Customizable. The system has been designed to be patient customizable through the Web Interface, however, this interface has not been exposed to study participants, so its effectiveness cannot be evaluated. In the pilot phase, patients expressed interest in technologies which would allow the messaging system to be patient configurable, either by Web interface or by messages from the messaging system. The latter might be a message from a separate administrator e-mail account sent monthly as to whether their schedule

had changed. They also felt that having pre-programmed replies to discontinue messages was desirable.

- Integration with Existing Electronic Medical Records (EMRs). While the messaging system has been architected to support incremental merging of records from the master EMR database, propagation of data for this study is being done manually, due to security concerns and lack of resources for creating the appropriate data extractions from the master EMR database (UWPN Epic system). This will be an important area of extension for the messaging system, as entering patient data and having to update it manually is tedious, potentially error prone, and time consuming.
- Integration with Existing Practices of Health Care Providers. This system has proven to be no burden to the physicians involved in the study, although it may result in patients coming in for office visits sooner, as advised by the administrator (me). The system places all patient-supplied responses to pager messages into a patient-specific feedback log. This log (please see Appendix E, "Patient Feedback Log") can be printed out and saved into a hard chart, or saved to a file and inserted into the master EMR database as an e-mail encounter, or can be accessed through the administrator or patient Web interfaces. Telephone encounters can likewise be recorded into the patient feedback log easily for future billing purposes. This feature should

make it easier for non-technical health care providers to access the information collected by the messaging system.

Clinical Trial

I will discuss patient attitudes during recruitment, and observations and recommendations resulting from feedback after the pilot part of the study.

Patient Comments at Time of Recruitment

Patients had very strong opinions during recruitment concerning the pagers. It would have been interesting to add a question to the preliminary and exit surveys of how useful (0 (not useful)- 5 (don't know) -10 (very useful)) did they feel the pager would be, and how useful did the pager prove to be? I hypothesize that patients can know before starting this intervention as to whether or not it will be effective, and that if we took these measurements, that the results for this question between the preliminary and exit surveys would correlate strongly and positively.

Observations and Recommendations from Pilot Phase Feedback

When discussing the current implementation of the messaging system with the participants in the pilot phase of the study, certain design considerations became more evident. These included:

- Messages should be coalesced if temporally close. Patients disliked receiving multiple pager messages spaced close together. They preferred single messages for all tasks to be performed in a short window (within 30 minutes, this may vary

between patients). Otherwise, there is the feeling that the pager keeps going off and it disrupts the ability to manage other tasks.

- Communications should be customized to individual patients. The first implementation of the messaging system in some ways tried to do too much. It allowed for the ability to specify reminders for all meals, and all medications. In fact, patients do not need to be reminded of the things which they are already doing routinely- they just need reminders for tasks which they are not performing in a timely or consistent manner. The two patients currently utilizing the messaging system have vastly different needs for reminders. One really enjoys getting night time reminders, and replies to every message that she receives. The other just wanted reminders for exercise and before appointments to get lab work done, as he would often forget and his clinic appointment would be wasted.
- Repetitiveness is acceptable. An early concern of mine was that the messages would be very repetitive, and that people would turn off the pagers due to boredom or annoyance. This has not proven to be the case, although one patient did report that variety in the messages (even with consistent content) would be appreciated – it was not mandatory.
- Patient-focused interventions can work. By self-report, both patients in the pilot phase of the study finding the pager useful. This is encouraging.
- Physician-focused interventions are difficult to sell. During the marketing phase for this tool, physicians were very wary that the messaging system would create an extra burden on their time, or that the system would attempt to exercise clinical judgment through guidelines into which they had no input. It is clear that if this

system were to develop heuristics to analyze patient medical records, that it would also have to be easily configurable on a per-provider basis – and even then, it would potentially be difficult to market the solution to physicians. To avoid this issue, lab results reported by the messaging system are not interpreted.

- Monitoring patient responses is important. If patients are being queried where their responses may be potential medical emergencies (e.g. messaging system reminds patient to check blood glucose, and patient is extremely hypo- or hyper-glycemic), it is imperative that the health care team be extremely and rapidly responsive. Systems which can add structure to the data, allowing identification of potentially critical messages can help to save patients in situations which the patients themselves may not realize are life-threatening.
- Reliability is important. Over the course of the study thus far, over 500 messages have been sent. At first, when the system was only robust enough to stay up on the average of 10 days, the patients really noticed (although they were tolerant because they knew the software was in the development phase). The current system is much more robust – it ran for 6 weeks over December and January, until it was shut down when the computer received routine maintenance. During this time, due to freezes in the UWPN network, approximately one in slightly over one hundred messages would arrive over an hour late. The messages may also arrive late if the pager is taken into an area which cannot be serviced (underground rooms, areas with poor Metrocall service). The patients noticed these occurrences and reacted to them – and all failures reflected upon the messaging system, even if they were more due to pager coverage area.

- Constant reminders train patients. With time, the patients mentioned that they start predicting when the pages will come (or the physical presence of the pager reminds them), and they remember the actions that they must take at specific times of the day, even if the messages fail to arrive on time. This suggests that pagers may be used as teaching tools, which can eventually be phased out.
- Wireless technology is not ubiquitous. The pagers currently seem to work best in the highly urban area of Seattle and its close suburbs – and this technology has the limitations that it can only be used where wireless service is provided reliably. This implies that although technology which supports the diabetes care plan may be helpful in rural areas, this solution cannot be used in those areas at this time.
- Security and privacy are important. It is clear that with HIPAA regulations, that patient information must be kept confidential. It has been possible to protect patient privacy by utilizing no names in communications; and by providing patients with pager e-mail addresses which do not identify them. If patients start to use a system like the one developed with their own e-mail addresses, there will be additional security and privacy concerns whereby encryption may be required; and if the Web interfaces are made generally available, the web pages must enforce stringent security protocols and identity validation. It will be important for patients using these systems to be informed in detail about security and privacy limitations of any interactive health care systems before agreeing to allow them to be utilized.

Future Directions

This novel approach to diabetes management leaves many areas for future research. These areas include: enhancement of the messaging system so that it can be utilized effectively in an actual clinic, integration of the messaging system with other tools which interact with patients to support their health care, determination of the efficacy of the messaging system, and expansion of the system to other domains where messages may be helpful.

The messaging system as currently implemented will require additional security features to ensure confidentiality of patient data. This will involve migrating the Web-based interface to utilize secure protocols, including secure login features, and utilization of encryption technologies as wireless devices grow to support them. The system will need to integrate more tightly with existing electronic medical record (EMR) systems, so that the diabetes records database can be populated and updated automatically from existing clinic records, and there will need to be a mechanism for patient communications recorded in the patient feedback log to be placed back into the patient's electronic chart. The messaging system diabetes records database will also need to undergo adjustments to its schema, to support efficient reporting of clinical information. It would also be nice to expand the messaging system to provide better support for patient-driven reconfiguration.

It will be important as more tools are developed to support patients in their health care for all the tools to be integrated seamlessly. Many systems today utilize patient-owned wireless devices to provide services such as stock quotes, diet reminders, joke of the day messages, and other one-way communications. In the future, more tools will utilize these devices with structured two-way communications, just as the messaging

system utilizes them. It will be important for these communications to be uniform, so that users will not be confused. That is why the Web-based Interface is important – it provides an integrated set of pages which cover a patient's view of their electronic chart. Real-time monitoring devices (e.g. for blood glucose checking) should also provide interfaces which integrate well within a patient's view of their electronic chart.

One limitation of most technological based solutions that I have noticed is that interesting solutions are developed, and they are marketed and implemented without studies proving that they are clinically efficacious with regards to patient outcomes. Very expensive technologies have been deployed without proof that they provide anything more than convenience to the health care team. It is important to focus on technologies which actually improve patient outcomes, just as we perform clinical trials on treatments to try and maximize patient benefit. We are continuing our clinical trial to determine if messaging systems are not only desirable to patients, but whether they also result in any improvements in clinical outcomes. We chose Hemoglobin A1c as our primary outcome measure, because it is an objective measure related strongly to long term complications in diabetes. Studies should be used to evaluate all new treatment plans, be they technologically based, pharmaceutical based, or clinical protocol based.

A natural question given the existence of the messaging system and the fact that it helps chronic disease management is: can this approach be expanded to other domains? There appear to be three groups who might benefit from this system – technologically savvy consumers with poor adherence, patients who are financially challenged, and patients with complicated care plans. A population with poor adherence that is technologically savvy is adolescents. Wireless devices are cool technology, and

receiving a device at low or no cost would be helpful given a potentially limited budget. The ability to perform constant surveying and monitoring (with the possibility of revoking the devices) might prove enough incentive for increased adherence in this population. The second population, financially challenged patients, might find the technology to be a great boon – it would allow them to stay "plugged in" to the health care system by making them easy to reach, and the technology would also make it easier for them to find jobs if the pagers could be covered by insurance or by an angel investor (pagers provided by grant to the homeless). Another group that might benefit from this intervention would be patients who have very complex care plans (e.g. patients on anticoagulant therapy, with changing doses of medications on a daily basis). This system could even be used to be more aggressive with managing diabetes in insulin-dependent patients, providing flexibility similar to that of the insulin pump. Patients could be on different insulin regimens on different days, even related to menstrual cycles, with complex insulin regimens supported by the messaging system.

Conclusion

Today, we are in a health care environment where medical records are being moved onto computer systems. It is increasingly important to leverage this investment in medical technology in ways which are of low incremental cost, yet have high patient utility. To do so, we have implemented a wireless messaging system and defined protocols for how to use this system to address specific clinical scenarios. This intervention improves adherence to diabetes care plans as per patient self-report, without creating significant additional overhead during clinic visits. Interacting with this partially-automated messaging system is acceptable to patients. This system lays the groundwork for how data in electronic medical record systems can be used not only for archival purposes, but also for active management of chronic medical conditions – providing a direct impact on patient health care and well being, and potentially reducing long term complications, morbidity, and mortality due to diabetes.

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The software used in this study was written in large part by myself. There is a possibility that I could profit from this software at some point in the future.

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Figure Legends and Figures

Figure 1. Study Overview

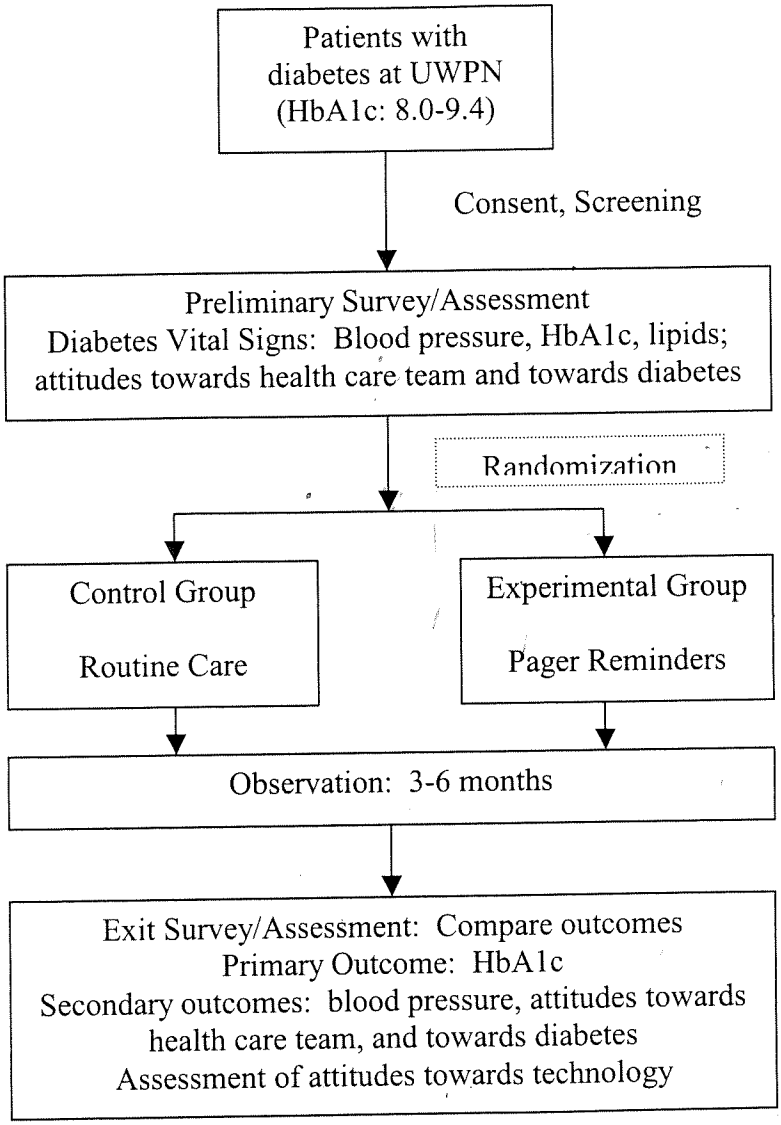


Figure 1. Study overview.

Figure 2: Motorola Talkabout ™ Model T900

This is a picture of a Talkabout ™.

This picture is approximately half

as large as a normally sized unit,

which is 2 ½"W x 1 ½"D x ½"H.

Figure 2. Motorola Talkabout ™ Model T900 Personal Interactive communicator.

Figure 3: Messaging System Conceptual Overview

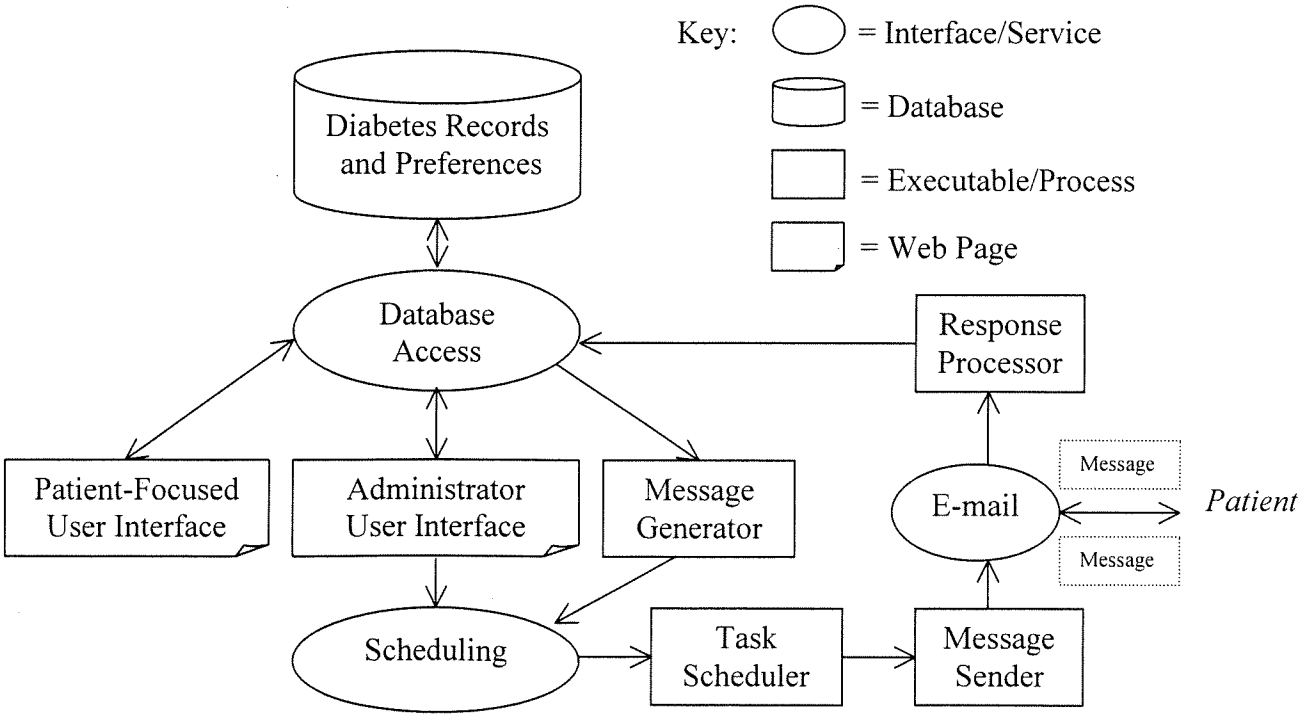


Figure 3. Messaging System Conceptual Overview.

Appendix A: Recruitment Letters

Physician's Letter

University of Washington
Informational Notice
Wireless Messages for Diabetes

Dear «Title» «LastName»,

We are looking for people with diabetes for a research study. In this study, we are seeing if receiving wireless messages via pager can help improve health outcomes.

This study will have two groups of patients. If you choose to be in this study, we will randomize you (like the toss of a coin) to one of two study groups. One group will receive a pager, through which you would be notified of diabetes-related news, and also about personal appointments, lab results, and other personal reminders (diabetes-related or not) that you specify. The other group will not receive pagers. We are researching whether these communications will help you to keep better informed, and help to make your care plan more clear, in an effort to reduce or postpone future complications from diabetes. All study participants will be asked to fill out short questionnaires at the beginning and at the end of the study.

We are contacting patients for enrollment in this study. If you have new contact information, or if you do not wish to be contacted, please fill out and return the attached response card. If we don't hear from you, the Study Coordinator will contact you by phone to see if you are eligible.

Thank you, and have a great day!

«ProviderName»

Response Card

Wireless Messages for Diabetes

___ YES, I am interested in participating in this study.
Please contact me. I can be reached at:

_____

___ NO, I am not interested in being a part of this study.

Recruitment Statement

Due to my personal development of the software involved in this project, if I recruited subjects who did not return a response card, I told the potential participants: "People in this study receive messages on pagers. These messages are determined, managed, and sent by a computer program. I wrote most of the program. I hope the results of this study will help me improve the program. There is a chance that I could profit from this program in the future."

Appendix B: Randomization Spreadsheet

The randomization spreadsheet was constructed by using Microsoft Excel 2000 to generate lists of random numbers between 0 and 1. These numbers were then rounded to generate a "0" or a "1" in the spreadsheet. Patients were randomized in groups of 6, to keep the experimental and the control groups roughly balanced.

The spreadsheet had the following format:

	A	B	C
1	=RAND()	=IF(A1<0.5,0,1)	=B1
2	=RAND()	=IF(A2<0.5,0,1)	=B2
3	=RAND()	=IF(A3<0.5,0,1)	=B3
4	=RAND()	=IF(A4<0.5,0,1)	=IF(SUM(C1:C3)=0,1,IF(SUM(C1:C3)=3,0,B4))
5	=RAND()	=IF(A5<0.5,0,1)	=IF(SUM(C1:C4)=1,1,IF(SUM(C1:C4)=3,0,B5))
6	=RAND()	=IF(A6<0.5,0,1)	=IF(SUM(C1:C5)=2,1,IF(SUM(C1:C5)=3,0,B6))

These formulas make it such that if we already have our quota of "1" or "0" values, then later cells would be filled in appropriately; otherwise, they would continue to be randomly generated. This table of 6 rows was duplicated 10 times, resulting in 60 random values which are evenly distributed over each group of 6 values.

Appendix C: Surveys

Screening Questionnaire

University of Washington
Screening Form
Wireless Messages for Diabetes

This form is to ensure that you meet the criteria to be included in this study. Please let us know if any of the following are applicable. Your interviewer will go through this list with you so that you understand what is being asked. Feel free to ask questions while filling out this form. This information will NOT be placed in your chart, and will be shredded at the end of the study. Thanks again for your interest!

==========

Do you manage your own health care? Circle Yes or No

Are you at least 18 years of age? Circle Yes or No

Can you read and understand English? Circle Yes or No

If you are female, could you be pregnant right now, or are you planning a child within the next 6 months? Circle Yes or No

Do you have any of the following medical conditions? Circle Yes or No

- Heart condition requiring a pacemaker
- Uncontrolled blood pressure (greater than 180/110)
- Unstable angina
- Heart attack in the last 3 months
- Seizures (2 or more episodes)
- Late stage complications of diabetes, including eye/kidney/foot problems?
- Severe combined immunodeficiency (SCID)
- Dependency on alcohol or severe liver problems (cirrhosis)
- Dependency on drugs (cocaine, heroin, etc.)

==========

Thanks for completing this screening survey. Please return this form to the interviewer.

Preliminary Survey

Please take a few minutes to fill out this survey. The purpose of this survey is to assess your opinions about your current care for diabetes. At the end of this project, we will give you a chance to answer these questions again, and also seek your opinion about whether the project helped you to manage your diabetes. All information will be kept completely confidential. Thanks again for your participation!

Study code: _____

1. Have you had a flu shot within the past 12 months (Yes/No)? ____

   If so, approximately when? _____
2. Do you take your medicines on a regular basis (Yes/No)? ____
   If so, what helps you remember, and if not, what could be done to help?

Please think about the health care that you have received for diabetes during the past year. For each of the following statements, please circle the number that best reflects whether you agree or disagree.

strongly disagree (0)	disagree	neutral (5)	agree	strongly agree (10)

3. Overall, I'm satisfied with the health care I currently receive for my diabetes.
   0 1 2 3 4 5 6 7 8 9 10

4. My doctor and I have a treatment plan (agreements for things we'll do, and how frequently) to manage my diabetes.
   0 1 2 3 4 5 6 7 8 9 10

5. I have a clear plan for what to do if my blood sugar is too high or too low.
   0 1 2 3 4 5 6 7 8 9 10

6. I have a good understanding of the potential problems that can be caused by my medicines.
   0 1 2 3 4 5 6 7 8 9 10

7. All of my questions concerning what diabetes is, and how to best manage it have been answered to my satisfaction.
   0 1 2 3 4 5 6 7 8 9 10

Please think about how diabetes has affected your life. For each of the following, please indicate how you feel about these health issues.

8. How would you describe your health?

feeling terrible					neutral					feeling great!
0	1	2	3	4	5	6	7	8	9	10

9. How do you feel about your skill in managing diabetes?

it's uncontrollable					neutral					it's manageable
0	1	2	3	4	5	6	7	8	9	10

10. How do you feel about checking your blood sugar?

it's unimportant					neutral					it's important
0	1	2	3	4	5	6	7	8	9	10
I don't check it					I check sometimes					I check regularly
0	1	2	3	4	5	6	7	8	9	10
it's hard to do					neutral					it's easy to do
0	1	2	3	4	5	6	7	8	9	10

11. My treatment plan is

impossible					neutral					realistic
0	1	2	3	4	5	6	7	8	9	10

Exit Survey

Please take a few minutes to fill out this survey. The purpose of this survey is to assess your opinions about your current care for diabetes, and to ask whether our project was helpful in improving this care. All information will be kept completely confidential. Thanks again for your participation!

Study code: _____

1. Have you had a flu shot within the past 12 months (Yes/No)? ____
   If so, approximately when?

2. Did you take your medicines on a regular basis (Yes/No)? ____
   If so, what helped you remember, and if not, what might have worked better?

Please think about the health care that you have received for diabetes during the past year. For each of the following, please state if you agree with the following statements and how much using the following scale:

strongly disagree (0)	disagree	neutral (5)	agree	strongly agree (10)

3. Overall, I'm satisfied with the health care I currently receive for my diabetes.
   0 1 2 3 4 5 6 7 8 9 10

4. My doctor and I have a treatment plan (agreements for things we'll do, and how frequently) to manage my diabetes.
   0 1 2 3 4 5 6 7 8 9 10

5. I have a clear plan for what to do if my blood sugar is too high or too low.
   0 1 2 3 4 5 6 7 8 9 10

6. I have a good understanding of the potential problems that can be caused by my medicines.
   0 1 2 3 4 5 6 7 8 9 10

7. All of my questions concerning what diabetes is, and how to best manage it have been answered to my satisfaction.
   0 1 2 3 4 5 6 7 8 9 10

8. My health care is better than at the start of the study.
   0 1 2 3 4 5 6 7 8 9 10

Please think about how diabetes has affected your life. For each of the following, please indicate how you feel about these health issues.

9. How would you describe your health?

feeling terrible					neutral					feeling great!
0	1	2	3	4	5	6	7	8	9	10

10. How do you feel about your skill in managing diabetes?

it's uncontrollable					neutral					it's manageable
0	1	2	3	4	5	6	7	8	9	10

11. How do you feel about checking your blood sugar?

it's unimportant					neutral					it's important
0	1	2	3	4	5	6	7	8	9	10

I don't check it					I check sometimes					I check regularly
0	1	2	3	4	5	6	7	8	9	10

it's hard to do					neutral					it's easy to do
0	1	2	3	4	5	6	7	8	9	10

12. My treatment plan is

impossible					neutral					realistic
0	1	2	3	4	5	6	7	8	9	10

For each of the following, please indicate how much of these statements is true or false given your experiences and beliefs. Use the following scale:

13. The messages were annoying.

disagree	partially disagree	partially agree	agree

14. The messages were from my doctor personally.

disagree	partially disagree	partially agree	agree

15. The messages were not applicable (give examples).

disagree	partially disagree	partially agree	agree

For each of the following, please indicate how you felt.

16. How was this experience?

worse than I expected					neutral					better than I expected
0	1	2	3	4	5	6	7	8	9	10

17. The messages were:

annoying					neutral					comforting
0	1	2	3	4	5	6	7	8	9	10

unhelpful					neutral					helpful
0	1	2	3	4	5	6	7	8	9	10

inconvenient					neutral					convenient
0	1	2	3	4	5	6	7	8	9	10

useless					neutral					useful
0	1	2	3	4	5	6	7	8	9	10

18. Most of the time, the pager:

didn't work										worked fine
0	1	2	3	4	5	6	7	8	9	10

19. Regarding my health care from my health care team, I felt:

no support										cared for
0	1	2	3	4	5	6	7	8	9	10

20. Regarding my family, I felt:

no support										support
0	1	2	3	4	5	6	7	8	9	10

Please think about the last few months while being enrolled in this study.

Did you enjoy participating in this study? Why or why not?

Do you want to continue this program now that the study is over? Why or why not?

Appendix D: Other Documents

Enrollment Document

University of Washington
Study Enrollment
Wireless Messages for Diabetes

Dear

Thank you for your participation in this study! Your study code is _____. You are being issued a pager, with pager number _____. This is a two-way pager and can be used to send messages to other people or back to me. If you require a prompt response (e.g. you notice that your blood sugar level is not in the normal range and you don't know what to do) please call the UWPN for assistance at (206) 443-0400.

If you are experiencing a life-threatening emergency, call 911 immediately! If you have any problems with your pager, please contact Metrocall at (800) 305-9494. If you would like your messages changed or are not receiving messages as per our first meeting, please contact me. Attached you will find a brochure describing the features of your pager. Good luck, and thanks again for helping us with this study!

Cheers,

Mike Leu, Study Coordinator
4th Year Medical Student
(866) 316-7328
michaelleu@my2way.com

Appendix E: Patient Feedback Log

Date	Time	From	Message
11/6/2001	4:37 PM	E-mail	Got it (Test message)
11/6/2001	4:59 PM	E-mail	Thank you! (Test message)
11/7/2001	5:06 PM	E-mail	Yes/OK (Reminders set up. Please notify me with any changes, or if you want more reminders (e.g. to check blood sugar).)
11/7/2001	5:30 PM	E-mail	Thank you (Your HbA1c on 11/6/2001 was 8.4.)
11/7/2001	8:07 PM	E-mail	Thank you! I received 3 messages off the system today. I had already taken the two meds but still need to check my sugars and do my evening insulin. (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/8/2001	11:37 AM	E-mail	I received both this message and the morning ones. Thank you. I would like the lunch time alert to come around 1:30 p.m. (It's lunchtime! Remember to take your Insulin.)
11/8/2001	5:16 PM	E-mail	Yes/OK (It's time for dinner, and your dinnertime Insulin...)
11/8/2001	5:17 PM	E-mail	Yes/OK (It's time to exercise!)

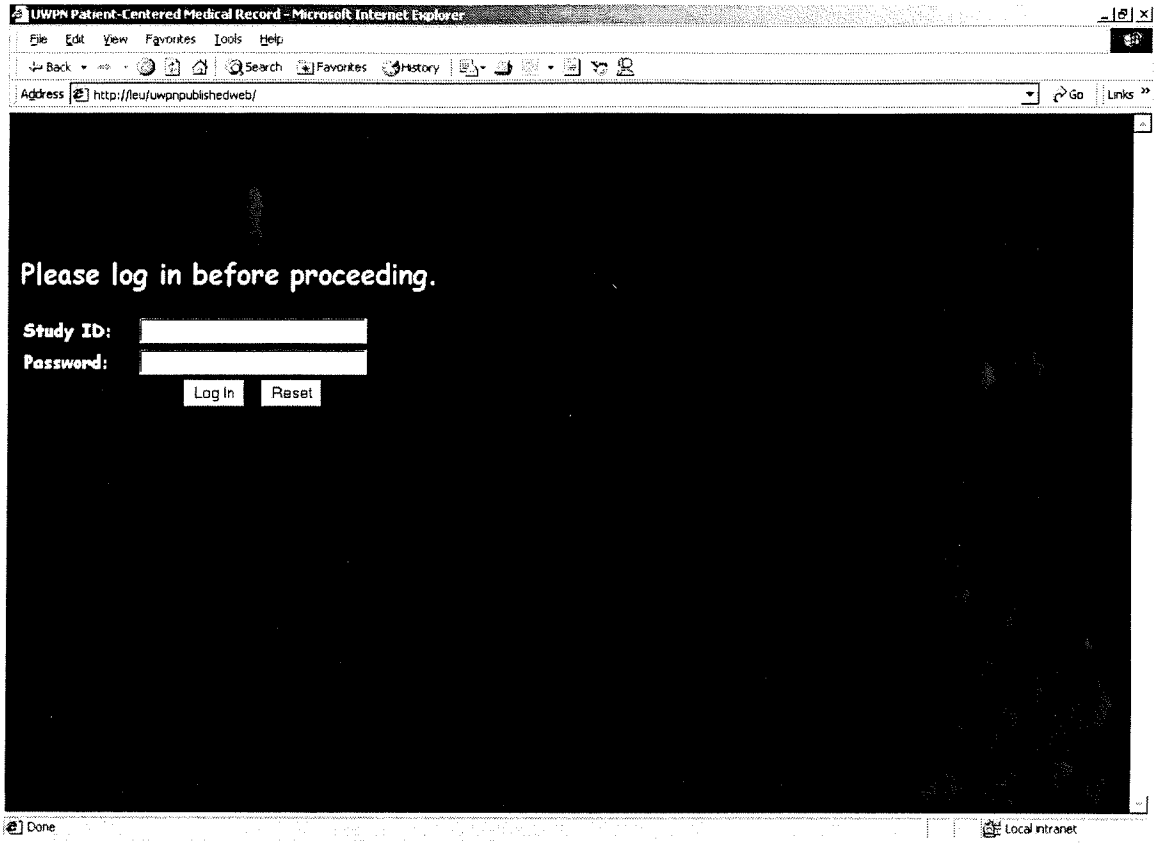
11/8/2001	8:32 PM	E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/9/2001	7:00 AM	E-mail	Thank you (Good morning, time for your breakfast and insulin!)
11/9/2001	7:02 AM	E-mail	Thank you (Good morning, time for your breakfast and insulin!)
11/9/2001	8:02 PM	E-mail	Thank you! I have received all the pages today. Good night to you too. (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/10/2001	11:15 AM	E-mail	Hi! I know this is late, I slept in and am just now starting to move about. That means I will probably be late on my first insulin of the day, combining them as I've done in the past. Thanks. (Good morning, time for your breakfast and insulin!)
11/10/2001	11:30 AM	E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/10/2001	5:05 PM	E-mail	Yes/OK (It's time to exercise!)
11/10/2001	5:07 PM	E-mail	Yes I'm getting dinner now. (It's time for dinner, and your dinnertime Insulin...)
11/10/2001	8:05 PM	E-mail	I am glad I had this reminder. J had forgotten my celexa and evista. (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/11/2001	5:01 PM	E-mail	Yes/OK (It's time for dinner, and your dinnertime Insulin...)
11/11/2001	7:58 PM	E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/12/2001	7:21 AM	E-mail	Thank you (Good morning, time for your breakfast and insulin!)
11/12/2001	11:39 AM	E-mail	Thanks. This is helping to keep me on top of my food and insulin intake. The only problem I am finding is that my timing for food and insulin is different on the weekends and holidays. we'll have to discuss some changes for this situation. Thanks again, go
11/12/2001	4:59 PM	E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/12/2001	7:57 PM	E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/13/2001	7:01 AM	E-mail	Good morning. I'm appreciative of these reminders. Thanks. (Good morning, time for your breakfast and insulin!)
11/13/2001	11:36 AM	E-mail	As I said yesterday, I will need to change times on some of these alerts. The 5 o'clock alerts especially. Please call around 7:30 pm. tonight, if possible. [Name deleted] (It's lunchtime! Remember to take your Insulin.)
11/13/2001	7:58 PM	E-mail	Yes/OK (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/13/2001	8:01 PM	E-mail	Exercise was not possible today. (It's time to exercise!)
11/13/2001	8:03 PM	E-mail	Thank you. I made the appointment in plenty of time. (Remember: appointment with [Provider name deleted] at 5 pm)
11/13/2001	8:08 PM	E-mail	I need to move the time of my dinner time and insulin. (It's time for dinner, and your dinnertime Insulin...)
11/14/2001	7:00 AM	E-mail	Thank you (Good morning, time for your breakfast and insulin!)
11/14/2001	11:28 AM	E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/14/2001	5:06 PM	E-mail	Yes/OK (It's time for dinner, and your dinnertime Insulin...)
11/14/2001	7:58 PM	E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/15/2001	7:00 AM	E-mail	Already ahead of the game. (Good morning, time for your breakfast and insulin!)
11/15/2001	11:28 AM	E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/15/2001	5:10 PM	E-mail	Yes/OK (It's time to exercise!)
11/16/2001	6:30 PM	E-mail	Thank you! It looks like we're back on line. [Name deleted] (It's time for dinner, and your dinnertime Insulin...)
11/16/2001	10:32 PM	E-mail	Thanks. I remembered all my night-time meds. (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/17/2001	8:31 AM	E-mail	Thanks. I got up early and took my insulin. Now i need to eat, then go for my flu shot. (Good morning, time for your breakfast and insulin!)
11/17/2001	1:03 PM	E-mail	Thanks. I already ate, but I'd forgotten to take my insulin. This reminder was terrific. (It's lunchtime! Remember to take your Insulin.)
11/17/2001	6:29 PM	E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/17/2001	10:28 PM	E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/18/2001	6:59 AM	E-mail	Thank you (Good morning, time for your breakfast and insulin!)

11/18/2001	1:55 PM E-mail	Thank you. I got the message but wasn't able to reply or take care my insulin til now. (It's lunchtime! Remember to take your Insulin.)
11/18/2001	6:44 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/18/2001	6:45 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/19/2001	6:28 PM E-mail	Yes/OK (It's time for dinner, and your dinnertime Insulin...)
11/19/2001	10:45 PM E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/20/2001	7:02 AM E-mail	Got it. Already had my insulin. Just having this pager is a remindr. (Good morning, time for your breakfast and insulin!)
11/20/2001	12:58 PM E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/20/2001	6:28 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/21/2001	7:08 AM E-mail	Thank you. I have the day off so I slept later. (Good morning, time for your breakfast and insulin!)
11/21/2001	1:02 PM E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/21/2001	6:30 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/22/2001	6:58 AM E-mail	Thank you (Good morning, time for your breakfast and insulin!)
11/22/2001	1:00 PM E-mail	Thank you! Since this a busy day the pages are truly helping. (It's lunchtime! Remember to take your Insulin.)
11/22/2001	6:39 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/23/2001	8:33 AM E-mail	This page was very good timing. I am just now getting my breakfast and insulin. (Good morning, time for your breakfast and insulin!)
11/23/2001	12:58 PM E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/23/2001	6:34 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)
11/23/2001	10:29 PM E-mail	Thank you (Time for your nighttime Insulin, Evista, Celexa... good night!)
11/24/2001	8:32 AM E-mail	Thanks. I am ahead of the game this morning. I ws up early so was done with my inslin and am almost done with breakfast. (Good morning, time for your breakfast and insulin!)
11/24/2001	1:03 PM E-mail	Thank you (It's lunchtime! Remember to take your Insulin.)
11/24/2001	6:44 PM E-mail	Thank you (It's time for dinner, and your dinnertime Insulin...)

Appendix F: Web-based Interface

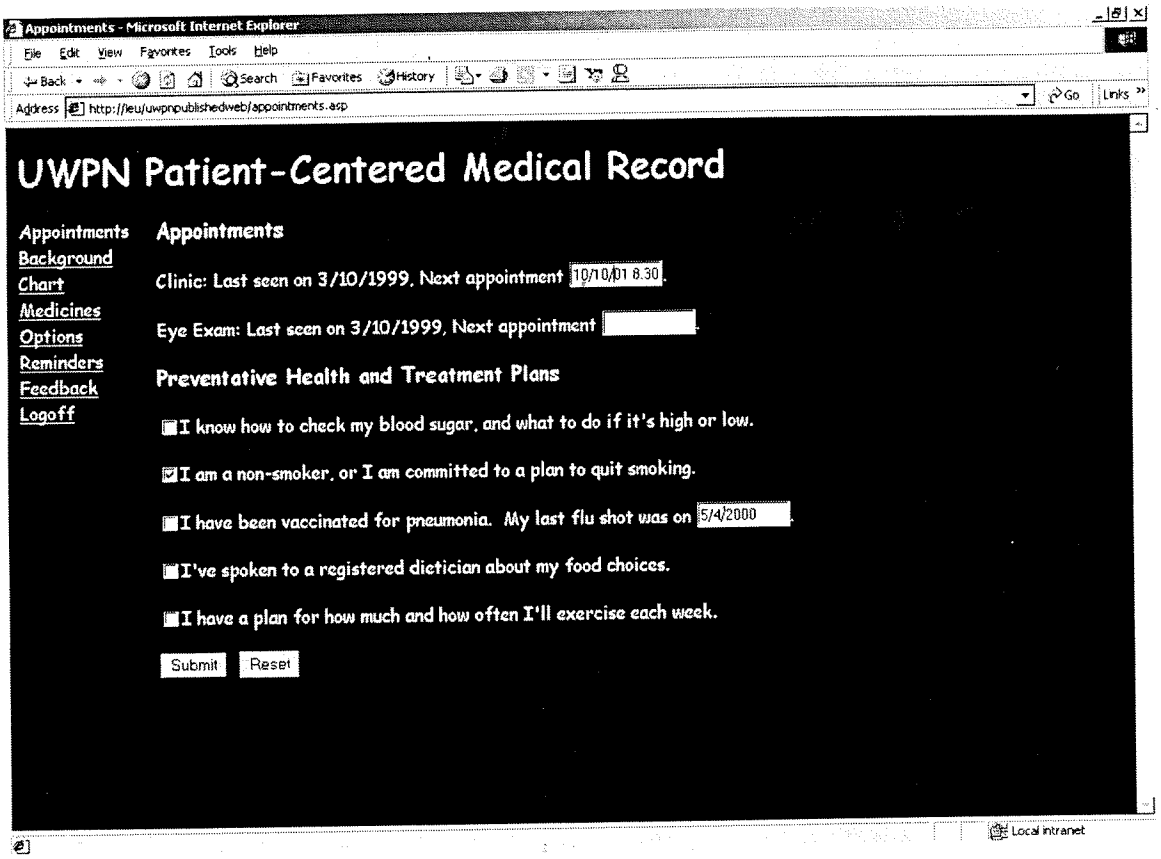
Attached are the patient-interface screens utilized in the pilot phase of this study. The user interfaces are under development and may be modified during the clinical trial in conjunction with database changes made for efficiency purposes. To protect patient confidentiality, the screens shown are from an earlier test version of the software.

Login Screen



Appointments tab

The appointments tab contains appointment dates (times can also be specified), and preventative health and treatment issues, which are reviewed with patients during the enrollment interview.



Background tab

The background tab contains patient-specific demographic information. Physician information is included so that in the future, patient care plans can be tailored based on an individual physician's practice style. Patient birthdate and age are not currently included due to HIPAA considerations.

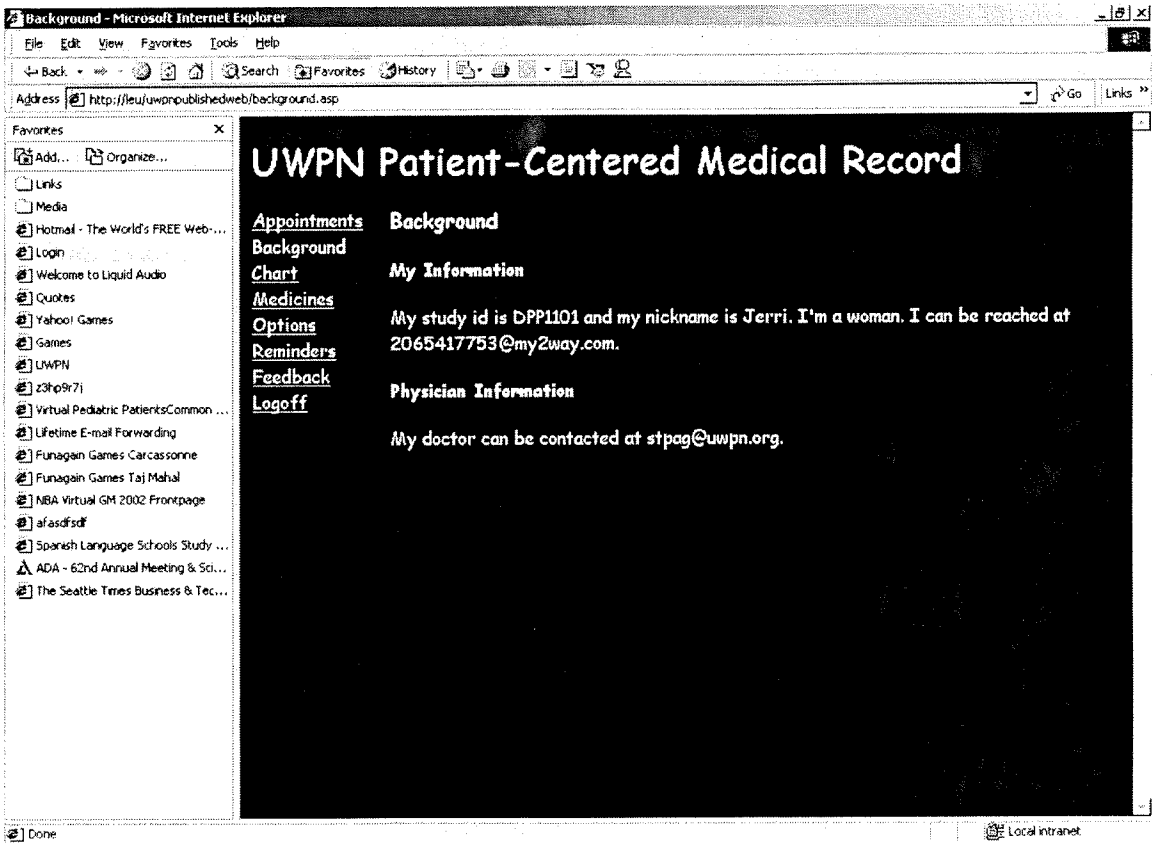
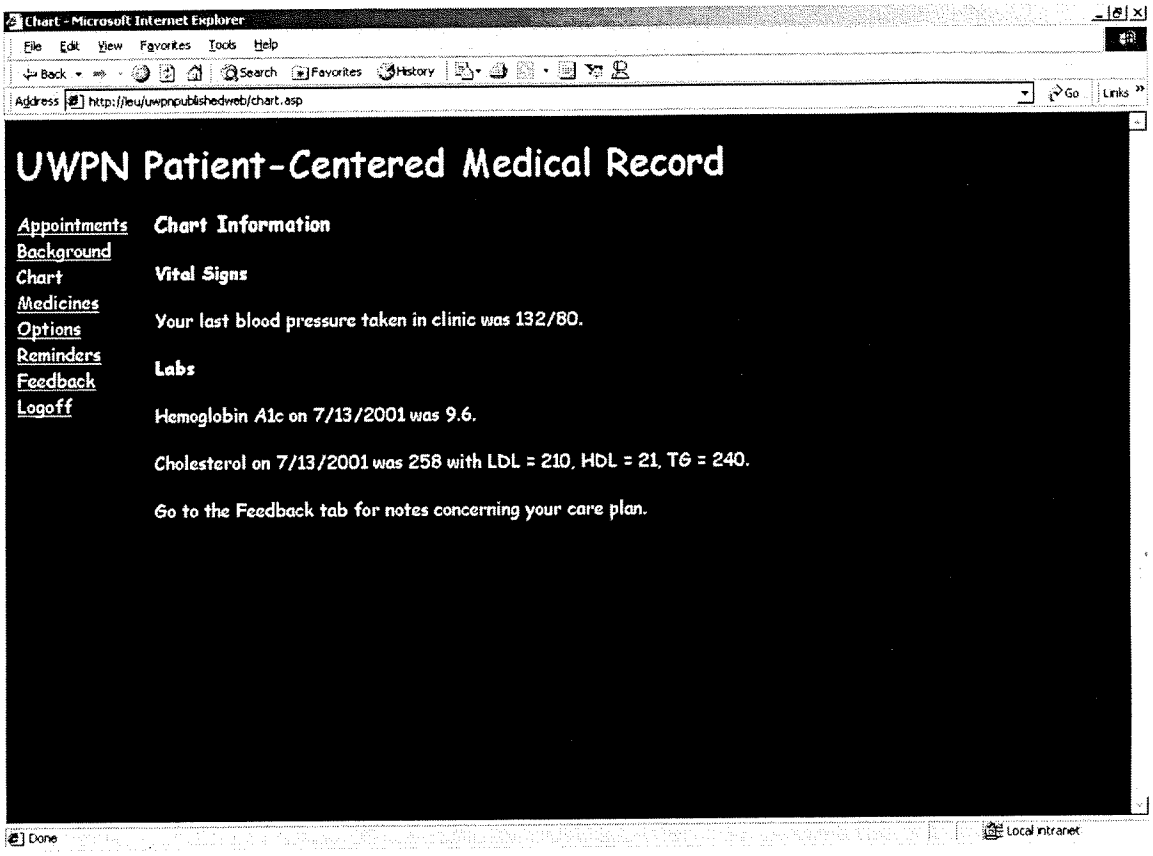


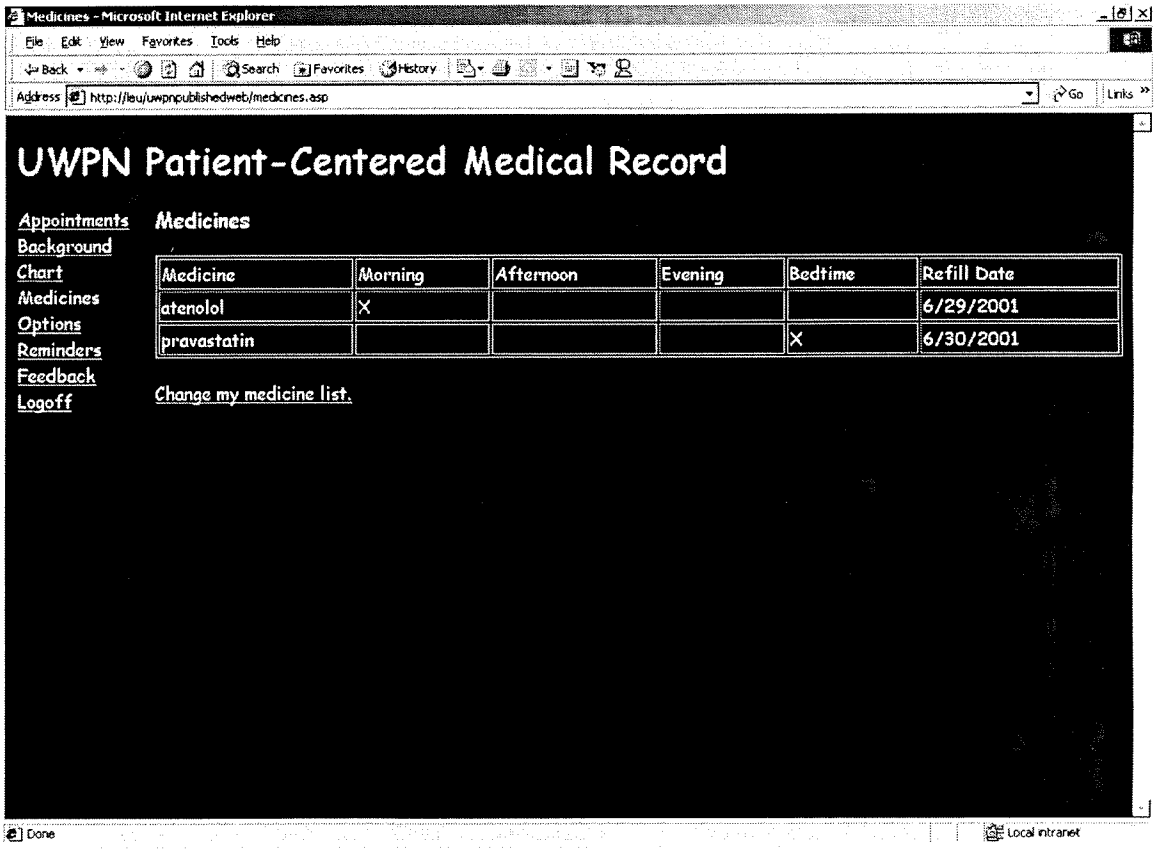
Chart tab

The chart tab includes values for blood pressure and lab results. These are reported, but not interpreted.



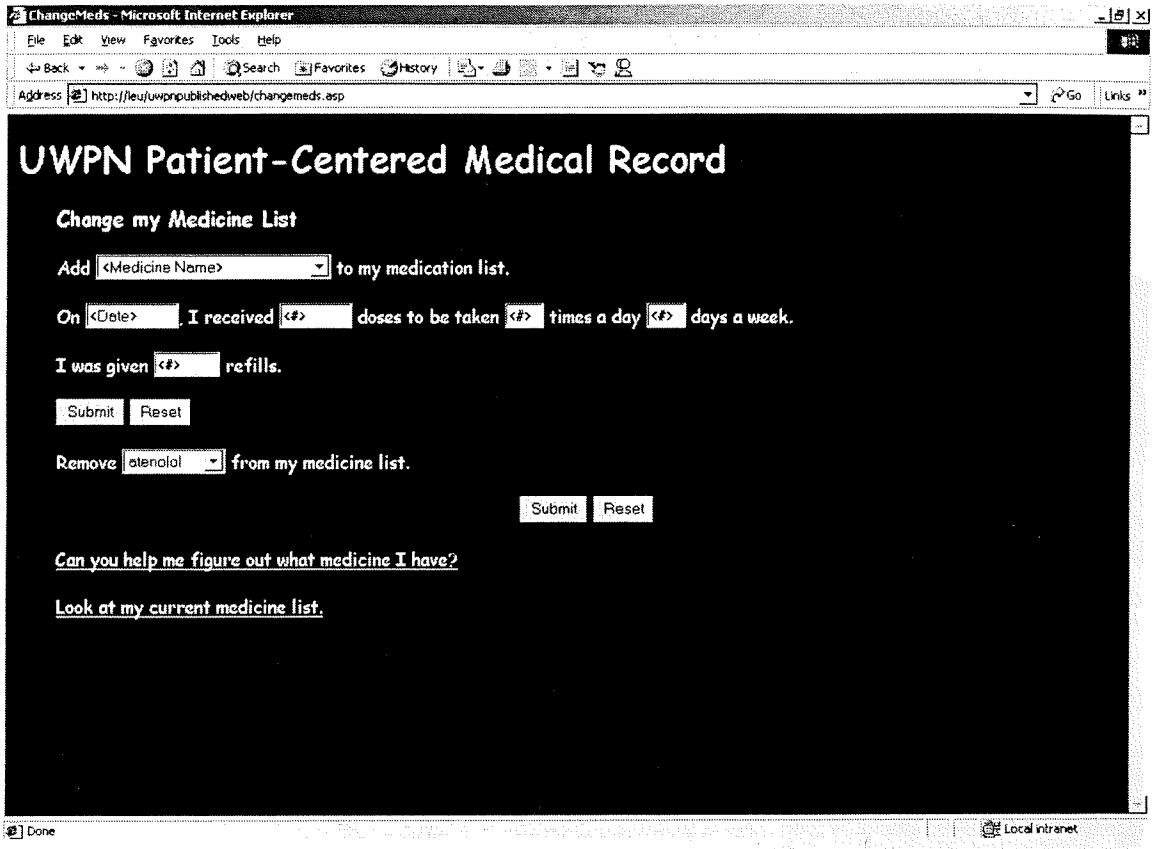
Medicines tab

The medicines tab displays patient medications, giving a visual display of when medicines are taken during the day. It also provides dates when medications will need to be refilled. These dates are computed from information specified when the medicines are added to the list.



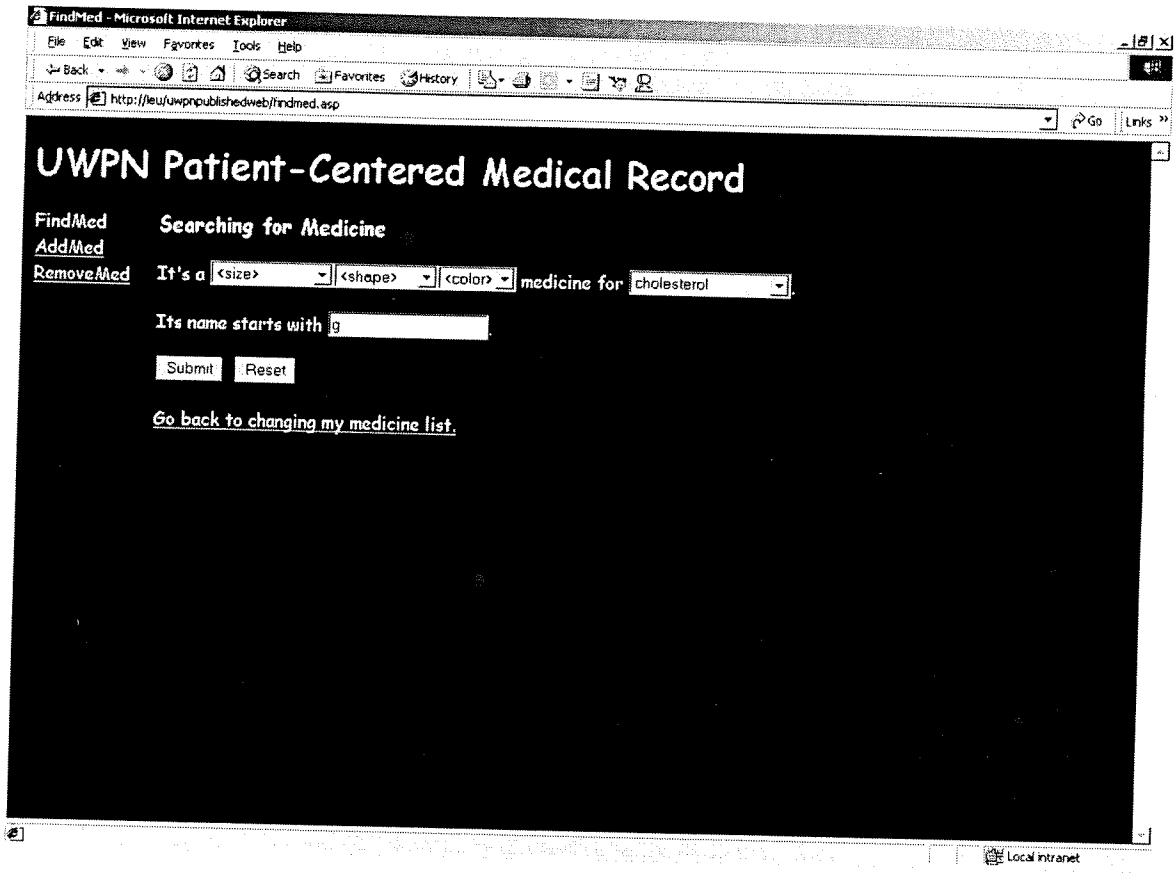
Change Medicines page

This page is used to add or remove medicines from the medicine list.



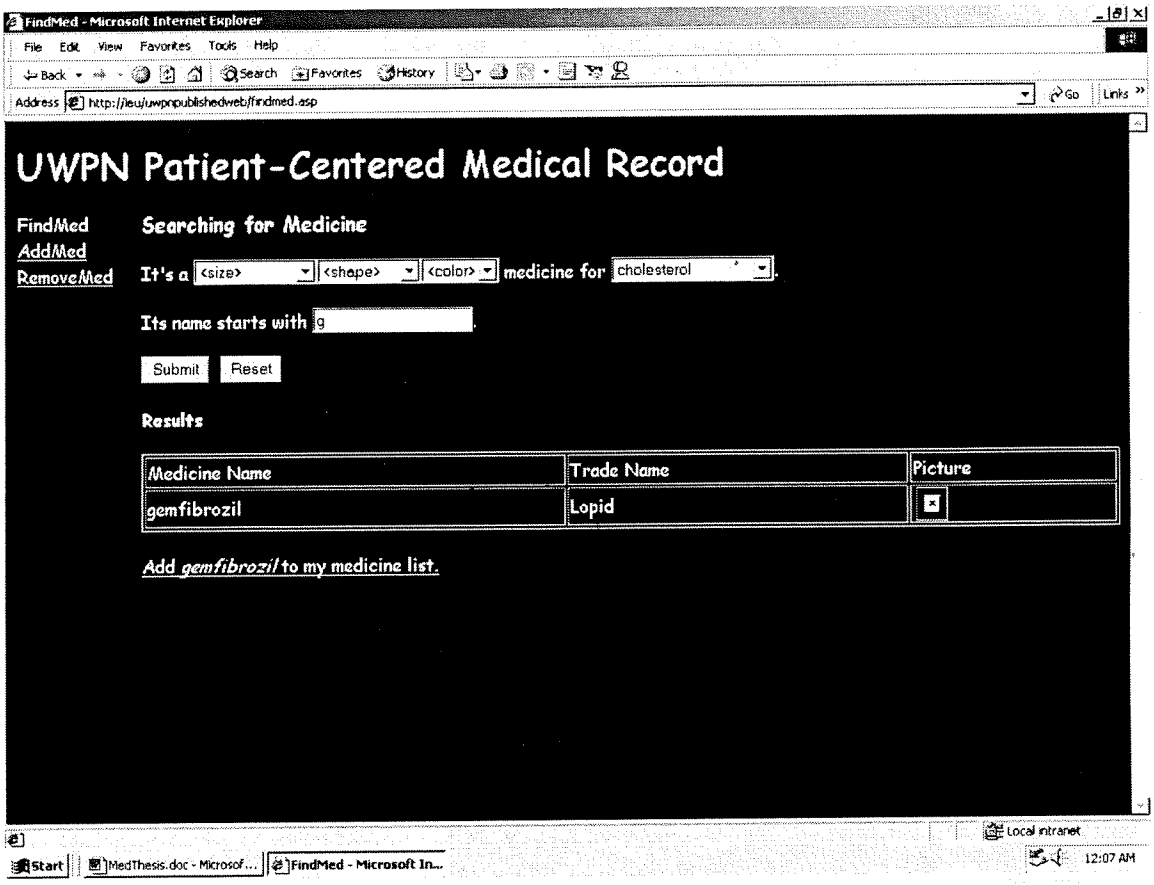
Find Medicine page

This page is used when patients are trying to find their medicine, because they cannot remember it. They can specify medicines by appearance keywords (e.g. small, white) and by prefix.



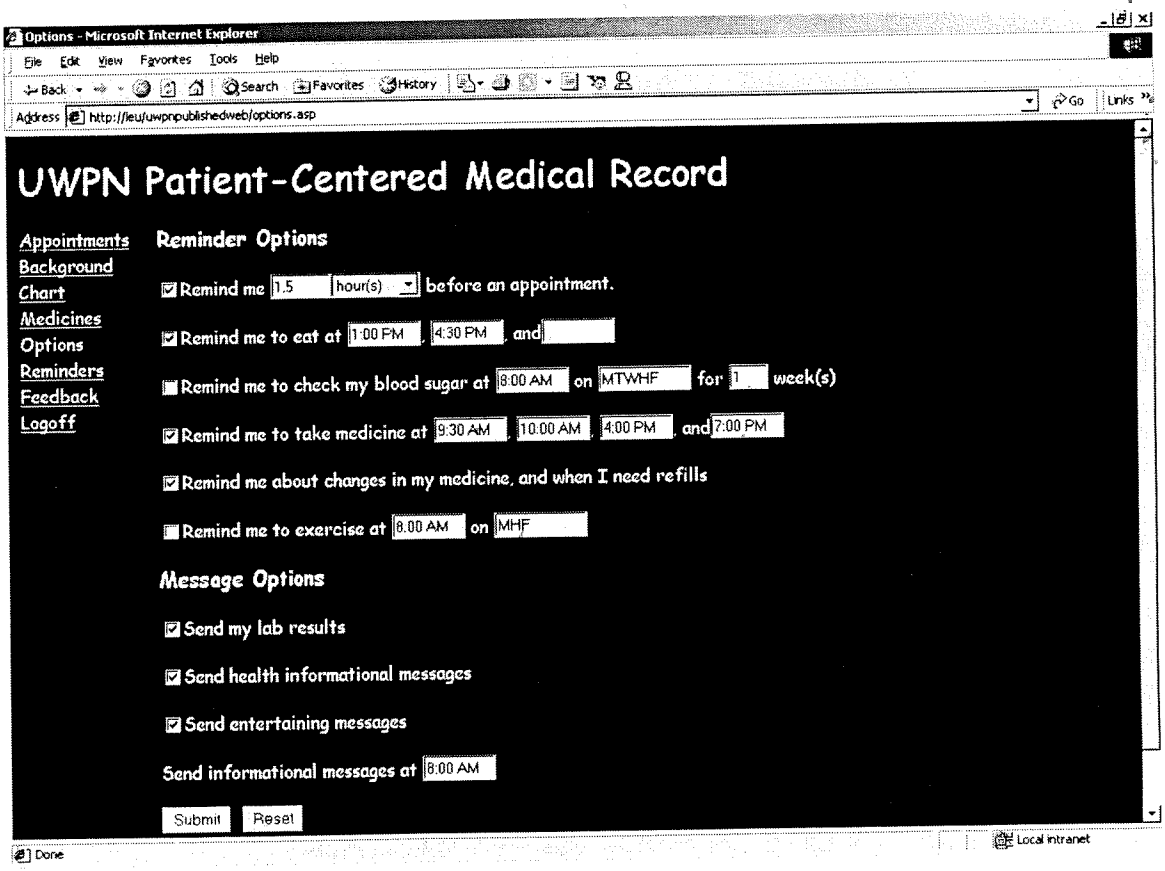
Find Medicine page (After successful look up)

If medicines are found that match the search criteria, they are listed. If only one medicine is listed, a hyperlink to add that medicine appears at the bottom of the page.



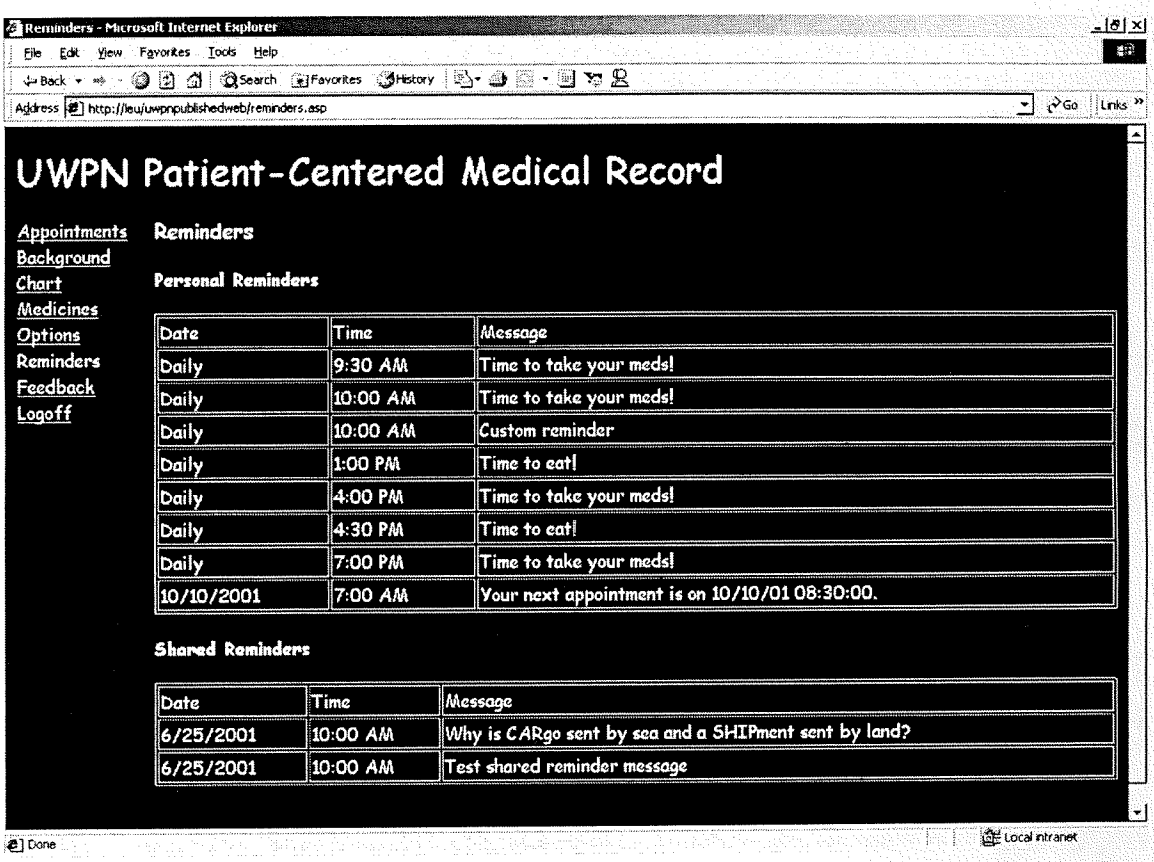
Options tab

This tab can be used to select the messages desired from the messaging system, and to provide an easier way to enter messages to be automatically generated by the message generator.



Reminders tab

This tab shows the reminders which will be scheduled. The reminders in this sample page have been generated using the



Feedback tab

The feedback tab displays the patient feedback log stored in the diabetes records database. It allows comments to be entered by the patient which are marked as "Internet", whereas pager responses are marked as "E-mail". Questions sent by administrators that are logged are marked "Provider". For a longer example of an actual patient log, please see Appendix E, "Patient Feedback Log."