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TITLE: Telehealth 2.0: Providing Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices

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14. ABSTRACT This project aimed to use mobile technology to leverage telehealth services as a means to maximize the continuity-of-care that the military healthcare system (MHS) can provide to Service Members when they are temporarily relocated due to military service requirements, but require and are engaged in behavioral health (BH) services. The effort focused on utilization of the patient's personal mobile device in an approved, secure fashion to maintain the established therapeutic relationships with their BH provider(s) during an outside the continental United States (OCONUS) temporary duty assignment (TDY) using a relational model of care delivery to complete a course of treatment that the patient sought out prior to being reassigned. There were four specific aims to this research effort: (1) develop the required technology enhancements to the existing mobile health (mHealth) product to support this project (2) to test the feasibility of the mobile interface for patient use; (3) to establish the acceptability of this technology approach with BH providers; and (4) deploy and evaluate the technology solution in a clinical context. As a result of this project lessons learned have emerged, particularly in regards to current connectivity limitations connecting behind the .mil network, port and firewall setting discrepancies between networks and recommendations to the Program Office with what needs to occur to continue the groundwork of secure provider desktop VTC behind the .mil firewall to a patients' mobile device.

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1. INTRODUCTION:

This project aimed to use mobile technology to leverage telehealth services as a means to maximize the continuity-of-care that the military healthcare system (MHS) can provide to Service Members when they are temporarily relocated due to military service requirements, but require and are engaged in behavioral health (BH) services. The effort focused on utilization of the patient's personal mobile device in an approved, secure fashion to maintain the established therapeutic relationships with their BH provider(s) during an outside the continental United States (OCONUS) temporary duty assignment (TDY) using a relational model of care delivery to complete a course of treatment that the patient sought out prior to being reassigned.

There were four specific aims to this research effort: (1) develop the required technology enhancements to the existing mobile health (mHealth) product to support this project (2) to test the feasibility of the mobile interface for patient use; (3) to establish the acceptability of this technology approach with BH providers; and (4) deploy and evaluate the technology solution in a clinical context. As a result of this project lessons learned have emerged, particularly in regards to current connectivity limitations connecting behind the .mil network, port and firewall setting discrepancies between networks and recommendations to the Program Office with what needs to occur to continue the groundwork of secure provider desktop VTC behind the .mil firewall to a patients' mobile device.

2. KEYWORDS:

Telehealth Virtual
Health Mobile Health
Remote Behavioral Health Remote
services Teletherapy
Telepsychology
Bring Your Own Device BYOD

3. ACCOMPLISHMENTS:

There were four overarching goals for this research effort outline in the project proposal:

A. Develop the capability to provide mobile telehealth to patients in remote locations

B. Maximize the patient and provider's usability ratings of the mHealth product(s)

C. Determine the technical feasibility of providing care from CONUS to OCONUS locations

D. Identify technical issues to revise in order to improve the quality of and access to care delivered remotely

Project accomplishments by date:

Actions Completed:	Date
A. JPC-1 Awarded Project	21 June 2016
B. Research Support Services Contraction action submitted to USARMAA	10 October 2016
C. Face-to-face meeting with USAMRAA to finalize procurement strategy	11 January 2017
D. Phase 1 of the research support services contract solicitation was posted on the Federal Business Opportunities Website	21 February 2017
E. Phase 1 vendor eligibility selection completed	29 March 2017
F. Phase 2 of the research support services contract solicitation was posted on the Federal Business Opportunities website	30 March 2017
G. USAMRAA Contract awarded to UTHSCSA	12 June 2017
H. Contract Kick-Off meeting with UTHSCSA	26 June 2017
I. Refinement of eligibility criteria, exclusion criteria and screening protocol for pilot	31 August 2017
J. Develop pilot protocol	31 August 2017
K. Finalize consent form and human subjects protocol	31 August 2017

Actions Completed:	**Completion Date**
L. Submit protocol for HRPO pre-review.	13 September 2017
M. Submit protocols to UTHSCSA IRB and seek Institutional Agreement for IRB review (IAIRs) from BAMC	31 August 2017
N. Protocol Submitted to MRMC HRPO for pre-review	12 September 2017
O. UTHSCSA IRB approval obtained	20 September 2017
P. MRMC HRPO pre-review completed	10 October 2017
Q. CRDAMC HRPP protocol review submission	22 December 2017
R. Desktop VTC infrastructure for Study Identified	21 March 2018
S. Definite/Finalize Technical Requirements	30 March 2018
T. mHealth Prototype Development	30 April 2018
U. mHealth Prototype Testing/Quality Assurance	15 May 2018
V. Desktop VTC technology and mHealth Platform installed T2 to conduct usability assessment	15 May 2018
W. Introduce project to the Fort Hood Community	31 May 2018
X. Expert Review of mHealth Prototype	July 2018
Y. Analysis of Design Features	July 2018

Actions Completed:	**Completion Date**
Z. Usability Testing of mHealth Prototype with Simulated Patients	August 2018
AA. Usability Testing with Clinical Providers	August 2018
BB. Development of Phase 2 Report Findings	29 August 2018
CC. mHealth Programming Refinements	September 2018
DD. Technical Testing	September 2018
EE. Quality Assurance Reviews	November 2018
FF. Development of End User Guides	December 2018
GG. mHealth Programming Refinements	January 2019
HH. Technical Testing	March 2019
II. Quality Assurance Reviews	March 2019
JJ. Finalize End User Guide	March 2019
KK. Consent, conduct pretest and enroll provider participants	March 2019
LL. Commence Recruitment of Provider Participants (n= 3-5 anticipated; as of date 7 enrolled)	March 2019
MM. Final Signed CRADA- Cooperative Research & Development Agreement for pilot	March 2019

Actions Completed:	Completion Date
NN. Ongoing QA testing behind .mil firewall to mobile device of connectivity	September 2019
OO. Implemented backup plan due to firewall and security updates; which were inconsistent across the DHA network versus the Army network; blocking video connectivity at times; implemented tablet backups for providers to work over roaming network if a clinical encounter is interrupted/dropped	April 2019
PP. Refined a provider-side mobile app to enhance security for the above backup plan when disrupted communication behind the .mil firewall blocks a clinical encounter; for a minimum to allow the two factor authentication from end to end.	June 2019
QQ. Pulled open pilot trial deployment due to inconsistency of connectivity behind the .mil firewall; continued with testing and assessment of bandwidth consumption and connectivity assessments of app to app connections as well as refining which updates on which networks concerned which ports (for final recommendations to the program office)	October 2019
RR. Presented status at the 2019 Military Health System Research Symposium (MHSRS); Orlando, FL	August 2019
SS. Project Closeout	December 2019

Opportunities for training and professional development provide by this research project:

Nothing to report.

Project results were disseminated to communities of interest as follows:

Presented (abstract and poster) findings at the 2019 Military Health Research Symposium, Orlando Florida.

Presently a manuscript is in preparation for submission to 2019 MHSRS Supplement to Military Medicine.

4. IMPACT:

Project impact on the development of the principal discipline(s) of the project:

From a technology perspective, this project allowed the research team to identify the technical barriers and challenges that would need to be overcome by the .mil network enterprise to allow virtual "visits" to be accomplished from the provider's desk within a military treatment facility to a patient using their personal mobile device. It has been demonstrated that this can be achieved without compromising security or privacy. Details and comparisons of the types of personal mobile devices and the mechanisms by which they can connect with to a .mil hosted WebRTC system have been established. The quality of service (QOS) of the connection using both cellular and WiFi connections have also been established. Details of the technical challenges that must be resolved at the DoD enterprise level to sustain this type of connectivity have been identified, and will require senior level support from the information technology community to resolve.

Project impact on other disciplines:

From a clinical perspective the ability to sustain the configuration and connections over time from this technology pilot demonstration could not be realized in a manner that would allow the health care providers to feel comfortable providing clinical care as a standard during this project. It is evident that healthcare providers are open to providing continuity of care through virtual visits, but they do not yet feel confident that the DoD infrastructure will reliably afford the opportunity to provide this type of outreach, and until that barrier is overcome, the patient safety risk concerns remain high with providers.

Project impact on technology transfer:

This project demonstrated means to leverage existing DoD systems synergistically, and did not involve any new technology development that would result in tech transfer.

Project impact on society beyond science and technology:

Civilian healthcare systems are increasing their use of virtual visits in significant orders of magnitude every month. Patients have already demonstrated a willingness and acceptance of receiving care remotely through their personal mobile devices, through either their existing healthcare insurance coverage or pay-as-you-go commercial apps (e.g. Doctors on Demand, etc,). The purpose of this research project was not to impact society outside of the military healthcare system, but rather to find a means to catch up with current practices outside of the DoD.

5. CHANGES/PROBLEMS:

Selection of a VTC system for the research study:

The project was initially planned to use an existing DHA VNC solution. At the time of the proposal submission, that system was the Cisco Jabber solution. By the time the proposal was awarded, the DHA VNC was sun setting the Cisco Jabber system, and was no longer granting any new user accounts. However, their follow-on solution, a Cisco video service (Web RCT) software experienced a number of technical configuration issues, and to date, is still not available to use. The issue seems to be that Cisco will not allow outside services, such as icelink to connect with their application. Separate technical testing by our team with a commercial version of this software replicated the issues being experienced with the DHA VNC team, and lead to a conclusion that this software product would not work as "advertised" to effectively sync with a secure mobile app.

As an alternative course of action, the research team explored other DoD resources that could be leveraged for this study. The DoD provides a NIPER and SIPER based solution, known as the Global Video Service or GVS. This system is capable of supporting mobile device users, however as of June 2018, the DoD had just procured this capability and had not yet installed it. As a result, a working solution with existing .mil infrastructure was unfortunately NOT going to be an option to execute this research study period of performance.

At which time, the research team elected to migrate to a commercial server connection, using the software that is the COTS solution being the GVS server, known as Viydo. The version of the Vidyo software used for this research study had the mobile device settings activated, whereas the GVS system did not. All technical assessments of this solution were successful, and this became the solution implemented for the research study. The connection method was for the providers desktop to open up a connection to a dedicated web portal for the research study, and select the patient he or she wanted to contact on their mobile phone. This only required the use of a web- browser and a credentialed login for the provider. No new software installations were required on the provider's computer.

From the web browser, the system used the Vidyo COTS system as middleware, and created a secure connection to the patient's mobile device (Android or iOS), allowing the patient to see the provider and vice versa. Throughout the summer of 2018, these connections were highly reliable.

In the late winter of 2018 various DHA wide updates were pushed out to all .mil users. Initially, these updates caused connectivity to fail, when the software was accessed over the .mil network. In early April of 2019, revised updates allowed once again for the system to connect. From April to October 2019, continued testing resulted in periods of successful connectivity and unstable connectivity.

To avoid the potential for a disruption during the live pilot trial with BH providers and Service Members, TATRC sponsored the use of tablets with wireless data plans to be used only the case of an emergency disruption as a backup secondary option if connectivity becomes impacted. These findings are significant with regards to firewall and other security updates over the .mil network as a sustainable and secure solution becomes necessary to account for future potential disruptions. From April-July 2019, the testing revealed more periods of unstable connectivity. Due to the unstable connectivity, the piloting the technology was likely to negatively impact patient care. With discussions with the team and the Department of Behavioral Health, it was decided to discontinue the pilot.

Technical impact of the Windows 10 upgrade on .mil computers:

In the late summer of 2018, DHA released a Windows 10 software upgrade to all desktop computer systems. After this upgrade, the connections to mobile phones became problematic. It was determined that the Windows 10 upgrade limited USB camera access to only Microsoft Edge browsers, requiring that this limitation be outlined in the user training guides.

USB port registration for approved desktop cameras:

In addition to the Windows 10 update, the DHA computer settings required that the USB ports used for the desktop computer connections would need to have IT waivers submitted through the Remedy system. The TATRC IAO has worked closely with the CRDAMC IAO to ensure these registrations are processed and will not impact the provider's attempts to reach the patients during the pilot project.

Determination to halt open pilot portion with live patients and BH providers due to network connectivity inconsistencies:

There were distinct differences and high levels or variability between the .osd.mil and the army.mil network connections (see below, table):

Mobile Connect Technical Assessment Summary:

	Connection Type	Results	Comments
DoD Computer	osd.mil domain	☒	Successful connections UNTIL Feb 2019 security updates blocked connection
DoD Computer	army.mil domain	☑	
DoD Computer	VPN to any .mil domain	☒	VPN rules prevented connections regardless of .mil domain type
Commercial Tablet	Wi-Fi Connection	☑	
Commercial Tablet	Cellular Network Connection	☑	

These network differences impacted quality of service (QOS) solution where Mobile Connect could NOT be used to provide care between the .mil and patient's personal mobile devices from an osd.mil domain connection. Thus, the researchers came to a consensus that the risk to clinical care (communications in a behavioral health tele-session) impediments would outweigh the benefits of proceeding with data collection in an open pilot.

Project Deviations:

The overall timeline of the project commenced on 12 June 2017 with the award of the research support services contract by USAMRAA. Because of technical delays, a no cost extension of 3 months has been granted to UTSHCA, which would delay the start of the Fort Hood 12 month evaluation to the end of September 2018, rather than late June 2018. This delays the overall timeline as well by 90 days. This was project timeline change was approved by CDMRP on 24 July 2018.

By June of 2019 the team made a collective decision to pull the open pilot trial deployment due to inconsistency of connectivity behind the .mil firewall; continued with testing and assessment of bandwidth consumption and connectivity assessments of app to app connections as well as refining which updates on which networks concerned which ports (for final recommendations to the program office)

Anticipated Problems/Issues:

Because this is a final report, no new problems or issues are anticipated.

6. PRODUCTS:

In addition to the port/firewall knowledge products the mobile app developed as a result of this endeavor, entitled "Mobile Connect" (see Appendices with imagery in the quad chart and User Guide), uses a secure, HIPPA compliant, two factor authentication which does allow mobile patients to connect with their providers behind the .mil firewall on the aforementioned networks (see chart, above), desktop VTC to mobile app user.

In addition to this capability of a secure patient user app, we further developed a provider mobile application, which allows a provider to populate their patient's data on a secure web URL and allow them to connect from the same secure mobile app in Mobile Connect (app to app). Having both patient and provider use the secure two factor authentication mobile application to connect on the backbone of the VIDYO (GVS) platform alleviates concern that the end user is who is the intended recipient of a contact request.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

Individuals that have worked on the project are as follows:

Name:	COL Jeffrey Yarvis
Project Role	Co-PI
Research Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	1
Contribution to the Project:	Co-PI
Funding Support:	None

Name:	Dr. Larry Pruitt
Project Role	Co-PI
Research Identifier (e.g. ORCID ID):	000-001-6925-7830
Nearest person month worked:	2
Contribution to the Project:	CoPI
Funding Support:	None

Name:	Dr. Katherine Dondanville
Project Role	Co-PI
Research Identifier (e.g. ORCID ID):	000-003-4204-7826
Nearest person month worked:	1
Contribution to the Project:	Co-PI
Funding Support:	JPC-1

Name:	Michelle Locklear Barrera, B.S.
Project Role	Project Coordinator
Research Identifier (e.g. ORCID ID):	n/a
Nearest person month worked:	1
Contribution to the Project:	Research Associate
Funding Support:	JPC-1

Name:	Amanda Schmeltz
Project Role	Research Project Manager Support
Research Identifier (e.g. ORCID ID):	n/a

Nearest person month worked:	2
Contribution to the Project:	Project Management
Funding Support:	JPC-1

Changes in the active other support of the PD/PI(s) or senior/key personnel since the project award:

There have been changes in assignment for 2 of the Co-PIs on this project:

COL Yarvis is no longer the Deputy Commander at CRDAMC, however his next duty assignment allowed him to stay at Fort Hood, so he continued to support the research project in his new role until the project was completed. COL Yarvis took command of the 21st Combat Support Hospital & 9th Hospital Center at Fort Hood Texas from December 2017-December 2019.

Dr. Larry Pruitt has left the PHCoE and taken a new position at the VA, but continues to support the project remotely.

Other organizations involved as partners:

Organization Name:	PHCoE (formerly T2) Research and Development (J-9) Defense Health Agency (DHA)
Location of Organization:	Joint Base Lewis-McCord, Washington
Partners Contribution to this Project:	Facilities (e.g. PHCoE Usability Lab) Collaboration Subject Matter Expertise
Organization Name:	Carl R Darnall Army Medical Center (CRDAMC)
Location of Organization:	Fort Hood, Texas
Partners Contribution to this Project:	Facilities Subject Matter Expertise (SMEs) and End-User IT Support Specialist
Organization Name:	University of Texas Health Science Center at San Antonio (UTHSCSA) and Strong Star Consortium
Location of Organization:	San Antonio, Texas
Partners Contribution to this Project:	Contract Personnel Support Services Subject Matter Expertise (SMEs) Local Institution Review Board (IRB) Support

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: Not Applicable

QUAD CHARTS: See Appendix A

9. APPENDICES:

Quad Charts: Appendix A.

Usability Testing Report: Appendix B.

Revised Statement of Work. Appendix C.

Approved Protocol: Appendix D.

CRDA: Appendix E

User Guide: Appendix F

Appendix A: Quad Chart

Telehealth 2.0; Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices

PI: Jeanette Little, MS CoPIs: Dr. Larry Pruitt/COL Jeffrey Yarvis Org: MRMC TATRC Amount of the Award: $1,571,021.00

Study/Project Aims:

1. Develop the required technology enhancements to the existing mobile health (mHealth) system, to support this project
2. Test the feasibility of the mobile interface for patient use
3. Establish the acceptability of this technology approach with BH providers
4. Deploy and evaluate the technology solution in a clinical context

Approach:

This project aims to use mobile technology to leverage telehealth services as a means to maximize the continuity-of-care that the military healthcare system (MHS) can provide to Service members when they are engaged in behavioral health (BH) services, but must temporarily relocate due to the requirements of their military service. The effort will focus on utilization of the patient's personal mobile device in an approved, secure fashion to maintain the established therapeutic relationships with their BH provider(s) during an outside the continental United States (OCONUS) temporary duty assignment (TDY) using a relational model of care delivery to complete a course of treatment that the patient sought out prior to being reassigned.

Accomplishments to Date: All Project work has been completed and documentation for the final report is underway

Activities	CY16	CY17	CY18	CY19
Develop tech enhancements				
Test feasibility of mobile interface				
Establish acceptability of technology approach with BH providers				
Evaluate technology in in light of disrupted network communications (port/firewall updates blocking video connection) for determination of final recommendations				
Estimated Budget ($)		**$1,024,091**	**$546,930**	

Goals/Milestones:

- **CY17 Goals** – Begin Technology Enhancements/Complete Technology Enhancements/Complete End User Usability Assessment
- **CY18 Goal** – Commence Pilot Project with Ft Hood EBH Team
- **CY19 Goal** – Project Completion

Comments/Challenges/Issues/Concerns:
DHA HIT VNC is no longer supporting use of the existing desktop VTC software that was proposed for this project, a request has been sent to support the next generation software on a pilot basis. Minor issue of changing technical approach. Contracting delays for research support services delayed timeline to project start of 12 June 2017. Network discrepancies were noted with regards to periodic updates (port and firewall blocking; not entirely consistent across the DHA or Army networks) causing the research team to halt deployment of the open pilot trial, even in light of having the I pad and secure provider app back-ups developed. It was agreed that the lessons learned in that alone were of great value to the Program Office, while the risk of interrupting a behavioral health teleconsult appointment due to impeded connectivity would not outweigh proceeding with the trial itself.

Budget Expenditure to Date:
FY16 Expenditures: $ 1,024,091
FY17 Expenditures: $151,486.70
FY18 Expenditures: $395,443.30

VidyoConnect Chat Initial Functionality Assessment Project: Telehealth 2.0 (#DHAI00004330535) Prepared by: DHA Usability Lab Team
Conducted: 29 August 2018

1. **Background**. The DHA Usability Lab (UL) team was provided the link to the video chat component of Telehealth 2.0 to perform a brief function and connectivity test. The UL team was forwarded the Google Chrome URL associated with VidyoConnect conference call, which can connect multiple devices into the same chat room. Once all links were verified as active, the UL team was prepared to conduct the assessment.

2. **Test Setup**. There were three connection options designed for the test: (1) Mobile app to browser, (2) mobile app to mobile app, and (3) browser to browser. For each mobile device, the "VidyoMobile" app was downloaded.
    a. On mobile devices, testers entered the URL in the browser, which led them to a screen showing two options: "Connect via the app" and "Connect via the browser." On the mobile devices, testers selected "Connect via the app", while testers selected "Connect via the browser" on laptops and desktop computers.
    b. Three network options were tested: (1) MAMC's military network "Med.ds.osd.mil" (2) cellular network hotspot, and (3) public Wi-Fi.
    c. The devices used for the test included one iPhone 6, one iPad, one Dell laptop (with external webcam installed), and one MacBook Pro.
    d. Other items evaluated were connectivity, usability, and sound/video quality.

3. **Findings**. The most important initial finding during this test concerns browser access to external webcams. While testing the browser video call, the camera could not be accessed when connected to the MAMC .mil network. Manual adjustments to allow Chrome to access the camera did not solve this problem while on the .mil network. This means that any local network restrictions would not allow providers to speak with patients remotely without special permissions to access the camera. All other components of the test were considered successful.
    a. Browser to mobile app: This connection was successful in all phases on both cellular network hotspot and public Wi-Fi. Sound and picture quality were sharp with limited pixilation. There was little to no delay in movement and sound, even with three devices connected to the same hotspot or Wi-Fi signal.
    b. Mobile to mobile: There were no notable differences from the previous item.
    c. Browser to browser: Because the UL team's Dell laptop connects exclusively to the MAMC .mil network, this design of the test was necessarily incomplete. However, the browser connection functioned well on the MacBook Pro, which can access other networks without restriction.

4. **Summary**. The VidyoConnect solution performed very well in all phases of testing. Connectivity, sound, picture quality, and usability were all assessed above average. However, the browser's inability to access the camera on some .mil networks will likely require additional solutions.

JPC-1 PROJECT STATE DATE: 16 July 2016
STATEMENT OF WORK: August 1, 2016
PROPOSED START DATE: November 1, 2016
ACTUAL START DATE: 12 June 2017

Site 1: Mobile Health Innovation Center (MHIC)
Telemedicine and Advanced Technology Research Center (TATRC)
Medical Research and Materiel Command (MRMC)
Building 38711
Fort Gordon, GA 30905-5650

Initiating PI: Jeanette Little, MS

Site 2: National Center for Telehealth and Technology (T2)

Defense Health Agency (DHA)

9933 West Hayes Street
Box 339500 MS 34
Joint Base Lewis-McChord, WA 98433-9500

Partnering PI: Dr. Larry Pruitt

Site 3 Carl R. Darnall Army Medical Center (CRDAMC)
36000 Darnall Loop
Fort Hood, Texas 76544

Partnering PI: COL Jeffrey Yarvis

Site 4: University of Texas Health Science Center at San Antonio (UTHSCSA)
7703 Floyd Curl Drive
San Antonio, Texas 78229-3900

Partnering PI: Dr. Katherine Dondanville

		Timeline Months	**MHIC** (Little)	**T2** (Pruitt)	**CRDAMC** (Yarvis)	**UTHSCSA** (Dondanville)
	Specific Aim 1: mHealth Technology Advancement					
☑	Task 1: Establish MOU with DHA VNC to host SIP Based Desktop VTC technology	1	X			
☑	Task 2: Procurement of SIP based Desktop VTC technology	1-4	X			
☑	Task 3: Define/Finalize Technical Requirements	2	X	X		
☑	Task 4: mHealth Prototype Development	2-3	X			
☑	Task 5: mHealth Prototype Testing/Quality Assurance	4-5	X			
☑	Task 6: Development of draft End User Guides (Patient & Provider)	5	X			

Appendix C: Revised Statement of Work,

		Timeline Months	MHIC (Little)	T2 (Pruitt)	CRDAMC (Yarvis)	UTHSCSA (Dondanville)
	Specific Aim 2: End User Usability Assessment					
☑	Task 1: Desktop VTC technology and mHealth Platform installed T2 to conduct usability assessment	6				
☑	Task 2: Expert Review of mHealth Prototype	6		X		
☑	Task 3: Analysis of Design Features	6		X		
☑	Task 4: Usability Testing of mHealth Prototype with Simulated Patients	6-8		X		
☑	Task 5: Usability Testing with Clinical Providers	6-8		X		
☑	Task 6: Development of Phase 2 Report Findings	8		X		
	Specific Aim 3: mHealth Technology Refinements					
☑	Task 1: mHealth Programming Refinements	9	X			
☑	Task 2: Technical Testing	9-10	X			
☑	Task 3: Quality Assurance Reviews	9-10	X			
☑	Task 4: Finalize End User Guide	9-10	X			

Appendix C: Revised Statement of Work,

		Timeline Months	MHIC (Little)	T2 (Pruitt)	CRDAMC (Yarvis)	UTHSCSA (Dondanville)
	Specific Aim 4: Pilot Investigation of Remote Care Delivery					
	Major Task 1: Administrative Preparation for Research					
☑	Subtask 1: Introduce project to the Fort Hood Community	1-3			X	X
☑	Subtask 2: Refine eligibility criteria, exclusion criteria, screening protocol for pilot	1-2			X	X
☑	Subtask 3: Develop pilot protocol	1-3			X	X
☑	Subtask 4: Finalize consent form and human subjects protocol	1-3			X	X
☑	Subtask 5: Submit protocol for HRPO pre-review.	4				X
☑	Subtask 6: Submit protocols to UTHSCSA IRB and seek Institutional Agreement for IRB review (IAIRs) from BAMC	5-6	X	X	X	X
☑	Subtask 8: Establish/Modify CRADA between Army and UTSCSA to bring research resources to Ft Hood to conduct study	1-4				X
☑	Subtask 9: Submit IRB Approvals for final HRPO review and approval	5				X
☑	Subtask 10: Hiring staff to support the study	6-8				X

		Timeline Months	MHIC (Little)	T2 (Pruitt)	CRDAMC (Yarvis)	UTHSCSA (Dondanville)
	Major Task 2: Technical Preparation for Research					
☑	Subtask 1: Desktop VTC Technology and mHealth Platform installed at CRDAMC	9	X	X	X	X
☑	Subtask 2: TATRC/T2 site visit to test mHealth Prototype connections at CRDAMC	9	X	X	X	X
☑	Subtask 3: Technical Meeting Kick-Off at CRDAMC to train PIs and key study staff on technology	9	X	X	X	X

Appendix C: Revised Statement of Work,

		Timeline Months	MHIC (Little)	T2 (Pruitt)	CRDAMC (Yarvis)	UTHSCSA (Dondanville)
	Major Task 3: Conduct Open Pilot of mHealth Technology					
☑	Subtask 1: Commence recruitment of provider participants (n=3-5)	6-9				X
☑	Subtask 2: Consent, conduct pretest and enroll provider participants	6-12				X
☑	Subtask 3: Provide training to provider participants	9-12			X	
☑	Subtask 4: Credential providers as telebehavioral health providers	9-12			X	
N/A	Subtask 5: Advertise and screen service member participants for participation in the pilot	12-18			X	X
N/A	Subtask 6: Consent, conduct pretest and enroll service member participants (n=10-50)	12-18				X
N/A	Subtask 7: Train participating service members in mHealth interface	12-18				X
N/A	Subtask 8: Conduct treatment as usual using the mHealth/desktop teleBH platform	12-21			X	
N/A	Subtask 9: Conduct post-pilot assessment (+12 weeks from pretest)	15-24				X
N/A	Subtask 10: Conduct analysis	21-24				X

Appendix C: Revised Statement of Work,

		Timeline Months	MHIC (Little)	T2 (Pruitt)	CRDAMC (Yarvis)	UTHSCSA (Dondanville)
	Specific Aim 5: Ongoing Tasks					
☑	Task 1: Maintain regulatory compliance with IRBs/HRPO to include initial review and approval, amendments, continuing review, adverse event and deviation reporting and closure reports.					X
	Task 2: Outreach				X	X
N/A	Task 3: Submit quarterly recruitment date to FITBIR and final outcomes at the end of the study	quarterly			X	
☑	Task 4: Provide Help Desk Support during normal business hours M-F to troubleshoot provider/patient issues and document/communication UTSCSA of all help desk encounters	9-24	X			
	Specific Aim 6: Dissemination and Deliverables					
☑	Task 1: Establish am Executive Committee to oversee dissemination activities including developing publication protocol for disseminations of findings through professional and scholarly venues (e.g. peer-reviewed publications, scientific conferences etc)	6-12	X	X	X	X
☑	Task 2: Write Publications for DoD and civilian peer review publications	21-24+	X	X	X	X
Dec 2019	Task 3: Final Report submitted to Department of Defense within 6 months of project completion	30	X	X	X	X

Projected Quarterly Enrollment

	Year 1				Year 2			
Target Enrollment (per quarter)	**Q1**	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
CRDAMC providers				3				
CRDAMC SMs					10	10		
Target Enrollment (cumulative)				**P:3**	**P:3 SM:10**	**P:3 SM:20**		

Appendix D: Approved Research Protocol

HUMAN SUBJECTS RESEARCH PROTOCOL

1. PROTOCOL TITLE: Telehealth 2.0: Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices

2. ABSTRACT

The DoD has adopted the use of telehealth services [6], however, currently established best practices for tele-behavioral health programs are still linked to the patient's physical location and ignore the importance of the connection and relationship that exists between the patient and provider. This project provides an opportunity to establish and test a bring- your-own-device (BYOD) model of care delivery that may free the patient from being physically located near a telehealth enabled clinic, and instead allows for a flexible delivery of care that adapts to the logistical demands of a service member's schedule, responsibilities, and assignment.

The purpose of this uncontrolled trial is to pilot feasibility and acceptability evaluation of treatment as usual using the mobile tele-behavioral health technology "Mobile Connect" with up to 10 Provider-Participants providing embedded behavioral health services in clinics at Fort Hood and up to 50 Service Member-Participants; individuals that are already receiving care from the provider-participant and willing to test the Mobile Connect product. Provider-participants will be assessed pre-treatment, during Mobile Connect treatment sessions, and at follow-up. Service member-participants will be assessed pre-treatment and at follow-up.

Mobile Connect is a secure, mobile application for smartphones with Android or IOS operating systems that will directly connect with a Secure Internet Protocol (SIP) based desktop video teleconferencing system.
For this study, a BH provider would initiate a SIP-based video teleconference from his or her desktop computer behind the
.mil firewall. The video teleconferencing system would contact the mobile connect application and authenticate that the patient is the correct recipient prior to establishing a "skype-like" session with the patient.

3. OBJECTIVES/SPECIFIC AIMS/RESEARCH QUESTIONS

Purpose: The purpose of the study is to conduct a pilot feasibility and acceptability evaluation of routine behavioral health clinical treatment as usual delivered using the mobile tele-behavioral health technology "Mobile Connect product."

Objectives/Aims/Research Question:

1. Will service member-participants find the "Mobile Connect product" acceptable for the receipt of routine behavioral health clinical treatment as usual as measured by Question 9 on the Telehealth Survey (Service Member version) "Overall, Mobile Connect is an acceptable modality for behavioral health treatment" at Follow-up? Exit interviews will provide exploratory qualitative data foracceptability.
2. Will provider-participants find the "Mobile Connect product" acceptable for the delivery of routine behavioral health clinical treatment as usual measured by Question 7 on the Telehealth Survey (Provider version) "Overall telehealth and Mobile Connect is an acceptable modality for the delivery of behavioral health treatment" at Follow- up? Exit interviews will provide exploratory qualitative datafor acceptability.
3. Will "Mobile Connect product" be a feasible modality to deliver routine behavioral health clinical treatment as usual?

Feasibility will be measured by:

- Proportion of session disruptions due to either technology issues measured by Treatment Session Checklist.

- Proportion of session disruptions due to environmental disruptions by Treatment Session Checklist.
- Proportion of discontinuation of Mobile Connect product to return to "in the office" treatment as usual measured by provider or service member self-report to research staff.
- Exit interviews will provide exploratory qualitative data for feasbility.

4. MILITARY RELEVANCE:

While the DoD has adopted the use of remote tele-behavioral health services to provide care, currently established best practices for tele-behavioral health programs are still linked to the patient's physical location and ignores not only the importance of the connection and relationship that exists between the patient and provider, but the mobile and transitory nature of service member's deployment, relocation, training, and temporary duty assignment schedules. This includes deployment to operational venues in which care is provided by behavioral health providers that are also deployed to tactical locations to assess and treat behavioral health problems among deployed service members.

As noted by the Assistant Secretary of Defense for Health Affairs, "The DoD is committed to optimizing care for members of the Uniformed Services in operational settings." This includes innovative manners of delivering care to service members that reduce the burden they face for seeking out behavioral health services. Indeed, the Joint Concept for Health Services (Joint Chiefs of Staff, 2015) calls for advanced technologies to be employed to provide care to service members deployed to in accessible locations that challenge the military's ability to physically evacuate a service member who is in need of care [12]. Further, telemedicine is specifically cited as an efficient innovation for providing care without adding burden to deployed Service members or the operational environment.

Remote, telehealth based care may meet this need, whether it is delivering care outside of the traditional clinic setting in order to reduce stigma; delivering care via a mobile device to reduce the travel and time commitment for attending sessions; or maintaining the relationship a patient has with their provider, regardless of where their service takes them. Additionally, it allows care to remain accessible during periods of physical relocation and stressful transition.

5. BACKGROUND AND SIGNIFICANCE.

The Department of Defense (DoD) has traditionally provided behavioral health (BH) services to patients based on their location, and when a patient changes duty station, relocates for a training exercise, or deploys to a theater of operations, those services are transitioned to a new provider at the new locale. This strategy not only disrupts the therapeutic relationship that is central to psychotherapeutic interventions, but it also slows the course of treatment given that a new relationship must be established with each new provider. Perhaps most importantly, it creates a gap in care during periods of transition, which have been demonstrated to be particularly risky periods for behavioral health crises, treatment dropout, and is a well-documented psychosocial stressor [1, 2]. While this practice made sense, historically, given that technological limitations necessitated in-person services, recent advances in behavioral health care have seen the development of telehealth programs that can provide seamless real-time video communication between a patient and provider across large geographical expanses that retain the efficacy, effectiveness, and therapeutic relationship of in-

person treatment [3, 4, 5].

Indeed, both the DoD and Veteran's Health Administration have adopted the use of remote services [6], however, currently established best practices for tele-behavioral health programs are still linked to the patient's physical location and ignore the importance of the connection and relationship that exists between the patient and provider. The current model includes care delivered in an operational venue, which requires behavioral health providers to be deployed to tactical locations to assess and treat BH problems among deployed service members.

This project aims to provide preliminary support for the transformation of the telehealth paradigm to migrate behavioral health services to a relational model, where the patient would receive standard, ongoing care from the same behavioral health provider, or team, regardless of the service member's current location [7]. Using the relational model, the patient to BH provider relationship would be based on the patient's location when the care was initiated. This allows the patient to maintain access to the behavioral health provider(s) and treatment(s) that they were engaging in prior to a transition, and to have access to care during highly stressful transitional periods.

Using this relational model for tele-behavioral health services, it cannot be assumed that patients would always have access to a formal DoD telehealth enabled location. Therefore, it is important to consider innovative ways of advancing the current telehealth network operating procedures to allow service members and behavioral health providers to connect, securely, using the patient's own mobile device (i.e. smartphone or tablet). It also continues to trend in the telehealth field of moving behavioral health services out of the traditional psychotherapy clinic and into the patient's home environment (Figure 1) in a move to increase treatment seeking by reducing barriers patients encounter when initiating behavioral health services (e.g. stigma, travel costs, time off of work).

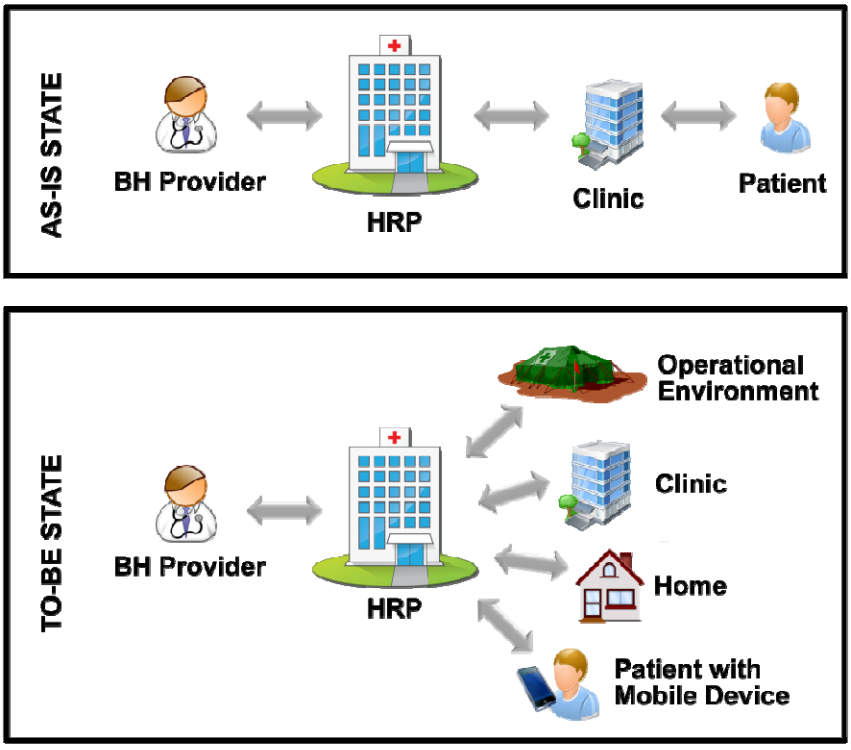
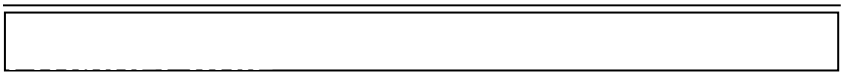


Figure 1. Innovative changes to the BH services via the Telehealth 2.0 project
Figure Legend: BH – Behavioral Health; HRP = Health Readiness Platform

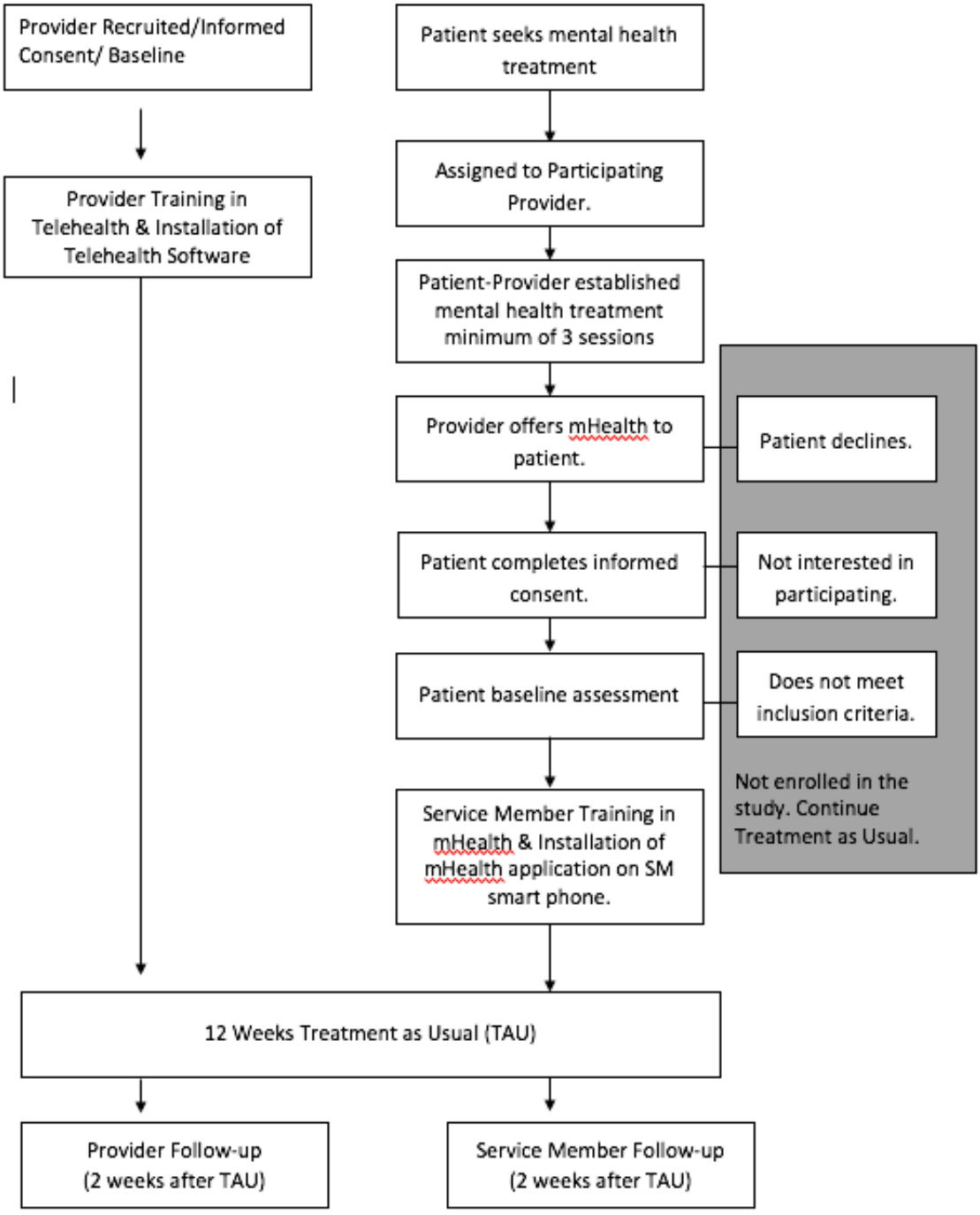
This project provides an opportunity to establish and test a bring-your-own-device (BYOD) model of care delivery that may free the patient from being physically located near a telehealth enabled clinic, and instead allows for a flexible delivery of care that adapts to the logistical demands of a service member's schedule, responsibilities, and assignment.

6. RESEARCH DESIGN

Design: The proposed study is an uncontrolled pilot. The overview of the study is summarized in Figure 2.



Provider-participants **Patient Participants**



7. RESEARCH PLAN

7.1 Selection of Subjects

7.1.1. Subject Population.

The pilot study will consent and screen up to 15 behavioral health providers from the Carl R Darnall Army Medical Center (CRDAMC) (Provider –Participants) and up to 60 active duty service member patient participants (Service

Member-Participants) receiving behavioral health care from one of the consented Provider-Participants to include 10 provider participants and 50 active duty service member participants for analysis.

7.1.2. Source of Research Material.

Measures include standard care measures (SOC) and measures for research (R) purposes

	Visit/Follow-Up Interval					
Study Procedure	Baseline/ Pre-Mobile Connect		Treatment as Usual		Follow-up	
	Provider	Service Member	Provider	Service Member	Provider	Service Member
Informed Consent (R)	x	x				
Provider Demographic Questionnaire (R)	x					
Demographic & Military Service Questionnaire (R)		x				
Review of Behavioral Health Data Platform (SOC)		x		x		x
Treatment Session Checklist (R)			x			
Telehealth Survey (Service Member Version) (R)						x
Telehealth Survey (Provider Version) (R)					x	
System Usability Scale (SUS) (R)					x	x
Exit Interview (R)					x	x

7.1.3. Inclusion and Exclusion Criteria.

Provider-Participant

Inclusion Criteria

- Credentialed behavioral health provider in the Department of Behavioral Health at the Carl R. Darnall Army Medical Center aged 18 to 65.
- Provides psychotherapy to active duty service members
- Current computer and technology in their office able to support telehealth application

Exclusion Criteria

- Expected to leave current position in the next 6 months

Service Member-Participant

Inclusion Criteria

- Enrolled in psychotherapy services with consented behavioral health provider participant for at least 3 psychotherapy sessions
- Behavioral health appointments are scheduled no greater than twice weekly
- Has a personal smartphone or tablet compatible with the Mobile Connect application (Apple or Android Operating System)
- Has access to a WiFi network signal through their personal smartphone or tablet

- Current mental health provider in agreement with enrollment

Exclusion Criteria

- Experiencing an acute mental health crisis necessitating in-patient treatment
- On the CRDAMC Behavioral Health "High-Risk" list

7.1.4. Description of the Recruitment and Prescreening Process.

Provider-Participants: The research staff will work closely with CRDAMC and Department of Behavioral Health Leadership to identify behavioral health clinics to participate in the pilot. The research team will contact each behavioral health clinic chief to identify a time to present the study to their team. The research team will conduct 20 minute presentations with each behavioral health clinic. All behavioral health providers at the identified clinics will have an opportunity to learn about the pilot study. After the presentation, interested individuals will complete a Consent to Contact form and a member of the study team will contact them at a later date to complete the pre-screen questionnaire. All participation is voluntary, and provider-participants' personal information will be

Service Member-Participant: Service members currently engaged in traditional in-the-office psychotherapy with a consented behavioral health provider participant will be given a recruitment flier (Appendix C) about the pilot study utilizing Mobile Connect by their current provider. Interested service members can be referred through their provider placing a consult in the electronic medical record, complete a consent to contact for study staff to follow-up with them or self-refer by calling research staff in response to the information sheet. Research staff will field incoming phone calls and walk-ins.

Under an IRB approved HIPAA Waiver of Authorization, Alteration of Informed Consent, and Waiver of Documentation of Informed Consent, study personnel will conduct a brief telephone pre-screening during which the basic study inclusion and exclusion criteria will be reviewed to help the individual determine if he or she meets the study criteria or has obvious exclusions from the study protocol so as to prevent individuals from making unnecessary travel for consent and more in- depth screening (see Appendix A Pre-Screening Form). This information will be entered into a secure database as a phone call to a potential participant or a phone call from a potential participant: name, phone number, name of study the caller is interested in, referral date, referral source, potential eligibility status, reason if not eligible, and verbal permission to contact the caller in the future for other studies. We will also record the date and time of the call, outcome of the call, and any notes. Participants who agree to study participation will sign a consent document before any further screening will take place. Any individually identifiable information and Protected Health Information (PHI) collected on individuals who do not consent to participation will not become part of the research data. If participants agree to participate in the research, the identifiable data collected will become part of the subjects' research records and will be stored according to the research confidentiality plan.

7.1.5. Consent Process.

There will be 2 ICD documents. The first ICD is for the behavioral health Provider-Participants and the second ICD is for the Service Member-Participants.

Provider-Participant: For behavioral health providers interested in participating who believe they may be eligible, an appointment will be made with the research staff. The Research Team will review the ICD verbally with the provider. After the provider has read the ICD they will be given the opportunity to take the consent home to

discuss the research with friends and family. The Research Team will be available to answer any questions about the study and ensure the potential provider participant understands the research. The advising staff member will have the provider participant sign the consent form. A copy of the signed ICD will be given to the provider participant. The advising staff member will document the informed consent process and the consent process will take approximately 30 minutes.

Service Member-Participant: For service members interested in participating who believe they may be eligible, an appointment will be made with the research staff. The Research Team will review the ICD verbally with the service member. After the service member has read the ICD they will be given the opportunity to take the consent home to discuss the research with friends and family. The Research Team will be available to answer any questions about the study and ensure the potential Service Member-Participant understands the research. The advising staff member will have the Service Member-Participant sign the consent form. A copy of the signed ICD will be given to the Service Member-Participant. The advising staff member will document the informed consent process in the electronic medical record. The consent process will take approximately 30 minutes.

7.1.5. Subject Screening Procedures*:* Immediately following the consent process, the baseline assessment will begin. The completion of questionnaires is outlined in Section 7.1.2. If the Provider is eligible, they will receive training in the telehealth site (e.g. Vidyo Mobile ConnectMeeting site) provided by the Defense Health Agency Video Network Center (DHA VNC) and instructions for TMS telehealth courses to provide training delivery of behavioral health telehealth. Similarly, for Service Member-Participants, the baseline assessment and screening will occur immediately following the consent.

7.1.7. Compensation for participation. There is no compensation for anyparticipants.

7.1.8. <u>Treatment Procedures.</u>

This is a pilot feasibility and acceptability evaluation of treatment as usual using the mobile tele-behavioral health technology “Mobile Connect product” in embedded behavioral health clinics at Fort Hood. Provider-Participants will utilize the DHA VNC Vidyo Mobile Connect Meeting site to access desktop video teleconferencing. Study staff will provide instructions to install the Mobile Connect application on the Service Member-Participant’s smart phone.

At the agreed upon appointment time, the Provider-Participant will use theVidyo Mobile Connect Meeting server to send a single session web link (e.g. URL) from the provider to the service member's cell phone for a specific “skype-like” VTC session between the Provider-Participant at his/her desktop and the Service Member-Participant on his or her personal mobile device (tablet or smart phone).

7.2 **Devices**: This research is testing a telecommunication application. Health care will be delivered in accordance with (Department of the Army issued OTSG/MEDCOM Policy Memo 13-009, 20 Feb 2013, Use of Telehealth in the United States Army Medical Command (MEDCOM)[9] and that meet all the privacy and confidentially requirements of HIPAA in accordance with 45 CFR 160 & 164 (HIPAA) and DoD 6025.18-R (Health Info Privacy Regulation). Below is a brief overview of the telecommunication system.

Mobile Connect is:

- A secure, mobile application for smartphones with Android or IOS operating systems that will directly connect with a Secure Internet Protocol (SIP) based desktop video teleconferencing system.
- Integrated system with an mobile application component
- Bi-directional synchronization of service members and providers/care team members over distance (synchronous and asynchronous)
- Secure, HIPAA compliant mobile messaging withFIPS-140-2 certified encryption
- Leverages a Bring Your Own Device (BYOD) model
- Mobile Device “Neutral” (Android, Blackberry, iOS, JAVA, Windows Mobile, etc.)
- A Defense Business Certification (DBC) credentialed system
- Longitudinal database captures trends and potential for cause – analysis
- Awarded one of the Army’s Greatest Inventions for 2010

- Accessing Mobile Connect Application on the Users Phone
- 6-Digit PIN Code Login and Security
- Two Factor Authentication

Encryption:

- Authenticates with PKI certificate on mobile device
- Verifies phone number is correct for mobile device
- Methodology mirrors best practices for mobile banking industry
- The mobile device/cell phone market has grown tremendously worldwide, reaching 6.8B total subscriptions, which translates to 96% global penetration. Specifically in the US, there are over 322M wireless subscriptions. While the smartphone health applications continue to grow commercially, reaching nearly 13,000 available on the Apple App Store, there have been few comprehensive implementations of secure bi-directional mobile technology efforts in the healthcare sector, and only one (Mobile Connect mobile app) in the Military Health System (MHS).
- The MHCE Research System and its Mobile Connect mobile app represent a secure, bi-directional, mobile solution that has been demonstrated to connect geographically distributed Soldiers with their care teams. Moreover, the Mobile Connect mobile app has been demonstrated to be technologically compatible on all major US cell phone service provider network, and on both smartphone (Android OS, Apple iOS, Blackberry OS, Symbian, Windows Mobile) and feature phone platforms. The backend database has been designed with consideration for integration with other healthcare information systems.

7.3. Study Procedures/Research Interventions.

- A member of the Research Team will explain the purpose of the study to potential Provider-Participants.
- Potential Provider-Participants will be asked to read and sign the consent document.
- Provider-Participants will be asked to complete baseline assessment.
- A member of the Research Team will provide the Provider-Participants the Telemental Health Guidebook (Appendix D) to provide training delivery of behavioral health telehealth.
- A member of the Research Team will provide in-person instruction and demonstration of the Vidyo Mobile Connect site for the Provider-Participants.
- The Provider-Participant will be given a flyer (see Appendix B Provider Recruitment Flyer) by the Research Team to introduce the Telehealth 2.0 Pilot Study to potentially eligible service members currently under their care for at least 3 sessions.
- Interested service members will meet with a member from the Research Team to explain the purpose of the study. Potential Service Member-Participants will be asked to read and sign the consent.
- Consented Service Member-Participants will be asked to complete baseline assessment.
- Eligible Service Member-Participants will meet with a member of the Research Team to load the Mobile Connect application on their personal smart phone and for instructions and training in using the Mobile Connect application on their smart phone.
- Eligible Service Member-Participants will continue to receive their clinical treatment as usual with their Provider-Participant using the Mobile Connect technology for 12 weeks.
- On the day of each scheduled appointment, a member of the Research Team will call the Service Member-Participants to administer required measures in the Behavioral Health Data Platform.
- Provider-Participants will complete the Treatment Session Checklist after each Mobile Connect treatment session with Service Member-Participants.
- After 12 weeks of treatment as usual, the Service Member-Participants will resume in their in-office treatment as usual with their behavioral health provider. The Service Member-Participants will be contacted by a member of the Research Team to conduct a follow-up assessment and exit interview.
- After a Provider-Participant has completed the Mobile Connect pilot with all of their enrolled Service Member-Participants, a member of the Research Team will contact the Provider-Participant to conduct a follow-up assessment and exit interview.

7.3.1 Collection of Human Biological Specimens. NONE

7.3.1.1 Laboratory evaluations and special precautions. NONE

7.3.1.2 Specimen storage. N/A

7.3.2 Data Collection

7.3.2.1 Instrumentation. See the table in section 7.1.2 above for a summary of the assessment and timing of administration. A description of each of the assessments can be found at the end of thisprotocol.

7.3.2.2 Data Storage and Access:

No data will be stored on either the Vidyo Mobile Connect desktop VTC site or the Mobile Connect application on the Service Member-Participant's smart phone. These applications are merely to facilitate communication. Research data will be coded using an assigned number. Hard copies of data collected during treatment will be placed into a lock box which will be transported by car to University of Texas Health Sciences Center San Antonio (UTHSCSA) STRONG STAR offices by a STRONG STAR staff member who will place it into the locked cabinets at the STRONG STAR offices. Data will be entered into a SPSS database on a secure UTHSCSA server by member of the research team. Electronic data will be inputted, stored, managed, and analyzed by the research staff working as part of the STRONG STAR Consortium.
This is a single-site study; all study procedures with human subjects will be conducted at the Carl R. Darnall Army Medical Center (CRDAMC) in Ft. Hood in Texas by UTHSCSA employees in collaboration with an active duty On-Site Military Collaborator.

Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data.

7.3.3 Human Biological Specimen (Biomarker) Processing. N/A

7.4 Statistical Consideration

7.4.1 Sample Size Estimation.

This study is a pilot acceptability and feasibility of Mobile Connect in treatment as usual with up to 10 provider-participants and up to 50 service member-participants. The sample sizes were selected to allow for a range of different provider and patient experiences to better inform acceptability and feasibility. Provider and service member withdrawal/discontinuation from the Mobile Connect pilot is a secondary outcome informing feasibility of the modality.

7.4.2 Primary (i.e., primary outcome variables) and secondaryendpoints.

The study aim is to evaluate service member patient acceptability (primary measure = Question 9 on the Telehealth Survey (Service Member version)), provider acceptability (primary measure = Question 7 on the Telehealth Survey (Provider version)) and feasibility (primary measure = Treatment Session Checklist & self-report) of the Mobile Connect product for the delivery of behavioral health treatment as usual.

7.4.3 Data analysis.

Data analysis will be performed by PI- Dr. Katherine Dondanville in collaboration of Dr. Jim Mintz, who is also the Data and Biostatistics Core Director of the STRONG STAR and CAP Consortiums. Prior to statistical analyses, the data will be inspected to identify missing data, outliers, or other unusual features.

1. Will service member patient participants find the "Mobile Connect product" acceptable for the delivery of behavioral health treatment as usual measured by Question 9 on the Telehealth Survey (Service Member version) "Overall, Mobile Connect is

an acceptable modality for behavioral health treatment" at Follow-up?

Responses on Question 9 on the Telehealth Survey range from 1 (Strongly Disagree) to 5 (Strongly Agree) with 3 representing (Neutral). Mean scores over 3.5 on service member-participants is representative of service member acceptability of the Mobile Connect product.

2. Will provider-participants find the "Mobile Connect product" acceptable for the delivery of behavioral health treatment as usual measured by Question 7 on the Telehealth Survey (Provider version) "Overall telehealth and Mobile Connect is an acceptable modality for the delivery of behavioral health treatment" at Follow-up?

   Responses on Question 7 on the Telehealth Survey range from 1 (Strongly Disagree) to 5 (Strongly Agree) with 3 representing (Neutral). Mean scores over 3.5 on service member-participants is representative of provider acceptability of the Mobile Connect product.

3. Will the"Mobile Connect product be a feasible modality to deliver behavioral health treatment as usual? Feasibility will be measured by:
   - Proportion of session disruptions due to either technology issues measured by Treatment Session Checklist.

     Proportion will be calculated by the total number of sessions with disruptions divided by the total number of sessions completed without disruptions. Proportions less than 50% are indicative of acceptable feasibility to deliver behavioral health treatment as usual using Mobile Connect.

   - Proportion of session disruptions due to environmental disruptions by Treatment Session Checklist.

     Proportion will be calculated by the total number of sessions with disruptions divided by the total number of sessions completed without disruptions. Proportions less than 50% are indicative of acceptable feasibility to deliver behavioral health treatment as usual using Mobile Connect.

   - Proportion of discontinuation of Mobile Connect product to return to "in the office" treatment as usual measured by provider or service member self-report to research staff.

     Proportion of discontinuation will be calculated by the total number of service members who discontinue Mobile Connect before the end of the 12 week trial divided by the total number of service members who complete the trial. Proportions less than 50% are indicative of acceptable feasibility to deliver behavioral health treatment as usual using Mobile Connect.

7.7 Confidentiality.

Provider-participants will be assigned a participant ID so that data records can be viewed by password-authenticated, authorized investigators and Consortium personnel. Specific patient identifiers are not used as part of the study code. Digital audio recordings of exit interviews will be labeled with the participant's study id number and saved on a secure password protected server.

Service Member-Participants will be advised to undergo treatment using this technology in a quiet and private space. The Research Team will discuss appropriate and inappropriate places and times to be speaking with their provider. Provider- Participants will conduct treatment sessions in their offices using their military computer. Research data will be stored by an assigned participant code number so that data records can be viewed by password-authenticated, authorized investigators and Consortium personnel. Digital audio recordings of exit interviews will be labeled with the participant's study id number and saved on a secure password protected server. Study participation is recorded in the military health record and viewable by the person's primary care provider and referring provider, if applicable. As described under Section 7.3.2, data will be de-identified and records will be stored in controlled environments to protect confidentiality.
Every member of the Research Team will be trained to maintain confidentiality of participants.

7.7.1 Certificate of Confidentiality.

We are not seeking a Certificate of Confidentiality.

7.7.2. Data Protection. Data will be coded using an assigned number. Audio recordings of the exit interviews with the Provider-Participants and Service Member Participants will be uploaded to the secure STRONG STAR database. Every member of the Research Team will be trained and monitored about how to handle and protect both medical and research records. Furthermore, the Research Team strictly controls access to study data. No identified data (either copies or originals) will be maintained at the study site. Local study site will maintain a list of assignment numbers for the purpose of linking subsequent research materials.

8.0 RISKS/BENEFITS ASSESSMENT

8.1 Risks.

Provider-Participants Rare and Serious

In 100 people, approximately (expected to occur in <5/100) may experience:

- With the handling of medical and research records, there is always the possibility of breach of confidentiality.

Service Member Participants

Less Likely, some may be Serious

In 100 people, approximately 20 may experience:

- Lack of confidentiality if family or friends ask Patient-Participants about their phone calls.
- Depending upon the Patient-Participant's phone plan and where and how they take their visit calls, data usage may increase incurring personal expenses.

Rare and Serious

In 100 people, approximately (expected to occur in <5/100) may experience:

- With the handling of medical and research records, there is always the possibility of breach of confidentiality.

Risks to Service Member-Participants regardless of participate in this research or not: Individuals receiving behavioral health care may have suicidal thoughts or attempt suicide. This is a risk whether they are in this study or not. Therefore, the risk of suicide is not any higher in the study than it would be if they were not in this study. The Mobile Connect phone app will NOT be monitored at times other than the appointed times when the Service Member is speaking with their behavioral health provider. Service Member-Participants are advised in the consent form and reminded in treatment sessions that, if at any time they are feeling significant distress or are having thoughts of hurting themselves or someone else, to come into the embed Behavioral Health Clinic as soon as possible. They can also be seen in the Urgent Care and Triage Center during duty hours, and in the Fort Hood Emergency Room after 1630 and on weekends and holidays at any time.

Safeguards for Protecting Participants:

During the pilot, Provider-Participants and their Service Member-Participants will follow the treatment as usual plan agreed to when they entered into therapy. Provider-Participants will provide immediate coping tools and techniques to Service Member-Participants used to manage distressing emotions. Distress experienced by Service Member- Participants is expected to be temporary and unrelated to the Mobile Connect platform. Any indication that the Service Member-Participant is considering suicide will be handled following care facility SOPs. Provider-Participants and Service Member-Participants can discontinue the Mobile Connect trial at any time if either participant or provider decides Mobile Connect is no longer an appropriate modality for treatment.

For urgent issues, participants will be instructed to get help immediately by going to the CRDAMC Emergency Department open 24 hours. Participants can be seen at the CRDAMC Emergency Department at any time.

8.2 Potential Benefits.

Provider-Participant:

There is no guarantee Provider-Participants will receive any benefit from taking part in this study. Providers will receive training in the delivery of Tele-Behavioral health. It is hoped that information gained from the study will inform DoD leadership about future modality of the delivery of behavioral health care.

Service Member-Participant:
There is no guarantee Service Member-Participants will receive any benefit from taking part in this study. It is hoped that information gained from the study will inform DoD leadership about future modality of the delivery of behavioral health care. The use of telehealth technologies to deliver care has several key benefits that include increased access to services, reduction of many barriers to receiving care, and reductions of wait times and travel costs. Further, receiving care in the setting of your choice may also help to reduce the fear of stigma associated with seeking behavioral health treatment.

8.3 Alternatives:

Provider-Participant: Not participate in study and continue treatment as usual with patients.
Service Member-Participant: Not participate in the study and continue treatment as usual with current behavioral health provider.

9.0 ADVERSE EVENTS, UNANTICIPATED PROBLEMS, AND DEVIATIONS

9.1 Adverse Events will be assessed and monitored according to the established STRONG STAR and CAP SOP and the IRB of record's policies and procedures.

9.2 Reporting Adverse Events, Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), and Deviations to the Office of the IRB.

All adverse events, unanticipated problems involving risk to subjects or others, and deviations will be reported to the Institutional Review Board (IRB) in accordance with current IRB policy. UPIRSOs and non-compliance with study procedures will be reported promptly to the IRB. All adverse events that do not meet the UPIRSO criteria and deviations that are not non-compliance will be summarized at Continuing Review per the IRB of record's policy.

10.0 WITHDRAWAL FROM STUDY PARTICIPATION.

Both Provider-Participants and Service Member-Participants may withdraw themselves from this study at any time and for any reason. Withdrawal from this study does not affect the participant's eligibility for care or any other benefits to which entitled.

If a Provider-Participant withdraws from the study, the corresponding active Service Member-Participants will discontinue the pilot trial of Mobile Connect and return to treatment as usual in the office. All participants will also be asked for permission to conduct a follow-up after the withdrawn date to answer some questionnaires and complete an exit interview.

Participation in this study may be ended at any time. Reasons why the researchers may need to end participation in the study are:
- The researcher or Provider-Participant believes that it is not in the Service Member Participant's best interest to stay in the study.
- The participant becomes ineligible to participate.
- A change in condition warrants treatment that is not allowed while participating in the study.

• Instructions from the researchers are not being followed.
• The study is stopped.

Service Member-participants discontinued in the study will return to treatment as usual in the office. The reason the participants are discontinued form the study will be documented in the study file.

11.0 USAMRMC Volunteer Registry Database. NA

12.0 REFERENCES.

References

[1] Godleski, L., Darkins, A., & Peters, J. (2012). Outcomes of 98,609 U.S. Department of Veterans Affairs patients enrolled in telemental health services, 2006-2010. *Psychiatric Services, 63*, 383-385. doi: http://dx.doi.org/10.1176/appi.ps.201100206

[2] Joint Chiefs of Staff. Joint Concept for Health Services (JCHS). 2015; Washington DC, USA; Department of Defense.

[3] Dohrwend, B.S., & Dohrwend, B.P. (1974). Stressful life events: Their nature and effects. New York: John Wiley Publishers.

[4] Miller, T.W. (2010). Handbook of stressful transitions across the lifespan. New York: Springer.

[5] Backhaus, A., Agha, Z., Maglione, M. L., Repp, A., Ross, B., Zuest, D., Thorp, S. R. (2012). Videoconferencing psychotherapy: A systematic review. *Psychological Services, 9(2),* 111-131. doi: http://dx.doi.org/10.1037/a0027924

[6] Gros, D. F., Morland, L. A., Greene, C. J., Acierno, R., Strachan, M., Egede, L. E., . . . Frueh, B. (2013). Delivery of evidence-based psychotherapy via video telehealth. *Journal of Psychopathology and Behavioral Assessment, 35*, 506-521. doi: http://dx.doi.org/10.1007/s10862-013-9363-4

[7] Hilty, D. M., Ferrer, D. C., Parish, M. B., Johnston, B., Callahan, E. J., & Yellowlees, P. M. (2013). The effectiveness of Telemental health: A 2013 review. *Telemedicine and e-Health, 19,* 444-454. doi: http[15]://dx.doi.org/10.1089/tmj.2013.0075

[8] Safran, J.D., & Muran, J.C. (2000). Negotiating the therapeutic alliance: A relational treatment guide. New York: Guilford Press.

[9] Department of the Army OTSG/MEDCOM Policy Memo 13-009, 20 Feb 2013, Use of Telehealth in the United States Army Medical Command (MEDCOM)

13.0 TIME REQUIRED TO COMPLETE THE RESEARCH (including data analysis). 2.5 years

14.0 STUDY CLOSURE PROCEDURES. A final close-out report will be submitted to the IRB upon end of study. Study data will be managed and stored at the STRONG STAR offices of UTHSCSA. Informed consent documents will be stored securely for a minimum of three years following completion of the research; HIPAA authorizations will be stored for a minimum of six years IAW Federal regulations.

15.0 Funding:

This study is being funded by the Joint Program Committee-1 (JPC-1) Medical Simulation and Information Sciences group with an award to the U.S. Army Medical Research and Materiel Command (USAMRMC) Telemedicine and Advanced Technology Center (TATRC) (PI: Jeannette Little, MS) (DM167009) and a subcontract from TATRC to UT Health San Antonio.

16.0 Description of Assessments:

Provider Demographic Questionnaire: The Provider Demographics Questionnaire measures standard demographics (race, gender, age) and professional practice information (e.g. discipline, education, licensure).

Demographics and Military Service Characteristics Form: The Demographics and Military Service Characteristics Form measures standard demographics (race, gender, age) and military service information (e.g., rank).

Review of Behavioral Health Data Platform: Research staff will log into the Behavioral Health Data Platform and document current behavioral health diagnoses and assessment scores administered in the last 30 days.

Treatment Session Checklist: The Treatment Session Checklist is completed by Provider-Participants after each treatment session. The Checklist documents any technology or environmental disruptions.

Telehealth Survey (Service Member Version): The Telehealth Survey is a 10 item measure assessing for acceptability and satisfaction with the Mobile Connect modality using a 5 point likert scale ranging from 1 “Strongly Disagree” to 5 “Strongly Agree.” The survey also includes 6 additional “Yes/No” questions about the Service Member’s usage of Mobile Connect. This will be completed at Follow-up.

Telehealth Survey (Provider Version): The Telehealth Survey is a 8 item measure assessing for acceptability and satisfaction with the Mobile Connect modality using a 5 point likert scale ranging from 1 “Strongly Disagree” to 5 “Strongly Agree.” The survey also includes 2 additional “Yes/No” questions about the provider’s usage of Mobile Connect.

System Usability Scale (SUS): The System Usability Scale (SUS) is a simple, ten-item scale giving a global view of subjective assessments of usability using a 5 point likert scale ranging from 1 “Strongly Disagree” to 5 “Strong Agree.” SUS yields a single number representing a composite measure of the overall usability of the system being studied.

Exit Interviews: The Exit Interview consists of a series of questions to understand the qualitative experience of using the Mobile Connect platform.

Appendices:

A: Telehealth 2.0 Pre-Screening Form
B: Provider-Participant Recruitment Flyer
C: Service Member-Participant Recruitment
Flyer D: Telemental Health Guidebook
E: Service Member Exit
Interview F: Provider Exit
Interview

Appendix E: CRDA

CRADA COVER SHEET

Action: New Agreement
Agreement Type: CRADA - Cooperative Research & Development Agreement

[NOTE: This Cover Sheet is for internal management purposes only. It is not part of the Agreement & neither party is bound to anything contained in it]

Title: "Telehealth 2.0: Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices". Short Title: "Telehealth 2.0."
Is this a clinical trial? Yes ☒ or No ☐

Effective Date:	3/18/2019	**Expiration Date:**	9/29/2020
MRMC Control No:	W81XWH-19-0171	**DA Control No:**	
MTF:	BAMC - Brooke Army Medical Center	**Lab Field:**	18-11
Concurrence obtained from appropriate IRB and CTRPO (if needed}:			YES
Concurrence obtained from US Trade Rep (if "YES" then concurrence must be attached}:			NO
Keywords:	Telehealth	Behavioral	Mobile

CTRPO's POC:	Ms. Lynn Platteborze			
	Office Symbol:	MCHE-RPC	**DTIC Source Code:**	427365
	2748 Worth Road			
	Fort Sam Houston	TX		78234
	Phone:	210-221-1988	**FAX:**	
MTF's POC:	Ms. Sharon Conable			
	3698 Chambers Pass JBSA Fort Sam Houston, TX 78234-6315			
	Office Symbol:	MCHE-ZHC	**Div/Dept:**	Dept of Clinical Investigation
	Phone:	210-916-2016	**FAX:**	
	Email Address:	sharon.r.conable.ctr@mail.mil		
Lab's Legal Counsel:	Commander, US Army Medical Research and Materiel Command ATTN: MCMR-JA (Technology Transfer Legal Staff) 810 Schreider Street, Fort Detrick, MD 21702-5012 **Phone:** 301-619-2065; **FAX:** 301-619-5034			
	Legal Reviewer:	N/A - no deviation from template		

Partner's Technical POC:	Chris G. Green, CPA			
	Director - Office of Sponsored Programs UTHSCSA			
	7703 Floyd Curl Drive, MSC 7828			
	San Antonio	TX		78229-3900
	Entity Status:	Educational	**DTIC Source Code:**	408847
	Phone:	210-567-2333	**FAX:**	
	Email Address:	greenc@uthscsa.edu		
	DoD Status:	Traditional (Collaboration with DoD in the past 3 years)		

Summary:

Pilot feasibility and acceptability evaluation of treatment as usual using the mobile tele-behavioral technology.

APPENDIX

STATEMENT OF WORK
TO
MASTER COOPERATIVE RESEARCH & DEVELOPMENT AGREEMENT
NO. MC-18-0305

A. IDENTIFICATION.

A.l. Subject Category: Medicine & Biology (Clinical Medicine), Code 57E, Title: "Telehealth 2.0: Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices." Short Title: "Telehealth 2.0".

A.2. The Clinical & Translational Research Program Office (Federal Laboratory) and The University of Texas Health Science Center at San Antonio (UTHSCSA) (Collaborating Party) desire to collaborate in research and development and will cooperate in support of the clinical investigation protocol at Carl R. Darnall Army Medical Center (CRDAMC) entitled, "Telehealth 2.0: Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices," (the "Study") by MAJ Christian Schrader, MD (On-Site Principal Collaborator), serving at the Carl R. Darnall Army Medical Center, 36000 Santa Fe Ave, Fort Hood, TX 76544, acting under the guidance of the Federal Laboratory.

A.3. This Statement of Work (SOW) is executed under authority of the Stevenson-WydlerTechnology Innovation Act of 1980 as amended by the Federal Technology Transfer Act (15 U.S.C. §3701 et seq.) and the Master CRADA between the Parties, dated 09 April 2018, and hereby incorporates all of the terms and provisions of the Master CRADA. Together, the Master CRADA and this SOW constitute the entire Agreement of the Parties. In the case of a conflict between the provisions of this SOW and the Master CRADA, the terms and provisions of the latter shall control.

B. PURPOSE.

B.l. Whereas, the Federal Laboratory and the Collaborating Party are entering into this Agreement for the mutual benefit of each Party. This joint research project will benefit the Collaborating Party by accomplishing its mission to promote and

support the advancement of military medicine and specifically military medical research. In addition, patients at Carl R. Darnall Army Medical Center receiving psychotherapy from a credentialed behavioral health provider will benefit through treatment as part of this protocol.

C. MEDICAL OBJECTIVE.

C.1. The primary objective of the proposed research is to conduct a pilot feasibility and acceptability evaluation of routine behavioral health clinical treatment as usual delivered using the mobile tele-behavioralhealth technology "mHealth product.

D. DESCRIPTION OF WORK.

D.1. Study Title: "Telehealth 2.0: Preserving Continuity of Behavioral Health Clinical Care to Patients Using Mobile Devices." The purpose of this uncontrolled trial is to pilot feasibility and acceptability evaluation of treatment as usual using the mobile tele-behavioralhealth technology "mHealth product" with up to 10 Provider-Participants providing embedded behavioral health services in clinics at CROAMC and up to 50 Service Member-Participants; individuals that are already receiving care from the provider-participant and willing to test the mHealth product. Provider-participants will be assessed pre-treatment, during mHealth treatment sessions, and at follow-u.p Service member-participants will be assessed pre-treatment and at followup.

D.2. Specific tasks include obtaining informed consent, collecting answers to standardized measures at specified intervals, administering treatment, and monitoring patient safety.

D.3. All performance under this SOW will cease at either the completion of the study, exhaustion of funds, unilateral or mutual termination, whichever occurs first.

E. RESOURCES PROVIDED BY COLLABORATING PARTY.

E.1. The Collaborating Party will furnish the following research resources:

E.2. Consumable Supplies: To be provided by Collaborating Party; TOTAL MARKET VALUE: UP TO $2,000

E.3. Services of Personnel: Provided by Collaborating Party:
0.5 FTE Protocol Coordinator X 2 years: up to $63,000
0.05 FTE Research Operations Manager X 2 years: up to $9,000
0.20 FTE Director of Research X 2 years: up to $50, 000
TOTAL PERSONNEL MARKET VALUE: UP TO $122,000

This is an estimated personnel cost and is inclusive of fringe benefits. Adjustments to study schedule may impact this projected expenditure and any impact will not result in a revised SOW.

E.4. The above are hereinafter referred to as "Resources". Information relating to them, including data generated under this Agreement, is hereinafter referred to as "Information." CRDAMC agrees that the Resources and Information will be used for research and clinical purposes only as provided in this Agreement. The Resources shall not be sold, offered for sale, used for commercial purposes, or furnished to any other Party without advance written approval from the Collaborating Party.

F. RESOURCES PROVIDED BY FEDERAL LABORATORY. Click here to enter text.

F.1. Collaborating Party will facilitate the conduct of this study at CRDAMC as is feasible in accordance with the project requirements and his regular work schedules. This includes consult for behavioral health issues, facilitate communication with the hospital command, assist with de-identified data interpretation, and assist with dissemination of the research findings for this research project.

F.2. CRDAMC will provide office space, private clinical space, work station furnitur,e utilities, housekeeping services, telephone services, faxes, printers, computers, and consumable supplies required for the use of CRDAMC equipment for Collaborating Party personnel while assisting with the study.

F.3. CRDAMC will provide assistance relocating clinical and office space as needed.

F.4. CRDAMC will provide sponsorship for study personnel working at CRDAMC to obtain access to Fort Hood, a Common Access Card (CAC), and computer systems needed to conduct the work of the research.

G. REPORTS. N/A

H. ON-SITE COLLABORATOR.

All notices required by this Agreement to be sent to the On-Site Collaborator will be sent to the following address:

Christian Schrader, MD
MAJ, MC
Psychiatry Program Director, Department of Behavioral Health
Carl R. Darnall Army Medical Center
36065 Santa Fe Ave, Fort Hood, TX 76544

I. EFFECTIVE AND EXPIRATION DATES. This SOW will be effective upon the date that the last Party signs this Agreement. SOW expires September 29, 2020, or thirty-six (36) months from receipt of last payment, whichever is later, unless mutually agreed upon and an appropriate amendment is executed.

Signatures appear on following page

J. SIGNATORIES.

J.1. Clinical & Translational Research Program Office (Federal Laboratory):

Jay Bucci, MD, PhD, RAC, CIP (Date)
COL, MC
Director, Clinical & Translational Research Program Office
Headquarters, U.S. Army Medical Research Command
2748 Worth Road (ATTN: MCMR-RPC)
JBSA Fort Sam Houston, Texas 78234-6000
Phone Number: (210) 808-7072
Cell: (210) 844-6204

J.2. The University of Texas Health Science Center at San Antonio (Collaborating Party)

Chris G. Green 3-6-19

Chris G. Green, CPA (Date)
Director - Office of Sponsored Programs
University of Texas Health Science Center San Antonio
7703 Floyd Curl Drive, MSC 7828
San Antonio, TX 78229-3900
Phone Number: (210) 567-2333

BUCCI.JAY.ROBE RT.1019984695

Appendix F: Provider User Guide

mCare VTC User Guide

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Technical Tips & Troubleshooting. 20

mCare VTC General Guide

What is within this guide?:

This guide will provide a general overview of key features of the mCare VTC application and website as well as some information on what makes mCare safe and secure.

What is mCare?:

The mCare initiative utilizes cell phone data exchanges between patients and their providers to modify behaviors and improve clinical outcomes by messaging patient specific notifications, reminders, and questionnaires over a secure technology platform.

How is mCare accessed?:

The “m” in mCare stands for mobile. mCare is about exploring mobile device technology for use in the military healthcare system.

mCare can be accessed through a compatible website browser on a personal computer or through an application on a supported mobile device; such as a smartphone or tablet.

How is patient data secured?:

The program is accessed over an encrypted HIPAA compliant system that provides secure bidirectional communication, logging all transactions, without patient identifiers while residing on a secure server at a Department of Defense facility.

Information that is sent to your mobile phone is transmitted through a secure Virtual Private Network (VPN) tunnel, and is only accessible by opening a dedicated application with a personal identification number (PIN) code.

Information that is accessed through the mCare website is hosted on a hypertext transfer protocol secure (HTTPS) site secured by Transport Layer Security (TLS). Access to the website is secured by requiring an active user name and complex password.

Website Login Instructions

Getting Started - What You Need

- ✓ A device with an active internet connection.
- ✓ A web browser with latest updates.

Instructions

This is a general guide to log into the mCare website. Depending on the device and web browser being used to access mCare website there are possible variations to these instructions.

1. Open FIREFOX or the recommended browser your onsite IT or security personnel recommends for camera security settings access.
2. In the browser's address bar enter the mCare website address https://mhcevtc.dvnet.com/vvportal/login.aspx

Above is the mCare Login Page.

3. Contact your mCare representative to be issued a Username and password.
4. Enter your Username and Password into the website and select the Log On button.

0. If you do not know your mCare representative or are having issues logging into the system please contact the mCare helpdesk at the below address.

Contact Us:

If you have any issues installing the mCare app on your phone or with the mCare website, please contact the TATRC Help Desk for assistance. Your point of contact is

Mr. Matthew A Goff

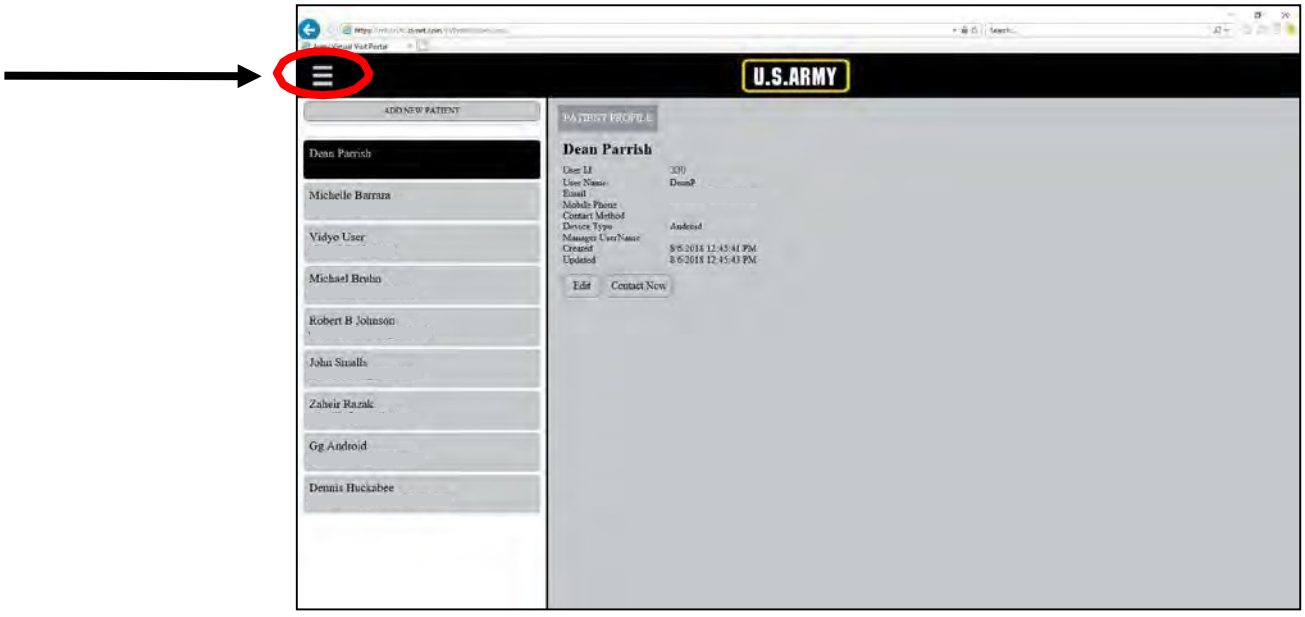
Email: usarmy.detrick.medcom-usamrmc.mbx.tatrc-mhic@mail.mil

Following the instructions on the previous page, access the mCare VTC Website at the URL: https://mhcevtc.dvnet.com/vvportal/login.aspx

Enter your username and password and click the SIGN IN button.

You will land on this page.

Click the "hamburger" menu button to toggle between Patients and Providers screens. This is the Patients screen.

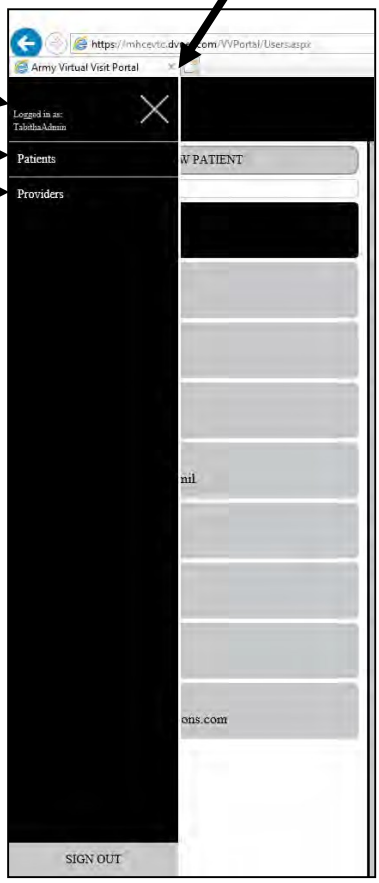


Click the "X" to exit this menu.

Role for which you are currently signed in.

Patients

Providers

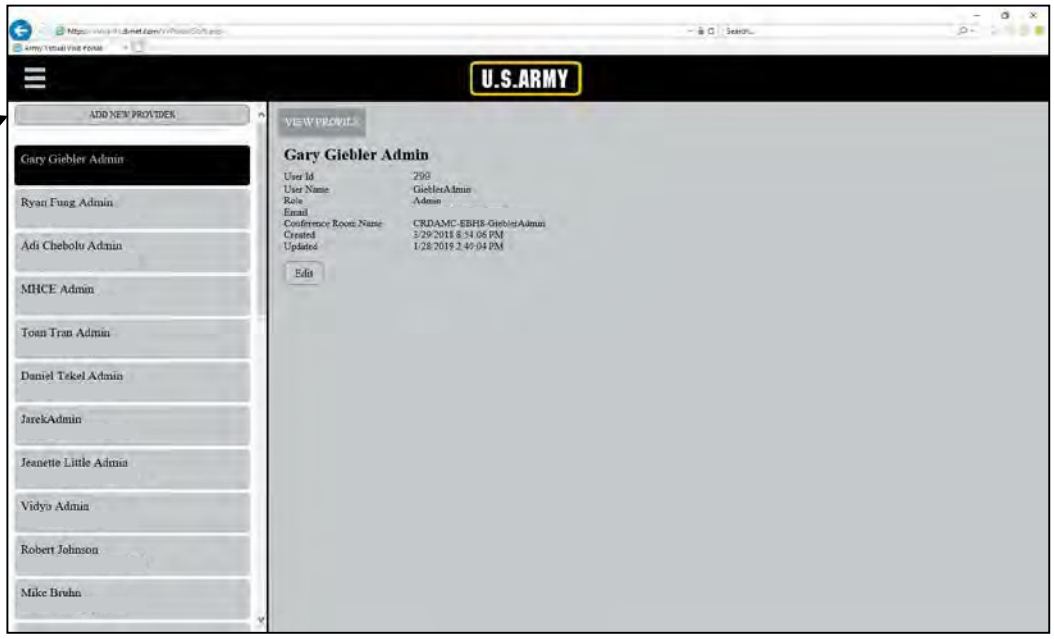


Click to SIGN OUT

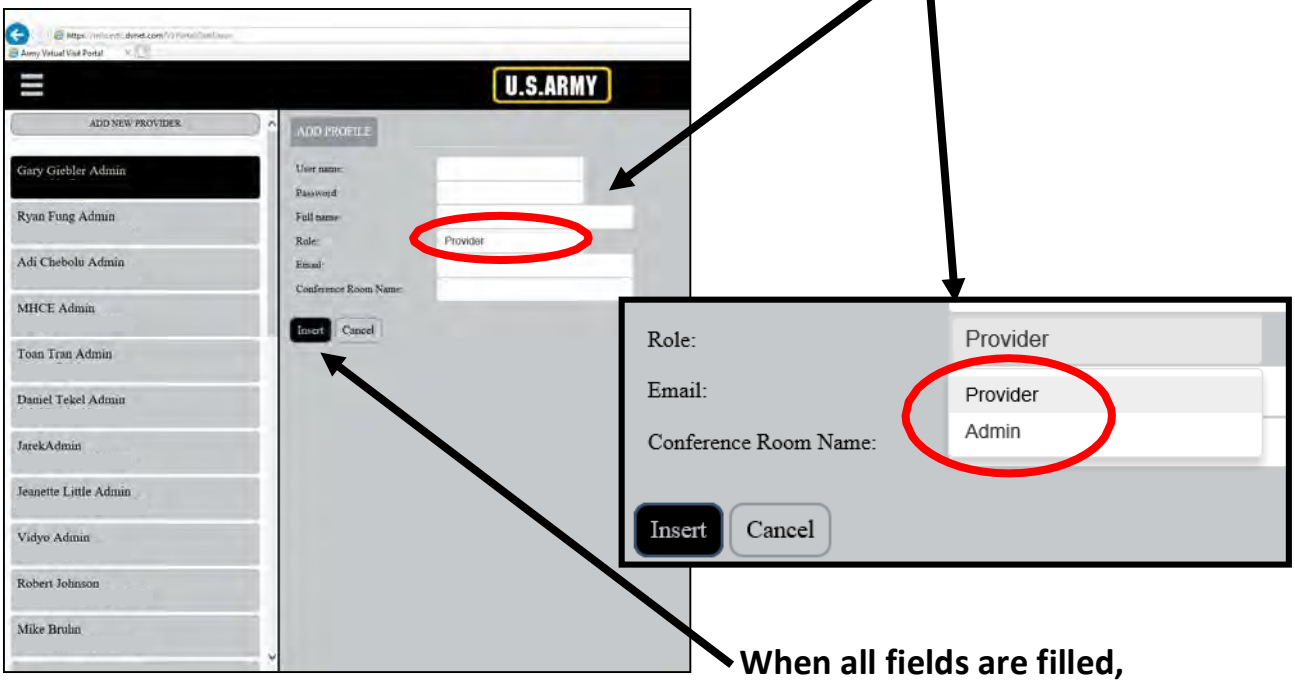
This is the Providers Screen.

On this screen, the Administrator can create a new Provider OR Administrator.

Click the ADD NEW PROVIDER button.



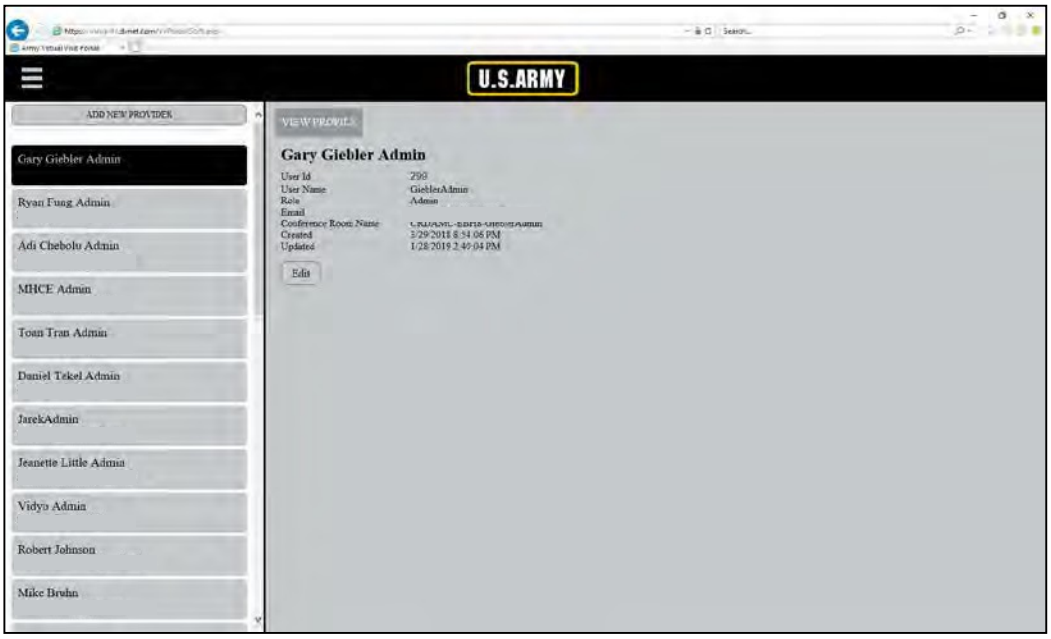
The ADD PROFILE screen will appear Complete the fields and select the appropriate role (Provider or Admin) for the user by clicking the Role field to expose the list of options.



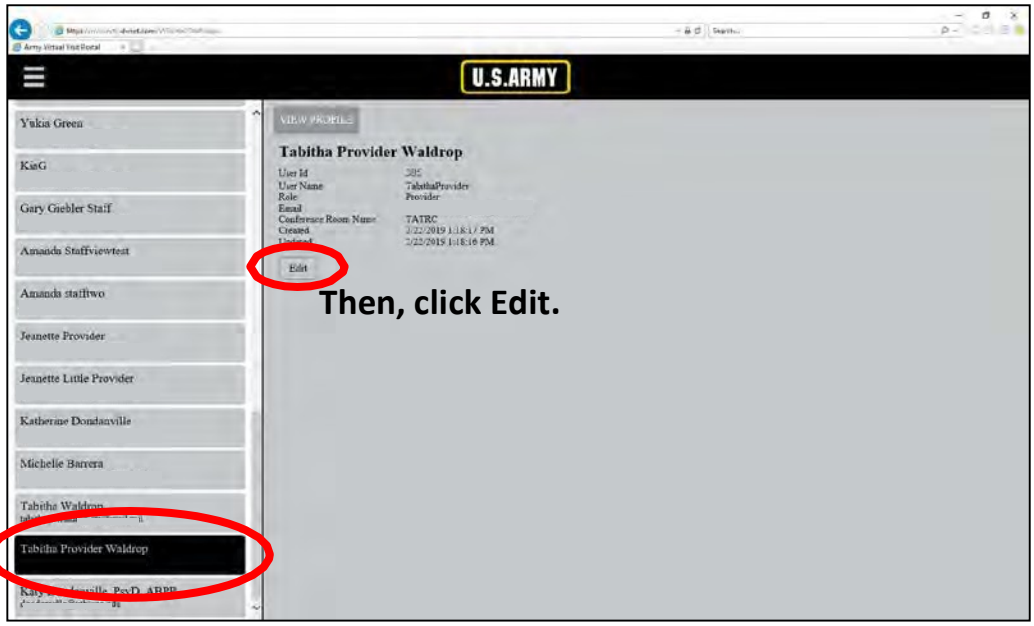
When all fields are filled, click the Insert button.

The new user will be added to the list in the left hand panel.

Admins and Providers list



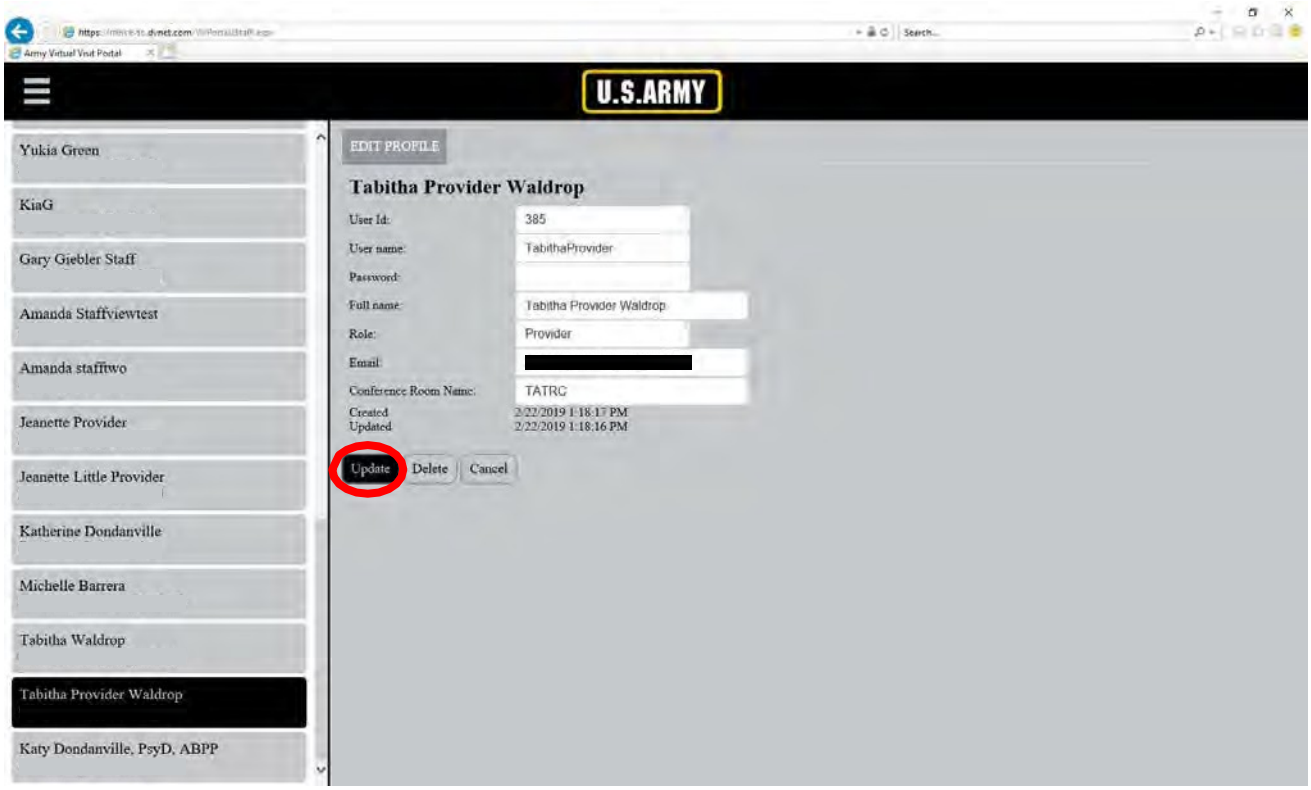
To edit a user profile, select the Admin or Provider from the list by clicking their name, then click the Edit button.



Select name, first.

Here, you may update a profile, delete the profile, or cancel any changes.

If changes are needed, make changes to the appropriate fields, then click the Update button.

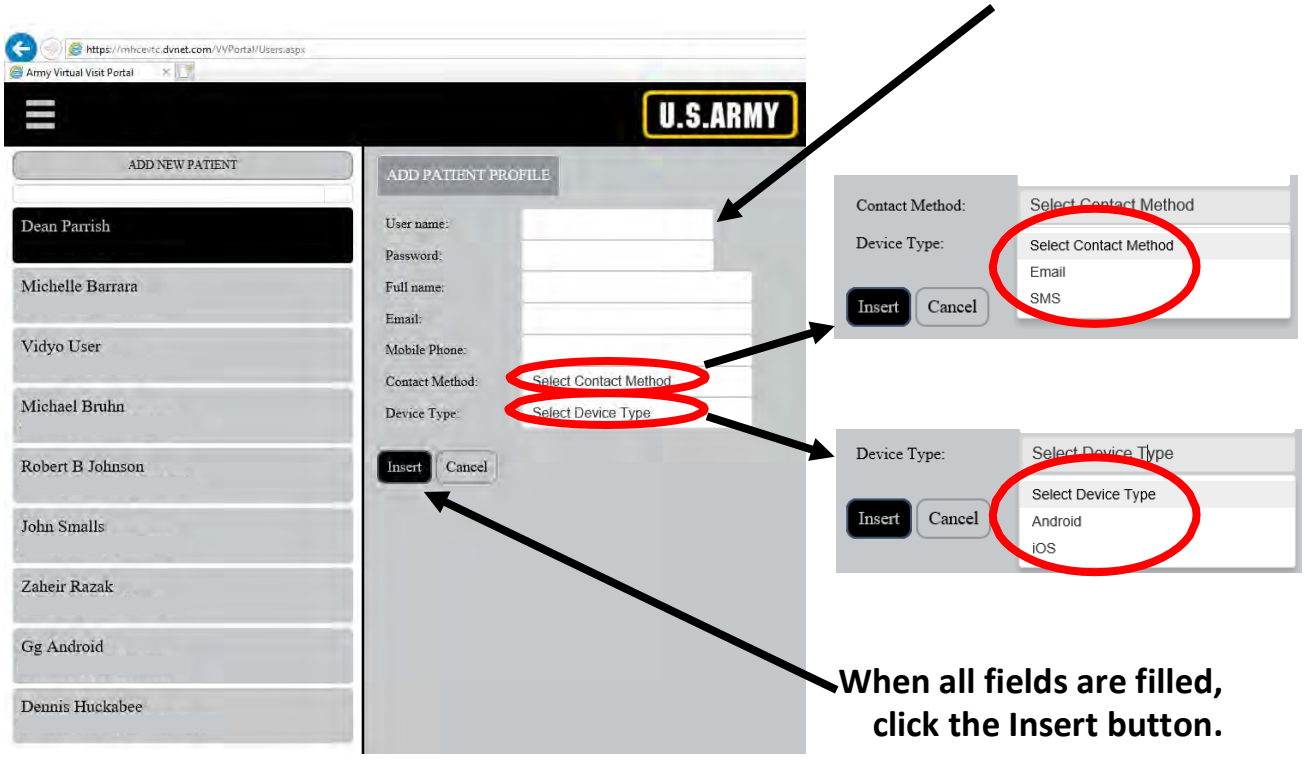


This is the Providers Screen.

On this screen, the Provider can add new patients and manage their profiles.

Click the ADD NEW PATIENT button.

The ADD PATIENT PROFILE screen will appear Complete the fields and select the appropriate Contact Method (Email or SMS) and Device Type (Android or IOS) for the user by clicking the each field to expose the list of options.

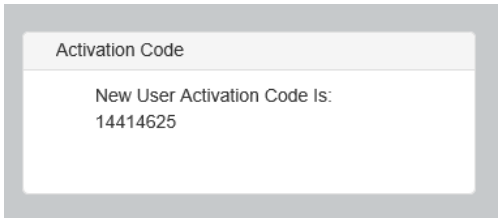


When all fields are filled, click the Insert button.

After the Insert button is clicked, the system will generate an Activation Code for the new patient user.

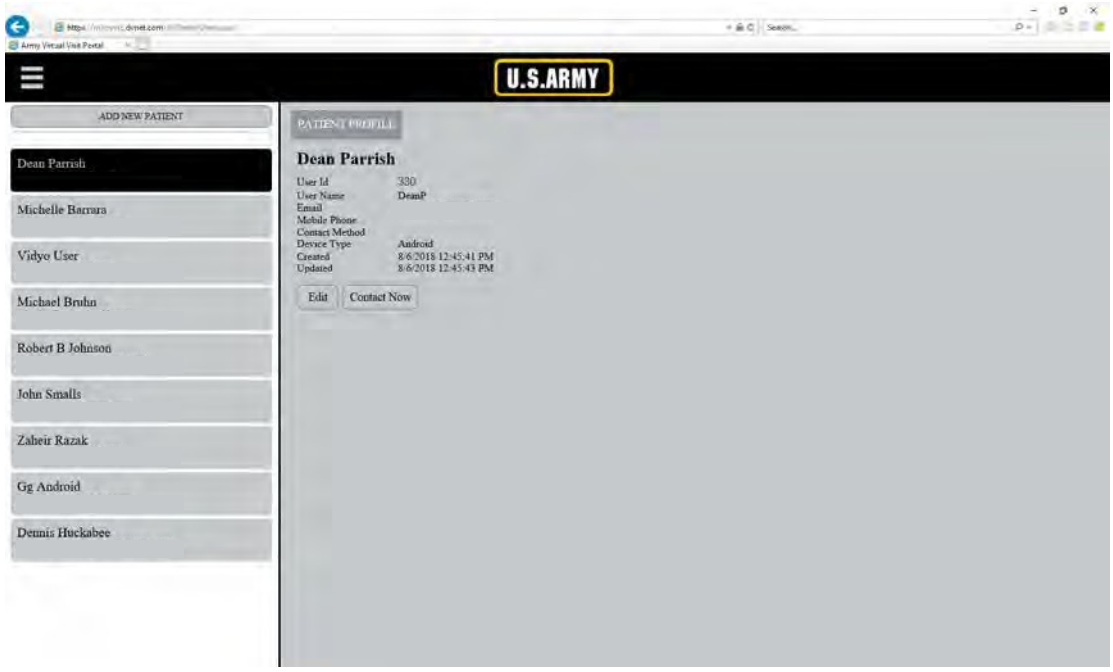
The system will also send this Activation Code to the patient's mobile device. The patient will then enter it into the mCare VTC app on their mobile device, to "activate" their app account.

More about installing the mCare VTC app begins on page 16 of this guide.



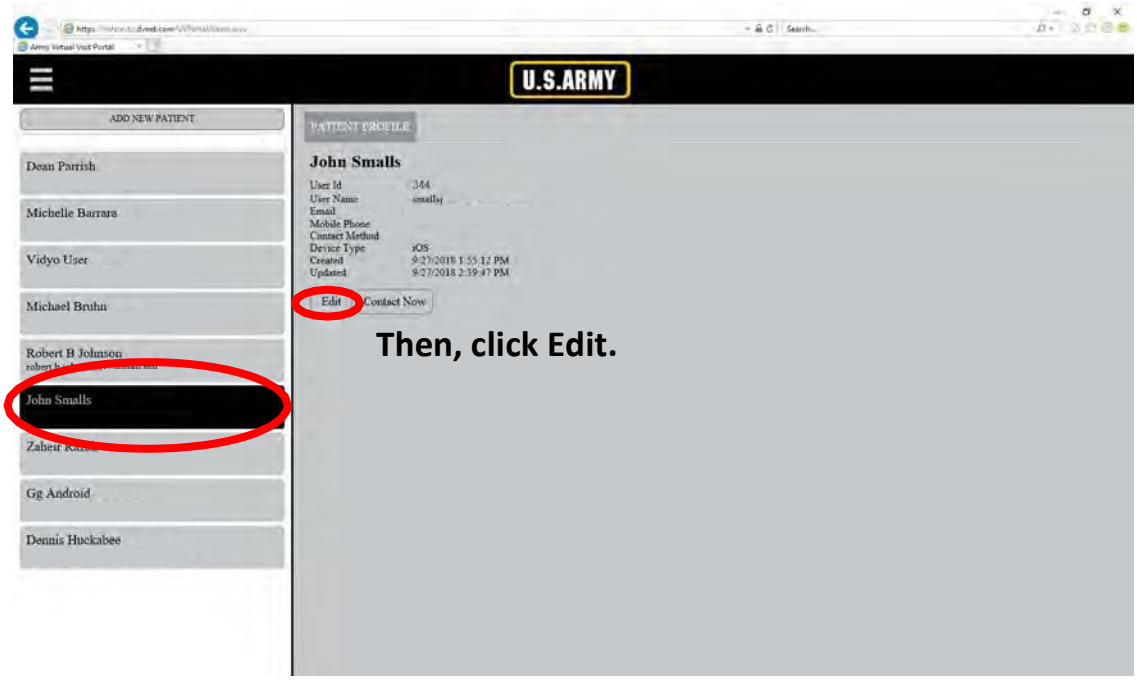
The new user will be added to the list in the left hand panel.

Patients List



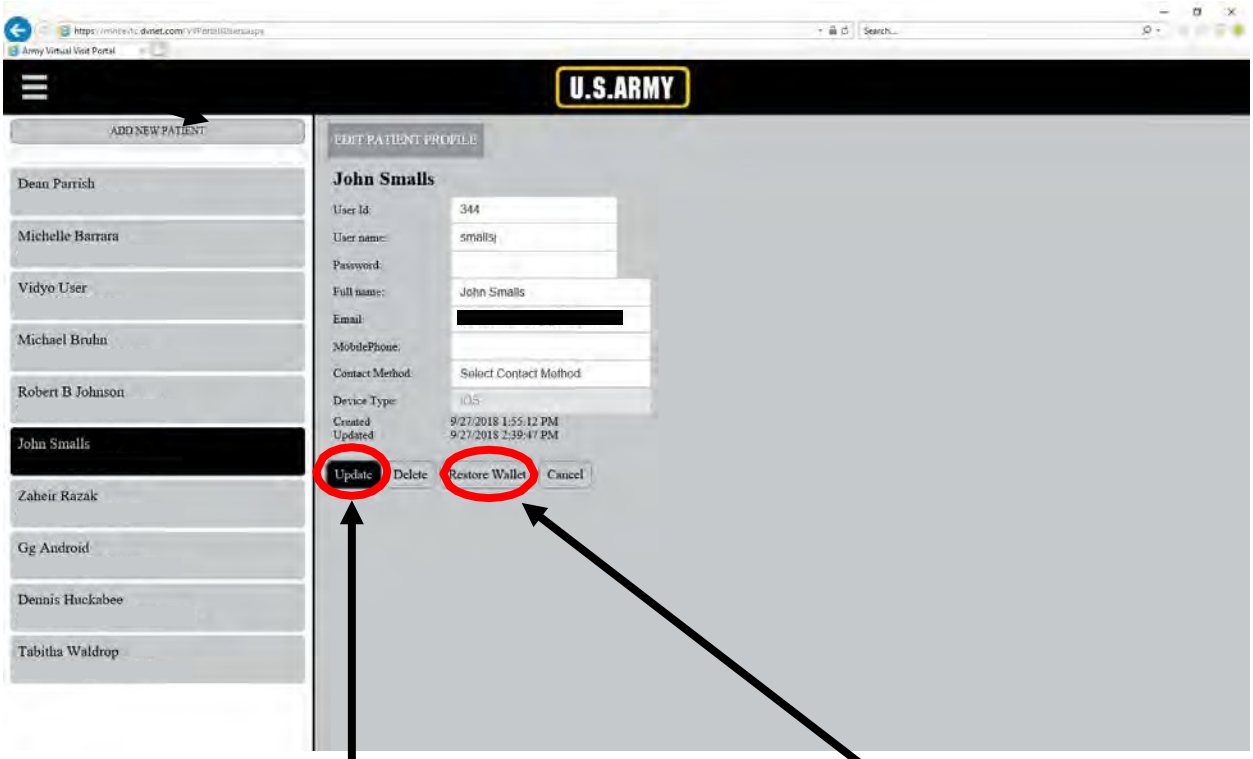
To edit a user profile, select the Patient from the list by clicking their name, then click the Edit button.

Select name, first.



Then, click Edit.

Here, you may update a profile, delete the profile, generate a new activation code, or cancel any changes.



If changes are needed, make changes to the appropriate fields, then click the Update button.

Click the Restore Wallet button to generate a new Activation Code.

How to start a VTC Session

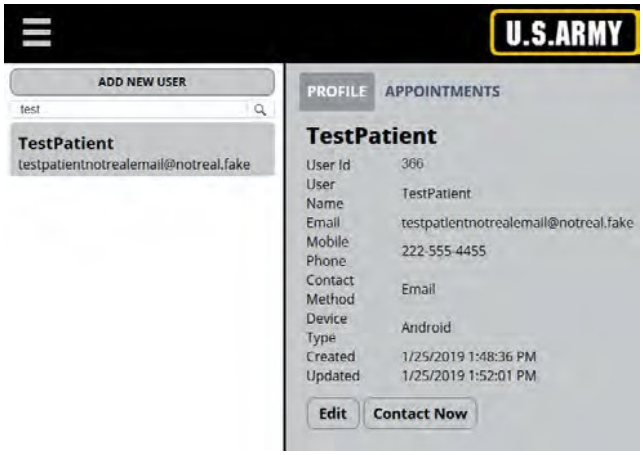
Access the mCare VTC Website:

The mCare website is hosted on the TATRC domain and can be accessed through https://mhcevtc.dvnet.com/vvportal/login.aspx using the Firefox web browser.

Log into the mCare VTC Website:

Once arriving at the mCare login page (https://mhcevtc.dvnet.com/vvportal/login.aspx) users will be required to enter a username and password.

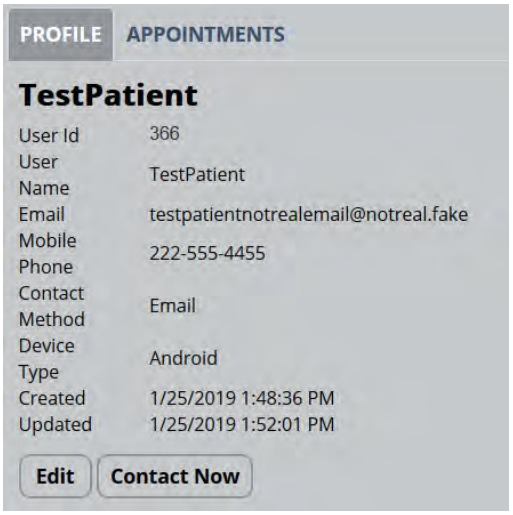
Start a session:



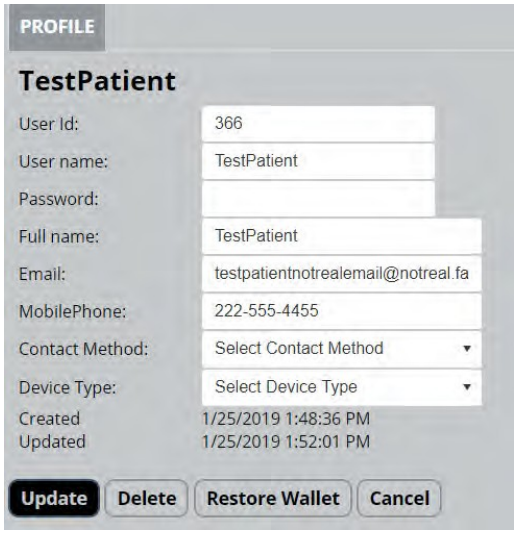
Upon logging into the VTC website a list of patients will be on the left hand side. Upon selecting a patient you will be able to edit the account or select Contact Now. Pressing Contact Now will send a 'Deeplink' to the patient using their requested contact method and start the VTC session.

Reissue Activation Codes

In the event that an activation code is not generated or if a new activation code needs to be generated. Select the patient profile and click the EDIT button as seen below.



After clicking on Edit you will be able to change any account information as well as gain access to new options. To issue a new activation code press the RESTORE WALLET button as seen below.



Clicking on RESTORE WALLET will generate a new window with a nine digit activation code. The patient will receive an e-mail alerting them that a reactivation request was made and a direct link to reset their password.

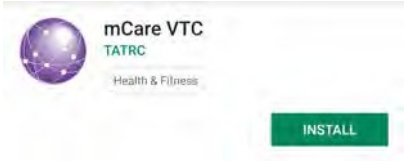
Getting Started - What You Need:

- ✓ An active Google Play Store account and password
- ✓ An active connection to the internet from your Android Phone

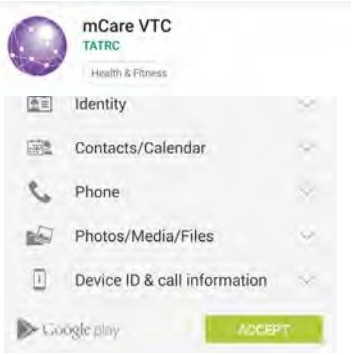
Instructions:

This is a general guide to install the mCare application. Based on the specific model of your phone, there maybe some slight variations to the installation process.

1. Open the Google Play Store Icon on your phone
2. Select the search icon within the App Store interface. Enter the following information***: mCare VTC***
3. Identify the following icon in your search results:



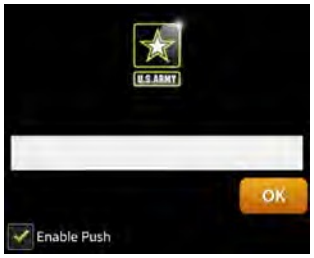
4. Select the INSTALL button. A second dialog box will appear asking you to grant access to the mCare app to several items.



5. Click on the ACCEPT button to continue with the installation.

   NOTE: This is a general guide to install the mCare application. Based on your specific model of your phone, there maybe some slight variations to the installation process.

6. Once the download is completed, open the mCare App which has been successfully loaded onto your phone.
7. An intial screen will appear prompting you to enter a one time activation code:



8. Contact your assigned mCare representative to provide you with your activation code.

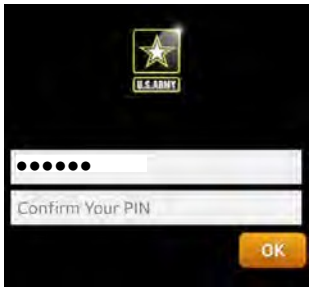
   If you do not know how to contact your assigned mCare representative, you can contact the TATRC Help Desk personnel for further assistance.

   Information on how to reach the TATRC Help Desk is found in the *Contact Us* section of this brochure.

9. Once you receive your activation code, enter it carefully into login screen on the mCare App as shown:

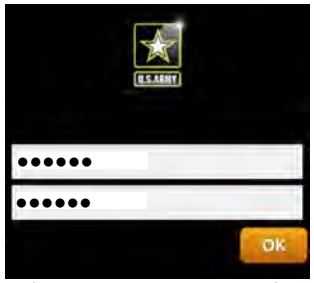
NOTE: The activation code issued to you is active for 1 hour only. If the activation code expires before you are able to enter it, you will need to request a new code to continue.

10. Select the OK buton to activate your mCare app with the backend system.
11. After successfully entering your one time user name and password, a screen will appear to create a six digit PIN code to access the mCare app. Enter your unique PIN code in the top field as shown:

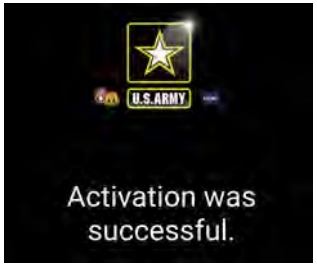


NOTE: Be sure to enter a six-digit PIN code you will be able to remember, as you are the only one who will know this number.

12. Re-enter the same six-digit PIN code to confirm this setting:



13. Select the OK button to set your PIN code.
14. Once you have successfully set up your PIN code access, the mCare App will open to the following message:



The app will be configured at this time to receive calls.

The app itself will not have any options and to initiate a teleconference please wait for either an e-mail or SMS from your provider. This message will have a deep link which initiates the app and starts the teleconference.

Launching mCare After Installation:

1. From either your device's home screen or from the programs menu, Locate and select the mCare App icon:

2. A PIN code login screen will appear. Enter your 6 digit PIN, as shown:

3. Select the OK button to continue. If you have entered your 6 digit PIN code correctly, the mCare app will synchronize, and then display the main menu screen.

   NOTE: If you do not enter your 6 digit PIN code correctly after six attempts, your access will be locked out. To reactivate your account contact your assigned mCare representive.

This is a general guide to install the mCare application. Based on your specific model of your phone, there maybe some slight variations to the installation process.

Introduction to mCare:

The "m" in mCare stands for mobile. mCare is about exploring mobile device technology for use in the military healthcare system.

The mCare initiative utilizes cell phone data exchanges between patients and their providers to modify behaviors and improve clinical outcomes by messaging patient specific notifications, reminders, and questionnaires over a secure technology platform.

The program is accessed over an encrypted HIPAA compliant system that provides secure bidirectional communication, logging all transactions, without patient identifiers while residing on a secure server at a Department of Defense facility.

mCare began in 2008 with the goal to develop an evidence-based support program for patients and their families in order to enhance their ability to meet therapy goals while at home utilizing cell phones and data responses uploaded to a secure central server.

Contact Us:

If you have any issues installing the mCare app on your phone, please contact the TATRC Help Desk for assistance. Your point of contact is:

Mr. Matthew A Goff

email: usarmy.detrick.medcom-usamrmc.mbx.tatrc-mhic@mail.mil

mCare

Android Installation Instructions

TATRC

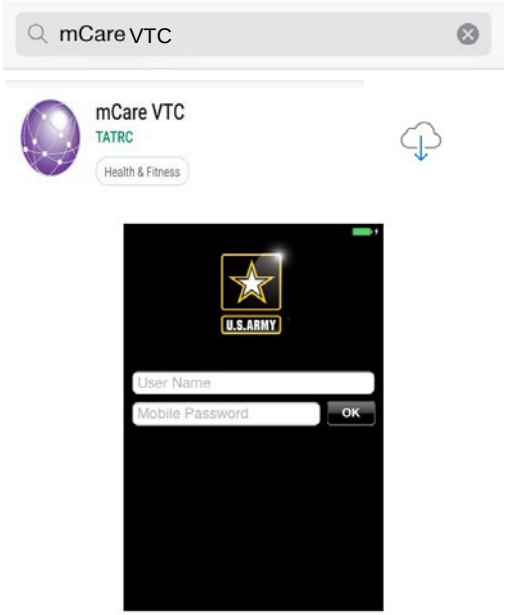
Getting Started - What You Need:

- ✓ An active App Store account and password
- ✓ An active connection to the internet from your Android Phone

Instructions:

This is a general guide to install the mCare VTC application. Based on the specific model of your phone, there maybe some slight variations to the installation process.

1. Open the App Store Icon on your phone
2. Select the search icon within the App Store interface. Enter the following information***: mCare VTC***
3. Identify the following icon in your search results:



4. Select the desired mCare icon and download this app to your iPhone.

NOTE: This is a general guide to install the mCare application. Based on your specific model of your phone, there maybe some slight variations to the installation process.

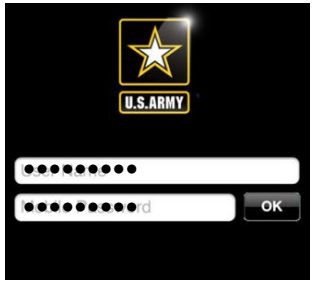
5. Once the download is completed, open the mCare App which has been successfully loaded onto your iPhone.
6. An initial screen will appear prompting you to enter a user name and mobile password:

7. Contact your assigned mCare representative to provide you with your activation code.

   If you do not know how to contact your assigned mCare representative, you can contact the TATRC Help Desk personnel for further assistance.

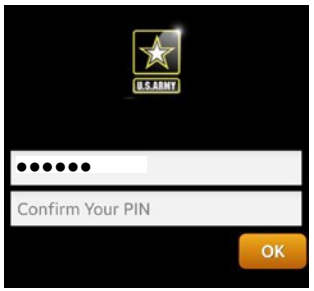
   Information on how to reach the TATRC Help Desk is found in the *Contact Us* section of this brochure.

8. Once you receive your activation code, enter it carefully into login screen on the mCare App as shown:



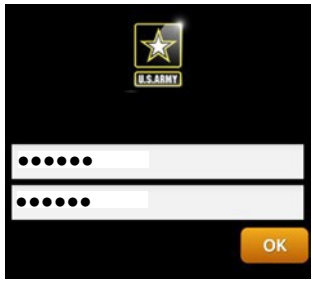
NOTE: The activation code issued to you is active for 1 hour only. If the activation code expires before you are able to enter it, you will need to request a new code to continue.

9. Select the OK buton to activate your mCare app with the backend system.
10. After successfully entering your one time user name and password, a screen will appear to create a six digit PIN code to access the mCare app. Enter your unique PIN code in the top field as shown:



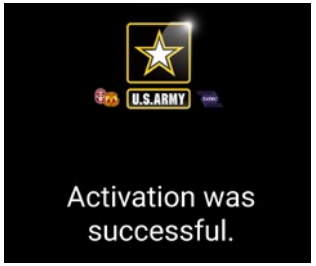
NOTE: Be sure to enter a six-digit PIN code you will be able to remember, as you are the only one who will know this number.

11. Re-enter the same six-digit PIN code to confirm this setting:



12. Select the OK button to set your PIN code.

    Once you have successfully set up your PIN code access, the mCare App will open to the following message:



The app will be configured at this time to receive calls.

The app itself will not have any options and to initiate a teleconference please wait for either an e-mail or SMS from your provider. This message will have a deep link which initiates the app and starts the teleconference.

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3. Select the OK button to continue. If you have entered your 6 digit PIN code correctly, the mCare app will synchronize, and then display the main menuscreen.

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Mr. Matthew A Goff

email: usarmy.detrick.medcom-usamrmc.mbx.tatrc-mhic@mail.mil

mCare

IOS Installation Instructions

TATRC

Technical Tips & Troubleshooting

Firefox and Google Chrome web browsers work best with the mCare VTC app.

You may elect to delete the old text link/session invites to prevent from attempting to go into an "old" previously used room, instead of the correct current room.

Providers: If you cannot remember your login or your password: please contact your project administrator. They will be able to obtain this information and reset your password.

If a patient is locked out of their app (forgets their pin or incorrectly enters a pin six times or more):

- login as their provider
- select them from the patient list
- select EDIT and click RESTORE WALLET (see Page 13)

This generates a whole new Activation Code.
***Please note: for the activation code to work properly the patient must enter the incorrect pin six times before their app will allow for a new code to be entered. Remind patients using IOS this activation code will go into the second field (Mobile Password field). They will then be prompted to choose a six digit pin. Enter this PIN twice.
Android users enter this new activation code on the one and only line there is to enter it, again followed by the prompt to chose a six digit pin (entering twice to confirm).

Other notables:

1. Patient and provider must "accept" or "allow" the use of their camera and audio or else they will not be able to see or hear each other.
2. Patient should delete old invite from provider to prevent them from clicking on the wrong link.
3. Provider must use the camera provided by the study team - producing a 720 dpi rating. A camera that produces too high definition will not work properly, at this time.
4. Adobe Flash must be turned off.
5. Camera settings must not be changed because this could result in the camera not working.
6. Popup blocker must be turned off.
7. If the provider does not see patient initially, they may need to refresh their screen. It could take several seconds for the patient to appear on the provider screen.
8. The providers CACHE on their computer should be cleared, at initial set up in Firefox.
9. The provider must update to the most current Firefox, their self. This is not an automatic update.
10. If there are new updates on the provider's computer, the provider will need to make sure to restart and clear CACHE again at this time.

If an iPad Mini was provided to you, it has its own wifi cellular service has been issued as a back up to ensure continuity of care during any unforeseen outages over the .mil network, mandatory DHA network security upgrade pushes etc.

Security of the patient is ensured on the iPad Mini, in that the mobile user will still require the two factor authentication and operating within the secure mCare security shell. Such a backup is helpful in preventing a lost clinical encounter but is not the contact method of choice, as this will be over the cellular provider's wireless network and not within the .mil. Nonetheless, keep the I pad charged before a clinical encounter.

Log in to the iPad Mini at least once before any remote clinical care sessions begin, to ensure you are familiar and comfortable with using this backup method for your clinical encounters.