

Virtual Health Research: Results of a Feasibility / Usability Assessment for Diabetic Remote Home Monitoring

TATRC has partnered with key leaders from the Patient Centered Medical Home (PCMH) and an extramural partner, the Clemson University Department of Public Health Services on a multi-phased research project funded by the Joint Program Committee (JPC-1) to monitor diabetic patients in their homes using patient's personal cell phones, and home bio-sensors. The primary goal of this research project is to improve the capabilities of current mHealth technology for use in the PCMH environment, and to provide chronic care patients (i.e. Type-2 diabetes) the capability to improve self-management of their disease.

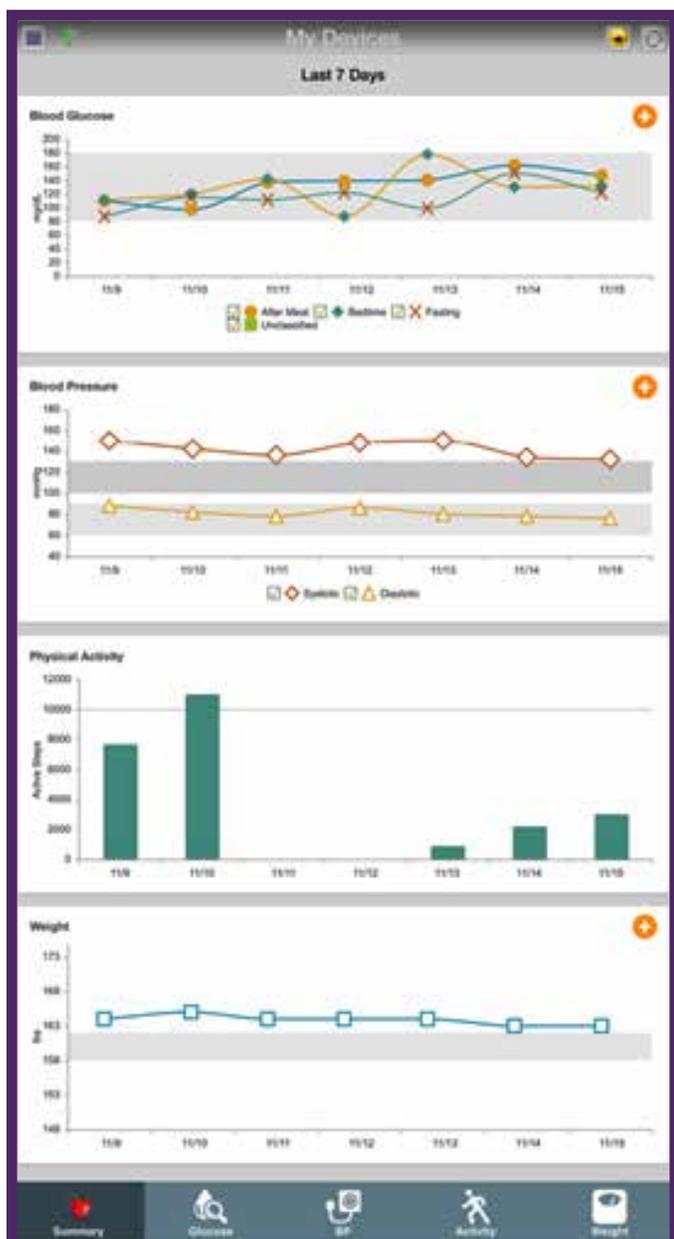


Figure 1. Patient 7-Day Summary View on a Mobile Device

Both the mobile application and the web-based portal allow for home monitoring data to be viewed as a seven-day summary (see Figure 1), comparing blood glucose, blood pressure, activity and weight. In addition, each data type can be viewed as a single day, a seven-day or a 30-day view. Patients can add notes to their readings on their mobile devices, and providers can roll

Class	Type	Alert Text	Alert Date	View	Action
Yellow	Red	***** has entered a Blood Glucose > 300 mg/dL.	2/7/2017	View	Archive
Yellow	Red	***** has entered Blood Glucose > 200 mg/dL for > 24 hrs.	2/7/2017	View	Archive
Yellow	Red	***** has entered a Blood Glucose < 100 mg/dL at bedtime	2/7/2017	View	Archive
Yellow	Red	***** has entered a Blood Glucose < 70 mg/dL.	2/7/2017	View	Archive
Yellow	Purple	***** has entered a Systolic BP > 180 mmHG.	2/7/2017	View	Archive
Yellow	Purple	***** has entered a Diastolic BP > 110 mmHG.	2/7/2017	View	Archive
Yellow	Red	***** has entered a pulse rate > 100	2/7/2017	View	Archive
Yellow	Red	***** has entered a pulse rate < 60	2/7/2017	View	Archive
Yellow	Yellow	***** has had a weight gain > 5 lbs. in 1 week	2/7/2017	View	Archive
Grey	Green	***** has had No Active Readings in last 48 hrs.	2/7/2017	View	Archive

Figure 2. Case Manager Alerts on the Portal View

over the data points on the graphs to view the notes, or access them in a text-based summary below the individual graphs via the web-based portal. Both patients and providers can sort the graphs by turning on and off data elements, so they can quickly see trends such as blood glucose levels before and after meals, in isolation, or as a comparison. Safety mechanisms are embedded into the system, alerting patients to either treat incidences of dangerously low or high blood glucose levels, or seek medical assistance with sustained high blood pressure readings. These interface features were designed by TATRC, based on an assessment of industry best practices, input from clinical champions in the PCMH community, and actual patients.

To validate these features, it was important to have users engage with the Virtual Health software in a systematic fashion, so that any end user issues could be identified, refined and resolved prior to launching a larger scale deployment. Phase 1 of this research project focused on this feasibility and usability assessment; where consenting patients and providers were introduced to software features. Patients also reviewed the FDA-approved home monitoring devices: a glucometer, blood pressure cuff, and weight scale.

Members of the research team were onsite at Nellis Air Force Base (AFB), Las Vegas, NV in mid-November 2016, where they conducted focus group assessments with patients and health care team members. These focus groups interacted with the equipment and graphical user interfaces developed for this pilot research project. Users were systematically asked to complete specific tasks with the application, and their engagement and reaction to the system features was noted by the researchers. Patients were also asked to complete a validated instrument, known as the System Usability Scale (SUS), to quantitatively assess the user interface. Identical group interviews were completed at Madigan Army Medical Center (MAMC) in

Tacoma, WA at the beginning of December 2016.

In January 2017, a multi-disciplinary research team completed an analysis of the Phase 1 effort; looking at the feasibility and usability of the current system features in accordance with PCMH user design principles and clinical workflow integration. The qualitative focus group data was organized into themes, and the SUS scores were analyzed against published scoring benchmarks for mobile technology interfaces to determine the refinements and adjustments that will be implemented prior to launching the Phase 2 study with 240 patients from the PCMH communities at Nellis AFB and MAMC.

Results of the quantitative scoring revealed that the usability factor of patient facing system features scored in the 99.8% percentile against published benchmarks for mobile devices as shown in Figure 4.

mHIC Research Program Manager, Ms. Amanda Schmeltz

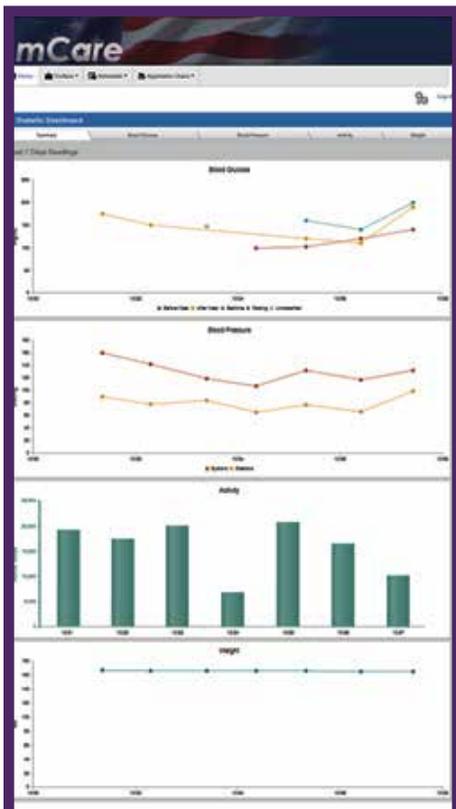


Figure 3. Provider - 7 Day Summary – Portal View

remarked that “while we felt the application was already intuitive and well thought out, the overwhelmingly positive feedback by end-users during Phase 1 testing, was both encouraging and validating of a project that has been under careful development for over two years. We can’t wait to deploy the final product for the large scale second phase randomized controlled trial.”

From a qualitative perspective, the major themes from the structured focus group interviews revealed:

- 100% of Phase 1 participants felt that the mobile app and home monitoring devices would help them manage their diabetes.
- 100% of these patients felt that the mobile app would give their healthcare provider a better report of what’s going on with their health.
- Clinicians were pleased with the mCare system and optimistic about both the backend portal and the patient application.
- Requests for alterations and additions to both the application and the provider portal were minimal and mainly aesthetic (e.g larger interactive buttons, color changes).

As a result of the Phase 1 analysis, minor adjustments are currently being implemented for both the patient and provider interfaces to this remote home monitoring project. mHIC Lab Manager, Ms. Jeanette Little, stated, “Once completed in the Spring of 2017, Phase 2 of the research project will explore the technical feasibility for 240 patients focused on improving the activation, quality of life, and clinical indicators of PCMH-empaneled complex diabetic patients. Outcomes for Phase 2 will evaluate self-management behaviors, medication adherence, patient satisfaction, quality of life, clinical measures, system usability, and usage statistics and will provide valuable lessons learned for the future of patient monitoring between clinical encounters.”

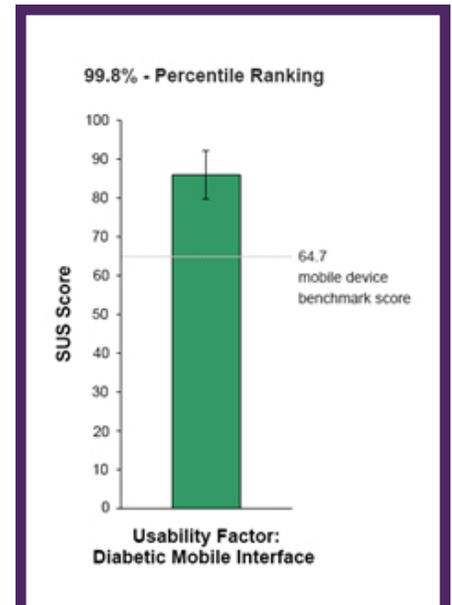


Figure 4. Phase 1 SUS Usability Factor Score