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TITLE: "Develop a Prototype Personal Health Record Application (PHR-A) that Captures Information About Daily Living Important for Diabetes and Provides Decision Support with Actionable Advice for Diabetes Self Care".

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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 designed an Internet-based and mobile application (software) 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, lab testing. Although not a primary focus, the application also addresses weight management and loss. The application is called Tracking My Diabetes (TMD). Using information that TMD receives on these self-management domains (from the user's own monitoring/journaling devices that store data in Microsoft HealthVault and/or from the user's manual data entry directly into TMD), TMD 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. 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.					
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Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	46
Reportable Outcomes.....	46
Conclusion.....	46
References.....	47
Appendices	None

INTRODUCTION

Despite the well-documented benefits of glycemic control^{1,2} and a secular trend to overall improvement in people with diabetes,³ glycemic control is still sub-optimal in many patients. According to the National Health and Nutrition Examination Survey, 43.2% of people with diabetes had A1c levels greater than or equal to the generally recommended target of 7.0%.³ Achieving target glycemic control typically requires a multi-factorial approach, with considerable commitment from the person with diabetes to examine and correctly interpret random blood glucose readings, take medications as prescribed, follow a balanced, whole foods-based diet and engage in regular physical activity. For a variety of reasons, many people with diabetes do not or cannot adhere to these requirements;⁴⁻⁸ failure to do so may be due to inadequate education about the purpose and outcomes of such behaviors and the absence of support and/or reminders.

Thus, the overall objective of this project is to develop (phase 1) and test (phase 2) a new tool for diabetes self-management that provides education, reminders, and support. The new tool is an internet-based and mobile application (software), now called Tracking My Diabetes (TMD). Our central hypothesis is that an application (such as TMD) 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. During development (phase 1), we created the functional requirements, rules and algorithms for TMD, and then coded these rules and algorithms to create a functioning, Internet-based tool. The study (phase 2) is a test of the TMD's clinical efficacy when used for 3 months by a cohort of people with diabetes.

BODY

TASK 1. Draft functional requirements -- COMPLETE

This is the first task that the project completed, and is foundational for the rest of the work. **THIS INFORMATION HAS BEEN REPORTED PREVIOUSLY, BUT WE INCLUDE IT HERE FOR CONTINUITY OF DOCUMENTATION.**

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
- Outlook
- Medications
- Monitoring (weight and blood glucose)
- Reducing Risks

Although not a separate module per se, the application also includes weekly diabetes tips (or twice weekly, depending on user preference) that cover the above areas (the user chooses the areas). We have 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 submitted the Functional Requirement Document (Task 1) to Stacey Zimmerman. The following is excerpted from the Functional Requirement Document submitted. ***We are including this information here because the contract transitioned from the TRUE Research Foundation to the Geneva Foundation, resulting in a new contract number, and we are not sure if all artifacts of the project were transferred with it. Note, the second task describes changes to the requirements that came out of our process for obtaining feedback.***

START OF EXCERPT FROM FUNCTIONAL REQUIREMENTS DOCUMENT

A. Operating Environment

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

- Two user interfaces
 - o An HTML and JavaScript browser-based front end designed for the desktop
 - o 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 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 • HTTP 1.1 • HTTPS 1.1

Software Requirements

The PHR-A has the following software requirements:

System	Requirements
Application Server	• BEA Weblogic Express 9.2 or higher • Java v5Apache Struts v2 • Hibernate v2 • C3PO • SQL*Net client / JDBC
Database Server	• Oracle 10.0.2
Desktop Client	• Internet Explorer v6/5 or • Firefox v3.5 or • 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 display.
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.
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Smartphone_1	Module Usage	The PHR-A modules must be usable on a mobile Smartphone browser	1.0	1.0
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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 new temporary password reminder to the user upon request by the user after correctly responding to a series of challenge questions	1.0	1.0
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.
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InitialSetup_1	Initial setup	They system must guide the user through an initial account setup	1.0	1.0
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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

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.
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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 brief 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 taken, to close reminder and not track compliance, or to remind again in X minutes	1.0	1.0
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
Medications_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	1.0	1.0

		automatic closing (ex. 2 days past due); delivery mechanism (ex. Web-based, text message, or email)		
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	1.0	1.0

		one was performed, and information about why it is important		
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 blocks.	1.0	1.0
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	The system must optionally allow the user to	1.0	1.0

	Options	display additional information on the graphs including medication taken information, mood data, activity data, and nutrition information		
--	---------	--	--	--

Monitoring -- Weight

Monitoring also focuses on improving a patient's well-being through proper weight management. The PHR-A's approach to weight management emphasizes 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

G. External Systems Interfaces

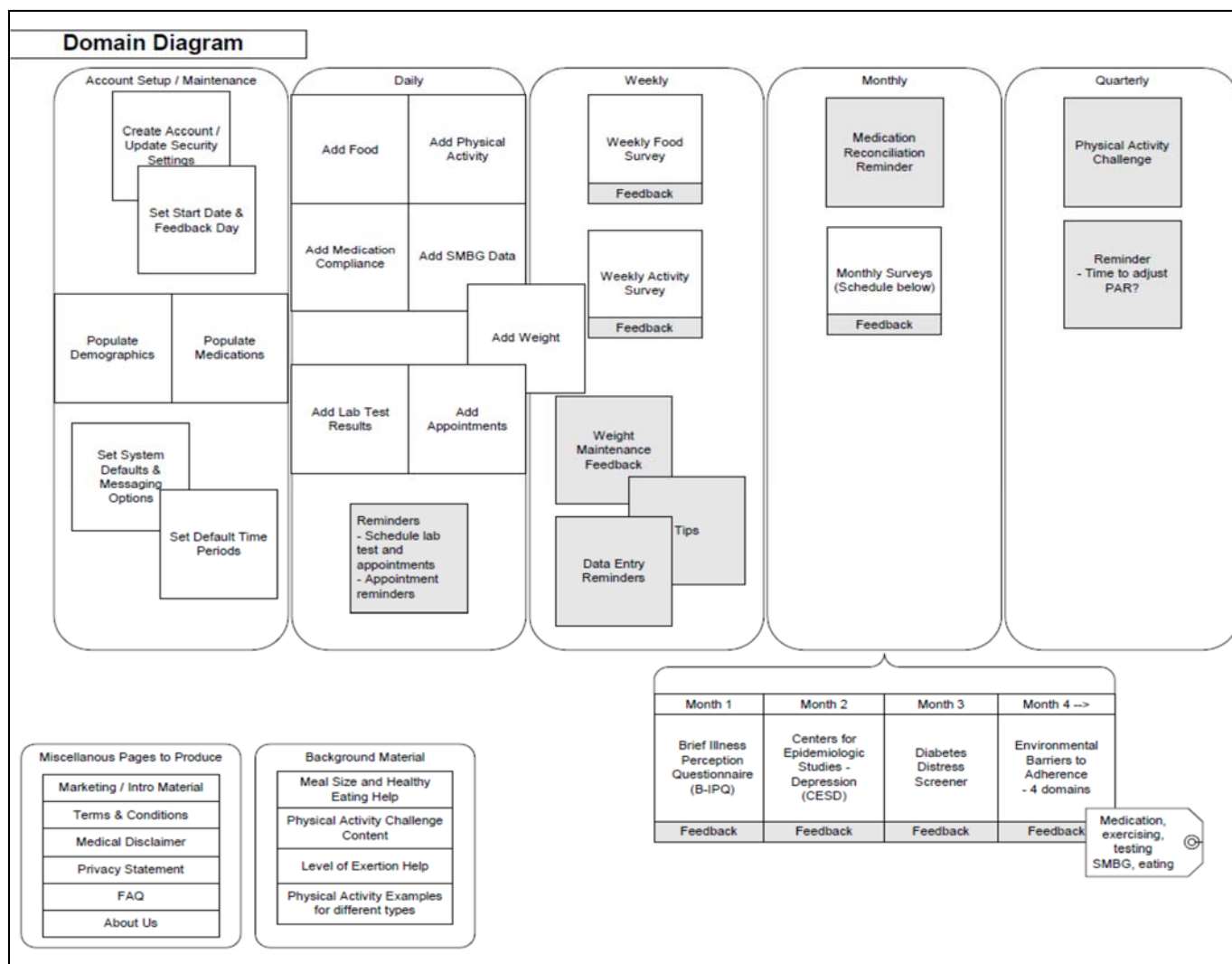
The following external system interfaces will need to be defined to interface with the Host System:

- Microsoft HealthVault

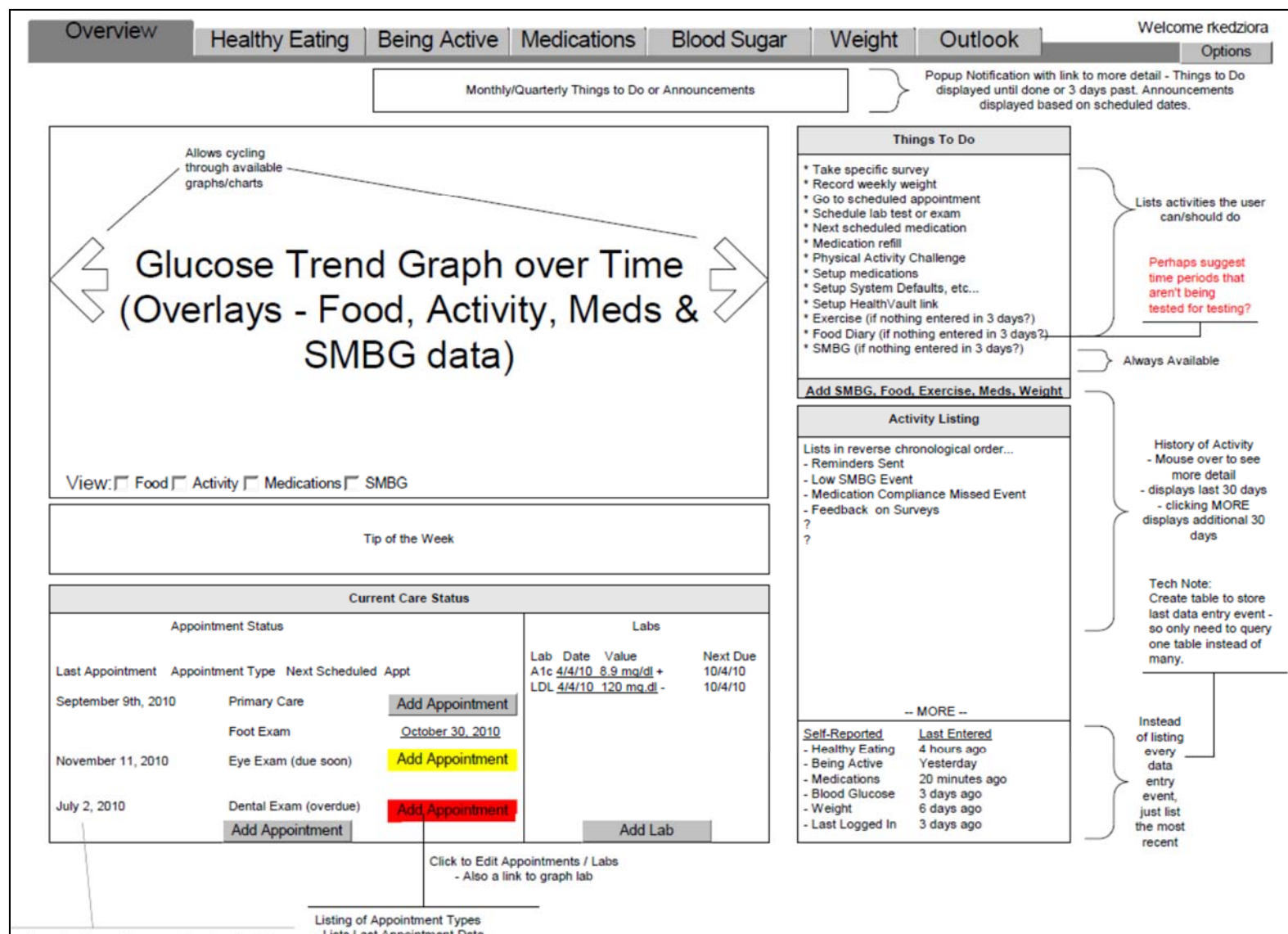
END OF EXCERPT FROM FUNCTIONAL REQUIREMENTS DOCUMENT

TASK 2: Finalize Version 1 of the Application – COMPLETE

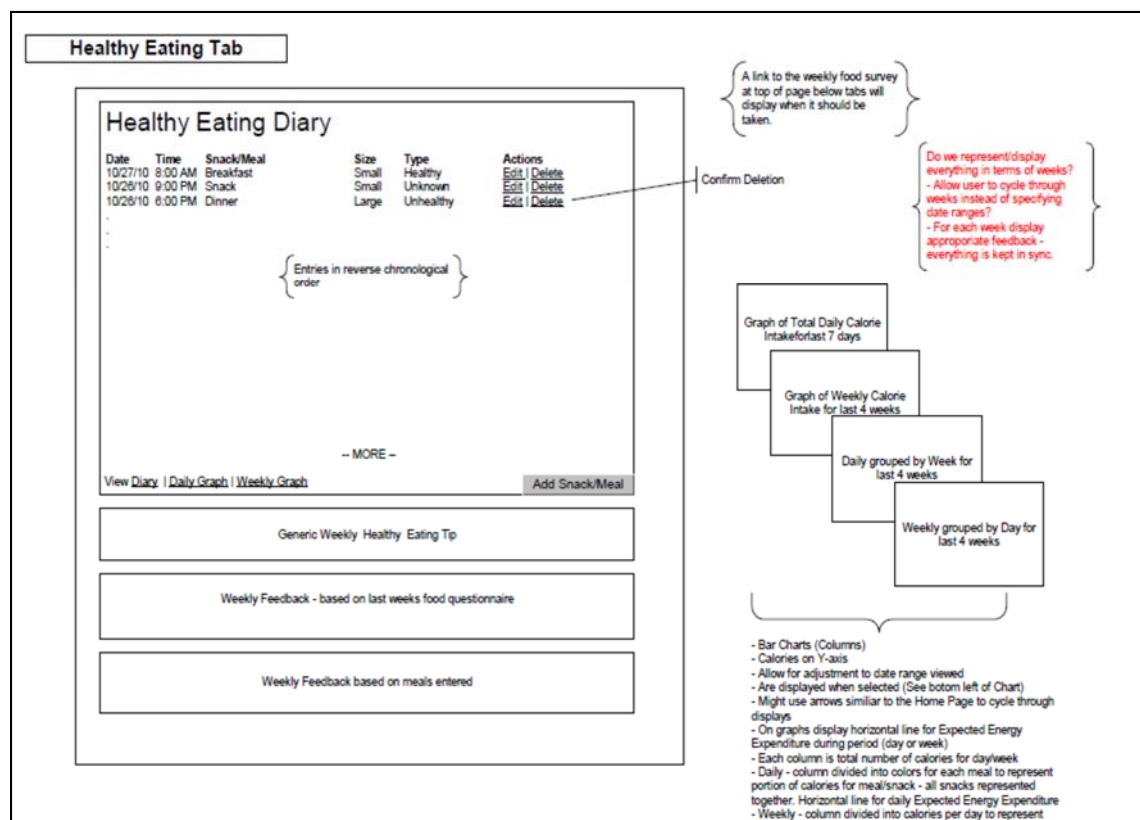
This task is complete. The next set of pages illustrates key aspects of Version 1. Note that certain features of Version 1 are now obsolete due to changes that resulted from later tasks in the project. We provide screen shots of Version 2 later in this document.



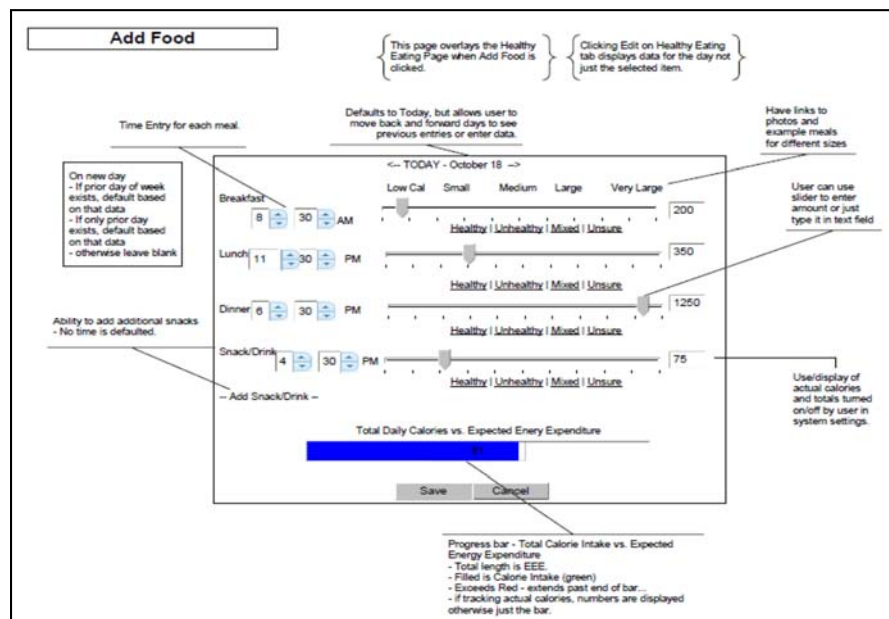
The Domain Diagram above indicates the time at which various events in the PHRA occur. For example, account set-up occurs once, and then the user can maintain/update information within this domain as needed. The entering of information pertaining to eating, physical activity, medications, etc. occurs daily. Surveys important for feedback on physical activity and healthy eating, however, take place once a week. Certain challenges built into Version 1 (and 2) occur monthly, so as to keep the user engaged. The project still needs to create disclaimer pages necessary for public distribution.

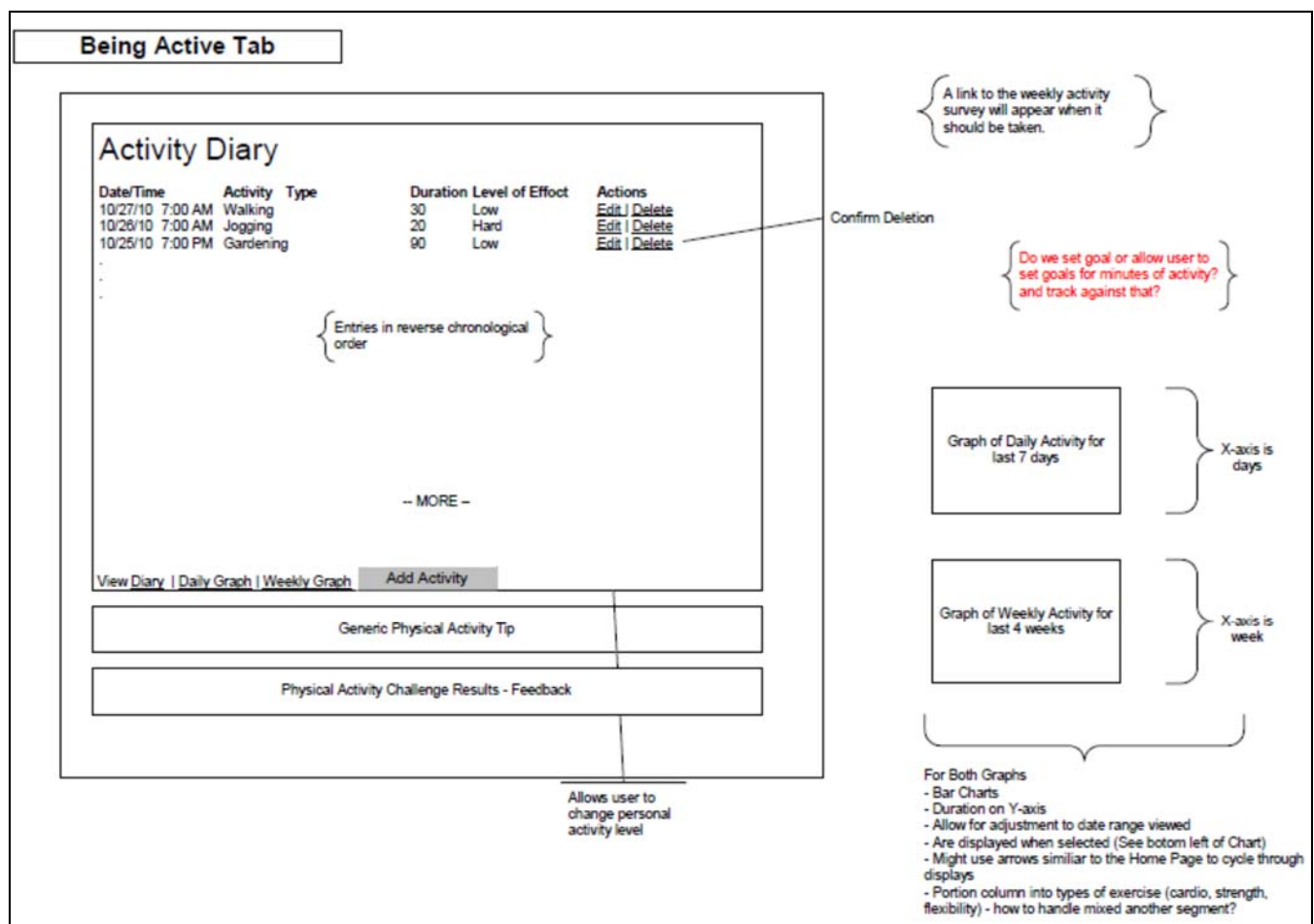


The above diagram from Version 1 shows the first page that the user (already registered) sees when logging into the application. This page or tab covers those activities considered part of 'reducing risks' (labs, appointments) as well as summary data on things to do and events within over tabs. It also displays results from monitoring -- in graphical format -- that the user can scroll through.



The Healthy Eating (above) and Add Food (below) graphics show the main features of this tab or domain within the PHRA. Note that with construction of Version 1, the emphasis on the Food Pyramid given in the Functional Requirements changed to a much simpler format. This change was driven by expert feedback.





The Being Active (above) and Add Activity (below) graphics depict the major features of the Being Active tab, which allows user to track physical activity, receive specific feedback, and review generic tips. As with Healthy Eating and compared with the Functional Requirements document, the input of physical activity was simplified in the construction of Version 1 in response to expert feedback.

Add Activity

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

Defaults to Today, but allows user to move back and forward days to see previous entries or enter data.

Have text to explain perceived level of exertion

User can use slider to enter amount or just type it in text field

Computed as user enters data

Ability to add additional activities

Cardio
Strength
Flexibility
Mixed

Type of Activity

Time of Activity

Duration

Perceived Exertion / Effort

Easy Moderate Moderate Hard Very Hard

Notes on Activity

Estimated Calories Burned: 200

Save Cancel

← TODAY - October 18 →

6 30 PM 30

200

— Add Activity —

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	Taken	Edit Medication	Remove
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

Medication Compliance Chart

Chart - Listing of medication and when taken over days (like SMBG chart)

Generic Weekly Medication Tip

Add Medication

Medication

Dosage

Frequency

Prescription Date

Days Supply

Next Refill Date

Notes

Select icons based on doctor's orders

Save

Cancel

Next Refill Date will autopopulate based on prescription date and days supply

User selects icons to display with med based on DR. orders

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 day you want to take your medication?

Wizard style panel displays to allow user to enter when they will take medications.

Selecting View Past Medications changes title and displays complete history...

Edit Medication allows altering the prescription or schedule.

The medication tab, shown at the left, is the aspect of the PHRA that allows users to track their medications – what they are taking and if they took it. They can also receive tips/reminders on medication, and can link out to education on particular medications so that they can better understand a medication's actions.

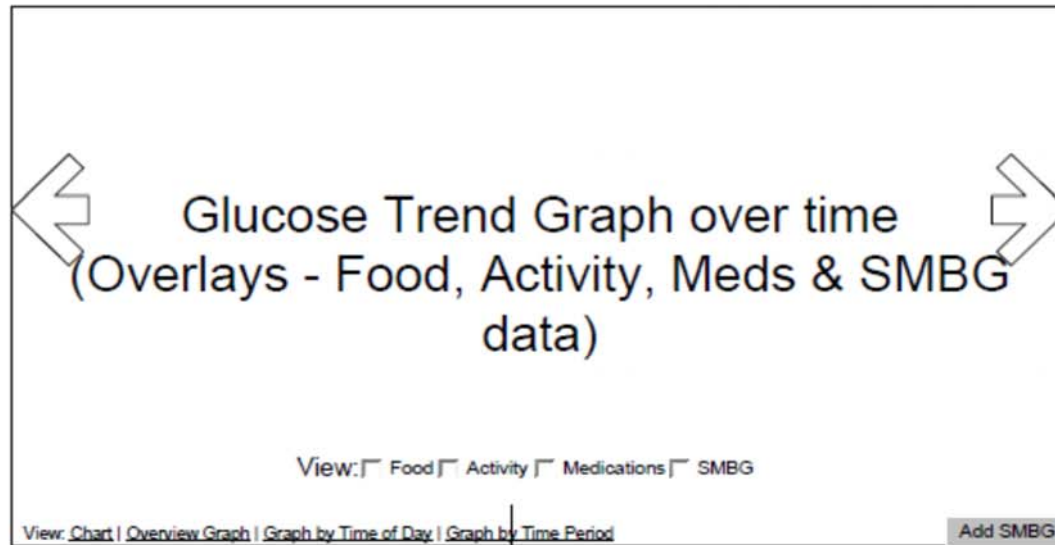
This tab does not suggest any adjustments to medications.

Also, while other medications are indeed important for diabetes management, at this time we are addressing only diabetes medications.

Previously we had an insulin dose calculator for people taking meal-time insulin, but the feedback we received led us to omit that functionality.

24

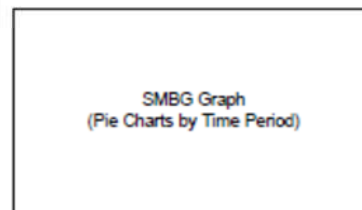
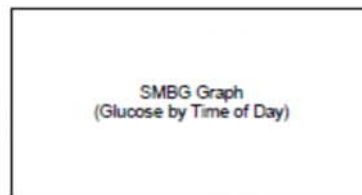
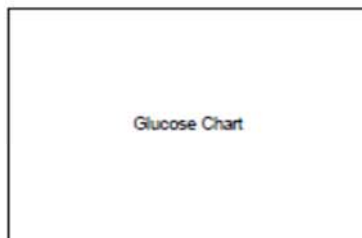
Blood Sugar Tab



Clicking arrows
displays other
graphs/charts

Clicking options
changes display

Checking options
displays data
overlaid on graph
of SMBG



} Similar
to
CDMP

This graphic displays Version 1 features for monitoring blood sugar, and the graphic on the following page displays Version 1 features for monitoring weight. Both are part of the “monitoring” concept overall. The PHRA does not provide weight loss feedback until after the user has done weight monitoring consistently for 6 weeks.

Displays UOM
based on system
parameter

Overlay -
displayed when
Add SMBG is
clicked

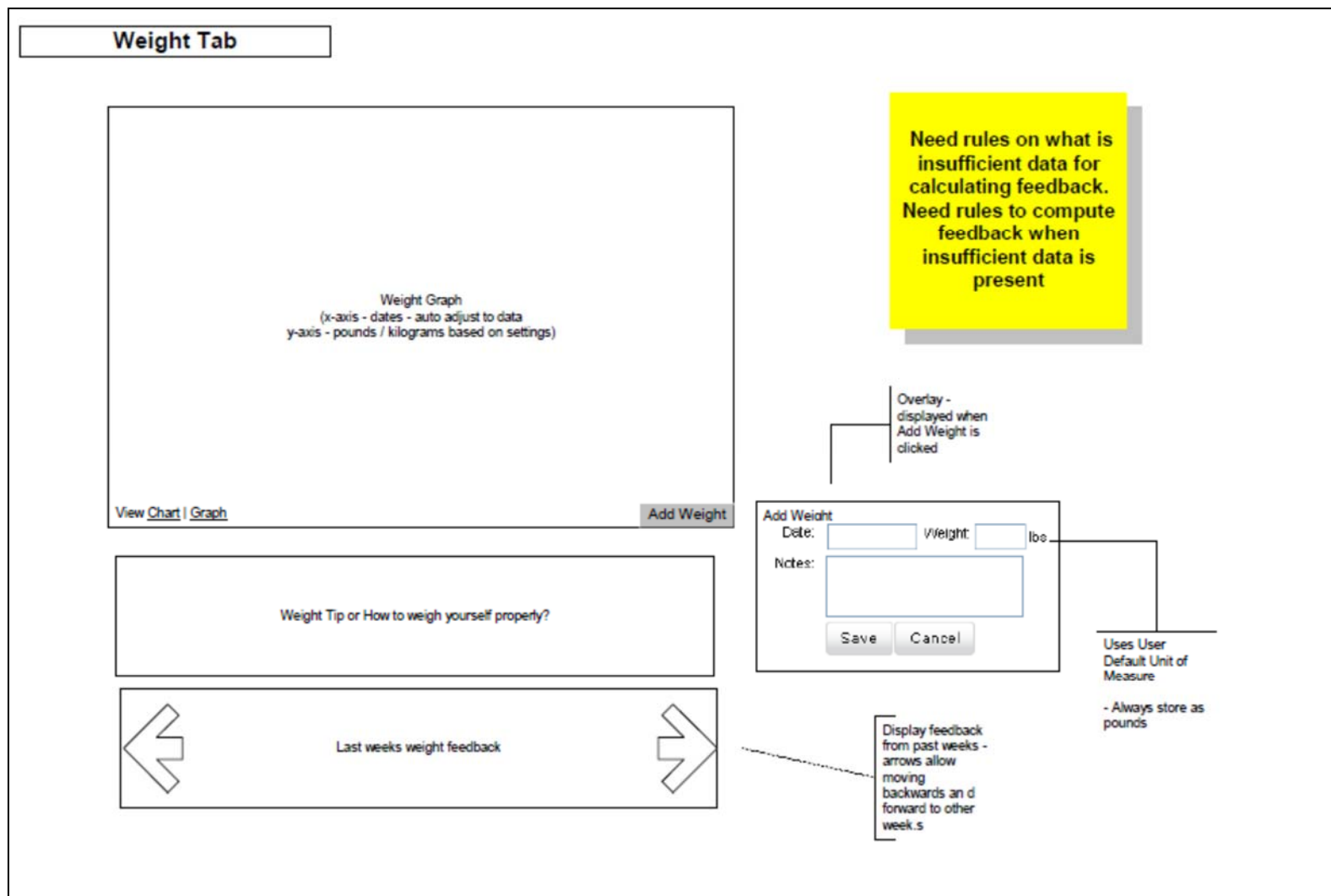
Add SMBG Panel

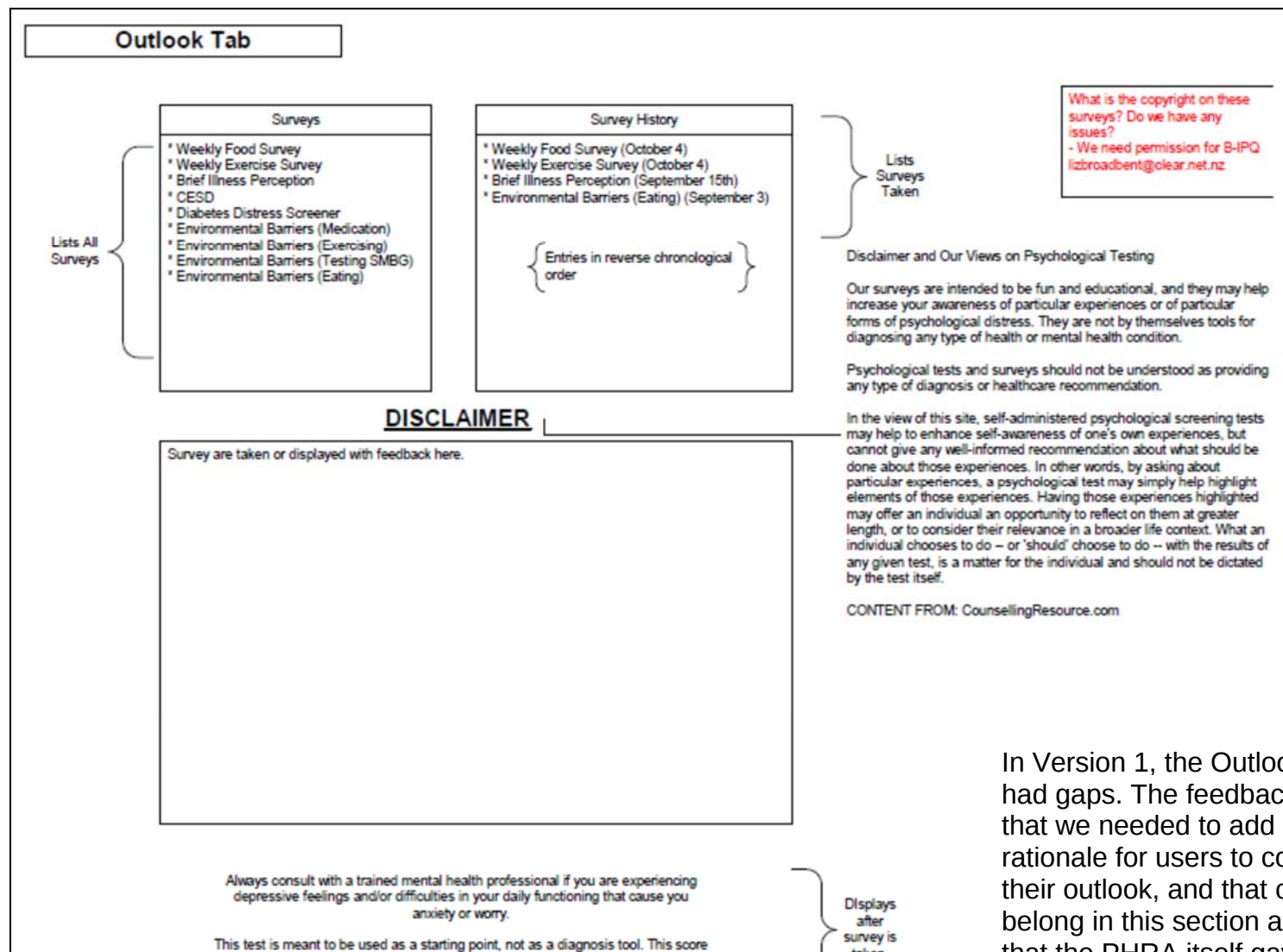
Date: Readings: mg/dl

Time: Period:

Notes:

Save Cancel





In Version 1, the Outlook tab (shown here) had gaps. The feedback we received said that we needed to add more content on the rationale for users to complete surveys about their outlook, and that certain surveys did not belong in this section at all. The feedback that the PHRA itself gave to users was insufficient. Hence, this section has changed.

User Setup / Configuration - Security Tab

Security
Demographics
System Settings
Default

Username: mjordan

Primary Email:

Secondary Email:

Password:

Confirm Password:

Security Question: ▼

Other:

Security Answer:

Save Cancel

Standard Set of Security Question.

If user selects "Other" as Security Question - this box is activated allowing the user to enter their own question.

The next set of graphics show the sections of Version 1 that allow the user to configure the PHRA to their needs and preferences. They can return to this section at any time.

User Setup / Configuration - Demographics Tab

Date of Birth: mm/dd/yyyy

Height: inches centimeters

Starting Weight: pounds kilograms

Gender: ☒ Male ☐ Female

Personal Activity Level: ▼ ?

Cell Phone Number: () -

Carrier: ▼

Zip Code:

Save Cancel

Always save as inches

Always store as pounds.

Automatically update both fields when user changes one of them.

Help Link to display details on meaning of the different levels of personal activity

User Setup / Configuration - System Settings

Default Blood Sugar Units ☒ mg/dl ☐ mmol

Weight ☒ pounds ☐ kilograms

Start week on: ▼

Days of the week ▼

Will turn on/off ability to actually enter a number.

Do you want to track actual calories consumed? ☒ Yes ☐ No

Do you want to track actual calories burned? ☒ Yes ☐ No

Do you want to receive email reminders? ☒ Yes ☐ No

Do you want to receive text messages? ☒ Yes ☐ No

Normal rates apply.

Usual warning message...

Only active if user wants to receive messages

Appointments ☒ Yes ☐ No

Labs ☒ Yes ☐ No

Medication Refills ☒ Yes ☐ No

Take Medication ☒ Yes ☐ No

Surveys ☒ Yes ☐ No

Do you want to limit the time when emails are sent? ☒ Yes ☐ No

No emails between the following hours:

11 30 PM

7 30 AM

Do you want to limit the time when text messages are sent? ☒ Yes ☐ No

No text messages between the following hours:

11 30 PM

7 30 AM

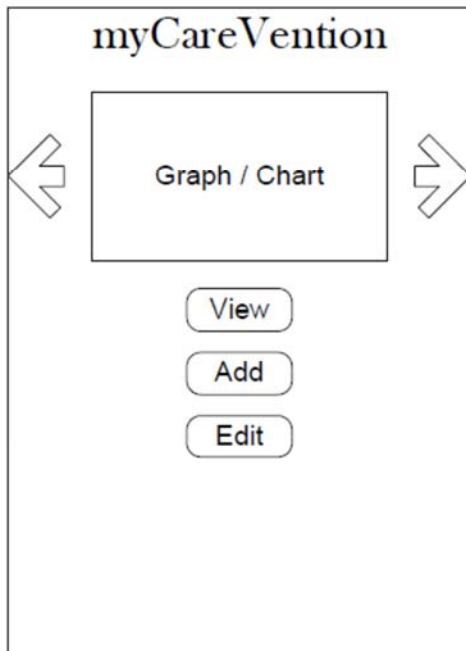
Only active if user wants to block sending emails.

Save Cancel

User Setup / Configuration - Default Time Periods

Time Period	From Time	Until Time	Glucose Lower Limit	Glucose Upper Limit
Any Day			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



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.)

Note: The PHRA is not a stand-alone application that can be downloaded from a smartphone's 'marketplace'. It is accessible via a smartphone browser – different format than the Version seen from a computer.



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

- View displays listing of items similar 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.

Task 3. Develop protocol and obtain approval from all appropriate Institutional Review Boards for User Testing of Version 1 -- COMPLETE

As mentioned in the Quarterly Report, for Task 3 we consulted with local and federal human subjects protection review experts. At that time, we learned that we did not need a formal protocol for the type of user input we are seeking, and because of the manner in which we are seeking it. The reason for this was because a) we were not formerly recruiting, b) we were not conducting “research” in the way it is defined, and c) when we received input from potential users, we did not collect any personal information from them. Indeed, the local IRB would not review a protocol that did not qualify as “research.” We instead were instead working with potential users as we would with any subject matter experts.

Using the Diabetes Institute’s quarterly publication of “In Control”, we circulated the aforementioned diabetes tips for review by content experts and people with diabetes (over 6,000 people receive this publication). We have also provided guided demonstrations of the web site to Primary Care Physicians who work with people with diabetes and obtained their feedback.

We also presented a component of this work at the Annual Meeting of the Diabetes Technology Society (November) and received useful feedback from diabetes technology experts (chiefly scientists, engineers, programmers, and social scientists). Their main criticism was that we make sure users are informed that the “decision support” the PHR-A gives them could (although not necessarily) contain errors just because it contains thousands of lines of computer code. As such, everything the PHR-A tells the user must include that disclaimer and urge them to use their own common sense as well. Further, the comments focused on the low literacy and numeracy levels of the U.S. population (as indicated by research presented at the same panel) and the need to insure that the PHR-A is “pitched” toward those low levels so as to make it as accessible as possible to a wide variety of people.

We have been incorporating these and other suggestions. We changed the name of the application as part of these changes – Tracking My Diabetes.

TASK 4. Test Version 1 of the Application, incorporate user feedback, and finalize a Version 2 --COMPLETE

Due to the cessation of TRUE Research Foundation activities 1 April 2011, and the ensuing 4-month hiatus in the life course of the project, completion of this task was delayed. However, we have now completed this task. The next series of pages shows what Version 2 looks like. To see the ‘live’ application, register at: <http://www.trackingmydiabetes.com/>.

The following gives instructions for getting into and using the application.

Create an account. You will select a user name and password. An email message will be sent to you, to confirm and initiate the account.

Once you have an account, enter your name and password and log in. Logging in will open to the Overview page.

Tracking My Diabetes

Username Password

Forgot password? Login

Providing actionable advice about daily living

Improving your overall health and well-being

Create an Account Today!

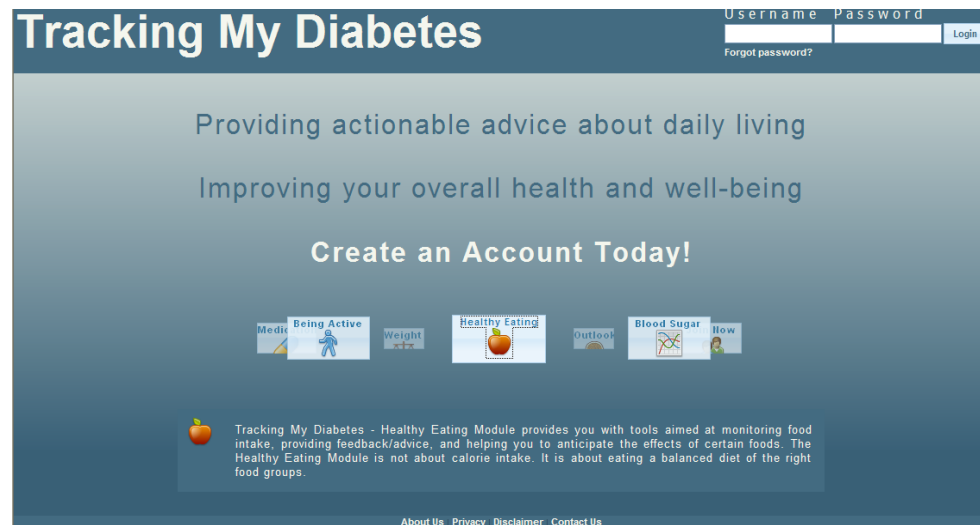
Medication Being Active Weight Healthy Eating Outlook Blood Sugar How

★ Click the images above to learn more!

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3. Before leaving the home page and/or logging in, you can click each of the images to learn more about the different components of effective diabetes self management.

For example, selecting Healthy Eating opens a text box that tells you what you can expect to find about the effect of certain foods on blood sugar, portion sizes, and healthy food choices.



After creating an account and gaining access to TMD, you will be asked for some basic information about you to get your started. TMD functions best with as much information as possible about you, but you can get started by entering very little at first and completing your profile as you go. Mousing over the question mark for activity level will explain what is meant by the various options.

The screenshot shows a 'Default Settings' form within the TMD application. The form is titled 'Default Settings' and has a subtitle 'Welcome to Tracking My Diabetes! Please enter the following information to help us get started.' It contains several input fields: 'Date of Birth' with dropdowns for 'Month', 'Day', and 'Year'; 'Height' with input fields for '67' and '170.18' and units 'inches' and 'centimeters'; 'Current Weight' with input fields for '139' and '63.2' and units 'pounds' and 'kilograms'; 'Gender' with radio buttons for 'Male' and 'Female' (where 'Female' is selected); and 'Personal Activity Level' with a dropdown menu showing 'Active' and a question mark icon. At the bottom of the form are 'Save' and 'Cancel' buttons. The form is set against a background that shows parts of the 'Overview' and 'Things To Do' pages.

After logging in, you will be at the overview page. See screen shot below. The overview page covers the 'meta' data of the application – listing the things you are due to do, the things you have done, and upcoming medical appointments. It also includes a rotating tip of the week, selected at random from the sub-categories of diabetes self-management. If you wish to pull your pertinent data from HealthVault into TMD, you can do it here by clicking the HealthVault button.

Tracking My Diabetes

Welcome mswalker (Settings | Logoff)
Last sign in: 09/20/2012 at 12:03 PM

Overview
Healthy Eating
Being Active
Medications
Blood Sugar
Weight
Outlook

Overview

Welcome to Tracking My Diabetes!

Add SMBG
Food
Activity
Medication
Weight

Tip of the Week

Burnout happens. It happens when you get tired of sticking to your regular routine of checking blood sugars, exercising, and eating right. One way to deal with burnout is to give yourself a break. Some days will be better than others. Try to learn from your mistakes instead of beating yourself up.

Things To Do

Brief Illness Perception (B-IPQ)
Exercise week 1
Add Appointment
Add LDL Lab
Add A1C Lab
Add Physical Activity
Add Snack/M meal
Add Medication
Add Weight
Add SMBG

Add SMBG | Food | Activity | Medication | Weight

Activity Listing

No Activity Listings Exist.

Appointments

Last Appointment	Appointment Type	Next Scheduled Appt
Not Entered	Dental Exam	Add Appointment
Not Entered	Eye Exam	Add Appointment
Not Entered	Foot Exam	Add Appointment
Not Entered	Primary Care	Add Appointment

Labs

There are no labs entered. Please enter your most recent lab values so we can generate accurate feedback and advice.

Add Lab

Self Reported	Last Activity
Overview	Never
Healthy Eating	Never
Being Active	Never
Medications	Never
Blood Sugar	Never
Weight	7 days ago.

Microsoft
HealthVault

Help

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Making and keeping regular screening exams is an essential part of preventing the complications of diabetes! To add an appointment, look at the lower left half of the Overview page, Appointments provides a space for you to record the dates of your last dental, eye, foot and primary care appointments. Clicking on Add Appointment brings up a box for you to enter the specifics.

Add Appointment

* Type:
Type

* Date/When:
Time:
HH
MM
AM

* Who:

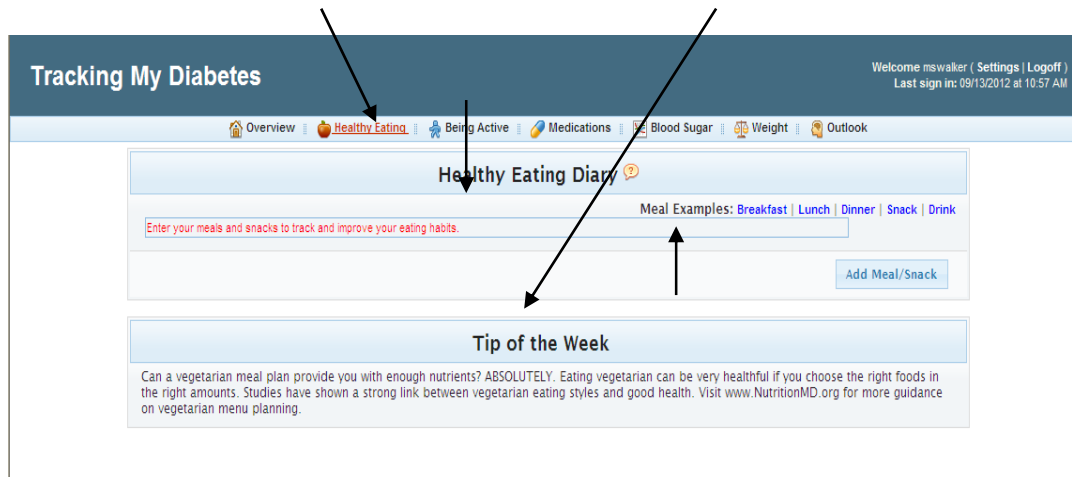
* Where:

Notes:

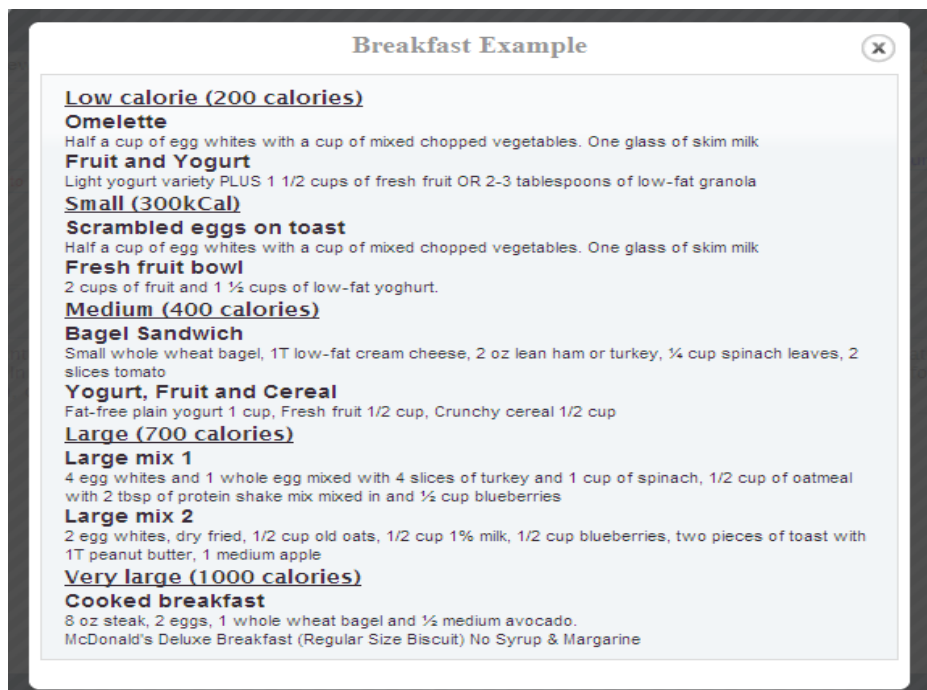
Save
Close

35

Selecting Healthy Eating from the overview page opens up your Healthy Eating Diary and displays the Tip of the Week.



Selections under Meal Examples display sample meal plans and calories. The purpose of this is to help you in completing your Healthy Eating Diary, which is intentionally simple, asking only for which meal, the approximate size of the meal, and whether you thought it was healthy or not (or mixed).



Clicking Add Meal/Snack opens up to a page with the current date and space to record the time that you ate, the amount that you ate (small, medium, large, very large), and whether it was healthy, unhealthy, mixed, or you are not sure.

Add Meal/Snack

Thu, 27 Sep, 2012

Breakfast AM ☐ Healthy ☐ Unhealthy ☐ Mixed ☐ Unsure

Lunch PM ☐ Healthy ☐ Unhealthy ☐ Mixed ☐ Unsure

Dinner PM ☐ Healthy ☐ Unhealthy ☐ Mixed ☐ Unsure

Snack/Drink PM ☐ Healthy ☐ Unhealthy ☐ Mixed ☐ Unsure

Add Snack/Drink

% of Calories Consumed Based on Expected Daily Calorie Burn 0 %

Save **Close**

Select Add Snack/Drink to open up additional space to document additional snacks or drinks. Select save after each entry and close when you are finished.

Tracking My Diabetes

Welcome mswalker (Settings | Logoff)
Last sign in: 09/20/2012 at 12:03 PM

Overview Healthy Eating Being Active Medications Blood Sugar Weight Outlook

Overview

Welcome to Tracking My Diabetes!

- Add SMBG
- Food
- Activity
- Medication
- Weight

Tip of the Week

Burnout happens. It happens when you get tired of sticking to your regular routine of checking blood sugars, exercising, and eating right. One way to deal with burnout is to give yourself a break. Some days will be better than others. Try to learn from your mistakes instead of beating yourself up.

Things To Do

- Brief Illness Perception (B-IPQ)
- Exercise week 1
- Add Appointment
- Add LDL Lab
- Add A1C Lab
- Add Physical Activity
- Add Snack/M meal
- Add Medication
- Add Weight
- Add SMBG

Add SMBG | Food | Activity | Medication | Weight

Activity Listing

No Activity Listings Exist.

Selecting Outlook will open up to a page that includes the tip of the week and several surveys that you can take. You will be prompted monthly to complete a survey, but you can choose to take one at any time as well. The surveys ask questions about what you find difficult about the various diabetes self care tasks like testing your blood sugar or taking your medications. There are also surveys that ask what you believe about diabetes and how your mood has been. When you complete a survey, you will be given specific feedback that is intended to encourage you and/or provide suggestions about how to cope with problems you might be facing. A list of the surveys is on the next page.

[Overview](#)
[Healthy Eating](#)
[Being Active](#)
[Medications](#)
[Blood Sugar](#)
[Weight](#)
[Outlook](#)

Tip of the Week

Burnout happens. It happens when you get tired of sticking to your regular routine of checking blood sugars, exercising, and eating right. One way to deal with burnout is to give yourself a break. Some days will be better than others. Try to learn from your mistakes instead of beating yourself up.

Surveys You Can Take

Survey	Text
Food Survey	This is your a brief, weekly survey of your diet during the past week. The surveys differ from week-to-week. They all help to structure the feedback that you receive about healthy eating.
Exercise Survey	This is your a brief, weekly survey of your physical activity during the past week. The surveys differ from week-to-week. They all help to structure the feedback that you receive about your physical activity.
Brief Illness Perception (B-IPQ)	This is a short survey that asks about your beliefs about diabetes. Often the beliefs we have about our health affect how we take care of ourselves. The survey has 6 questions.
Epidemiologic Studies – Depression (CESD)	This next survey asks about how your mood has been lately. Sometimes our mood affects how we take care of ourselves, and sometimes how we take care of ourselves affects our mood! So it is important to know what are mood is like. There are 20 questions about how you have felt and behaved during the last week.
Diabetes Distress Screener	Living with diabetes can sometimes be tough, with lots of hassles and problems that come and go. This next survey asks about things about your diabetes that might have bothered you during the past month. If you feel that a particular item is not a bother or problem for you, choose '1'. If it is very bothersome to you, choose '6'
Environmental Barriers (Medication)	Taking medications can be an important part of diabetes care. The next his survey is to identify any problems you might be having taking medications as prescribed.
Environmental Barriers (Exercising)	Exercise is important for lowering or maintaining weight, improving cardiovascular health, and lowering blood sugar. This survey is to identify any obstacles to exercise that you might have.
Environmental Barriers (Testing SMBG)	Testing your blood sugar can tell you and your health care provider about how your medications are working, how the food you eat affects you, and how the exercise you do helps you. So testing your blood sugar is important! This survey is to see if you have any problems with testing your blood sugar, and what those problems are.
Environmental Barriers (Eating)	This survey asks about any problems you might have eating the way you think you should, or sticking to your diet plan. It asks about such problems because what and how much you eat might affect your diabetes more than anything else you do.

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If you place your mouse on and double click a survey, it will open for you to complete. The example below shows what happens when we click on the survey named Brief Illness Perception (B-IPQ).

Brief Illness Perception (B-IPQ)

Tracking My Diabetes

Welcome mswalker (Settings | Logoff)
Last sign in: 09/28/2012 at 11:00 AM

Overview Healthy Eating Being Active Medications Blood Sugar Weight Outlook

We want to know what your beliefs are about your diabetes. Often the beliefs we have about our health affect how we take care of ourselves. We are going to ask you questions.

For the following questions, please choose the number that best corresponds to your views. Choose from a scale of 0 to 10, with 0 being 'no effect at all, none, or not at all' and 10 being 'severely, extremely, or a lot'. For question 2, 0 means 'not very long' and 10 means 'forever.'

1. How long do you think your diabetes will continue?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
2. How much control do you feel you have over your diabetes?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
3. How much do you think your treatment can help your diabetes?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
4. How much do you experience symptoms from your diabetes?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10
5. How well do you feel you understand your diabetes?
☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

Save Cancel

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Tracking My Diabetes

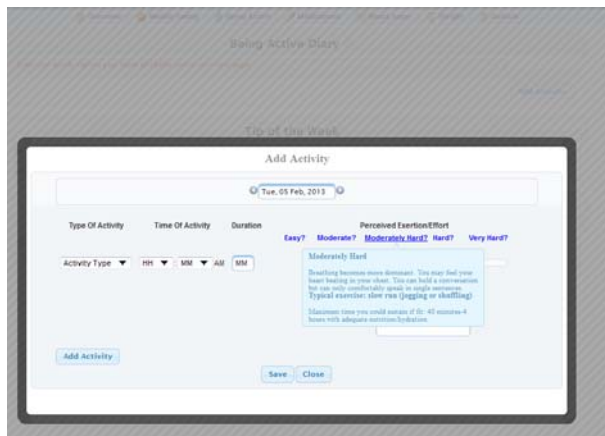
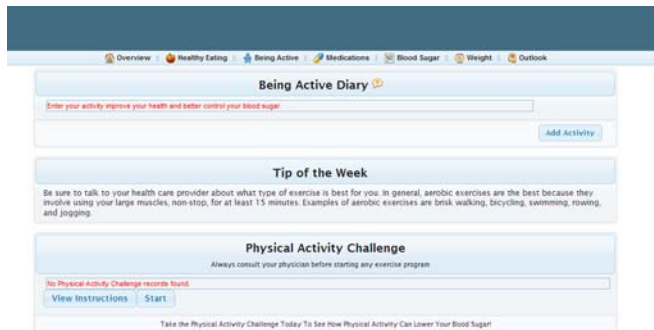
Welcome mswalker (Settings | Logoff)
Last sign in: 09/28/2012 at 11:20 AM

Overview Healthy Eating Being Active Medications Blood Sugar Weight Outlook

Surveys You Have Taken

Date/time	Survey Taken	Action
09/28/2012 12:32 PM	Brief Illness Perception (B-IPQ) (September 28, 2012)	View Feedback

The Being Active tab has a format and function similar to the Healthy Eating tab in that it is intended to be simple for you to use, allows you to enter activity you do with a self-rating of exertion, gives feedback on the data that you enter, and provides a tip of the week. The two screen shots below show, first, the first page of the Being Active tab and, second, the box for entering activity.



The Being Active tab also includes monthly physical activity challenges, to keep you interested and 'on your toes', and to show the relationship between physical and activity and blood glucose, among other things. You will be prompted to complete these regularly. You can choose to ignore them, if you wish.

Every week, you will also be asked to complete brief surveys (about 5 questions) about your diet and physical activity.

The Medications tab allows you to enter the *diabetes* medications that you are taking so that you can track (such as on your smartphone) when you take them and can receive reminders and education about medications. This functionality is shown in the next two graphics. The Medications tab also includes a tip of the week.

Overview | Healthy Eating | Being Active | Medications | Blood Sugar | Weight | Outlook

Medications

Enter your medications to track and improve your health

Add Medication

Medication Tip of the Week

Take the time to make a list of your medications, including those for your diabetes and other medications as well. For each pill write the name, dose, when and how often you are supposed to take it and the reason for each medication. Show the list to your pharmacist and talk with him/her about the side effects of your medications and whether or not they can be taken together. Remember to always carry the list with you, especially when you go to any of your healthcare appointments.

Medications

Enter your medications to track and improve your health

Add Medication

* Medication:

* Dosage:

* Frequency:

* Prescription Date:

* Days Supply:

* Next Refill Date:

Notes:

Select eating based on doctor's orders

☐ Food ☐ Water

Save Close

The last tab we will show you is the Blood Sugar tab. You can either upload your meter readings via Microsoft HealthVault, if you have an account there, or you can enter your readings one at a time.

Overview | Healthy Eating | Being Active | Medications | Blood Sugar | Weight | Outlook

Blood Sugar

Enter your Blood Glucose to track and improve your health

Add SMBG

Blood Sugar Analysis

Range: ☐ By Date ☐ By Date 7 Days

No Blood Sugar data analysis for selected period.

Add Blood Sugar

* Enter the Date:

* Reading:

* Enter the Time:

Notes:

Save Close

Once you have self-monitoring (SMBG) data in TMD, you will be able to look at graphs of your glucose trends (highs, lows, etc.) and will be able to overlay (with a graph) your trends on your Food Diary, Activity Diary, and Medications Log to see how those components of diabetes self-care affect your blood sugar.

As with the other tabs, the Blood Sugar tab includes a tip of the week.

For now, we are not reviewing the functionality of the Weight tab, since we don't want you to address weight until you have used TMD for at least 6 weeks and recorded your weight every week as prompted.



TASK 5. Develop protocol and obtain approval from all appropriate Institutional Review Boards for Pilot Study of Version 2 PHR-A – NOT COMPLETED

In May 2011, with the cessation of operations at TRUE Research Foundation, we submitted at revision to the Statement of Work through the Geneva Foundation. This was necessary to a) transfer the remaining funds and b) to adjust to the reduction in budget that was “lost” (never spent by the project) at TRUE. The Revisions to the Statement of Work pertain to Tasks 5 – 7. The revision was approved in August when the funds were officially transferred to Geneva.

In brief, we proposed to modify the study design of the Pilot. These changes included:

- 1) Reduce duration of the study from 6 months to 3 months. Three months is the minimum period to observe clinically meaningful changes in diabetes-related outcomes, namely A1c.
- 2) Reduce the sample size from 90 (45 per arm) to 32 per arm. This estimate is based on the following assumptions: alpha = 0.05 (two-sided); power = 0.80, mean decline in A1c for PHR-A group = 1.0 (sd = 1.0); mean decline in A1c for attention control group = 0.5 (sd = 0.50); n2/n1 = 1.00; number of follow-up measurements = 1; number of baseline measurements = 1; correlation between baseline & follow-up = 0.60; method of analysis = change.

Although a larger sample size (e.g., the one originally proposed!) would have been our preference given how important larger samples are for statistically controlling for certain subject characteristics (e.g., age, type of diabetes, etc.), this smaller sample is sufficient for a basic test of the hypotheses and is consistent with related studies, such as that

published in *Diabetes Technology and Therapeutics* regarding a mobile diabetes application called “WellDoc” (Quinn et al.. WellDoc™ Mobile Diabetes Management Randomized Controlled Trial: Change in Clinical and Behavioral Outcomes and Patient and Physician Satisfaction. *Diabetes Technology and Therapeutics* 2008; 10: 160-168.).

3) Require that all study participants have their own smart phones or that they will access the application via an Internet-connected computer.

In brief, for the Pilot Study, we were going to recruit people with diabetes and randomly allocate them to use the PHR-A for 3 months or to ‘attention control.’ After confirming eligibility using some simple tests of manual dexterity and cognitive function, we were going to 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 were going to repeat collection of A1c, self-monitoring of blood glucose data, SDSCA, and PAID, and 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 were going to analyze the data with t-tests, repeated measures ANOVA, and multinomial logistic regression models.

With this revised Pilot Study in mind, we wrote the protocol documents for submission at Womack at Fort Bragg in NC. Our contact there was Dr. Laura Bowers. We submitted a Revision to the Statement of Work at the end of the Period of Performance to conduct the study at Womack, and this was approved by TATRC.

Then the project hit two substantial roadblocks. First, the full transfer to Womack never occurred, because their leadership changed their minds. So we elected to move the study back to Walter Reed, despite problems with our local IRB and the challenges of having many clinical trials running concurrently in the same clinic.

Soon after the decision to move the study back to Walter Reed, Dr. Vigersky, the founder, director, scientific leadership of the Diabetes Institute at Walter Reed announced that he would be leaving the military and will no longer be able to participate in this project. In conjunction, other members of the Diabetes Institute were set to relocate to other departments within Walter Reed, primarily due to funding concerns and the changing of the structure of the Diabetes Institute. Thus, the team to support this project by identifying potential subjects, assisting with paperwork, providing space for appointments, etc. was drastically cut.

The new director of the Diabetes Institute indicated that she was unable to oversee all the projects currently ongoing or planned for the Diabetes Institute.

Dr. Fonda and other Geneva staff determined, therefore, that the best course of action is to close down the project and return unexpended funds.

TASK 6. Initiate and maintain Pilot Study through Completion—NOT COMPLETED

This Task was dependent on the preceding task and not completed.

TASK 7. Prepare reports and manuscripts for presentation at national meetings regarding the technology and our findings from the Pilot Study—NOT COMPLETED

This Task was dependent on the preceding task and not completed.

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, leading to a Version 1
- Drafting of over 200 tips that pertain to each component of the PHR-A
- Documentation of code establishing linkages between the PHR-A and a PHR – Microsoft HealthVault only
- Solicitation of and receipt of feedback on the PHR-A from experts, namely people who care for people with diabetes and people who have diabetes
- Revision of the PHR-A (feedback, surveys, tips, introduction to each section and task), leading to a Version 2
- Transfer of funds from TRUE Research Foundation to the Geneva Foundation, with re-establishment of sub-contracts, etc.
- Establishment of a final site for the Internet “presence” to host the PHR-A and a new name, called Tracking My Diabetes-- <http://trackingmydiabetes.com>
- Revision to the design of the Pilot Study, to better fit the reduction in budget and time resulting from the cessation of operations at TRUE Research Foundation
- Presentations about the PHR-A at national meetings
- Further revision of a pilot study – but this was not completed. The documents are available for use by someone with adequate financial, clinical, and research support.

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 (such as Microsoft HealthVault), lack decision support, or some combination of these things. A new tool for diabetes care that can be mobile, if desired, 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 called Tracking My Diabetes (TMD). For the Pilot Study, our central hypothesis is that a PHR-A (TMD) 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 in this project are to develop a new PHR-A for diabetes self-management, to obtain feedback 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 and then experienced a cessation of operations from April to August 2011 when TRUE Research Foundation declared bankruptcy. However, we have completed ALL development and have written a revised research protocol for the proposed Pilot Study, to be conducted at Womack, all things going as planned. In the coming year, we plan to conduct the Pilot Study.

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APPENDICES:

None.

SUPPORTING DATA:

None.