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TITLE: Enhancing mHealth Technology in the PCMH Environment to Activate Chronic Care Patients

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CONTRACTING ORGANIZATION: Clemson University
Clemson, SC 29634

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14. ABSTRACT - The potential of mobile health (mHealth) technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques including web-based portals, tailored behavioral text messaging, remote collection of biometric data, electronic coaching, electronic-based health education, secure e-mail communication between visits, and electronic collection of lifestyle and quality of life surveys. Each of these tools, used alone or in combination, have demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices, tailored behavioral messaging, secure e-mail communication with clinical teams, and regular reporting of quality of life variables. In this study, we seek to incorporate several of the most promising mHealth capabilities in a patient centered medical home (PCMH) workflow. We aim to address underlying technology need and gaps related to the use of mHealth technology and the activation of patients living with Type-2 diabetes. Stated differently, we enable supporting technologies while seeking to influence patient activation and self-care activities.

15. SUBJECT TERMS

MHCE, Mobile Health Care Environment

mHealth, mobile health

MHS, Military Health System

PAM®, Patient Activation Measure

CS-PAM®, Clinician Support for Patient Activation Measure

PCMH, patient centered medical home

SDSCA, Summary of Diabetes Self-Care Activities

SUS, System Usability Scale

Type 2 Diabetes

User-Centered Design Research

TATRC, Telemedicine and Advanced Technology Research Center

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1. **INTRODUCTION:**

The potential of mobile health (mHealth) technologies in the care of patients with diabetes and other chronic conditions has captured the attention of clinicians and researchers. Efforts to date have incorporated a variety of tools and techniques including web-based portals, tailored behavioral text messaging, remote collection of biometric data, electronic coaching, electronic-based health education, secure e-mail communication between visits, and electronic collection of lifestyle and quality of life surveys. Each of these tools, used alone or in combination, have demonstrated varying degrees of effectiveness. Some of the more promising results have been demonstrated using regular collection of biometric devices, tailored behavioral messaging, secure e-mail communication with clinical teams, and regular reporting of quality of life variables. In this study, we seek to incorporate several of the most promising mHealth capabilities in a patient centered medical home (PCMH) workflow. We aim to address underlying technology need and gaps related to the use of mHealth technology and the activation of patients living with Type-2 diabetes. Stated differently, we enable supporting technologies while seeking to influence patient activation and self-care activities.

2. **KEYWORDS:**

MHCE, Mobile Health Care Environment
mHealth, mobile health
MHS, Military Health System
PAM®, Patient Activation Measure
CS-PAM®, Clinician Support for Patient Activation Measure
PCMH, patient centered medical home
SDSCA, Summary of Diabetes Self-Care Activities
SUS, System Usability Scale
Type 2 Diabetes
User-Centered Design Research
TATRC, Telemedicine and Advanced Technology Research Center

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

FOCUS: Prepare to conduct Phase I (user-centered research) and Phase II (feasibility study) research at Sites 1 & 2

Major Task 1: Regulatory and administrative approvals to conduct Phase I and II study

Subtask 1: Acquire approved CRADA at the Nellis AFB site; CRADA not required at Madigan Army Medical Center **(Target Date: 8/15/15-10/15/15; Completion Date: 1/20/16)**

Subtask 2: Acquire signed regulatory agreement documents allowing Madigan Army Medical Center to serve as Military IRB of record **(Target Date: 8/15/15-10/15/15; Completion Date: 12/12/14)**

Subtask 3: Complete, submit, and obtain regulatory approvals to conduct the research study

Clemson University package **(Target Date: 9/15/15-3/15/16; Completion Date: 8/28/15; 4/19/16)**

Madigan package **(Target Date: 9/15/15-3/15/16; Original Submission Date: 11/12/15; Re-Submission 3/1/16; IRB approval received 9/8/16)**

USAMRMC (secondary review) package **(Target Date: 9/15/15-3/15/16; Submission Dates: 11/17/15; 5/3/16; Final Review Pending)**

Major Task 2: Establish and launch advisory team structure to assist in the development and refinement of key infrastructure and implementation processes.

Subtask 1: Establish and launch the Clinical Advisory Team with tasks to include:

a. Member appointments **(Target Date: 9/15/15-3/15/16; Completion Date: 1/8/16)**

b. Agreement on basic operational processes (e.g. meeting frequency, voting structure, conflict resolution) **(Target Date: 9/15/15-3/15/16; Completion Date: 1/8/16)**

c. Advise the Development Advisory Team on issues related to clinical data thresholds, alerts, and safety algorithms to be built into MHCE **(Target Date: 9/15/15-3/15/16; Completion Date: 3/4/16)**

d. Design optimal implementation strategies for mCare use in clinical workflow of PCMHs (both sites) **(Target Date: 9/15/15-3/15/16; Completion Date: 4/22/16)**

e. Agreement on optimal strategies for reviewing patient oversight during phase II of study **(Target Date: 9/15/15-3/15/16; Completion Date: 4/22/16)**

f. Become familiar with patient activation concepts and theories to better advise the development of patient activation-based messaging. **(Target Date: 9/15/15-3/15/16; Completion Date: 3/4/16)**

g. Agree on mechanisms and processes for de-identification of select data/information to be accessed by a remote research portal **(Target Date: 9/15/15-3/15/16; Completion Date: 3/4/16)**

Subtask 2: Establish and launch the Development Advisory Team with tasks to includ:

a. Member appointments **(Target Date: 9/15/15-3/15/16; Completion Date: 1/27/16)**

b. Agreement on basic operational processes (e.g. meeting frequency, voting structure, conflict resolution) **(Target Date: 9/15/15-3/15/16; Completion Date: 1/8/16)**

c. Receive feedback from Clinical Advisory Team on issues related to clinical data thresholds, alerts, and safety algorithms to be built into MHCE; advise development contractors (TATRC JPC-1 funding) **(Target Date: 9/15/15-3/15/16; Completion Date: 3/4/16)**

d. Agree on structure of study database, analytical module, research portal, de-identification process, data mapping, data security, and related concepts **(Target Date: 9/15/15-3/15/16; Completion Date: 8/1/16)**

e. Agree on processes related to peripheral equipment issuance to research subjects, device quality checks, device training issues, MHCE training issues, operations issues, and device replacement process (if necessary). **(Target Date: 9/15/15-3/15/16; Completion Date: 6/1/16)**

Major Task 3: Hire and train support staff for the study

Subtask 1: Complete all human resource requirements then hire Clemson Research Associates for Sites 1-3 **(Target Date: 8/15/15-12/15/15; Completion Date: 9/8/15; 10/5/15; 2/8/16)**

Subtask 2: Develop training manuals and procedures to be used by SRAs/RA during the study; train Clemson Research Associates when hired **(Target Date: 8/15/15-12/15/15; Completion Date: 12/15/15)**

Subtask 3: New Clemson Research Associates get acclimated to the clinical environment (and workflow) where employed **(Target Date: 9/15/15-2/15/16; Completion Date: 2/15/16)**

FOCUS: Phase I user-centered design research – Preliminary work for this component of the work has been completed. This will begin immediately upon approval from MAMC IRB.

Phase 1, Patient-Participants: Patient recruitment will occur via review of the PCMH clinic schedule, referrals from providers, distributed fliers, and population health databases. We will also prescreen potential subject's medical record for inclusion and exclusion criteria to verify eligibility for the study. The PI will verify inclusion and exclusion criteria.

Phase 1, Provider-Participants: Contrary to the main site protocol, Madigan will not send invitation letters to potential clinicians. Clinicians will be invited to participate by word of mouth from the site PI and the Chief of Internal Medicine Department. During a weekly meeting, the Chief of Internal Medicine will provide a brief background of the study and ask for volunteers who are interested and want to support the study. The subjects who would like to participate in the study will then meet with the senior research associate and be asked to review the minimal risk information sheet to be included in the study. There is no planned supervisory staff involved in this process.

Major Task 1: Identify potential DM patients to participate in the study **(Target Date: 9/30/16)**

For Phase 1 of Patient recruitment, we have requested use of a ***Partial HIPAA Waiver of Authorization*** **for Recruitment** for patient recruitment. Patient recruitment will occur via review of the PCMH clinic schedule, referrals from providers, distributed fliers, and population health databases. We will also prescreen potential subject's medical record for inclusion and exclusion criteria to verify eligibility for the study. An inclusion/exclusion sheet will be used to verify inclusion/exclusion criteria and will be signed by the site PI before initiating study procedures.

Major Task 2: Recruit, randomize, and consent patients to participate in user-centered design research; n=15 per site **(Target Date: 10/15/16)**

For both Phase 1 for the patients, an Informed Consent Document (ICD) and HIPAA authorization will be sought in advance from each prospective subject and appropriately documented in accordance with 32 CFR 219.117. The patient may decline to consent in this study without prejudice. At the patient's discretion, they may take the ICD home to discuss further prior to making a decision. If the patient agrees to participate a full copy of the ICD will be given to them to keep. The senior research associate or PI is available to answer any questions that the patient may have in regards to the study. Patients who cannot provide Informed Consent will not be allowed to participate; no Legally Authorized Representatives (LAR) will be utilized. Some subjects may be patients of the Investigators; however, the Investigators will have the SRA recruit their subjects to prevent any perception of coercion or undue influence.

For Phase 1 Clinicians a minimal risk information sheet will be given to providers before participating in any study-related procedures. For phase 2 clinicians, an Informed Consent Document (ICD) will be sought in advance from each clinician. In both cases the clinicians may decline to consent in this study without prejudice. The senior research associate or PI is available to answer any questions that the patient may have in regards to the study. If the PI is the supervisor or any of the clinicians, the SRA recruit their subjects to prevent any perception of coercion or undue influence.

Major Task 3: Conduct 4-5 days of user-centered design research (qualitative) with research participants – each site **(Target Date: 11/18/16)**

Patient-participants for Phase 1 will not receive any devices or equipment to participate in the study.

Research Steps (Phase I). Provider-participants will participate in a focus group session held in a conference room or other suitable location at MAMC during a one hour period with two or more of the research team regarding the use of biomedical devices and technology in patient self-management of diabetes. They will be shown a series of mock up (under development) technology devices and user interfaces and asked to provide feedback on their preferences. The session will be audio recorded for note-taking purposes. No subjects will be able to be identified from recording. The recording will be erased/destroyed after analysis. We anticipate that analysis will be completed within 6 months from data collection and recording will be stored in a locked

cabinet in a locked room in the SRA's office at which time the recording will be destroyed.

Action	**Visit / Follow Up (F/U) Interval**		
Research process	1 mo before	2 wks before	Intake day / begin study
Screening	X		
Enrollment/			X
User-centered research interview			X
Completion of study /			X

Clinician-participants for Phase 1 will not be provided with any devices or equipment to participate in the study.

Major Task 4: Analysis and reporting of user-centered design research **(Target Date: 12/31/16)**

Subtask 1: Assemble, code, interpret and triangulate all data collected in user-centered design research

Subtask 2: Author user-centered design assessment report; to be used in infrastructure/design modification prior to Phase II study ***(Report + manuscript = major milestone #1)***

Subtask 3: Advise TATRC of user-centered research driven modification recommendations to MHCE; request implementation of recommendations prior to Phase II feasibility study

FOCUS: MHCE modification and readiness to conduct Phase II feasibility study (Pending MAMC IRB approval and completion of Phase I research)

Major Task 1: TATRC team modifies MHCE based on findings from user-centered design research

Major Task 2: Coordinate all logistical issues and other preparation for Phase II research

Major Task 3: Identify potential DM patients to participate in the study

Major Task 4: Recruit, randomize, and consent patients to participate in feasibility study

FOCUS: Phase II formal feasibility study (Pending MAMC IRB approval and completion of Phase I research)

Major Task 1: Launch the conduct a formal 12 month feasibility study of patient activated MCHE

Major Task 2: Per protocol collect and analyze (using appropriate statistical testing) data from MHCE, clinical data from SRAs (each site), and other data sources

Major Task 3: Author 2-3 manuscripts on patient activated MHCE system design, implementation and on-going use in chronic care self-management

FOCUS: Phase II study wrap up and reporting (Not applicable for current reporting period)

Major Task 1: Complete all data analysis from Phase II study

Major Task 2: Complete formal reporting and follow-on manuscripts (if any) from Phase II study. Formal DoD report will include specific design and investment recommendations grounded in evidence collected during Phase I and Phase II of the study

Major Task 3: Formal study closure and IRB closure reports

- **What was accomplished under these goals?**

Major Task 1: Subtask 1 – Submitted CRADA for Nellis AFB 3-SEP-2015; CRADA received from Nellis AFB (not required at MAMC) 20 JAN 2016

Major Task 1: Subtask 2 – Acquired signed regulatory agreement documents allowing MAMC to serve as Military IRB of record 12 DEC 2014

Major Task 1: Subtask 3 - Completed, submitted and obtained regulatory approvals for Clemson University 28-AUG-2015

Major Task 1: **Subtask 3** – Completion and original submission of regulatory approvals for Madigan Army Medical Center (MAMC) 12-NOV-2015; MAMC IRB approval 8 SEPT 2016); Original Submission USAMRMC (secondary review) package 17 NOV 2015, Pending Final Review (Target Date: 20 SEPT 2016); Original Clemson IRB approval 27 AUG 2015; Clemson IRB Request for Amendment approval received 29APR2016; Submitted MAMC IRB Site Specific Addendum 1MAR2016

Major Task 2: **Subtask 1 (a)** – Establish Clinical Advisory Team members 1-OCT-2015 (Completed and on-going)

a. Member appointments – 27 JAN 2016

b. Agreement on basic operational processes (e.g., meeting frequency, voting structure, conflict resolution)

c. Advise the Development Advisory Team on issues related to clinical data thresholds, alerts, and safety algorithms to be built into MHCE 4MAR2016

d. Design optimal implementation strategies for mCare use in clinical workflow of PCMHs by 22APR2016

e. Agreement on optimal strategies for reviewing patient oversight during Phase II of study by 22APR2016

f. Become familiar with patient activation concepts and theories to better advise the development of patient activation-based messaging by 4MAR2016

g. Agree on mechanisms and processes for de-identification of select data/information to be accessed by a remote research porta by 4MAR2016

Major Task 2: **Subtask 2 (a)** – Establish Developmental Advisory Team members 1-OCT-2015 (Completed and on-going)

a. Member appointments - 8 JAN 2016

b. Agreement on basic operational processes (e.g. meeting frequency, voting structure, conflict resolution – 8 JAN 2016

c. Receive feedback from the Clinical Advisory Team on issues related to clinical data thresholds, alerts and safety algorithms to be built into MHCE; advise development contractors by 4MAR2016

d. Agree on structure of study database, analytical module, research portal, de-identification process, data mapping, data security, and related concepts

e. Agree on processes related to peripheral equipment issuance to research subjects, device quality checks, device training issues, MHCE training issues, operations issues, and device replacement process by 4MAR2016

Major Task 3: Subtask 1 - Hired Research Associate at Clemson University 8-SEP-2015

Major Task 3: Subtask 1 - Hired Senior Research Associate at Nellis AFB 5-OCT-2105

Major Task 3: Subtask 1 - Hired Senior Research Associate at MAMC 8 FEB 2016

Major Task 3: Subtask 2 - Developed training manuals 15 Dec 2015; Clemson Research associates at Clemson and Nellis Air Force Base trained. Training for MAMC based employee to be accomplished following hire. 15 FEB 2016

Major Task 3: Subtask 3 – New Clemson Research Associates get acclimated to the clinical environment (and workflow) where employed – MAMC SRA 15 FEB 2016

- **Preliminary Report on Clinical Data Standards, Alerts and Safety Algorithms to USAMRC, TATRC and the Development Advisory Team delivered 15MAR2016**

What opportunities for training and professional development has the project provided? (Not applicable for current reporting period. Training and professional development will concur during and following Phase II)

a. **How were the results disseminated to communities of interest?**

2016 AMSUS Annual Continuing Education Meeting - Poster #1 – To be presented 11/29/16, National Harbor, Maryland - "New Biometric Data Collection, Analysis and Visualization in the DoD's Mobile Health Care Environment"; Authors: Ron Gimbel, PhD, Clemson University; Jeanette Little, MS, TATRC; Terry Newton, MD, OTSG – USA.

2016 AMSUS Annual Continuing Education Meeting - Poster #2 – To be presented 11/29/16, National Harbor, Maryland – "Enhancing mHealth Technology in the DoD's PCMH Environment to Activate Type 2 Diabetes Patients; Authors: Ron Gimbel, PhD; Joel Williams, PhD; Liwei Chen, MD, PhD; Cheryl Dye, PhD; Karen Edwards, MEd; Jeanette Little, MS, Terry Newton, MD

A full manuscript describing protocol developed and currently being routed for DoD clearance. Anticipate submission to journal in September 2016.

b. **What do you plan to do during the next reporting period to accomplish the goals?**

FOCUS: Phase I user-centered design research

Major Task 1: Identify potential DM patients to participate in the study

Major Task 2: Recruit, randomize, and consent patients to participate in user-centered design research; n=15 per site

Major Task 3: Conduct 4-5 days of user-centered design research (qualitative) with research participants – each site

Major Task 4: Analysis and reporting of user-centered design research

FOCUS: MHCE modification and readiness to conduct Phase II feasibility study (Pending MAMC IRB approval and completion of Phase I research)

Major Task 1: TATRC team modifies MHCE based on findings from user-centered design research

Major Task 2: Coordinate all logistical issues and other preparation for Phase II research

Major Task 3: Identify potential DM patients to participate in the study

Major Task 4: Recruit, randomize, and consent patients to participate in feasibility study

FOCUS: Phase II formal feasibility study (Pending MAMC IRB approval and completion of Phase I research)

Major Task 1: Launch and conduct a formal 12 month feasibility study of patient activated MCHE

Major Task 2: Per protocol collect and analyze (using appropriate statistical testing) data from MHCE, clinical data from SRAs (each site), and other data sources

Major Task 3: Author 2-3 manuscripts on patient activated MHCE system design, implementation and on-going use in chronic care self-management

4. **IMPACT:**

- **What was the impact on the development of the principal discipline(s) of the project?** Research benefits include improved understanding of how to advance three joint PCMH principles (coordination of care, improved quality and safety, and enhanced access to care) through the use of mobile technology. We expect to improve the understanding of how to include mHealth technology into the PCMH workflow, as well as exploring how to use mHealth technology in the activation of patients diagnosed with Type 2 diabetes. We also explore how patient complexity and degree of "sickness" may influence whether and how patients use mHealth technologies in self-management of their disease. Finally, we will map patient-entered biomedical data into clinical documentation and a decision support platform useful in chronic care management.
- **What was the impact on other disciplines?** The Clinical Advisory Team, populated by MHS clinicians, academicians, and research associates, established clinical and safety thresholds and provided clinician preferences on optimal data visualization and clinical workflow. To ensure the MHCE thresholds were grounded in evidence, CAT members compared them to those presented in current clinical practice guidelines, systematic reviews, and other peer-reviewed biomedical manuscripts.
- **What was the impact on technology transfer?** (Not applicable for this reporting period)
- **What was the impact on society beyond science and technology?** Phase II research will make an impact on society by improving patient activation through the use of the MHCE which is expected to improve their chronic disease self-management behaviors. When chronic disease self-management behaviors improve, clinical outcomes and a reduction of high-intensity health services utilization will decrease. Our efforts and expected knowledge generated from this study will make a substantial contribution on how to use PAM in health services delivery.

5. **CHANGES/PROBLEMS:**

- **Changes in approach and reasons for change** (Nothing to report)
- **Actual or anticipated problems or delays and actions or plans to resolve them**

  Delay with final DoD IRB approval to proceed with Phases I and II of the study. *Note: Final IRB approval received September 8, 2016.*

- **Changes that had a significant impact on expenditures**

  Phase I and Phase II research activities (and resulting expenditures) have been delayed due to a protracted IRB approval process.

- **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents** (Not applicable)
- **Significant changes in use or care of human subjects** (No significant changes)
- **Significant changes in use or care of vertebrate animals.** (Not applicable)
- **Significant changes in use of biohazards and/or select agents** (Not applicable)

Despite the MAMC delay in IRB approval, Phase 2 research is expected to stay on track as scheduled for January, 2017 as originally planned. To accommodate delay in schedule, researchers have revised planning and there will be less time between Phase 1 and 2 of the study. This will be accomplished through regular and comprehensive communication between Clemson University researchers and TATRC technology enablers.

6. **PRODUCTS:**

- **Publications, conference papers, and presentations**

  - **Journal publications.**

    Manuscript on protocol developed and currently being routed for DoD clearance

- **Books or other non-periodical, one-time publications.** (Not applicable)
- **Other publications, conference papers, and presentations.**

  2016 AMSUS Annual Continuing Education Meeting - Poster #1 – To be presented 11/29/16, National Harbor, Maryland - "New Biometric Data Collection, Analysis and Visualization in the DoD's Mobile Health Care Environment"; Authors: Ron Gimbel, PhD, Clemson University; Jeanette Little, MS, TATRC; Terry Newton, MD, OTSG – USA.

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- **Website(s) or other Internet site(s) –** Nothing to report during this reporting period
- **Technologies or techniques**

  The Telemedicine and Advanced Technology Research Center (TATRC), in partnership with Clemson University, are expanding the capabilities of the Mobile Health Care Environment (MHCE) to support enhanced communication and patient self-management behaviors in Type 2 diabetes care.

  In fiscal year 2016/17 the TATRC-Clemson University team designed and launched a project Development Advisory Team (DAT) and a Clinical Advisory Team (CAT) to guide the effort. The DAT led all technical research (e.g. DoD information security & privacy requirements, data mapping requirements) and related design and process requirements (e.g. interface with wireless communication providers, visualization capabilities and options, data analytic structure) while seeking regular feedback from the CAT.
  The project included three major components: data collection, data analysis, and data visualization.

  1. Primary data collection issues included DoD regulatory requirements, data mapping from peripheral devices, patient entry of free-text data, and agreements with wireless communication providers.
  2. Data analysis issues included temporal issues (e.g. intra-day measures) regarding when to apply computational tasks, establishing minimum thresholds for patient safety, identifying when biomedical data should trigger behavioral reinforcement, and other reporting tasks.
  3. Data visualization issues included assessing visualization placement within the screen (differing devices), presentation options for patients (e.g. presenting data aggregation, temporal options, options on averaging or raw presentation).

- **Inventions, patent applications, and/or licenses** (Not applicable)
- **Other Products** (Not applicable)

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS**

- **What individuals have worked on the project?**

Name:	*Ronald W. Gimbel, PhD*
Project Role:	*Principal Investigator*
Nearest person month worked:	2.4
Contribution to Project:	*Dr. Gimbel has performed work as the Principal Investigator.*
Name:	*Karen Edwards*
Project Role:	*Research Associate*
Nearest person month worked:	*12*
Contribution to Project:	*Karen oversees all aspects of the study along with Dr. Gimbel.*
Name:	*Jennie Moss*
Project Role:	*Senior Research Associate*
Nearest person month worked:	12
Contribution to Project:	*Jennie oversees all aspects of the study located at Nellis AFB.*
Name:	*Marie Rempola*
Project Role:	*Senior Research Associate*
Nearest person month worked:	12
Contribution to Project:	*Marie oversees all aspects of the study at Madigan AMC.*

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?** Nothing to report for this reporting period
- **What other organizations were involved as partners?**

- **<u>Organization Name</u>: TATRC**
- **Location of Organization:** Building 38711, Fort Gordon, Georgia 30905-5650
- **Partner's contribution to the projec**t
  - **Financial support –** n/a
  - **In-kind support** – n/a
  - **Facilities** – n/a
  - **Collaboration** – TATRC's *staff is working with Clemson University project staff on the project.*
  - **Personnel exchanges** – n/a
  - **Other – n/a**

8. **SPECIAL REPORTING REQUIREMENTS**

- **COLLABORATIVE AWARDS:** No applicable for this reporting period
- **QUAD CHART:** see Appendix

9. **APPENDICES:**

Abstract for AMSUS Poster #1

Abstract for AMSUS Poster #2

Power Point sample slides from the mCare product

Quad Chart

Title:

New biometric data collection, analysis, and visualization in the DoD's Mobile Health Care Environment

Abstract:

The Telemedicine and Advanced Technology Research Center (TATRC), in partnership with Clemson University, is expanding the capabilities of the Mobile Health Care Environment (MHCE) to support enhanced communication and patient self-management behaviors in Type 2 diabetes care. The expanded capabilities are a critical component of research aimed at enhancing patient activation in the patient centered medical home (PCMH) environment. We outline the collaborative process leading to these new capabilities of MHCE biometric data collection, analysis, and visualization.

In fiscal year 2016/17 the TATRC-Clemson University team designed and launched a project Development Advisory Team (DAT) and a Clinical Advisory Team (CAT) to guide the effort. The DAT led all technical research (e.g. DoD information security & privacy requirements, data mapping requirements) and related design and process requirements (e.g. interface with wireless communication providers, visualization capabilities and options, data analytic structure) while seeking regular feedback from the CAT. The CAT, populated by MHS clinicians, academicians, and research associates, established clinical and safety thresholds and provided clinician preferences on optimal data visualization and clinical workflow. To ensure the MHCE thresholds were grounded in evidence, CAT members compared them to those presented in current clinical practice guidelines, systematic reviews, and other peer-reviewed biomedical manuscripts.

The project included three major components: data collection, data analysis, and data visualization.

- Primary data collection issues included DoD regulatory requirements, data mapping from peripheral devices, patient entry of free-text data, and agreements with wireless communication providers.
- Data analysis issues included temporal issues (e.g. intra-day measures) regarding when to apply computational tasks, establishing minimum thresholds for patient safety, identifying when biomedical data should trigger behavioral reinforcement, and other reporting tasks.
- Data visualization issues included assessing visualization placement within the screen (differing devices), presentation options for patients (e.g. presenting data aggregation, temporal options, options on averaging or raw presentation).

The outcomes are represented in the attached figures and vary by type of device. The devices include an approved Wi-Fi/Bluetooth-enabled scale, blood pressure cuff, glucometer, and an activity monitor. The product will be subjected to user-centered usability testing and ultimately included in a large multisite feasibility study within the MHS.

Learning objectives:

- The learner will be able to identify key steps in adding biometric data to a mobile health care environment.
- The learner will be able to explain desired data visualization options in mobile health projects that might influence patient use and clinical workflow.
- The learner will recognize the need and challenge of establishing clinical and patient safety algorithms in use of biometric data.
- The learner will be able to recognize common peripheral devices used in chronic care patient self-management for diabetes care.

Title:

Enhancing mHealth Technology in the DoD's PCMH Environment to Activate Type 2 Diabetes Patients

Abstract:

Mobile health (mHealth) technology in the care of patients with diabetes has demonstrated varying degrees of effectiveness. In this project we seek to incorporate the most promising capabilities of mHealth technology in a Patient-Centered Medical Home (PCMH) to support the activation of patients with Type 2 diabetes. We anticipate that greater patient activation will lead to improved self-care behaviors and outcomes (clinical and health service).

Method:

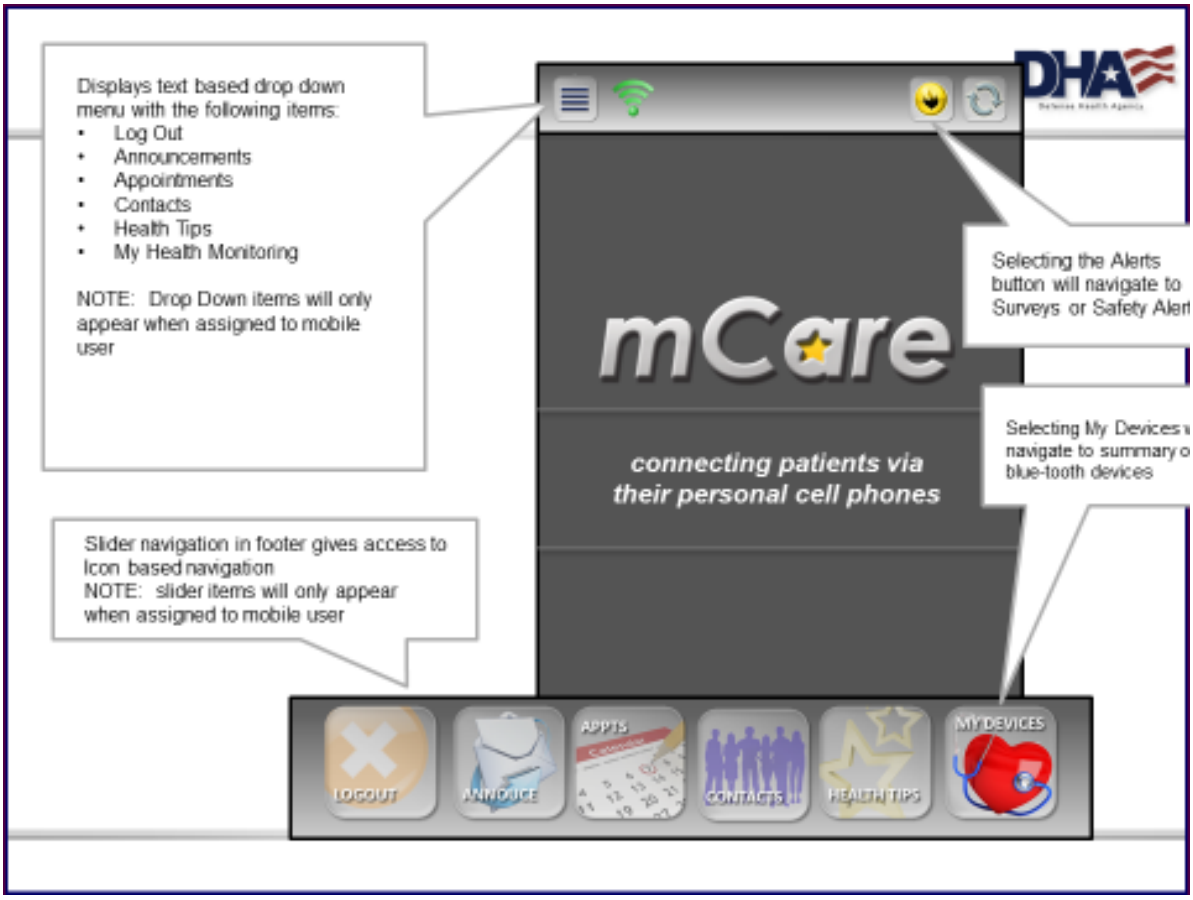
Formal single-blinded (patients) 12-month feasibility study conducted within the PCMH environment of two Military Treatment Facilities (MTFs). While not a randomized controlled trail, there are stratified randomization elements built into study design. Study has two interconnected components which include enhancement of the MHCE to add mobile patient equipment and collection, analysis, and visualization of biometric data as well as tailored behavioral messages aligned with Patient Activation Measure (PAM®) scores. Study is being preceded (2016) by a user-centered design phase that includes both patients and PCMH clinicians. The formal study will recruit 240 patients (120 intervention, 120 control) who meet inclusion criteria. There are four primary and two secondary hypotheses as well as numerous analyses of interest. Primary measures of interest include PAM and Summary of Diabetes Self- Care Activities (SDSCA) scores and clinical measures. Study advised by a clinician-driven team and development team. Algorithms for safety and behavioral reinforcement are also included.

Discussion:

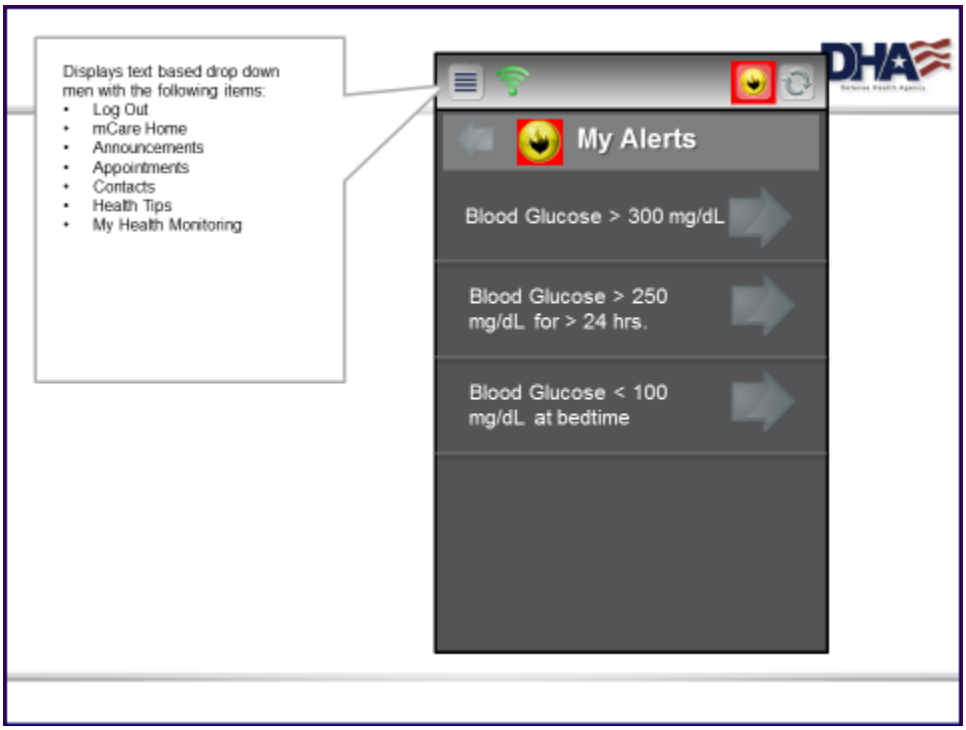
Research benefits include improved understanding of how to advance three joint PCMH principles (coordination of care, improved quality and safety, and enhanced access to care) through the use of mobile technology. We expect to improve the understanding of how to include mHealth technology into the PCMH workflow, as well as exploring how to use mHealth technology in the activation of patients diagnosed with Type 2 diabetes. We also explore how patient complexity and degree of "sickness" may influence whether and how patients use mHealth technologies in self-management of their disease. Finally, we will map patient-entered biomedical data into clinical documentation and a decision support platform useful in chronic care management.

Learning objectives:

1. The learner will recognize the need and challenge of establishing clinical and patient safety algorithms in the use of biometric data.
2. The learner will be able to recognize common peripheral devices used in chronic care patient self-management for diabetes care.
3. The learner will be able to identify valid and reliable socio-behavioral survey instruments used to measure patient activation and self-care activities.
4. The learner will be able to explain desired data visualization options in mobile health projects that might influence patient use and clinical workflow.


Displays text based drop down menu with the following items:
• Log Out
• Announcements
• Appointments
• Contacts
• Health Tips
• My Health Monitoring
NOTE: Drop Down items will only appear when assigned to mobile user
Selecting the Alerts button will navigate to Surveys or Safety Alert
Selecting My Devices will navigate to summary of blue-tooth devices
Slider navigation in footer gives access to Icon based navigation
NOTE: slider items will only appear when assigned to mobile user
mCare
connecting patients via their personal cell phones
DHA
LOGOUT
ANNOUNCE
APPTS
CONTACTS
HEALTH TIPS
MY DEVICES


Health Tip
Muscle Strengthening
Muscle strengthening can be done using weights, elastic bands or body weight for resistance such as doing a push-up.
Example of an Activity Message-PAM level 3


Displays text based drop down men with the following items:
• Log Out
• mCare Home
• Announcements
• Appointments
• Contacts
• Health Tips
• My Health Monitoring
My Alerts
Blood Glucose > 300 mg/dL
Blood Glucose > 250 mg/dL for > 24 hrs.
Blood Glucose < 100 mg/dL at bedtime

Demonstration

Enhancing mHealth Technology in the PCMH environment to Activate Chronic Care Patients

ERMS/Log Number: 14210004

Award Number: W81XWH-15C-0070

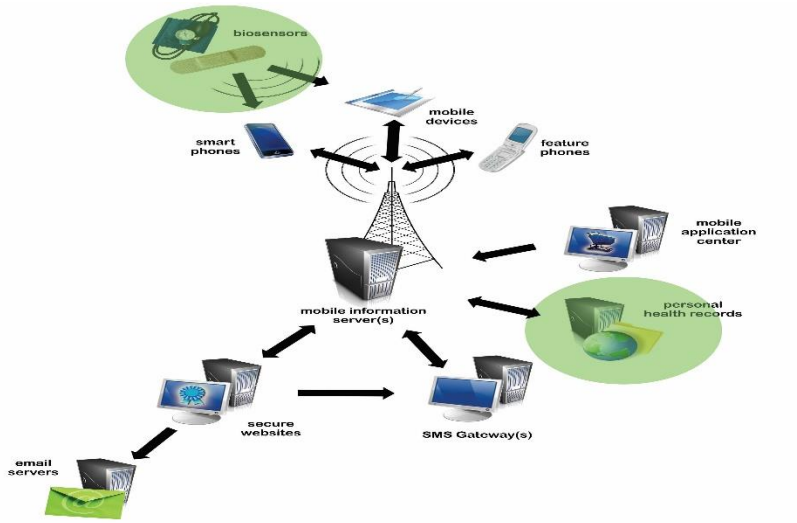
PI: Ronald W. Gimbel, PhD **Org:** Clemson University

Study/Product Aim(s)

- Integrate mHealth technology into the clinical workflow of the PCMH model;
- Activate Type 2 diabetes patients in disease self-management behaviors through novel use of mHealth technology;
- Advance understanding of how patient complexity and degree of "sickness" may influence mHealth technology use in disease self-management; and
- Map patient-initiated biomedical data into clinical documentation and a decision support useful in chronic care management.

Approach

A multi-site phased feasibility study, conducted in the PCMH environment of Nellis AFB and Madigan AMC. Includes user-centered design research and feasibility testing followed by 12 month clinical trial. Study is partnership between TATRC (technology developers), Clemson University (researchers), and MTFs.



Timeline and Cost

Activities	CY 15	16	17	18
CRADA & IRB approvals				
User-centered design & testing				
Clinical trial at 2 MTFs				
Data analysis & reporting				
Estimated Budget ($K)	**$151**	**$480**	**$518**	**$81**

Updated: 15 AUG 2016

Goals/Milestones

CY15 Goal –*Regulatory & administrative approvals (2 months)*

- ❑ Clemson IRB and CRADA approval obtained
- ❑ Madigan IRB approval pending
- ❑ Research team training conducted; Clemson RA, Madigan AMC and Nellis AFB SRAs hired; Clinical and Developmental Advisory Teams established

CY16 Goals – *Phase I user-centered design and feasibility testing*

- ❑ User-centered design research
- ❑ Obtain Madigan IRB approval
- ❑ Feasibility testing with patients
- ❑ Modify mHealth technology incorporating lessons learned

CY17 Goals – *Phase II clinical trials at 2 MTFs*

- ❑ Randomize patients
- ❑ Formal clinical trials of enhanced mHealth technology

CY18 Goal – *Data analysis and reporting (4 months)*

- ❑ Analyze data (including time series data)
- ❑ Formal reports and manuscripts

Budget Expenditure to Date

Projected Expenditure: $1.22M

Actual Expenditure: $296,362 at 8/15/16