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14. ABSTRACT

The overarching vision of this project is to help people with diabetes better manage their condition by providing them with a tool that will make self-management less confusing, less stressful, and less constrained.

This is a two-phase project. In phase 1, we are designing a Personal Health Record Application (PHR-A) to assist with the following domains pertinent to diabetes self-management: 1) nutrition/diet (healthy eating) 2) physical activity (being active); 3) blood glucose (self-monitoring); 4) medications (tracking and adherence only); 5) outlook and beliefs; and 6) reducing risks through recommended medical visits and lab testing. Using information that the PHR-A receives on these self-management domains (from the user's own monitoring/journaling devices that store data in a PHR called Microsoft HealthVault and/or from the user's manual data entry directly into the service/PHR-A), the PHR-A analyzes, interprets, provides feedback, and makes recommendations bolstered by educational content on diabetes self-management. All of the feedback and recommendations are focused on lifestyle. Some feedback provides information on the relationships among the various self-care domains.

We are obtaining user and clinical responses to the PHR-A as we develop it. In phase 2, the project is conducting a brief pilot study of the clinical efficacy of the PHR-A in people with diabetes. The main outcome is glycemic control. A secondary outcome is diabetes-related distress.

**15. SUBJECT TERMS**
Telemedicine, diabetes, technology, self-management mobile

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**Introduction**

Diabetes mellitus is a significant cause of morbidity and mortality in the United States (1). Reduction or prevention of diabetes-related complications requires blood glucose levels be kept as close as possible to the normal range (2-3). Daily self-care behaviors carried out by the person with diabetes are of central importance in attaining good blood glucose control. In addition, hypoglycemia and hyperglycemia recognition and management, foot care, eye care, clinic visits, diabetes education, and various necessary medical screenings must all be incorporated into daily life (4-7).

Self-management to bring blood glucose levels into "good control" varies and is related to the current condition or health status and emotional well-being of the person with diabetes. Regarding the health status of the so-called "typical" person with diabetes, we know from previous research that most people with diabetes have type 2 (90-95% of people with diabetes) (8), have excess body weight (1), and are in their late 50's (9). Further, their hemoglobin A1c (A1c) levels, an indicator of the average blood glucose levels over approximately the last 90 days, are above the recommended levels. Many people with type 2 diabetes have a reduction in endogenous insulin production as well as insulin resistance, resulting in a progressive loss of effective insulin secretion and/or action. Lastly, people with diabetes are twice as likely to be depressed as someone who does not have diabetes (10-12). This is important because emotional problems are related to people's ability to initiate or sustain appropriate behaviors for managing their disease (13-16).

Given the current health condition of many people with diabetes, self-management minimally involves a complex and variable regimen of appropriate weight management, ongoing healthy nutrition, moderate physical activity, and blood glucose monitoring. For many, it also involves judicious use of medication; e.g., about 84.1% of people with diabetes take medication (oral medications or insulin), with 50% of people with diabetes (type 2) taking oral medications only, 18.4% taking insulin only, and the remaining 15.7% taking both (17). Frequent self-monitoring of blood glucose levels is also required to guide self- and medical management decisions.

But people with diabetes often do not adhere to all aspects of an appropriate self-management regimen. Over 64% of people with type 2 diabetes have a hemoglobin A1c (A1c) that is higher than the level recommended by the American Diabetes Association (18). Many people report not testing their blood glucose as frequently as they should (19-21). Survey (22, 23) and surveillance system data (24) show that only 50%-70% of Americans with diabetes receive the recommended, annual, dilated eye examinations.

There are numerous technologies available intended to assist with diabetes care- and self-management and reduce the burden of this disease. Although the evidence on previous technologies for diabetes care- and self-management suggests they are helpful for improving certain patient outcomes and clinician behaviors, there are several limitations in this field. First, as noted by Brown and associates (25) in their review of web-based interventions for type 2 diabetes, lack of reimbursement to providers for using web-based technologies limits deployment and sustainment, and patients are unwilling to pay for such technologies. This observation applies to cell phone-based systems as well. These limitations mean that emerging technologies must be free to consumers and not require continual input from a clinician or clinic. Second, to our knowledge, existing systems have not included consumers in the design process. Consumers have instead participated in usability

tests or focus groups of nearly complete or mature products (26, 27). Thus, current technologies may not be congruent with the expectations and needs of their target populations, which may account for the high attrition in usage typical of health-related technologies (28). Third, a review of the literature on self-monitoring of blood glucose notes that few programs/studies offer specific algorithms for modifying medication dosages, diet, or exercise -- let alone all three -- in response to the data collected (29). The same critique can be made of existing tools for diabetes care- and self-management. Care- and self-management applications and devices currently available target only part of the complex diabetes self-management regimen, provide only data management, are retrospective, and/or do not have any decision support or offer only limited decision support. Moreover, most existing diabetes self- and care-management technologies do not yet make use of the data storage and functionality available from PHRs (30).

Thus, the objectives of this project are:

1) To develop a new PHR-A for diabetes self-management that is mobile, easy-to-use, focuses on the major domains of diabetes self-management, and makes use of a PHR as appropriate for the user.
2) To conduct a Pilot Study testing the efficacy of the PHR-A.

Currently the overall project and its components are ongoing.

**This report describes our progress to date based on the original Statement of Work – by Task -- and our plans for the following year. It is important to note that, due to errors in the Original Contract (incorrect Period of Performance and incorrect PI listed), the project was substantially delayed in starting.**

**Body**

*1) **Draft functional requirements for a Personal Health Record-Application (PHR-A)***

This is the first task that the project completed, and is foundational for the rest of the work. To complete this task, the project identified, discrete, user-friendly 'modules' that address the main components of diabetes care. The modules, borrowed from the American Association of Diabetes Educators are:

- Healthy Eating
- Being Active
- Problem Solving & Coping (now renamed "Outlook")
- Medications
- Monitoring (two separate – one for weight and one for self-monitoring of blood glucose)
- Reducing Risks

Although not a separate module per se, the PHR-A will also include weekly diabetes tips (or twice weekly, depending on user preference) that cover the above areas (the user chooses the areas). We have since drafted tips pertaining to the above areas.

Furthermore, the ‘Reducing Risks’ module is not stand-alone; rather it is incorporated into the user’s Home Page and addresses issues such as lab results and appointment reminders.

We have submitted the Functional Requirement Document (Task 1) to Stacey Zimmerman, but not the tips (part of Task 2). The aforementioned decision about the collection of user’s data on ‘healthy eating’ and ‘being active’ is incorporated in that Functional Requirement Document.

The following is excerpted from the Functional Requirement Document submitted for this task. Note that this is an iterative project based on clinician and user feedback, so certain details of the Functional Requirements have changed since the submission to TATRC.

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## A. Operating Environment

The PHR-A is a web-based application that consists of:

- Two user interfaces
    - An HTML and JavaScript browser-based front end designed for the desktop
    - An HTML and JavaScript browser-based front end designed for mobile Smartphones
- A Java-based framework utilizing Apache Struts on the server
- Relational database to handle data storage requirements

## B. PHR-A Technical Requirements Summary

### Technical Architecture / Deployment Module

The PHR-A must be designed to be deployed as one universally-available application. Specific technical architecture guidelines can be found in the PHR-A Technical Architecture Document.

### User Prerequisites

While intended to support the person with diabetes, the PHR-A will be publicly-available to anyone interested in using it. No formal training is required. However, some baseline familiarity with internet technologies will be necessary to interact with the various application modules.

Use of the desktop browser version requires only basic internet connectivity and a reasonably modern computer.

Use of the mobile version requires a device with both internet connectivity and an internet browser.

Some components of the PHR-A utilize data from third-party Personal Health Record (PHR) data repositories, such as Microsoft HealthVault. In order to take advantage of those components users will be required to both create their personal account and facilitate the transfer of their personal health record information.

**Hardware Requirements**

The PHR-A has the following hardware requirements:

| System | Type | Requirements |
|---|---|---|
| BEA Weblogic | Application Server | • Server class machine with Windows Windows 2003/8 Server |
| | Communications | • TCP/IP |
| Oracle 10g | Database Server | • Server class machine with Windows 2003/8 Server |
| | Communications | • JDBC |
| PHR-A Client | Desktop Client | • Desktop class machine with Windows XP SP2 or newer |
| | Mobile Client | • Smartphone with connectivity to the Internet |
| | Communication | • TCP/IP<br>• HTTP 1.1<br>• HTTPS 1.1 |

**Software Requirements**

The PHR-A has the following software requirements:

| System | Requirements |
|---|---|
| Application Server | • BEA Weblogic Express 9.2 or higher<br>• Java v5Apache Struts v2<br>• Hibernate v2<br>• C3PO<br>• SQL*Net client / JDBC |
| Database Server | • Oracle 10.0.2 |
| Desktop Client | • Internet Explorer v6/5 or<br>• Firefox v3.5 or<br>• Safari 4 |
| Mobile Client | • Javascript/EMCAScript enabled Mobile Browser |

**Technology Requirements**

The recommended technologies are as follows:

| Technology | Use | Requirements |
|---|---|---|
| Java | Application | Provides the backend application software to drive the PHR-A |
| BEA Web Logic | Application Hosting | Application server, which hosts the Java application |
| Oracle 10 | Data Storage | Robust data storage for PHR-A data |
| HTML/JavaScript | Client-browser presentation | Markup language used to display information in a web browser and interact with the user |

**Development Environment**

**Software**

| Tool | Purpose |
|---|---|
| Eclipse | Java development environment |
| ERWin | Data Modeling |
| Oracle 10g | Database |
| Apache Tomcat v5.5 or higher | Application Server |
| Java Virtual Machine v5 | Java runtime environment |

**Desktop User Interface Guidelines**

The following user interface guidelines should be used in implementing the desktop version of the PHR-A.

1. Desktop page size will be optimized for a resolution of *1024 x 768 pixels*. The application will be usable at lower resolutions, but may require horizontal and vertical scrolling.
2. The application will be targeted for multi-browser support.
3. Each page of the application will contain a page title.
4. The desktop client will display the username of the user who is logged in, a link to logout, and a link to access the user's personal settings.
5. For all date fields the following behaviors will be implemented:
    a. A Calendar should be enabled for all date fields that are not likely to have dates older than 5 years entered to allow the user to graphically select the date.
    b. If the user enters only a 4 digit year the date will default to "01/01" of the entered year.
    c. If the user presses the "t" key on the keyboard in the date field the current date will

6. The user will be able to sort the contents of a panel within the desktop client by clicking on the column header within the Panel.
    a. The first click on a column header will sort the data in ascending order.
    b. The second click on the same column header will sort the data in descending order.
    c. Subsequent clicks on the same column header will alternate the sort order between ascending and descending.
7. Data entry pages will exhibit the following interface behaviors:
    a. Required fields are designated by using a red "*" to the left of the field label. Additionally a "* = Required Field" text will display on the page.
    b. A message prompt will display if the user is editing or adding data and navigates away from the page. The prompt will display a message that the data were not saved and the user can cancel the navigation or proceed without saving.
    c. Users of the desktop client will be able to navigate through the fields via the TAB key on the keyboard. Default tab movement will be from starting at the top and moving left to right then top to bottom. Within the sections where the tabbing is different than the default a special requirement/consideration will state this fact.
8. The application will provide context sensitive tool tips (mouseover messages) as much as possible to aid the use and navigation of the user.

**Mobile Client User Interface Guidelines**

The following user interface guidelines should be used in implementing the mobile version of the PHR-A.

1. Mobile page size will be optimized for a resolution of 480x854 *pixels*. The application will be usable at lower resolutions, but may require horizontal and vertical scrolling.
2. The application will be targeted for multi-browser support.
3. Each page of the application will contain a page title.

**Development Best Practices**

To the extent feasible, the PHR-A will follow both the mobile website and mobile application best practices published by W3C. The current versions of these practices may be accessed with the following URLs:

1) http://www.w3.org/TR/mobile-bp/
2) http://www.w3.org/TR/mwabp/

**Special Testing Tools/Constraints**

The mobile version of the PHR-A requires a Smartphone. Smartphone technologies evolve very rapidly and vary widely between both manufactures and network carriers. The PHR-A will be designed to work on the widest range of devices possible; however it will not be possible to fully test every device on every network. Initial development testing will utilize the desktop computer based phone / mobile browser emulators typically made available to application developers by the

device manufactures. Additional information on emulators and a best practices testing approach may be found at http://mobiforge.com/testing/story/a-guide-mobile-emulators.

After initial emulator based testing is complete, the software will be formally tested using the default web browser applications on the following popular Smartphones:

- Apple iPhone (AT&T 3G network/Apple OS)
- Blackberry Storm2 (Verizon 3G network/Blackberry OS)
- Motorola Droid (Verizon 3G network/Google OS)
- Samsung Omnia (Verizon 3G network/Windows OS)

## C. System Functional Requirements

### General

The PHR-A will consist of three modalities for viewing content and using the application functionality. These are the PHR-A website, iGoogle, and a mobile Smartphone. The PHR-A website will be viewable in a Smartphone browser, but will not be optimized for the screen size and resolution, only specific content will be optimized. Certain functions may be limited to specific modalities and this will be noted in each section's requirements.

### PHR-A Website

The PHR-A website is the user's introduction to the PHR-A and will serve as a general marketing and informational website. It will allow the user to create an account and access the system functionality. Certain functionality will only be available within the PHR-A website.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| PHRA_Website1 | General Application and Module Information | The system shall present a publically-available website which describes the PHR-A; provides detailed information on the function and use of each module; provides links for adding selected modules to the users portal framework | 1.0 | 1.0 |
| PHRA_Website2 | Account Management | The system shall allow users to sign up for PHR-A services; manage their account and configure their personal preferences | 1.0 | 1.0 |
| PHRA_Website3 | Account Setup | The system shall present users with an initial setup process | 1.0 | 1.0 |
| PHRA_Website4 | Module Usage | The PHR-A modules must be usable within the website itself and not require the use of iGoogle or mobile phone to view and use | 1.0 | 1.0 |

### iGoogle

Individual modules can be used within iGoogle as gadgets.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| iGoogle_1 | iGoogle Framework | The iGoogle framework must be available to all users and manages the user's ability to view, execute, add, drop and arrange PHR-A modules as desired | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| iGoogle_2 | Module Usage | The PHR-A module must be usable within the iGoogle framework | 1.0 | 1.0 |

**Mobile Smartphone**

Individual modules can be viewed on a Smartphone browser.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Smartphone_1 | Module Usage | The PHR-A modules must be usable on a mobile Smartphone browser | 1.0 | 1.0 |

**PHR-A Website Requirements**

**Create Account**

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| CreateAccount_1 | Account Creation | They system must allow the user to create an account | 1.0 | 1.0 |
| CreateAccount_2 | Account Confirmation | The system must send a confirmation email to the user before the account becomes active | 1.0 | 1.0 |

**Login/Logout**

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Login_1 | Login to PHR-A | The system must allow users with current security rights to successfully access the PHR-A content | 1.0 | 1.0 |
| Login_2 | Logout of PHR-A | The system must allow users to successfully logout of the PHR-A | 1.0 | 1.0 |
| Login_3 | Timeout of PHR-A | The system must automatically logout the user after a system configurable time period has expired | 1.0 | 1.0 |

**Password Management**

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| PasswordMngmt_1 | Password Reminder | The system must be capable of sending a | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| | | new temporary password reminder to the user upon request by the user after correctly responding to a series of challenge questions | | |
| PasswordMngmt_2 | Password Change | The system must allow the user to change their password | 1.0 | 1.0 |
| PasswordMngmt_3 | Challenge Phrase | The system must allow the user to change the challenge phrase and answers | 1.0 | 1.0 |
| PasswordMngmt_4 | Temporary Password | The system shall require the user to immediately change a temporary password after successfully logging | 1.0 | 1.0 |

**Initial Setup**

Upon initial creation the user will be guided through an initial setup process by which they can set application preferences and learn about the PHR-A.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| InitialSetup_1 | Initial setup | They system must guide the user through an initial account setup | 1.0 | 1.0 |

**Account Personalization**

The user will be able to update their account information.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| AccountPersonalization_1 | Account Update | The system must allow the user to update their account information. | 1.0 | 1.0 |

**Microsoft HealthVault Account Setup**

Use of Microsoft HealthVault is not required, but the PHR-A can synchronize with Microsoft HealthVault. To do so, the user must give the PHR-A explicit permission. Additional requirements will be added to this section as the details of this process are discovered.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| HealthVault_1 | HealthVault Initialization | The PHR-A must have the ability to synchronize the user's account with their Microsoft HealthVault account according to Microsoft's published guidelines | 1.0 | 1.0 |

## D. General Module Requirements

Modules represent individual functional areas within the application. The following requirements pertain to each individual module.

### Module Presentation

Modules can be presented in a number of different modalities.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| ModuleOverview_1 | Website Presentation | Modules must be presentable within the PHR-A website | 1.0 | 1.0 |
| ModuleOverview_2 | iGoogle Gadget Presentation | Modules must be presentable within iGoogle as a Gadget | 1.0 | 1.0 |
| ModuleOverview_1 | Mobile Presentation | Modules must be presentable within the browser on a Smartphone | 1.0 | 1.0 |

### Secure Login/Logout

The following requirements address entering and exiting secured PHR-A modules. Not all modules will have a security requirement but login may still be required for accurate system usage monitoring.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Login_1 | Login to PHR-A | The system must allow users with current security rights to successfully access the PHR-content | 1.0 | 1.0 |
| Login_2 | Reset User Password | The system must allow users to reset their password after attempting to access the PHR-A with an expired password. | 1.0 | 1.0 |
| Login_3 | Logout of PHR-A | The system must allow users to successfully logout of the PHR-A | 1.0 | 1.0 |
| Login_4 | Forgot User Password | The system must allow users to request a new password if the password was forgotten. The system should provide a new temporary password via email | 1.0 | 1.0 |
| Login_5 | Password Expiration | The user's password should expire after a system configurable time frame | 1.0 | 1.0 |

### Password

Password requirements will follow DoD standard password requirements.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Password_1 | Length | The system must require a password be at least 10 characters | 1.0 | 1.0 |
| Password_2 | Number of Characters | The system must require a password contain at least 1 upper case, 1 lower case, 1 numerical, and 1 special character | 1.0 | 1.0 |
| Password_3 | Reuse of Passwords | The system must require a password must not be one of the last five (5) passwords already used | 1.0 | 1.0 |

### E. PHR-A Module Content

The PHR-A implements a cohesive set of user functions loosely modeled around the following American Association of Diabetes Educators (AADE) recommended topic areas.

**Healthy Eating Module**

The Healthy Eating Module provides users with several related tools aimed at monitoring food intake, providing feedback/advice, and helping users to anticipate the effects of certain foods ("What if I ate…" analysis). The Healthy Eating Module's focus is eating a balanced diet of the right food groups (not about calorie and/or carbohydrate intake per se). Tracking nutrition intake will utilize a diabetes food pyramid methodology whereby the user will track data based on the number of servings they eat from each category, such as starches, protein, fruits, vegetables, or high fat or sweet foods. Feedback will be based on the user's eating behavior relative to the pyramid guidelines. Feedback will include information related to diabetes and healthy eating habits.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| HealthyEating_1 | Nutrition Data Entry By Category | Allows user to enter number of servings for a nutrition category | 1.0 | 1.0 |
| HealthyEating_2 | Nutrition Time Data Entry By Category | Optionally, allows user to track the time they ate a meal/snack. | 1.0 | 1.0 |
| HealthyEating_3 | Daily Nutrition Feedback | Provides user feedback on their progress towards healthy eating for the day based on data entry and food pyramid guidelines. Feedback shall be textual and graphical | 1.0 | 1.0 |
| HealthyEating_4 | Weekly Nutrition Feedback | Provides user feedback on their progress toward healthy eating for the past seven days based on data entry and food pyramid guidelines. Feedback shall be textual and graphical | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| HealthyEating_5 | Personalized Food Pyramid | Allows user to personalize the daily required servings for each food pyramid category | 1.0 | 1.0 |
| HealthyEating_6 | Food Pyramid Reset | Allows user to reset food pyramid to recommended guidelines | 1.0 | 1.0 |
| HealthyEating_7 | Estimated Daily Nutrition Data Entry | Allows the user to quickly enter estimated future servings of food | 1.0 | 1.0 |
| HealthyEating_8 | Projected Daily Nutrition Feedback | Provides user feedback using actual and estimated food intake data verse daily goals to determine how best to meet their daily goal | 1.0 | 1.0 |
| HealthyEating_9 | Food Pyramid Information | Provide user with information about the nutritional categories. Information should include what food items belong in each category and sample serving size information for representative foods | 1.0 | 1.0 |
| HealthyEating_10 | Nutrition Information Links | Provider users with a list of additional external vetted sources (websites) of information about nutrition | 1.0 | 1.0 |

**Being Active Module**

The Being Active Module provides users with several related tools aimed at improving their understanding and ability to improve their flexibility, strength, and cardiovascular fitness. Feedback will include diabetes specific information.

Once a month, the Being Active Module will include the Diabetes Activity Challenge. This is a one-week activity that will ask the user to record their blood sugar before and after sustained physical activity. The application will have specific graphs to show the correlation between the blood sugar levels before and after the activity demonstrating how activity can improve blood sugar control.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| BeingActive_1 | Activity Data Entry By Category | Allows user to enter number of minutes or duration spent based on category (flexibility, strength, or cardio) | 1.0 | 1.0 |
| BeingActive_2 | Activity Data Entry By Identified Activity | Allows user to enter number of minutes or duration spent engaged in a specific activity | 1.0 | 1.0 |
| BeingActive_3 | Activity Time Data Entry | Optionally allows user to enter start time of activity | 1.0 | 1.0 |
| BeingActive_4 | Activity Intensity Data Entry | Optionally allows user to specific the level of intensity for an activity | 1.0 | 1.0 |
| BeingActive_5 | Estimated Calories Burned Data Entry | Optionally allow user to enter calories burned during an activity | 1.0 | 1.0 |
| BeingActive_6 | MS Health Vault Link | If a link exists with Health Vault the system must have the capability to synchronize activity data | 1.0 | 1.0 |
| BeingActive_7 | Activity Feedback Based on Time | Provides users feedback on activity level trends, progress towards personalized activity goals based on time. Feedback shall be textual and graphical | 1.0 | 1.0 |
| BeingActive_8 | Activity Feedback Based on Calories Burned | Provide users feedback on activity level trends, progress towards personalized activity goals based on calories burned. Feedback shall be textual and graphical | 1.0 | 1.0 |
| BeingActive_9 | Estimated Activity Data Entry | Allows the user to quickly enter estimated activities | 1.0 | 1.0 |
| BeingActive_10 | Personalized Daily Goal Entry | Allows the user to enter daily goals for each category. Initial suggested goals will be based on standardized recommendations for activity (i.e. 1 hour of cardio per day) | 1.0 | 1.0 |
| BeingActive_11 | Personalized Weekly Goal Entry | Allows the user to enter weekly goals for each category. Initial suggested goals will be based on standardized recommendations for activity (i.e. 3 hours of strength training per week) | 1.0 | 1.0 |
| BeingActive_12 | Activity Goal Reset | Allows the user to reset their goals based on standards | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| BeingActive_13 | Projected Daily Activity Feedback | Provides user feedback using actual and estimated activity data verse daily goals to determine how best to meet their daily goal | 1.0 | 1.0 |
| BeingActive_14 | Projected Weekly Activity Feedback | Provides user feedback using actual and estimated activity data verse weekly goals to determine how best to meet their weekly goals | 1.0 | 1.0 |
| BeingActive_15 | Activity Information | Provide user with information about the categories of activity. Information should include what activities belong in each category | 1.0 | 1.0 |
| BeingActive_16 | Activity Information Links | Provider users with a list of additional external vetted sources (websites) of information about activity | 1.0 | 1.0 |
| BeingActive_17 | Diabetes Activity Challenge Notification | Notify user of Diabetes Activity Challenge | 1.0 | 1.0 |
| BeingActive_18 | Diabetes Challenge Feedback | Provide user specific feedback related to the Challenge include data (textual/graphical) based on blood glucose levels before and after an activity | 1.0 | 1.0 |

**Taking Medications Module**

The Taking Medications Module provides users with a detailed medication reminder / compliance tracker and, if applicable, a meal-time insulin dosage calculator and a supplemental bolus insulin estimator.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| Medications_1 | Scheduled Medication Reminder | Based on a user configured medication schedule the system shall generate a reminder for each medication dose. Based on delivery mechanism, the content of the reminder will differ | 1.0 | 1.0 |
| Medications_2 | Email Medication Reminder | The reminder shall include the time the drug is supposed to be taken, name of the medication, the dosage, an image of the medication; dosage; link to externally maintained medication reference materials; a link to a web page allowing the user to indicate if/when the dosage was actually | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| | | taken, to close reminder and not track compliance, or to remind again in X minutes | | |
| Medications_3 | Text Message Reminder | The reminder shall include the name of the drug, the dosage, and the time the drug should be taken | 1.0 | 1.0 |
| Medciations_4 | Gadget or Website Reminder | The reminder shall include the time the drug is supposed to be taken, name of the medication, the dosage, an image of the medication; dosage; link to externally maintained medication reference materials; a link to a web page allowing the user to indicate if/when the dosage was actually taken, to close reminder and not track compliance, or to remind again in X minutes | 1.0 | 1.0 |
| Medications_5 | Medication Regimen Setup | The system shall provide the user with a method for inputting and managing their medication regimen including medication name, dosage, and schedule. Medicine selection shall include a method for users to visually confirm that the automatically selected image matches the actual medication on hand | 1.0 | 1.0 |
| Medications_6 | Medication Reminder Preferences | The system shall provide users the ability to manage all preferences related to Medication Reminders such as reminder timing (ex. 10 minutes before scheduled time); reminder blackout periods (ex. 11pm – 5am); reminder automatic closing (ex. 2 days past due); delivery mechanism (ex. Web-based, text message, or email) | 1.0 | 1.0 |
| Medications_7 | Mealtime Bolus Insulin Estimator | The system shall provide users with a specific insulin units recommendation and carb to insulin ratio data based on user entered/specific carbohydrate to insulin ratio and planned carbohydrate consumption | 1.0 | 1.0 |
| Medications_8 | Supplemental Bolus Insulin Estimator | The system shall provide users with a specific insulin units recommendation and insulin sensitivity factor data based on manual entry of their current blood glucose level, total daily insulin requirement, ideal blood glucose, and selected rule (1500 or 1800) | 1.0 | 1.0 |

Reducing Risks focuses on standards of care including appropriate lab testing and examinations.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| ReducingRisk_1 | Microsoft Health Vault | The system shall synchronize A1c and cholesterol lab data and appointment information with Health Vault | 1.0 | 1.0 |
| ReducingRisk_2 | Lab Data Entry | The system shall allow the user to enter A1c and cholesterol lab data including lab test date and value | 1.0 | 1.0 |
| ReducingRisk_3 | Exam Data Entry | The system shall allow the user to past examination data for primary care, podiatry, and eye exams including data and type of exam | 1.0 | 1.0 |
| ReducingRisk_4 | Appointment Data Entry | The system shall allow the user to enter future appointment data including type of appointment (dr. visit or lab test), date/time, location, who with, and contact information | 1.0 | 1.0 |
| ReducingRisk_5 | Appointment Maintenance | The system shall allow the user to modify the appointment information. They shall be allowed to mark it kept | 1.0 | 1.0 |
| ReducingRisk_6 | Appointment Reminder Configuration | The system shall allow the user to configure how they are reminded of appointments. Options include text message, email, or website usage | 1.0 | 1.0 |
| ReducingRisk_7 | Appointment Reminder Action | The system shall allow the user to close a reminder, mark the appointment as kept, or remind again in X time | 1.0 | 1.0 |
| ReducingRisk_8 | Appointment Reminder Delivery | The system shall send appointment reminders based on the user's preference | 1.0 | 1.0 |
| ReducingRisk_9 | Lab Testing Reminder | The system shall reminder the patient about the need to get lab tests based on data enter and standard lab testing schedules | 1.0 | 1.0 |
| ReducingRisk_10 | Lab Testing Reminder Email Message | The lab test reminder will contain information about which lab test is required, when the last one was performed, and information about why it is important | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| ReducingRisk_11 | Lab Testing Reminder Text Message | The lab test reminder will state the lab test that is required and date of last lab test | 1.0 | 1.0 |
| ReducingRisk_12 | Appointment Reminder Text Message | The system shall send the user a text message reminder about their next appointment including the appointment date/time and who it is with | 1.0 | 1.0 |
| ReducingRisk_13 | Appointment Reminder Email Message | The system shall send the user an email reminder about their next appointment including the appointment date/time, type, who it is with, contact information, and a link to a take an action on the appointment | 1.0 | 1.0 |
| Reducingisk_14 | Gadget or Website Reminder | The system shall provide functionality to reminder the user of appointments and lab tests | 1.0 | 1.0 |

**Monitoring – Blood Sugar**

Monitoring focuses on improving a patient's well-being through proper blood sugar monitoring.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| MonitoringBG_1 | Microsoft HealthVault | The system shall synchronize blood sugar data with Microsoft HealthVault | 1.0 | 1.0 |
| MonitoringBG_2 | Blood Sugar Data Entry | The system must allow the user to enter blood sugar information including date/time of reading and result. | 1.0 | 1.0 |
| MonitoringBG_3 | Blood Sugar Time Period Maintenance | The system must allow the user to specify what times each time period (before/after breakfast, etc) falls into. | 1.0 | 1.0 |
| MonitoringBG_4 | Blood Sugar Range Maintenance | The system must allow the user to specify high/low values according to time periods for blood sugar readings. | 1.0 | 1.0 |
| MonitoringBG_5 | Blood Sugar Log Book | The system must display blood sugar information in a standard log book format broken down by time period including total readings per time period/day and average values per time period/day. The data should be colored and use different shapes according to high/low specifications. Normal values should be black circles, low values blue diamonds, and high values red | 1.0 | 1.0 |

| | | | | |
|---|---|---|---|---|
| | | blocks. | | |
| MonitoringBG_6 | Blood Sugar Trending Graph | The system must display a blood sugar trending graph for a specified number of days. | 1.0 | 1.0 |
| MonitoringBG_7 | Blood Sugar Log Book and Graph Time Range Selection | The system must default to the last seven days when displaying the log book or graphs. The system must allow the user to specify a custom date range or quickly select last seven days, last week, last two week, last month or last three months. | 1.0 | 1.0 |
| MonitoringBG_8 | Blood Sugar Graph Options | The system must optionally allow the user to display additional information on the graphs including medication taken information, mood data, activity data, and nutrition information | 1.0 | 1.0 |

**Monitoring -- Weight**

Monitoring also focuses on improving a patient's well-being through proper weight management. The PHR-A's approach to weight management emphases a balanced approach incorporating concepts of health eating and being active.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| MonitoringWeight_1 | Microsoft HealthVault | The system shall synchronize weight data with Microsoft HealthVault | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Data Entry | The system must allow the user to enter weight information including date/time of reading and the weight in pounds | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Trending Graph | The system must display a weight trending graph for a specified number of days | 1.0 | 1.0 |
| MonitoringWeight_1 | Weight Graph Time Range Selection | The system must default to the last seven days when displaying graph. The system must allow the user to specify a custom date range or quickly select last seven days, last week, last two week, last month or last three months | 1.0 | 1.0 |

**Outlook**

The Outlook Module administers pre-configured surveys on a monthly basis with feedback to the user on both.

| | | | | |
|---|---|---|---|---|
| Coping_1 | Questionnaire Presentation | The system shall present users with brief questionnaires based on a pre-determined schedule, user preferences and/or responses to daily mood updates | 1.0 | 1.0 |
| Coping_2 | Automated Feedback | The system shall automatically review questionnaire data in conjunction with other user data points to make specific suggestions for ways the user might resolve current issues or better cope with a their specific situation | 1.0 | 1.0 |

### F. Tips

The PHR-A shall provide users with the ability to subscribe to tip topic areas and types as well as their preferred time to receive tips and mode of tip delivery (e.g., within gadget, email, text message). The tips are organized around the aforementioned AADE categories.

| REQ ID | REQUIREMENT NAME | DESCRIPTION | VERS NEW | VERS UPD. |
|---|---|---|---|---|
| TipOptions_1 | User Tip Maintenance | The system must allow users to subscribe to different tip topic areas and types | 1.0 | 1.0 |
| TipOptions_2 | User Tip Opt Out | The system must allow users a mechanism to unsubscribe from future tips upon receipt of a tip. The user must be presented with options to unsubscribe from either the individual tip topic area or all future tips | 1.0 | 1.0 |
| TipOptions_3 | User Tip Schedule | The system must allow users the ability to set preferences for what time and how often the system distributes their tips | 1.0 | 1.0 |
| TipOptions_4 | User Tip Delivery Mechanism | The system must allow users the ability to set how tips are delivered. Options are email, text message, or gadget/website | 1.0 | 1.0 |

**We include the Tips as an Addendum to this report.**

### G. External Systems Interfaces

The following external system interfaces will need to be defined to interface with the Host System:

- Microsoft HealthVault

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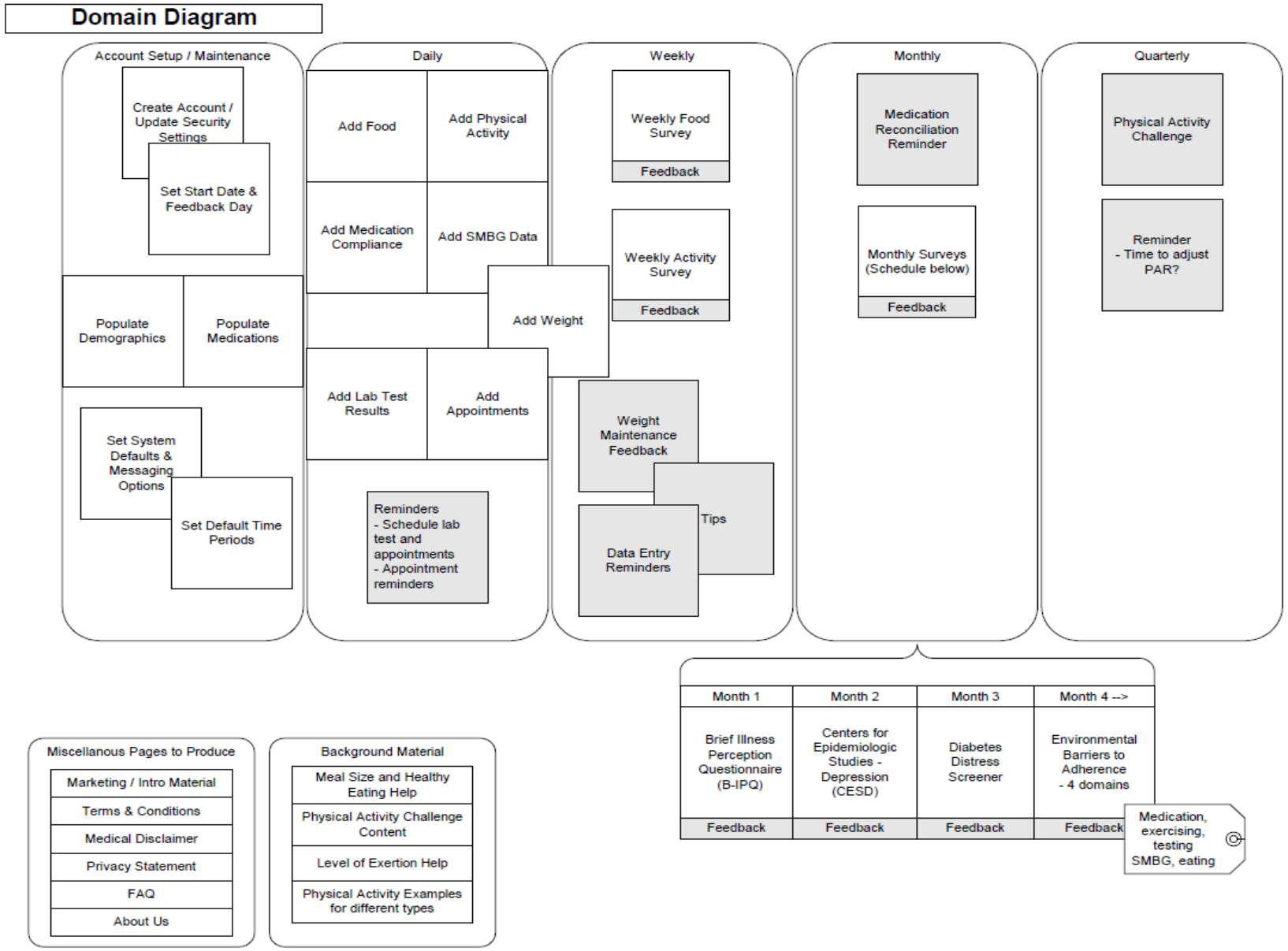
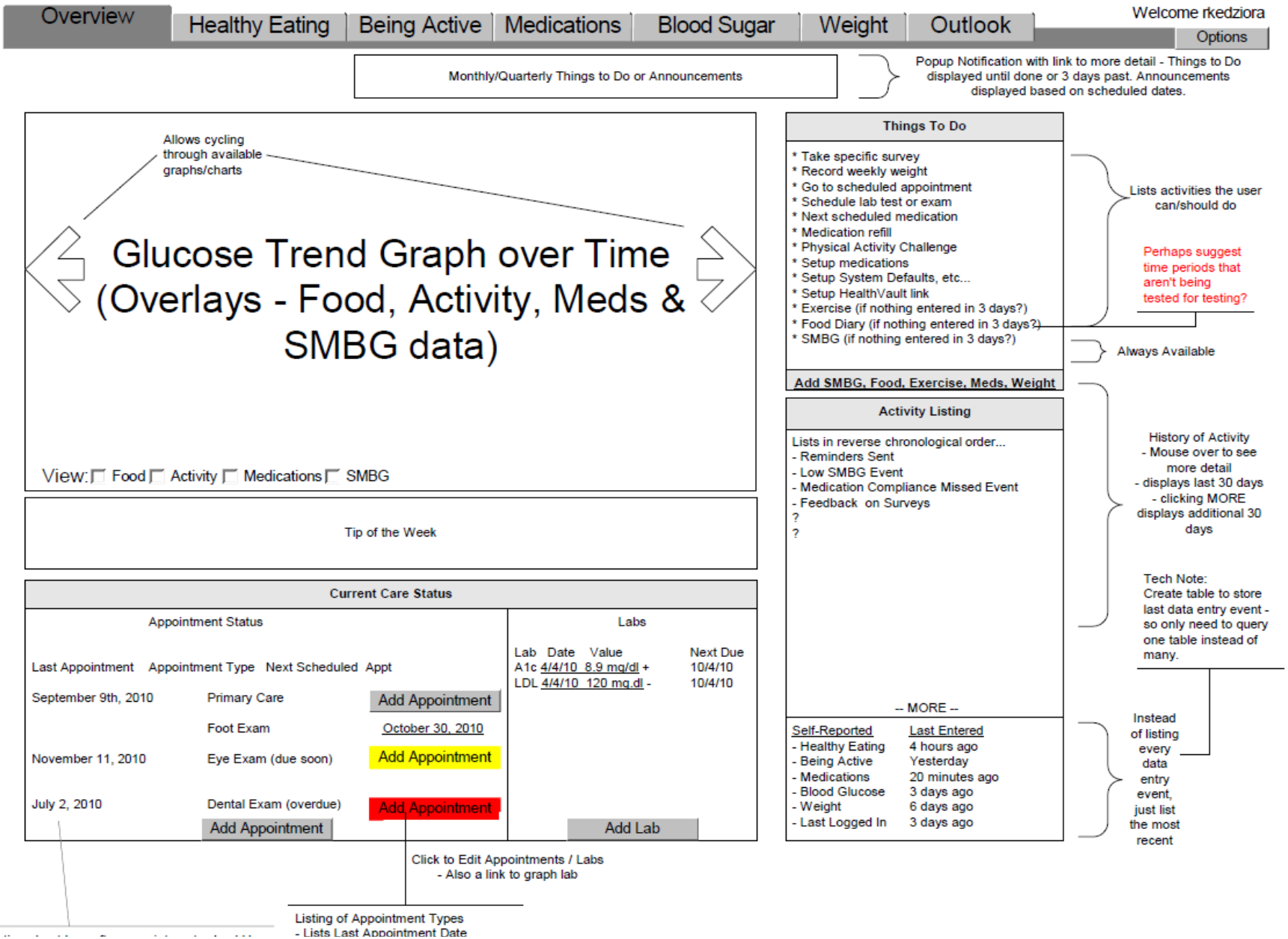
*2)* ***Finalize version 1 of the PHR-A***

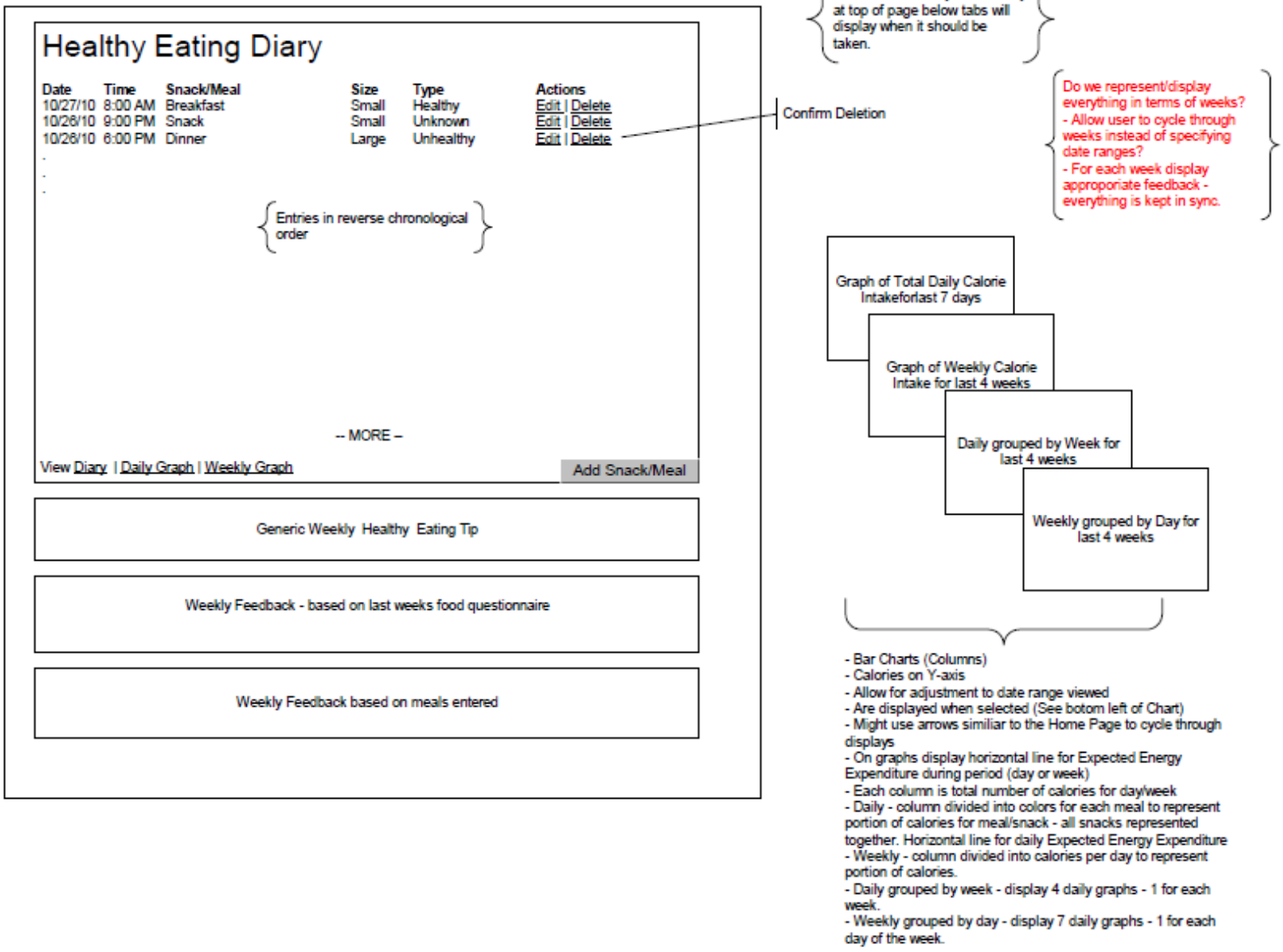
This task is ongoing. However, we are very close to a final version 1. The following insertions provide an overview of what version 1 looks like. Note that the rules and algorithms that provide the "intelligence" of the system are not shown, as they are too lengthy for this report.

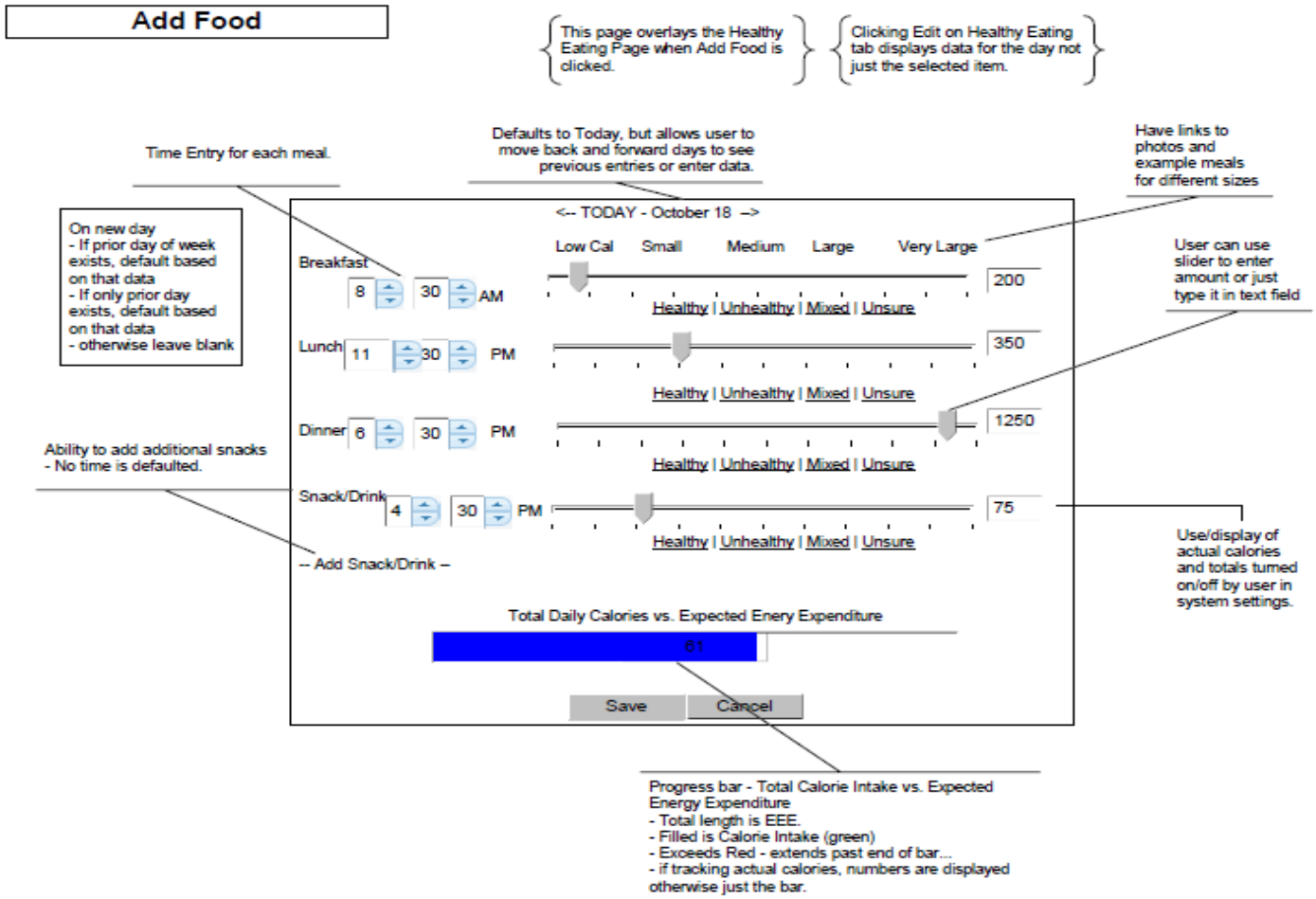
The Graphic Design of the PHR-A is to be determined by the upcoming user-centered review of the application (Task 3).


Domain Diagram
Account Setup / Maintenance
Create Account / Update Security Settings
Set Start Date & Feedback Day
Populate Demographics
Populate Medications
Set System Defaults & Messaging Options
Set Default Time Periods
Daily
Add Food
Add Physical Activity
Add Medication Compliance
Add SMBG Data
Add Weight
Add Lab Test Results
Add Appointments
Reminders
- Schedule lab test and appointments
- Appointment reminders
Weekly
Weekly Food Survey
Feedback
Weekly Activity Survey
Feedback
Weight Maintenance Feedback
Tips
Data Entry Reminders
Monthly
Medication Reconciliation Reminder
Monthly Surveys (Schedule below)
Feedback
Quarterly
Physical Activity Challenge
Reminder
- Time to adjust PAR?
Month 1
Month 2
Month 3
Month 4 -->
Brief Illness Perception Questionnaire (B-IPQ)
Centers for Epidemiologic Studies - Depression (CESD)
Diabetes Distress Screener
Environmental Barriers to Adherence
- 4 domains
Feedback
Feedback
Feedback
Feedback
Medication, exercising, testing SMBG, eating
Miscellanous Pages to Produce
Marketing / Intro Material
Terms & Conditions
Medical Disclaimer
Privacy Statement
FAQ
About Us
Background Material
Meal Size and Healthy Eating Help
Physical Activity Challenge Content
Level of Exertion Help
Physical Activity Examples for different types

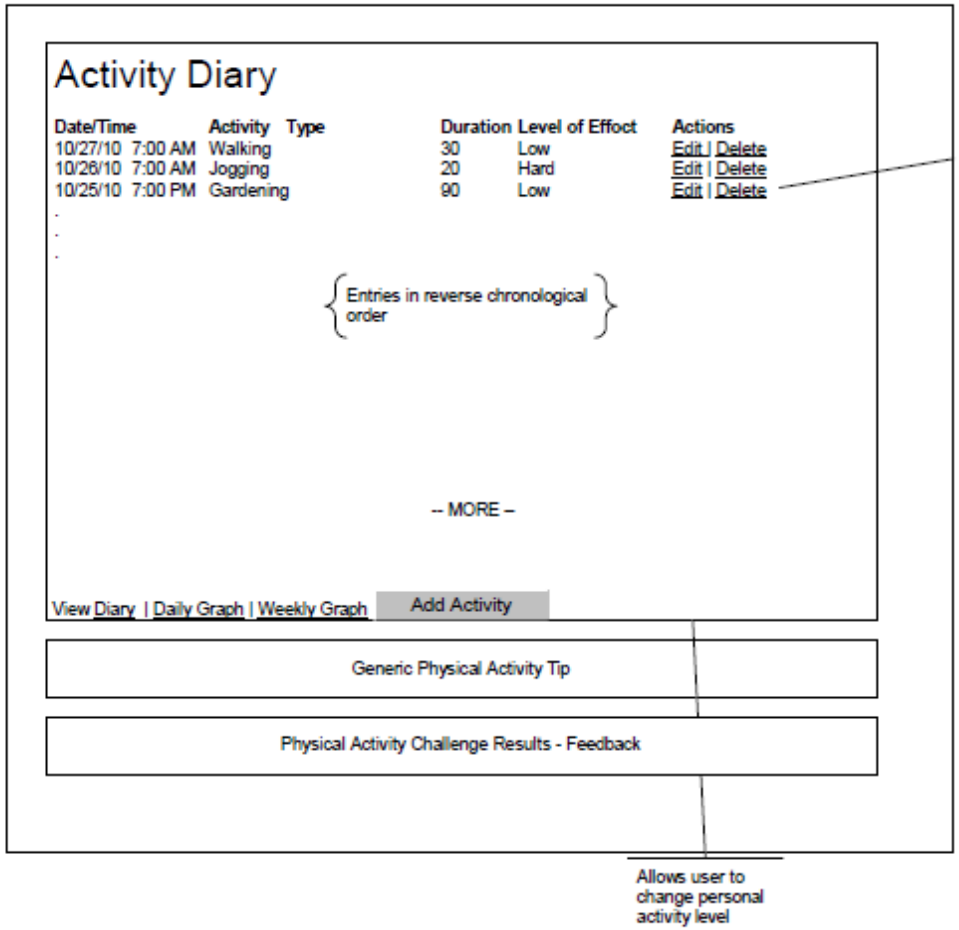

Overview
Healthy Eating
Being Active
Medications
Blood Sugar
Weight
Outlook
Welcome rkedziora
Options
Monthly/Quarterly Things to Do or Announcements
Popup Notification with link to more detail - Things to Do displayed until done or 3 days past. Announcements displayed based on scheduled dates.
Allows cycling through available graphs/charts
Glucose Trend Graph over Time (Overlays - Food, Activity, Meds & SMBG data)
View: Food Activity Medications SMBG
Tip of the Week
Current Care Status
Appointment Status
Last Appointment
Appointment Type
Next Scheduled Appt
September 9th, 2010
Primary Care
Add Appointment
Foot Exam
October 30, 2010
November 11, 2010
Eye Exam (due soon)
Add Appointment
July 2, 2010
Dental Exam (overdue)
Add Appointment
Add Appointment
Labs
Lab Date Value Next Due
A1c 4/4/10 8.9 mg/dl + 10/4/10
LDL 4/4/10 120 mg.dl - 10/4/10
Add Lab
Click to Edit Appointments / Labs
- Also a link to graph lab
Listing of Appointment Types
- Lists Last Appointment Date
Things To Do
* Take specific survey
* Record weekly weight
* Go to scheduled appointment
* Schedule lab test or exam
* Next scheduled medication
* Medication refill
* Physical Activity Challenge
* Setup medications
* Setup System Defaults, etc...
* Setup HealthVault link
* Exercise (if nothing entered in 3 days?)
* Food Diary (if nothing entered in 3 days?)
* SMBG (if nothing entered in 3 days?)
Lists activities the user can/should do
Perhaps suggest time periods that aren't being tested for testing?
Always Available
Add SMBG, Food, Exercise, Meds, Weight
Activity Listing
Lists in reverse chronological order...
- Reminders Sent
- Low SMBG Event
- Medication Compliance Missed Event
- Feedback on Surveys
?
?
-- MORE --
History of Activity
- Mouse over to see more detail
- displays last 30 days
- clicking MORE displays additional 30 days
Tech Note:
Create table to store last data entry event - so only need to query one table instead of many.
Self-Reported Last Entered
- Healthy Eating 4 hours ago
- Being Active Yesterday
- Medications 20 minutes ago
- Blood Glucose 3 days ago
- Weight 6 days ago
- Last Logged In 3 days ago
Instead of listing every data entry event, just list the most recent

## Healthy Eating Tab




Add Food
This page overlays the Healthy Eating Page when Add Food is clicked.
Clicking Edit on Healthy Eating tab displays data for the day not just the selected item.
Time Entry for each meal.
Defaults to Today, but allows user to move back and forward days to see previous entries or enter data.
Have links to photos and example meals for different sizes
On new day
- If prior day of week exists, default based on that data
- If only prior day exists, default based on that data
- otherwise leave blank
<-- TODAY - October 18 -->
Low Cal
Small
Medium
Large
Very Large
Breakfast
8
30
AM
200
Healthy | Unhealthy | Mixed | Unsure
Lunch
11
30
PM
350
Healthy | Unhealthy | Mixed | Unsure
User can use slider to enter amount or just type it in text field
Dinner
6
30
PM
1250
Healthy | Unhealthy | Mixed | Unsure
Ability to add additional snacks
- No time is defaulted.
Snack/Drink
4
30
PM
75
Healthy | Unhealthy | Mixed | Unsure
-- Add Snack/Drink --
Use/display of actual calories and totals turned on/off by user in system settings.
Total Daily Calories vs. Expected Enery Expenditure
81
Save
Cancel
Progress bar - Total Calorie Intake vs. Expected Energy Expenditure
- Total length is EEE.
- Filled is Calorie Intake (green)
- Exceeds Red - extends past end of bar...
- if tracking actual calories, numbers are displayed otherwise just the bar.

## Being Active Tab




A link to the weekly activity survey will appear when it should be taken.

Confirm Deletion

Do we set goal or allow user to set goals for minutes of activity? and track against that?

Graph of Daily Activity for last 7 days

X-axis is days

Graph of Weekly Activity for last 4 weeks

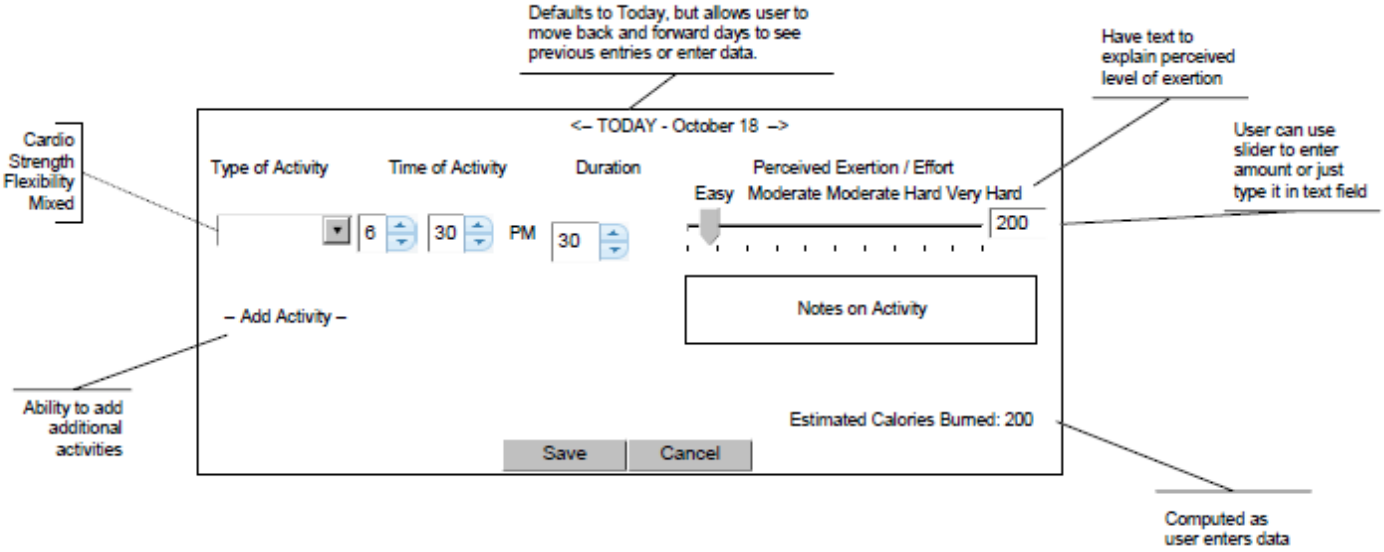
X-axis is week

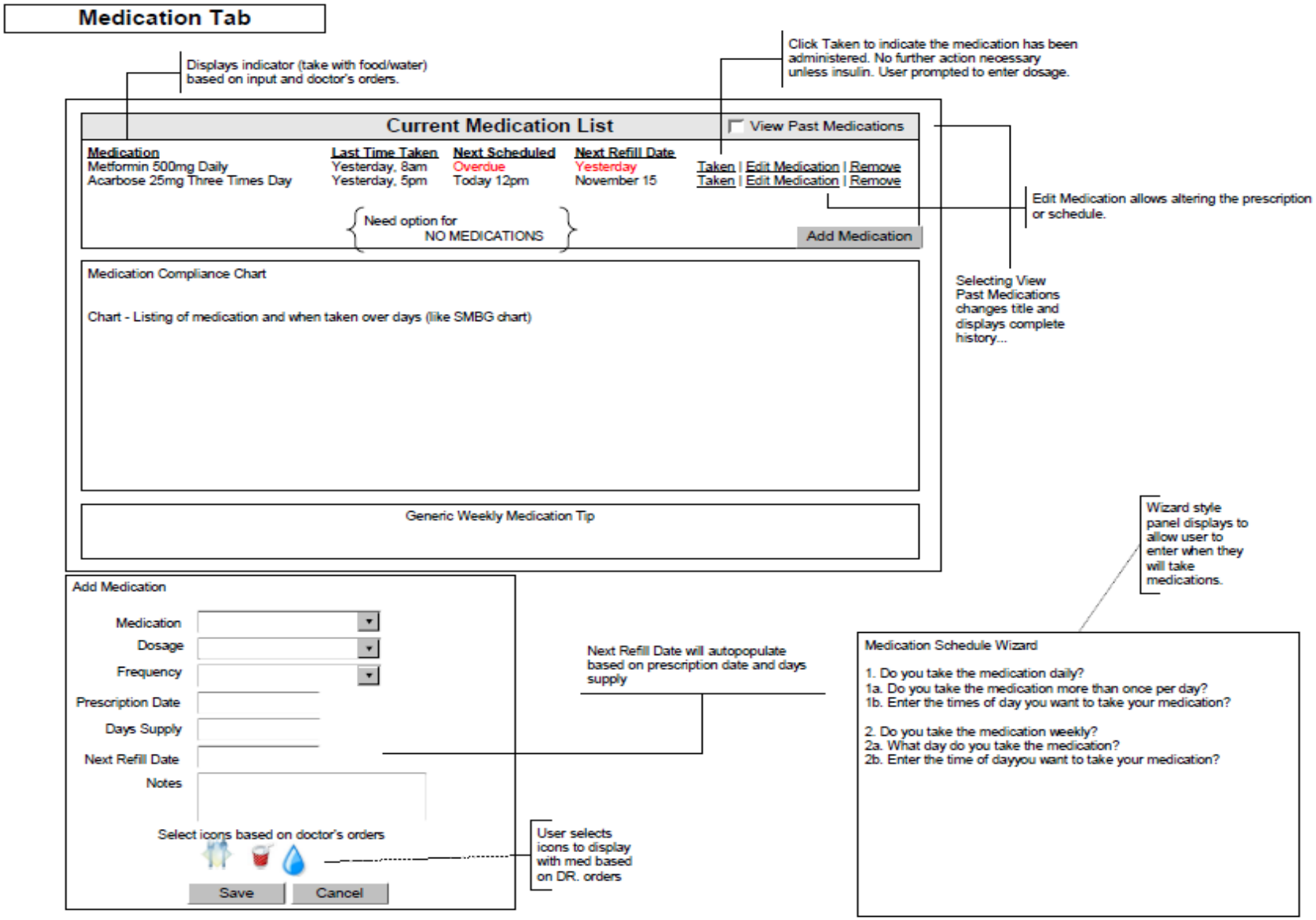
For Both Graphs
- Bar Charts
- Duration on Y-axis
- Allow for adjustment to date range viewed
- Are displayed when selected (See botom left of Chart)
- Might use arrows similiar to the Home Page to cycle through displays
- Portion column into types of exercise (cardio, strength, flexibility) - how to handle mixed another segment?

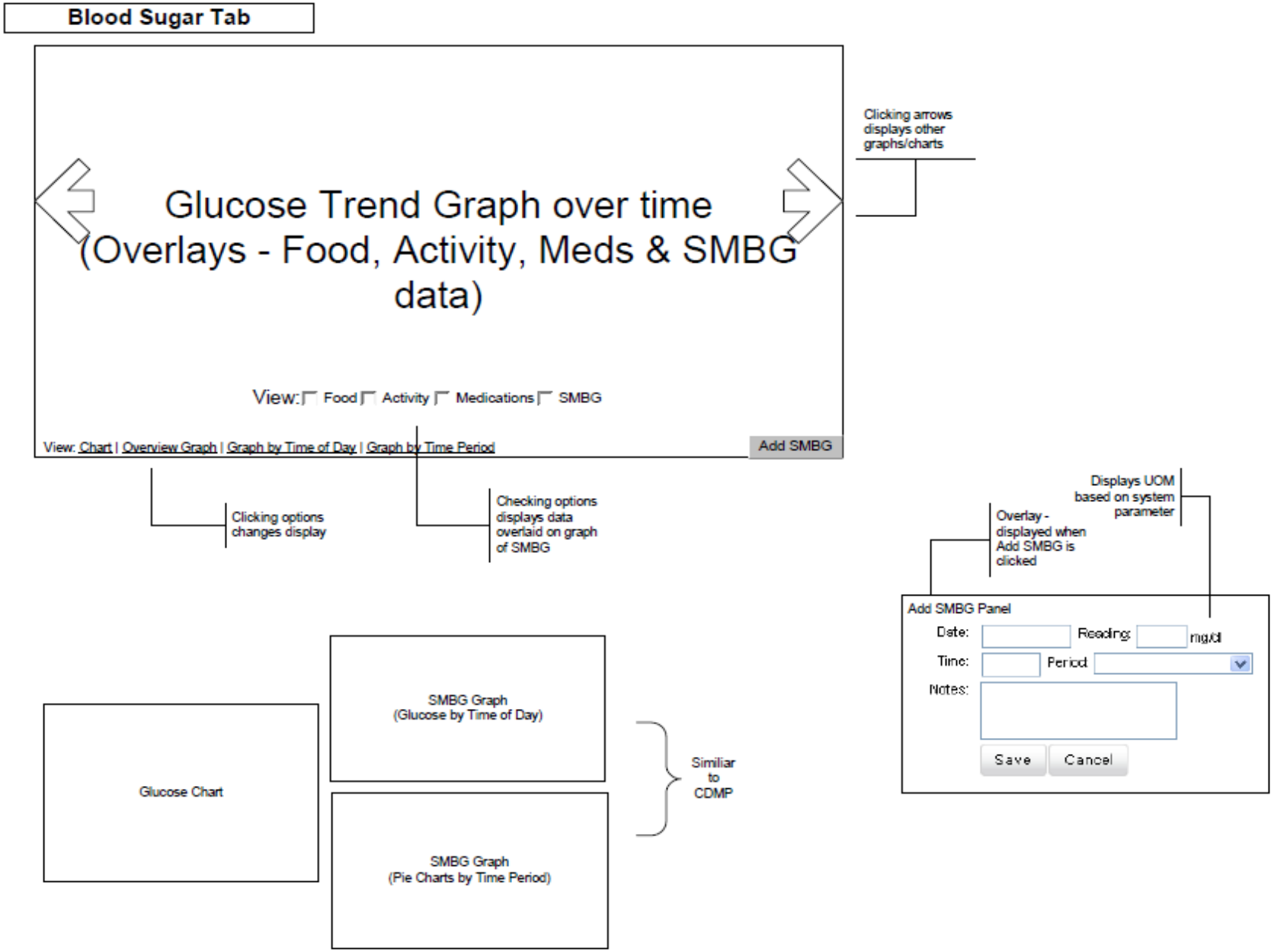
)

## Add Activity

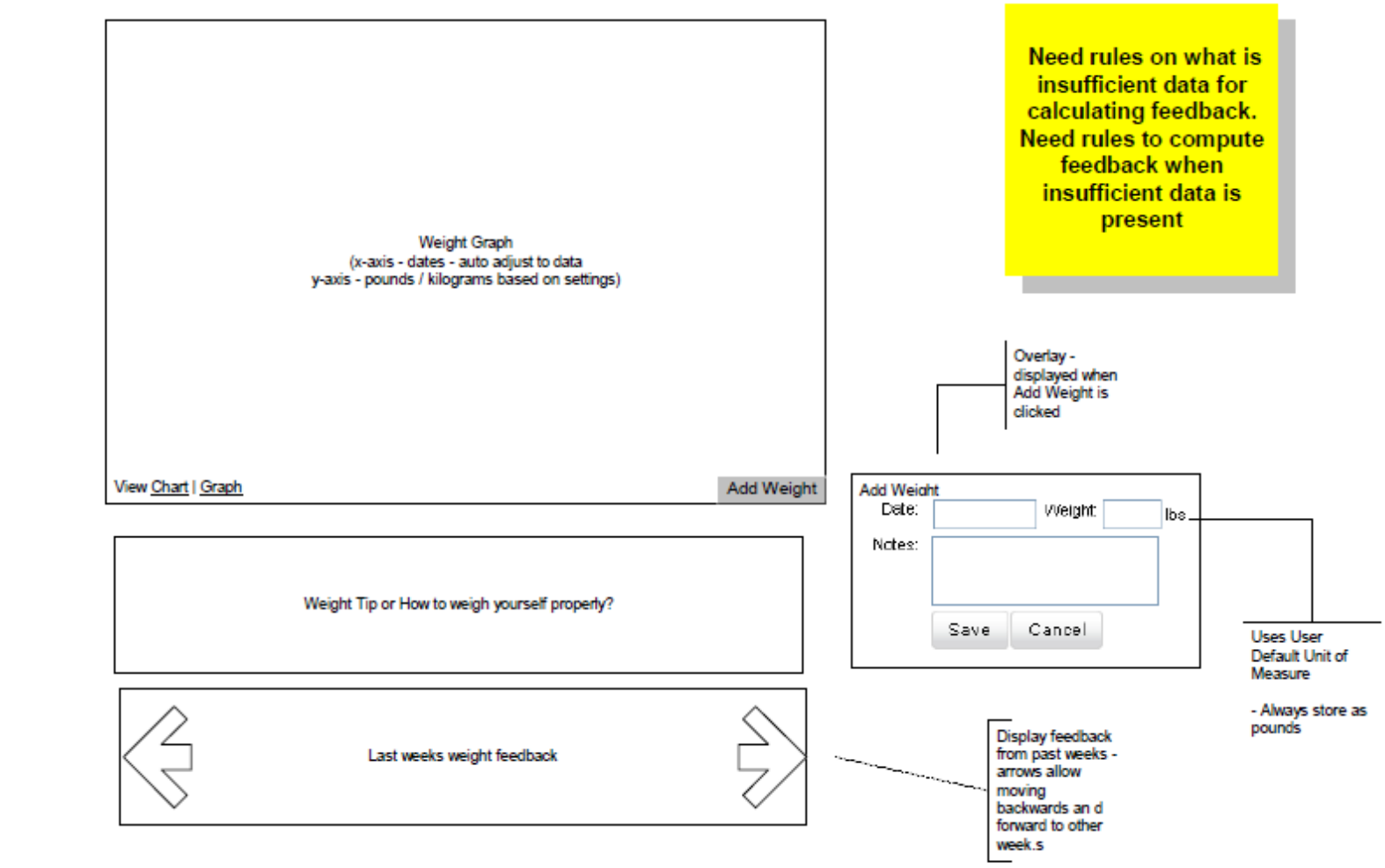
This page overlays the Being Active Page when Add Activity is clicked.



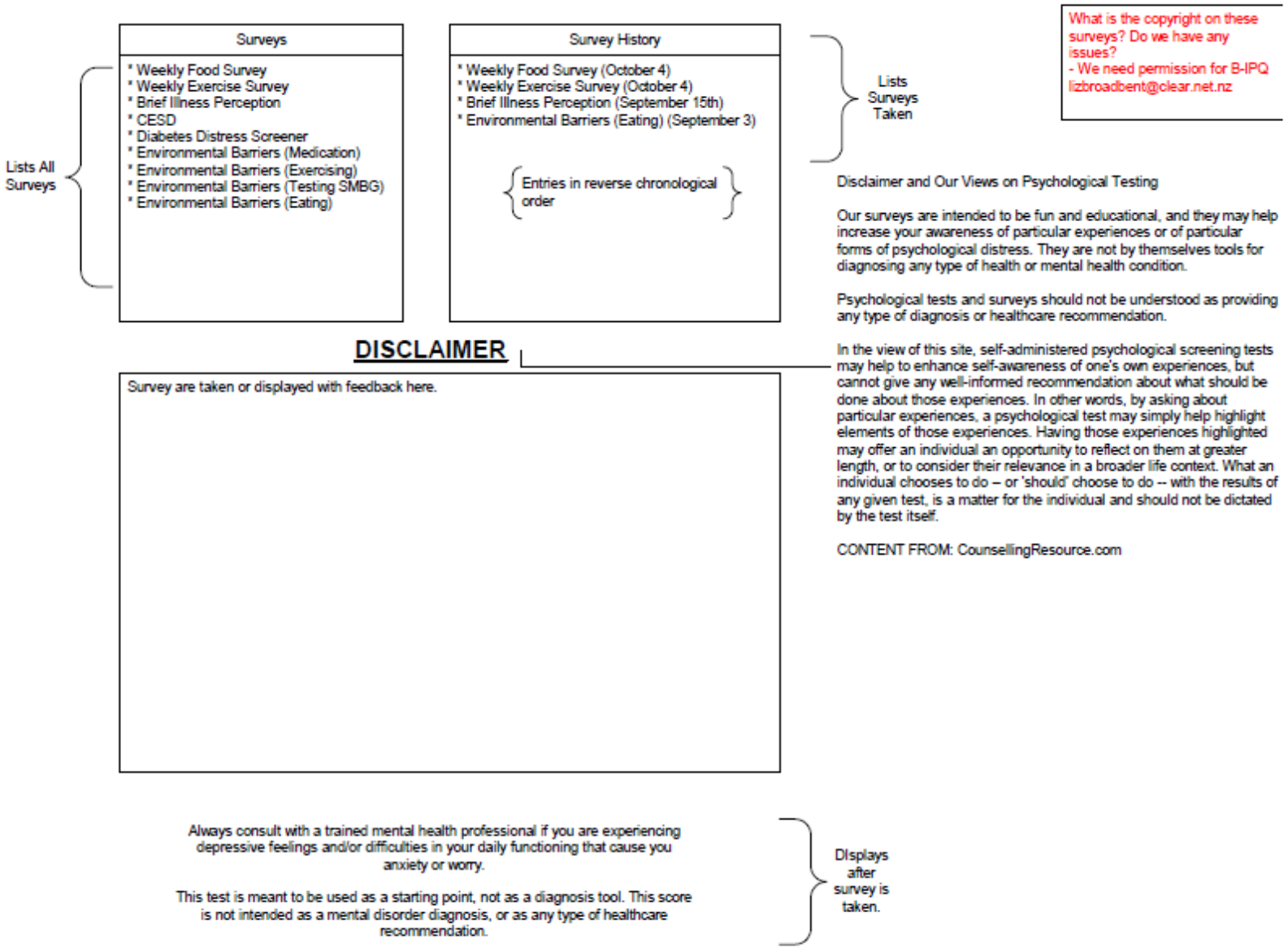

Medication Tab
Displays indicator (take with food/water) based on input and doctor's orders.
Click Taken to indicate the medication has been administered. No further action necessary unless insulin. User prompted to enter dosage.
Current Medication List
View Past Medications
Medication
Last Time Taken
Next Scheduled
Next Refill Date
Metformin 500mg Daily
Yesterday, 8am
Overdue
Yesterday
Taken | Edit Medication | Remove
Acarbose 25mg Three Times Day
Yesterday, 5pm
Today 12pm
November 15
Taken | Edit Medication | Remove
Need option for NO MEDICATIONS
Add Medication
Edit Medication allows altering the prescription or schedule.
Medication Compliance Chart
Chart - Listing of medication and when taken over days (like SMBG chart)
Selecting View Past Medications changes title and displays complete history...
Generic Weekly Medication Tip
Wizard style panel displays to allow user to enter when they will take medications.
Add Medication
Medication
Dosage
Frequency
Prescription Date
Days Supply
Next Refill Date
Notes
Next Refill Date will autopopulate based on prescription date and days supply
Medication Schedule Wizard
1. Do you take the medication daily?
1a. Do you take the medication more than once per day?
1b. Enter the times of day you want to take your medication?
2. Do you take the medication weekly?
2a. What day do you take the medication?
2b. Enter the time of dayyou want to take your medication?
Select icons based on doctor's orders
User selects icons to display with med based on DR. orders
Save
Cancel


Blood Sugar Tab
Glucose Trend Graph over time (Overlays - Food, Activity, Meds & SMBG data)
Clicking arrows displays other graphs/charts
View: Food Activity Medications SMBG
View: Chart | Overview Graph | Graph by Time of Day | Graph by Time Period
Add SMBG
Clicking options changes display
Checking options displays data overlaid on graph of SMBG
Displays UOM based on system parameter
Overlay - displayed when Add SMBG is clicked
Add SMBG Panel
Date:
Reading:
mg/dl
Time:
Period
Notes:
Save
Cancel
Glucose Chart
SMBG Graph (Glucose by Time of Day)
SMBG Graph (Pie Charts by Time Period)
Similiar to CDMP

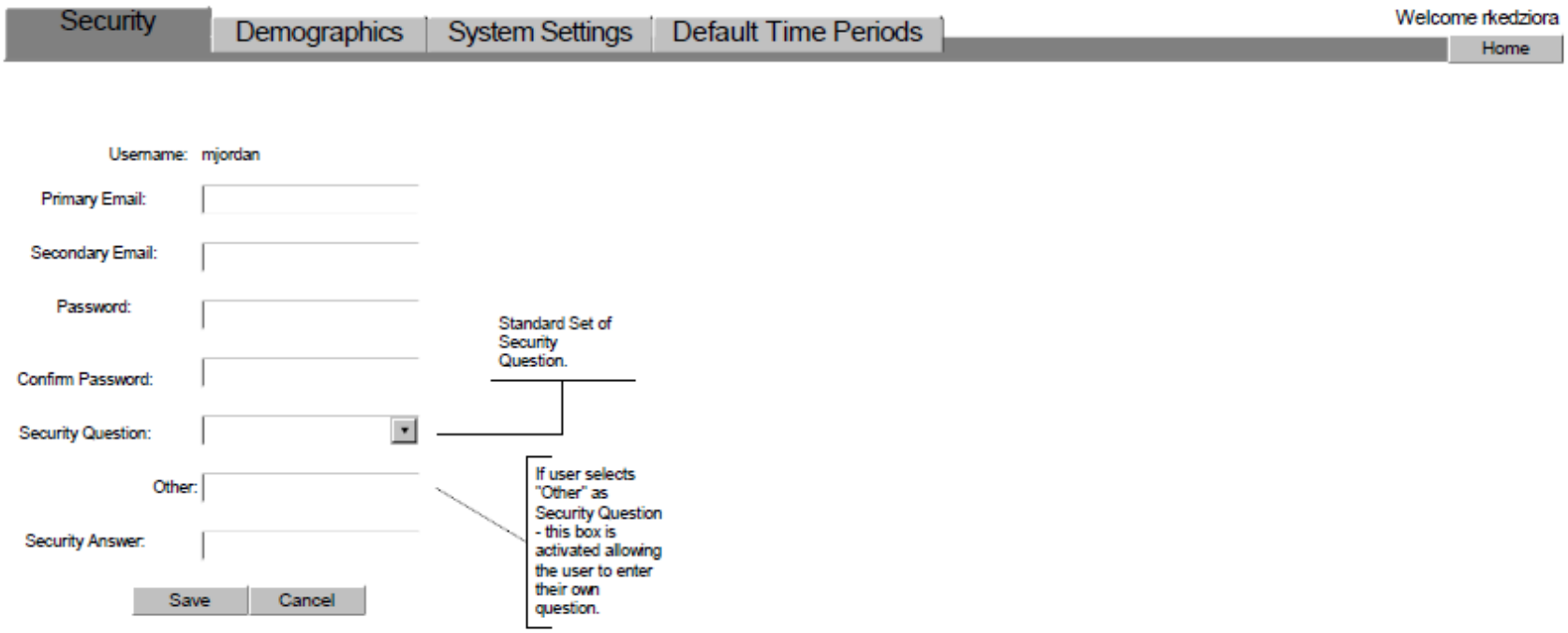
## Weight Tab


Weight Graph
(x-axis - dates - auto adjust to data
y-axis - pounds / kilograms based on settings)
View Chart | Graph
Add Weight
Weight Tip or How to weigh yourself properly?
Last weeks weight feedback
Need rules on what is insufficient data for calculating feedback. Need rules to compute feedback when insufficient data is present
Overlay - displayed when Add Weight is clicked
Add Weight
Date:
Weight:
lbs
Notes:
Save
Cancel
Uses User Default Unit of Measure
- Always store as pounds
Display feedback from past weeks - arrows allow moving backwards an d forward to other week.s

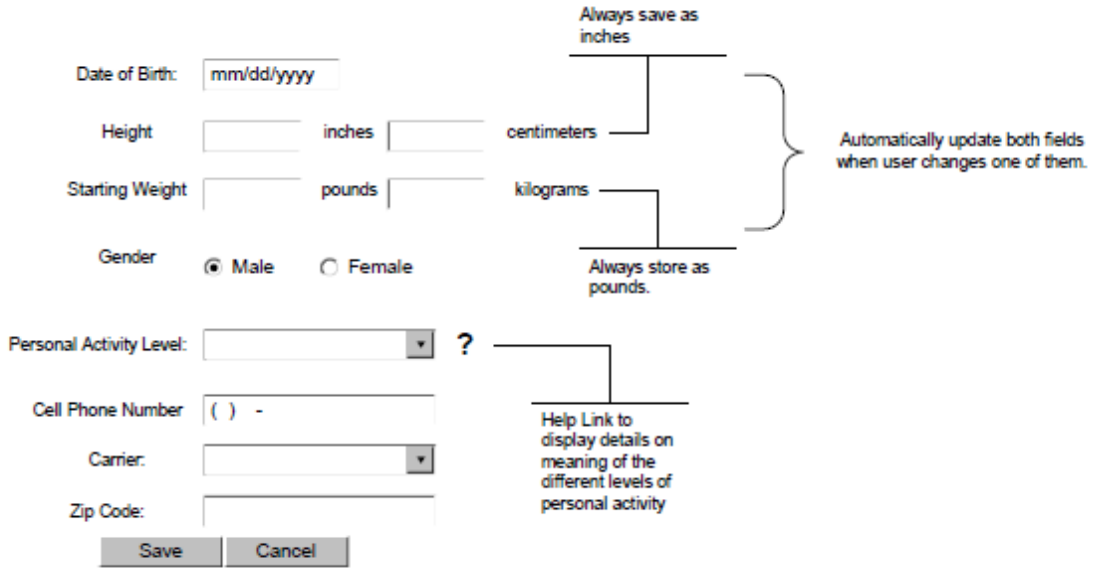
## Outlook Tab


Surveys
* Weekly Food Survey
* Weekly Exercise Survey
* Brief Illness Perception
* CESD
* Diabetes Distress Screener
* Environmental Barriers (Medication)
* Environmental Barriers (Exercising)
* Environmental Barriers (Testing SMBG)
* Environmental Barriers (Eating)
Lists All Surveys
Survey History
* Weekly Food Survey (October 4)
* Weekly Exercise Survey (October 4)
* Brief Illness Perception (September 15th)
* Environmental Barriers (Eating) (September 3)
Entries in reverse chronological order
Lists Surveys Taken
What is the copyright on these surveys? Do we have any issues?
- We need permission for B-IPQ
lizbroadbent@clear.net.nz
DISCLAIMER
Survey are taken or displayed with feedback here.
Disclaimer and Our Views on Psychological Testing
Our surveys are intended to be fun and educational, and they may help increase your awareness of particular experiences or of particular forms of psychological distress. They are not by themselves tools for diagnosing any type of health or mental health condition.
Psychological tests and surveys should not be understood as providing any type of diagnosis or healthcare recommendation.
In the view of this site, self-administered psychological screening tests may help to enhance self-awareness of one's own experiences, but cannot give any well-informed recommendation about what should be done about those experiences. In other words, by asking about particular experiences, a psychological test may simply help highlight elements of those experiences. Having those experiences highlighted may offer an individual an opportunity to reflect on them at greater length, or to consider their relevance in a broader life context. What an individual chooses to do – or 'should' choose to do -- with the results of any given test, is a matter for the individual and should not be dictated by the test itself.
CONTENT FROM: CounsellingResource.com
Always consult with a trained mental health professional if you are experiencing depressive feelings and/or difficulties in your daily functioning that cause you anxiety or worry.
This test is meant to be used as a starting point, not as a diagnosis tool. This score is not intended as a mental disorder diagnosis, or as any type of healthcare recommendation.
Displays after survey is taken.

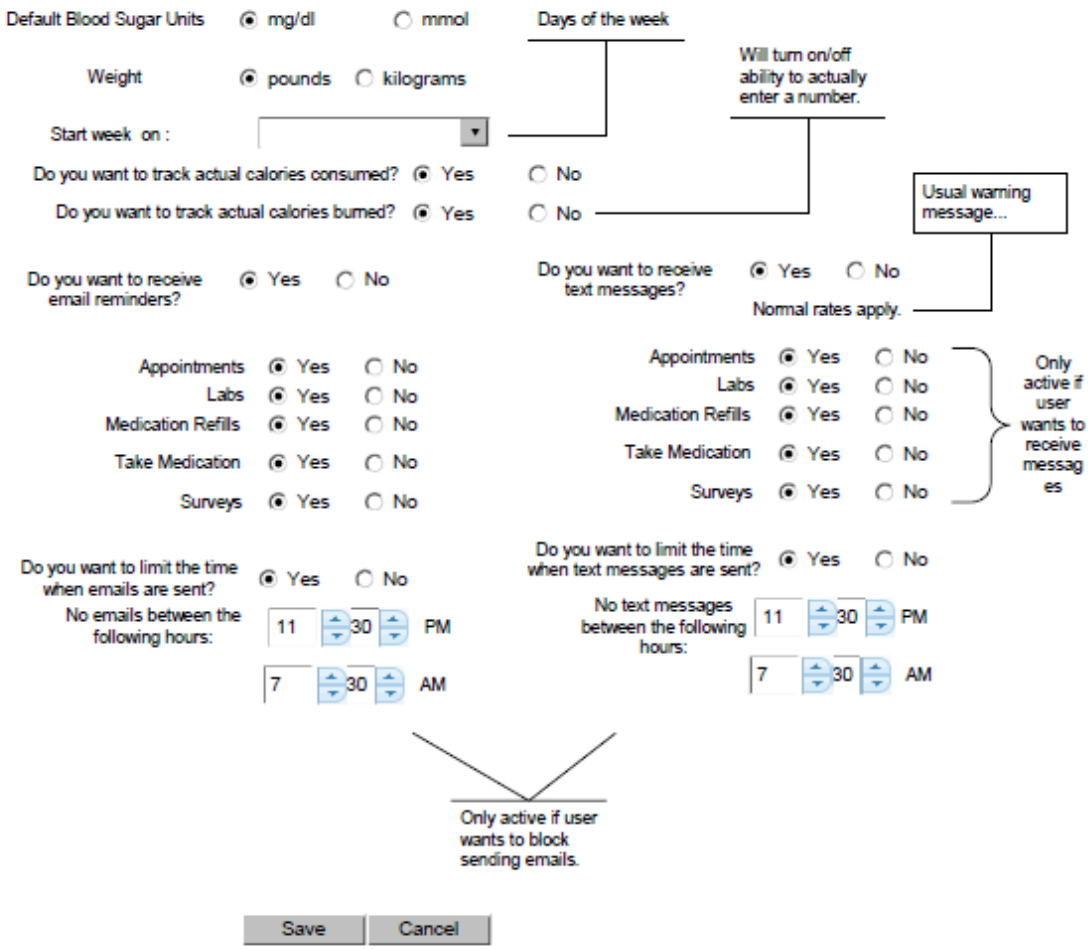
## User Setup / Configuration - Security Tab



## User Setup / Configuration - Demographics Tab



## User Setup / Configuration - System Settings

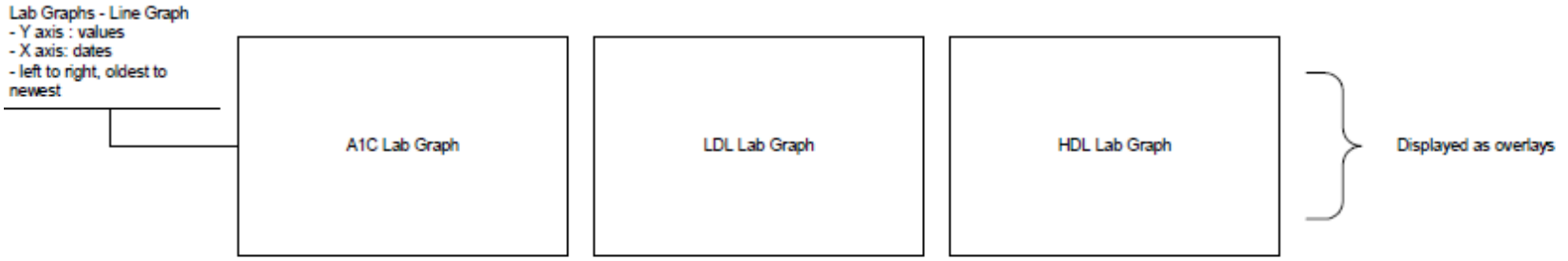


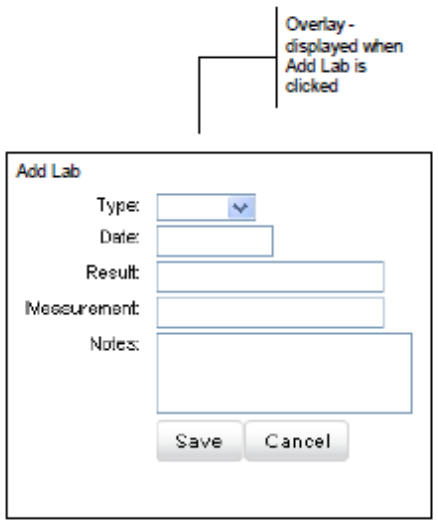
**User Setup / Configuration - Default Time Periods**

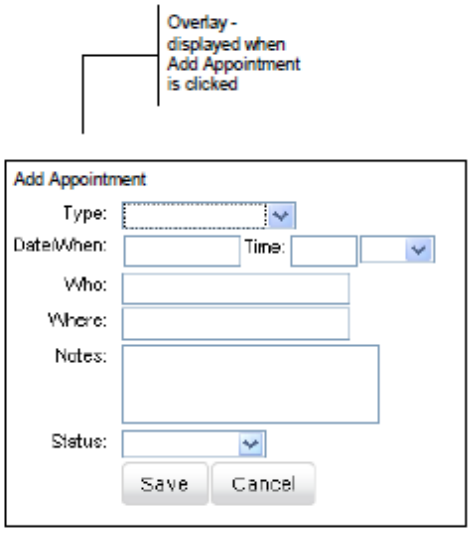
| Time Period | From Time | Until Time | Glucose Lower Limit | Glucose Upper Limit |
|---|---|---|---|---|
| AllDay | | | 80 | 120 |
| Before Breakfast | 7 : 00 AM | 09 : 00 AM | 80 | 120 |
| After Breakfast | 9 : 00 AM | 11 : 30 AM | 80 | 120 |
| Before Lunch | 11 : 30 AM | 12 : 30 PM | 80 | 120 |
| After Lunch | 12 : 30 PM | 03 : 00 PM | 80 | 120 |
| Before Dinner | 3 : 00 PM | 06 : 00 PM | 80 | 120 |
| After Dinner | 6 : 00 PM | 09 : 00 PM | 80 | 120 |
| Bed Time | 9 : 00 PM | 11 : 00 PM | 80 | 120 |
| Night | 11 : 00 PM | 07 : 00 AM | 80 | 120 |

Save Cancel

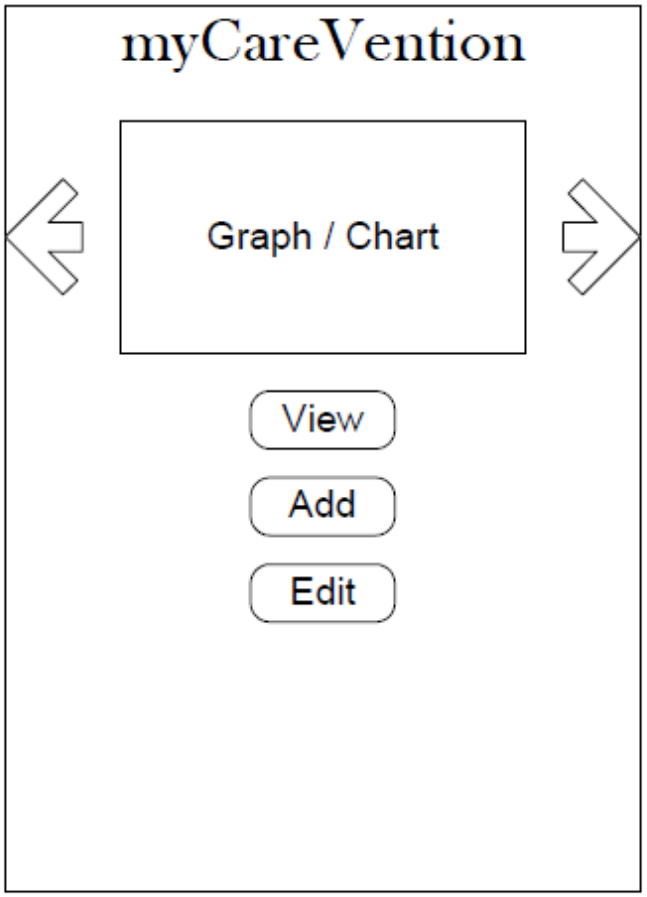
This page does not exist as a separate tab or page. It is a place holder for for other content.



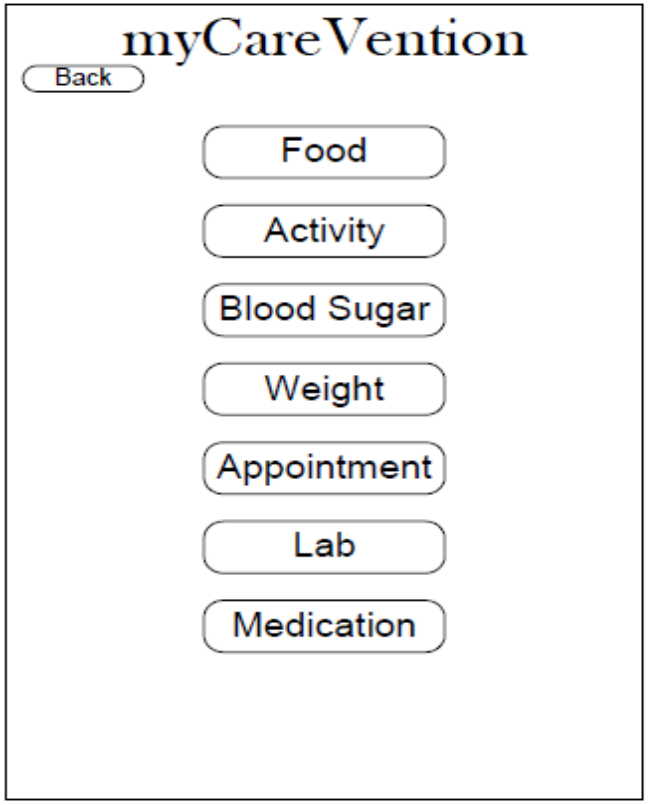



**Mobile Website - Home**




**Mobile Application notes**
- Top portion displays graph/chart - will be a static graphic (most mobile phones cannot handle flash graphics, which are used on the website.)
- Arrows allow user to cycle through the available charts (SMBG graph and charts, Weight, Labs, Meds, etc...)
- Clicking on View, Add or Edit displays a listing of items that can be acted upon. (See Next Page.)

**Mobile Website - 2nd page (View, Add, Edit)**




- Clicking on the item takes you to a page that performs the previously selected action (view, edit, add).

- View displays listing of items similiar to diary listing in reverse chronological order

- Edit displays listing of items, but allows user to select them for editing.

- Once the user is on the View/Add/Edit or deeper pages a Back button is displayed.

3) ***Develop protocol and obtain approval from all appropriate Institutional Review Boards for User Testing of Version 1***

The project staff has written a protocol that we expect will be exempt because we will not be obtaining any personal health information or other identifiers. The purpose of the protocol is to obtain user feedback on the application before it is finalized and pilot tested.

Prior to this project, we conducted a Needs Assessment that helped us to identify the Design Requirements and Specifications. The goal of obtaining user feedback at this stage – with the aforementioned protocol -- is to ensure that the look and feel and usability of the PHR-A are congruent with users' expectations. It will also help us to draft the instructions for use, as we identify areas where potential users become confused.

Once we have completed enough of the PHR-A to show it to our IRB, we will submit the protocol.

4) ***Test version 1 of PHR-A, incorporate user feedback, and finalize a version 2***

The protocol in Task 3 above is the basis for this test in Task 4. The actual "testing" will involve recruiting 6-10 people with diabetes and asking them, in a group interview format, what they think of each part of the PHR-A we have developed. We will tape record everything that they say, analyze the results (e.g., look for common themes and strong, outlying opinions), and revise the look and feel of the PHR-A accordingly.

5) ***Develop protocol and obtain approval from all appropriate Institutional Review Boards for Pilot Study of Version 2 PHR-A***

We are drafting but have not completed this Task as of yet. We will complete this task by the spring.

In brief, for the Pilot Study, we will recruit 90 people with diabetes from the Walter Reed Health Care System (WRHCS) and randomly allocate them to use the PHR-A for 6 months or to 'attention control.' After confirming eligibility using some simple tests of manual dexterity and cognitive function, we will collect metrics on the subjects' backgrounds, glycemic control (A1c and self-monitoring of blood glucose data), self-reported self-care [Summary of Diabetes Self-Care Activities (SDSCA)], and diabetes-related distress [Problem Areas in Diabetes (PAID) scale]. At various points throughout the study, we will repeat collection of A1c, self-monitoring of blood glucose data, SDSCA, and PAID, and we will measure subjects' engagement by tracking the contacts that they initiate with their providers and their adherence to appointments. At the completion of data collection, we will analyze the data with t-tests, repeated measures ANOVA, and multinomial logistic regression models.

6) ***Initiate and maintain Pilot Study through Completion***

This Task is for next year and is not complete.

7) ***Prepare reports and manuscripts for presentation at national meetings regarding the technology and our findings from the Pilot Study***

This Task is for next year and is not complete.

**Key Research Accomplishments**

- Finalization of the rubric for the PHR-A (e.g., modules for Healthy Eating, Being Active, Monitoring of Blood Glucose, etc.)
- Document with functional requirements
- Determination of how users will do manual data entry, as needed
- Drafting and documentation of rules and algorithms for specific components/modules of the PHR-A
- Drafting of code for the components of the PHR-A based on the written rules and algorithms
- Documentation of code establishing linkages between the PHR-A and a PHR – Microsoft HealthVault only
- Establishment of an Internet "presence" to host the PHR-A
- Drafting of over 200 tips that pertain to each component of the PHR-A

**Reportable Outcomes**

The following publications reference design aspects of the PHR-A:

Fonda SJ, Kedziora RJ, Vigersky RA, Bursell SE. Evolution of a web-based, prototype Personal Health Application for diabetes self-management. *Journal of Biomedical Informatics* 2010; 43: S17 – S21.

Although it was not the focus of the talk, the following presentation included mention of the PHR-A concept and our development efforts to date:

Invited presentation, "e-, i-, or m-health? Blurring Boundaries between Provider and Patient-Centered Management". Annual Meeting of the Diabetes Technology Society, November 13, 2010.

**Conclusion**

Reduction or prevention of diabetes-related complications requires blood glucose levels be kept as close as possible to the normal range. Daily self-care behaviors carried out by the person with diabetes are of central importance in attaining good blood glucose; however, many people struggle with appropriate or consistent self-care. Tools have evolved over the past decade to help with diabetes self-care, but they are either tied to a clinic or provider, do not make use of Personal Health Records (PHR) as a place for storing and accessing useful diabetes data, lack decision support, or some combination of these things. A new tool for diabetes care that is mobile, uses a PHR, is not tied to a clinic, and can provide decision support with actionable recommendations is needed. Thus, our objective is to develop a new tool for diabetes self-management, involving potential end-users in the process, and to conduct a Pilot Study of the efficacy of the new tool. The new tool is a Personal Health Record - Application (PHR-A). For the Pilot Study, our central hypothesis is that a PHR-A that coordinates the major components of diabetes self-management, is mobile, provides decision support with actionable options, and is based on user input will enhance diabetes self-care, improve glycemic control, and lower psychological distress related to diabetes.

Our specific aims are to develop a new PHR-A for diabetes self-management, to obtain feedback from 6-10 potential users of this product regarding its “look and feel”, and then to conduct a Pilot Study with people with diabetes that will test the following hypotheses: 1) Glycemic control will be more improved among people with diabetes who receive the PHR-A compared with people with diabetes who receive “attention control”.; and 2) Self-reported diabetes self-care, engagement with care, and psychological distress related to diabetes will be more improved among people with diabetes who receive the PHR-A compared with people with diabetes who receive “attention control.

The project had a late start due to errors in the contract. However, we have completed a substantial portion of the development (developed the the rubric for the PHR-A, developed a web site, connected with Microsoft HeathVault, written all the tips, written the rules and algorithms, drafted a protocol for user testing, etcand are soon ready to obtain user feedback. The user feedback may result in changes to how the application looks and to our instructional materials. In the coming year, we will obtain the user feedback and conduct the Pilot Study.

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**Appendices**

Tips (pdf)

TITLE:
The Use of a Computer-Assisted Decision Support (CADS) System to Improve Outcomes in Patients with Type 2 Diabetes Who are Treated by Primary Care Providers

PRINCIPAL INVESTIGATOR:
Robert A. Vigersky, COL MC

**14. ABSTRACT**
Diabetes accounts for an enormous fraction of the cost of health care in the US and presents a major burden on Military Medical Facilities. There are insufficient endocrinologists and other diabetes specialists to manage all patients with diabetes mellitus (DM) and a significant fraction of these patients have less than optimal control (hemoglobin A1C's [A1Cs] over 7%). Multiple barriers prevent the necessary improvement in glycemic control that would result in savings in lives and costs. The implementation of a telemedicine and web-based approach for patients to send their blood glucose data which, when combined with relevant laboratory, pharmacy, and A1C targets as set individually for each patient by the Primary Care Physician (PCP), triggers a clinical decision support system (DSS) for the providers can be expected to improve quality of care and efficiency of care. Therefore, this study will test the safety and efficacy of a computer assisted decision support (CADS) system as used by PCPs in a multi-site, ethnically and geographically diverse study in a 12-month, open, prospective, cluster-randomized, controlled clinical trial.

**15. SUBJECT TERMS**
Diabetes mellitus, computer assisted decision support (CADS) system, primary care providers (PCPs)

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## Introduction

Diabetes accounts for an enormous fraction of the cost of health care in the United States and presents a major burden on Military Medical Facilities for care of retirees and dependents with diabetes. There are insufficient endocrinologists and other diabetes specialists to manage all patients with diabetes mellitus (DM) and a significant fraction of these patients have less than optimal control (hemoglobin A1C's [A1Cs] over 7%). Multiple barriers prevent the necessary improvement in glycemic control that would result in savings in lives and costs. The implementation of a telemedicine and web-based approach for patients to send their blood glucose data which, when combined with relevant laboratory, pharmacy, and A1C targets as set individually for each patient by the Primary Care Physician (PCP), triggers a clinical decision support system (DSS) for the providers can be expected to improve quality of care and efficiency of care. The computer assisted decision support (CADS) system has been integrated with the Comprehensive Diabetes Management Program (CDMP), a web-based, multi-platform, interactive patient and provider tool which is currently operative in the three sites that are participating in this study—the Walter Reed Health Care System (WRHCS), Wilford Hall Medical Center (WHMC) at Lackland Air Force Base (AFB), and five community clinics affiliated with the University of Hawaii (UH). This existing infrastructure permits CADS to be tested in a multiple sites that are geographically diverse with diverse patient populations.

This study will test the safety and efficacy of CADS as used by PCPs in a multi-site, ethnically and geographically diverse study in a 12-month, open, prospective, cluster-randomized, controlled clinical trial. The specific aims of the study are to: (1) monitor the impact of the intervention on: a) measures of glycemic control, b) the number of diabetes –related hospitalizations and emergency room visits, c) the control of co-morbidities, hyperlipidemia and hypertension, d) the number of clinic visits, e) the change in the patients' quality of life as a result of the intervention; and (2) evaluate the PCPs' satisfaction with the technology.

We will employ a cluster-randomized, controlled, clinical trial involving 30 PCPs who will each recruit approximately 19 patients from their respective geographic site. After completion of recruitment, PCPs and their patients will be randomly assigned to 1 of 2 "treatment" categories: CADS, or "Usual Care". Input data for use by the CADS system will come from the electronic medical record (laboratory and pharmacy data) and from the PCP who will set goals for each individual patient's glycemic control. Patients will upload blood glucose data through a modem to a password-protected, secure server at least every 2 weeks and receive modification in their treatment regimen at least every three months from their PCP, based in part on the recommendations provided by the CADS system to the PCP. We will compare quantitative outcome measures of glycemic control (the primary outcome is the change in the patient's A1C), blood pressure,

and lipid levels from the two treatment groups. In addition, subjective qualitative data from the patients and providers will be obtained.

This annual report provides the background for the study, key research accomplishments, and plans for Year 2.

## Background

Diabetes mellitus (DM) affects approximately 24 million people in the United States and is associated with devastating complications in both personal and financial terms. Diabetes is the leading cause of blindness, non-traumatic amputations, and renal failure in adults and reduces life expectancy by 5-10 years. The direct ($116 billion) and indirect ($68 billion) costs of DM care have dramatically increased along with the epidemic increase in the number of those with DM over the past 10 years. The cost of medical care per capita is approximately $10,000 per year compared with $2,700 per year for those without DM. The vast majority of these costs are related to hospitalizations resulting from the chronic complications of DM, with only about 15% of the costs attributable to professional visits and pharmaceuticals. The Diabetes Control and Complications Trial (DCCT), the United Kingdom Prospective Diabetes Study (UKPDS), and the "Kumamoto" study conclusively proved that improved glycemic control was important in reducing microvascular complications.[1, 2, 3] Together, these studies showed that for every 1% decrease in A1C, there is a 25% decrease in microvascular complications. Based on these studies, the American Diabetes Association recommends that the goal for A1C should be below 7% (normal 4-6.1%)[4], and the American Association of Clinical Endocrinologists recommends that it should be below 6.5%, corresponding to an average blood glucose (BG) values of 150 and 135 mg/dL, respectively, [normal 70-126 mg/dl].[5] Furthermore, years of improved glycemic control appear to have a legacy effect and not only reduce the future rate of microvascular complications but also decrease the incidence of macrovascular complications in both Type 1 and Type 2 diabetes. [6, 7] SBGM has become one of the essential tools in achieving improved glycemic control. Several studies have shown that improved glycemic control is cost effective in both Type 1 and Type 2 diabetes despite the increase in cost of supplies, a greater number of clinic visits, and more pharmaceuticals used. [7-13]

Despite increased accessibility, affordability, and accuracy of BG meters, glycemic control remains sub-optimal in most patients. Although there is a trend toward improved glycemic control, the latest (2004) National Health and Nutrition Examination Survey (NHANES) data demonstrated that 42.3% of patients with DM have A1Cs above the 7% goal set by the American Diabetes Association (ADA.[14] The military healthcare system (MHS), where there is no out-of-pocket cost to the patient for care, has similar results with 42% having hemoglobin A1C values above 7%, and with 23.3% of patients with an A1C's greater than 9.0%. Of the more than 6,000 active patients with diabetes in

the WRHCS, 51% have A1C above 7%. Further, blood pressure (BP) control in our patients is similar to the national average with 62% of our patients having either systolic BP above 140 mmHg and/or diastolic above 90 mmHg under current treatment. Recommended levels to reduce the risk of cardiovascular mortality and morbidity are less than 130/80 mmHg using criteria as set by the ADA, the American Association of Clinical Endocrinologists (AACE), the International Diabetes Federation (IDF), the NIH-National Heart, Lung, and Blood Institute (NHLBI), and several professional organizations of cardiologists.

The reasons why more patients do not reach appropriate goals for glycemic control are multiple and complex. Patients with diabetes, with their co-morbidities of hypertension and hyperlipidemia, are best monitored by highly skilled health care professionals who are equipped with the latest information to help ensure early detection of complications and appropriate treatment and to provide diabetes education to patients. But due to a dearth of Endocrinologists and Certified Diabetes Educators in both military and civilian health care settings, PCP's, including family practitioners, nurse generalists, nurse practitioners, and physicians' assistants, who are not always equipped with the latest information and tools, provide care to the vast majority of patients with type 2 diabetes.[15] The patient may bring his/her handwritten logbook and/or meter to the clinic where the data are reviewed manually or the patient may bring his/her memory-equipped meter to the clinic, where it may be downloaded to the provider's computer and analyzed. Manual review of the records precludes any statistical and graphical analysis of the data and often limits the provider's ability to recognize patterns and trends. Moreover, this approach is time-consuming and an inefficient use of both the provider's and patient's time. While all the major manufacturers of capillary blood glucose meters provide PC-based software for data analysis, each has its own proprietary software and unique connecting cables. Thus, the multiplicity of programs and connecting cables that are needed to efficiently review SMBG data poses a significant barrier to using this technology.

The use of a computer assisted decision system (CADS) that combines the knowledge, experience, and insight of endocrinologists with relevant patient information, including current and target A1C levels, BG data, and current medications has the potential allow non-specialist physicians and physician extenders to provide a higher quality of care for routine cases, thus freeing specialists to evaluate and manage more complex patients. Although many studies have trumpeted the potential advantages of telemedicine, web-based, and/or web-assisted DM management, most have used the web for patient education, performance monitoring, risk stratification, and case management by nurses.[16-18] A few studies have shown that using the web and/or e-mail improves glycemic control[19-21] or can reduce the number of clinic visits,[22] but several other studies have failed to demonstrate such an effect.[23, 24]

Computer-assisted algorithms to provide decision support for interpretation of the glucose profile have been previously developed

and published by two of the collaborators on this project, as well as by others.[25-28] We and our associates have previously developed methods to automatically select regimens and doses of insulin for patients with type 1 diabetes[29] but these methods were not tested clinically.

This study will determine whether or not the use of a computer assisted decision support system by primary care providers, can improve outcomes in patients with poorly controlled Type 2 DM (T2DM). If the use of the combined system involving CDMP with CADS results in better compliance with Physician Quality Reporting Initiative (PQRI) measures and improved glycemic control, we would ultimately expect to see a reduced rate of complications of DM in our patients as well as an improved quality of life. It would then be appropriate to disseminate the program throughout AMEDD. There are approximately 500 PCPs in Army MTF's in the continental U.S. and another 200 in Army MTF's outside the continental U.S. Assuming that the prevalence of diabetes in the 12 million MHS beneficiaries is similar to that in the civilian sector (7%) and that they have the same prevalence of type 2 diabetes (90%), we estimate that there are approximately 756,000 patients with Type 2 diabetes who are eligible for military health care benefits either at MTFs or through TRICARE. The cost to the MHS from these patients is estimated to be about $8 billion per annum. Using the cost-effectiveness criteria in a recent study at the Geisinger Clinic[30], an HMO which implemented a disease management program and which realized a $108 per month reduction in claims per patient, the military health care system would have a yearly projected savings of over $80 million.

## Phases of Project

The project has two major phases – a CADS development phase and a clinical randomized clinical trial (RCT) phase. Each phase will be presented separately.

The following summarizes the progress in the CADS Development Phase. This Phase consists of four categories of tasks: ***CADS CDMP User Interface***, ***CADS Algorithms***, ***CADS Administration Website***, and ***Information Systems Assurance and Approval***

***CADS Development Phase***

### Statement of Work and Key Research Accomplishments

**Tasks that have been completed in the fourth quarter have been bolded:**

1. **CADS CDMP User Interface**:
   All tasks for this were accomplished by the end of the second
   quarter and are detailed in the second quarter report.

2. **CADS Algorithms**
   a. The scope of the algorithms and the logic incorporated

into the CADS system have been greatly expanded from the original prototype.

b. The clinical rules and algorithms that were developed for the first version of CADS have been expanded, revised, and updated to include new medications and combinations of medications by Col Vigersky and his colleague, Dr. David Rodbard.

c. Estenda Solutions has completed all of the functional requirements, rules and algorithms for CADS. The scope of the algorithms and the logic incorporated into the CADS system have been greatly expanded from the earlier prototype.

d. The logic for these algorithms has been completed. The algorithms and related logic include:

1. detailed lists of available medications, their starting and available doses, contraindications, and potentially adverse events associated with them;
2. approximately 60 available medication regimens
3. preferred sequence of regimens
4. detailed lists of coexisting conditions
5. logic for modification of medications (dosage, type, or timing) for hypoglycemia and hyperglycemia
6. algorithms for situations where a patient is experiencing both hypoglycemia and hyperglycemia, either at the same time of day (e.g. before dinner) or at different times of day.
7. logic for determining whether to increase or decrease the dosage of a medication, add or discontinue a medication, or make a referral to an endocrinologist or diabetes nurse practitioner
8. a table containing information regarding the pharmacodynamics of the various medications
9. the logic to determine which medication (or group of medications) is most likely responsible for a particular problem at a particular time of day messages that would be presented to the provider (end-user) when a particular set of conditions has been observed.

**e. The recommendations for nearly all single oral and Injectable diabetes medications agents and all possible combinations of single, dual, triple, and quadruple agents (oral and injectable) have been extensively tested for appropriateness by a diabetes nurse practitioner (MSN, RN) and a certified diabetes educator (PhD, RN), both of whom have had more than 10 years of experience managing and/or teaching diabetes. This testing included review of all explanations and justifications of recommendations and/or**

**reasons for not recommending. Testing also included situations in which the blood glucose values were all low (hypoglycemia, high (hyperglycemia), and mixed as well as co-existing conditions.**

**f. Results of the testing have been shared with Drs.Vigersky and Rodbard, the endocrinologists who developed the program,and with RJ Kedziora, Estenda Solutions, who created all the functional requirements, rules, and algorithms for CADS and integrated CADS into CDMP.**

**g. Changes to recommendations, options, and/or precautions Have been revised when indicated.**

3. **CADS Administration Website**

A CADS Administration web application has been created which allows select end users to adjust the overall algorithms, settings and medication regimes used within CADS. **Additional screens allow configuration of side effects and diagnosis used in the CADS algorithms**. The CADS site will also allow for cross-site anonymous research reporting through the use of an integrated reporting engine. Upon completion of coding, the site must then meet all the requirements of Estenda's Quality Assurance program.

a. The CADS Administration website enables select study personnel the ability to update CADS Analysis information and view reports of the data. The ability to update drug information has been complete along with site and user maintenance. While report generation will be an ongoing process, the following reports have been created as proof of concept: Patient Listing, Patient SMBG Data Listing, Drug Combination/Progression Listing, **Drug Group Diagnosis Contraindication Mapping, Drug Mono and Combo Max, and Patient Analysis by Site grouped by Patient or by Requestor (physician).**

b. Additionally to assist in testing a set of web pages was created to allow for the easy entry of test cases that can be used to test the medication adjustment algorithms. This functionality is meant for testing only and will not go through the QA process or be deployed to production.

c. **The Estenda Quality Assurance process has also begun**

**testing the user interface and completing the appropriate documentation. Discussions have also been held regarding FDA review and approval of an eventual public release of the CADS software, but no definitive action has been taken at this time.**

**4. Information Systems Assurance and Approval**

**a. Certificate of Networthiness**

**The Comprehensive Diabetes Management Program (CDMP) has been approved and installed on a WRAMC server for several years. CDMP hosts CADS and has been updated to accommodate CADS. Due to changes in the security requirements, the Integrative, Security, and Network sections of the DOIMs at WRAMC and at the National Naval Medical Center (NNMC) mandated that CDMP be re-evaluated to identify potential vulnerabilities. Dual approval is required as integration of the two departments is already in progress. In order not to disrupt use of Study Manager, a feature of CDMP currently employed by 2 studies, CDMP was installed on another server and Web Inspect testing was undertaken as part of this process. The findings were reported to Estenda and Estenda corrected the identified issues. After initially requiring independent testing, both parties agreed to accept the Air Force DIACAP once finalized.**

**b. DoD Information Assurance Certification and Accreditation Process (DIACAP**).

DIACAP defines a DoD-wide formal and standard set of activities, general tasks and a management structure process for the certification and accreditation of a DoD IS that will maintain the information assurance (IA) posture throughout the system's life cycle. **Estenda has worked extensively on the DIACAP application for the Air Force and submitted it early this year.** Estenda has weekly conference calls with their DIACAP representative to facilitate the process and **the final executive package was submitted the third week of November. We are waiting the results of the review.**

***Clinical Trial Phase***

The following summarizes the progress in the **Randomized Clinical Trial Phase.** The Statement of Work and Key Research Accomplishments have been grouped together. **Tasks that have been completed in the fourth quarter have been bolded:**

**Statement of Work and Key Research Accomplishments**

***Task 1.*** Develop protocol and obtain approval from all appropriate Institutional Review Boards (IRBs) (WRHCS, WHMC, UH), design and test a Technical Assessment Questionnaire (TAQ) (Month 4)
*Deliverables:*
a. Final Approved Protocol, Consent, and Approval forms (Month 4)
b. Establishment of a Data Safety and Monitoring Committee (DMSC) (Month 3)
c. Technical Assessment Questionnaire written and tested (Month 3)

***Task 1 Accomplishments:***

a.1 The protocol and all related documents were approved by the individual Institutional Review Boards (IRB) at WHMC and UH during the second quarter.

**a.2 The protocol and all related documents were approved by the Department of Clinical Investigation (DCI) at WRAMC during the fourth quarter. The process which began at WRAMC in December 2009 was delayed by the lengthy approval process in both the DCI and the Department of Information Management (DOIM) at WRAMC.**

**a.3 The protocols from the three participating sites were sent to the Human Research Protection Office (HRPO) at U.S. Army Medical Research & Materiel Command (USAMRMC) on October 6, 2010. We are awaiting the results of the reviews.**

**b.1 A** Data Safety and Monitoring Committee (DMSC)has been established

**b.2 The** Technical Assessment Questionnaire has been written; testing has not been completed.

***Task 2.*** **Recruit health care providers** (1-2 months after IRB approvals; expected complete by Month 5)

***Task 2 Accomplishments:***
*Primary Care Providers at all sites have been made aware of the study and have been given a preliminary demonstration of CADS. PCPs at all sites have expressed an interest in participating in the study. PCPs have been updated periodically on status of study approval and ongoing refinement of CADS.*

***Pending***
*Recruitment will begin at each site once HRPO grants final approval.*

***Task 3.*** **Recruit patients; informed consent procedure** (2-3 months after IRB approvals; expected complete by Month 7)

***Pending***

*Recruitment will begin at each site once HRPO grants final approval.*

***Task 4.*** **Initiate study** (5 months after IRB or Month 9)

a. Cluster randomization of health care providers and patients
b. Distribution of iMetrikus ® devices (Month 9)
c. Patient education regarding the use of the memory glucose meters (if necessary) (5 months after IRB approvals; Month 9)
d. Education of health care providers regarding use of CADS for viewing patient home blood glucose monitoring data and the CADS recommendations (5 months after IRB; Month 9)

***Pending:***

Tasks 4a – 4d will be implemented once HRPO grants final approval. Providers will be randomized once they have enrolled 19 patients. Cluster randomization will be accomplished by a computer program.

***Task 5.*** **Follow up logistics to ensure continuity of patients and providers in the research study, with ongoing patient visits, and ongoing use of the technology by the patients the health care providers** (Month 9 continuing through Month 20)

*Processes (internal deliverables):*

a. Follow up visits to health care providers and phone calls to patients as needed to maintain compliance with the requirements of the protocol
b. Monitoring performance of CADS
c. Data collection regarding compliance of patients and health care providers
d. Data collection from Diabetes Treatment Satisfaction Questionnaire (DTSQ), the Standard Form (SF) – 8, and from Technology Assessment Questionnaire (TAQ-PT)
e. Collection of outcome measurements on an ongoing basis

***Pending***

***Tasks 5a –5b will be initiated once the HRPO grants final approval and the study has been initiated at each site***

***Research Accomplishments***

***Tasks 5c –5e*** **Dr. Walker, Dr. Mary Chellappa, an Associate Investigator and research coordinator at WRAMC, and Mr. Anthony Hooker, DI Technical Support at WRAMC, have nearly completed adaptation of Study Manager to the CADS protocol. Study Manager is a stand-alone component of CDMP that facilitates comprehensive management and documentation of all aspects of a study. Study Manager will be used by the research coordinators at each site to manage and track data collection, including the DTQS, the SF-8, and the TAQ, as well as all primary and secondary outcome measures.**

***Task 6.*** **Data monitoring for safety and analysis of interim results** (Ongoing from onset of Task 4, continuing through Month 20)

*Deliverable:*

a. Monthly and quarterly reports to DMSC; quarterly and annual reports to IRBs

***Research Accomplishments***

6a. First and second quarter reports have been submitted to USAMRMC/TATRC.

6b. The third quarter report was waived as a result of COL Vigersky's presentation of progress and demonstration of the CADS at the 2010 Product Line Review in June sub

***Task 7.*** **Conclude study and debrief patients and health care providers 12 months after onset of Task 4 (initiation of study)** (Month 20)

***Pending completion of study.***

***Task 8.*** **Analyze results at conclusion of study: statistical analysis** (Month 21-24)

*Deliverable:*

Statistical analyses, charts, graphs, documentation, and interpretation

***Pending completion of study.***

***Task 9.*** **Prepare reports for publication and presentation at national meetings related to management of patients with chronic diseases such as diabetes and medical informatics** (Month 21-24)

*Deliverable:*

a. Manuscripts for the scientific and medical literature of quality sufficient for publication in a well respected, peer-reviewed medical, medical informatics, and other scientific journals

***Pending completion of analysis of study data.***

**Plans or milestones for Year 2 of Funding**

**The primary focus of Year 2 is implementation of the clinical trial. In addition to executing the above pending tasks that speak to study initiation and conduct we will:**

**a.** Complete the clinical review of recommendations

b. Finalize recommended changes to complete all clinical rules and algorithms

c. Complete the adaptation of Study Manager to the CADS study

d. Regularly check the status of the DIACAP review and promptly respond to the results

e. Recruit, screen and interview potential a Project Officer to manage the studies in San Antonio

f. Continue to actively engage HRPO and promptly respond to

their reviews in order to secure all approvals necessary to begin the study by the 2nd quarter of Year 2

g. Visit, if necessary, the WRHCS, WHMC and UH clinics, and providers to facilitate participation and enrollment into the study.

h. Meet with the Principal and Collaborating Investigators and Research Coordinators at each site to comprehensively review implementation and management of the study and the use of Study Manager.

i. Once the study is underway, Dr. Walker, the Associate Investigator at WRAMC and overall study manager, will establish monthly conference calls to determine and insure study progress.

## Conclusion

Diabetes mellitus is a significant cause of morbidity and mortality in the United States, and the leading cause of new blindness, chronic kidney disease, and non-traumatic amputation in the working-aged American population. Although the financial costs to individuals, communities, and health care systems are measurable, the devastating costs in terms of quality of life personal costs are not easily measured. A computer assisted decision support system that makes available the knowledge and expertise of endocrinologists to primary care providers who care for the majority of people with Type 2 diabetes has the potential to significantly improve the level of care provided to people with T2 DM, thus preventing or delaying the onset of and/or reducing the severity of diabetes-related complications. Reducing the risk and/or severity of complications promises to improve the quality of life for people with T2 diabetes and decrease the financial impact on the individual as well as both the military and civilian health care systems.

CADS is a web-based interactive application that enables primary care providers to aggressively and systematically use available medications to help their patients move increasingly and safely toward a level of glycemic control that minimizes their risk of developing diabetes-related complications and/or the severity of these complications. The successes and lessons learned from this study can be applied to an even larger population of people with Type 1 and Type 2 diabetes, thus further mitigating the devastating financial and personal costs of poorly controlled diabetes mellitus.

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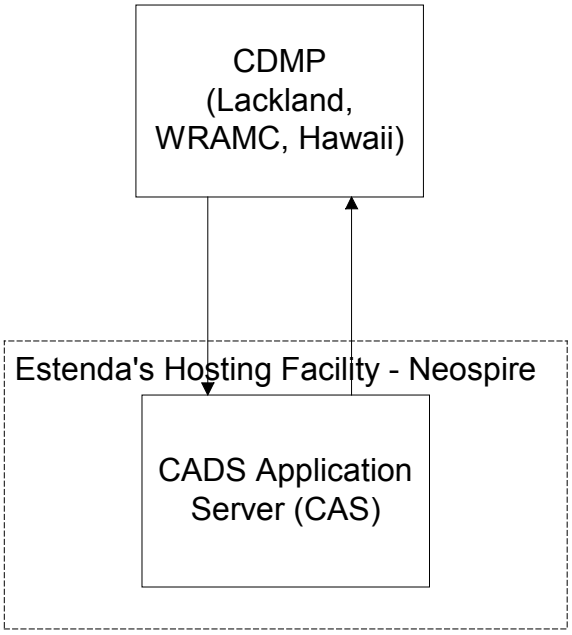
**Appendix 1 CADS Identifier Usage and Data Flow**

**CADS Identifier Usage and Data Flow**
This document outlines which identifiers are stored where, how they are transmitted between services, and how they are generated.




**CDMP – CADS Application Server (CAS)**
CADS consists of two main components, the CADS user interface in CDMP and the CADS Application Server (CAS).

On a nightly schedule, CDMP extracts patient demographics and clinical data from ICDB and/or AHLTA. This extract contains HIPAA-specified patient identifying information including the patient's full name, birth date, social security number, gender, complete address, phone number, and where applicable, military rank. This information is not transmitted to the CADS Application Server. It is only used to allow the provider to locate the patient in CDMP.

Requests sent from CDMP to the CADS Application Server will contain the following identifiers: Patient Study ID, Provider ID, and CADS Site ID, Each identifier is described in the chart below. No patient identifying information except for gender is sent to the CADS Application Server.

| Identifier | Background |
|---|---|
| Patient Study ID | This identifier is a combination of elements separated by dashes to uniquely identify a patient across the study. It will follow the following convention: geographic location – site – study arm – provider number – patient number by provider. An example identifier would be 'WR-01-0-01-01'.<br>- The first block is the geographic location. These are WR for Walter Reed, WH for Wilford Hall, and HI for Hawaii.<br>- The second block is the specific site at the location. For Walter Reed, this would be:<br>o IM at Dewitt – 1 |

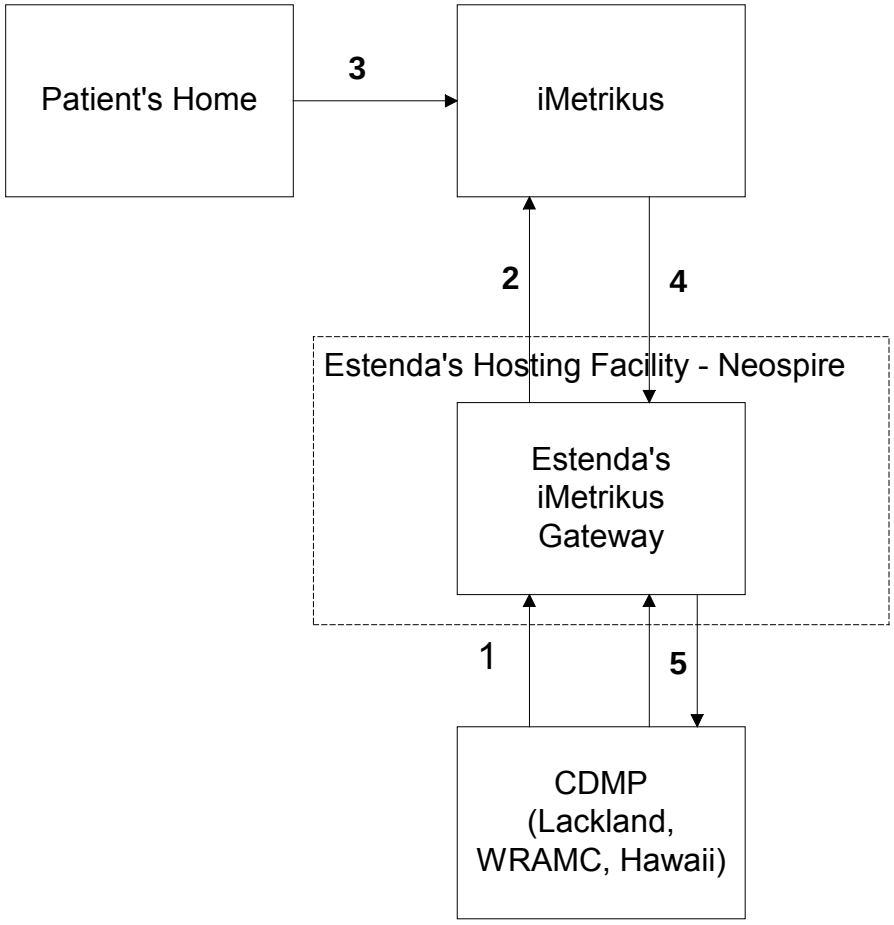
| | |
|---|---|
| | o Fairfax -2<br>o Kimbrough -3<br>o Rader – 4<br>o WRAMC – 5<br>o Woodbridge – 6<br>- The third block is the study arm.<br>o 0 = usual care<br>o 1 = CADS<br>- The fourth block is the provider number. This is a simple sequential number assigned to the provider as they are included in the project.<br>- The fifth block is the patient number for the provider. This is a simple sequential number assigned to the patient based on their provider. |
| Provider ID | The Provider identifier is a combination of identifiers that will follow the convention established for the patient study ID, that is, the geographic location, specific study site, and study arm. |
| CADS Site ID | The site identifier is a simple value used to identify the source of an analysis request. The following values will be used: 'WRAMC', 'WILFORD", and "HAWAII" to identify each group of sites. |
| CAS ID | The CAS ID is an integer value that will be generated by CAS in response to the first request from CDMP and returned instantaneously to CDMP. This identifier has no relationship to any other study ID and contains no information that would identify either a provider or a patient. An example is 123030. |

Thus, the process flows as follows:

When a CDMP user first activates a CADS request, the CDMP application sends a request to the CADS Application Server (CAS), where it is processed and the result is returned to CDMP for display. The results will contain the unique identifier, the CAS ID. This identifier will be used by CDMP to make subsequent requests to the CAS to retrieve the analysis results from the CADS Application Server. Each interaction is date and time-stamped and stored on the CDMP server.

**iMetrikus Process**

The following section outlines the communication and identifiers used between CDMP, the *i*Metrikus® Gateway, *i*Metrikus®, and the patient's home. *i*Metrikus is a device, similar to a modem that will be attached to a landline telephone and will be used by the patients to upload their glucometer data. The following diagram outlines the flow of data and is followed by a detailed explanation of each step.



Each implementation of CDMP stores the following identifiers with respect to its interaction with *i*Metrikus®:

| Identifier | Background |
|---|---|
| HIPAA Patient Identifiers | This is the same data stored as outlined in CDMP-CADS. It includes patient full name, birth date, social security number, gender, complete address, phone number, and where applicable military rank. No patient identifying information is transmitted to the *i*Metrikus® Gateway or *i*Metrikus®. |
| CDMP iMetrikus Site Id | This is a site identifier used by the *i*Metrikus® Gateway to uniquely identify each implementation of CDMP. It is a simple string value. The following values will be used: 'WRAMC', 'WILFORD", and "HAWAII". This identifier is used to route messages between the Gateway and individual CDMP implementations. While similar to the CADS Site Id, this is a separate stored value. |
| MetriLink Device Serial Number | The actual device serial number. |
| CDMP Internal Patient Id | This is a generated identifier used to uniquely identify a patient within CDMP. It is an integer value. An example is 34344. It is an internal identifier and not used by the end user. |

Estenda's iMetrikus Gateway stores the following identifiers:

| Identifier | Background |
|---|---|
| CDMP *i*Metrikus® Site Id | The CDMP site identifier described above. |
| MetriLink Device Serial Number | The actual device serial number. |
| CDMP Internal Patient Id | The same identifier as described above. |
| *i*Metrikus® Site Id | A unique identifier used to identify the Gateway within *i*Metrikus®. |

iMetrikus stores the following identifiers:

| Identifier | Background |
|---|---|
| MetriLink Device Serial Number | The actual device serial number. |
| *i*Metrikus®Site Id | A unique identifier used to identify the Gateway within *i*Metrikus®. |

**Process Flow**

The following outlines the data flow of identifiers for the iMetrikus Proces***s:***

***Step 1***
The initial step requires the CDMP user to register a patient to a specific device using the *i*Metrikus®Device Serial Number. The CDMP iMetrikus Site Id, CDMP Internal Patient ID and MetriLink Device Serial Number are sent to the Gateway.

***Step 2***
When the Gateway receives a registration request from CDMP, it forwards the request to *i*Metrikus® using the *i*Metrikus® Site Id and MetriLink Device Serial Number.

***Step 3***
When a patient uploads glucose monitoring information from home it contains the MetriLink Device Serial Number.

***Step 4***

Using this serial number, *i*Metrikus® finds the associated *i*Metrikus® Site Id and if it has been registered to the Gateway, the message will be routed to the Gateway. Data is not automatically forwarded to CDMP because of network firewall restrictions.

***Step 5***
CDMP requests new data from the Gateway using the CDMP *i*Metrikus® Site Id on a nightly basis or per user request. If new data is stored at the Gateway, it is returned to CDMP for storage, processing, and display.