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TITLE: Implementation of the AWARE System to Support Virtual Critical Care in a MEDCEN and CSH

PRINCIPAL INVESTIGATOR: Christopher Colombo

CONTRACTING ORGANIZATION: The Geneva Foundation, Tacoma, WA

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Christopher Colombo, Justin Valovich, Stacie Barczak

E-Mail: christopher.j.colombo.mil@mail.mil; jvalovich@genevausa.org; sbarczak@genevausa.org

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The Geneva Foundation

917 Pacific Ave Ste. 600
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14. ABSTRACT
In combat casualty care environments, decisions about triage, treatment, and evacuation are commonly made quickly, using limited and fragmented data. These decisions are difficult for novice clinicians to make due to lack of situational experience. Enabling critical care experts to be easily and immediately available to inexperienced clinicians using virtual critical care technologies could significantly improve their medical decision making and patient care by increasing process adherence, reducing errors, and improving outcomes. This study aims to determine if implementing a virtual critical care service that utilizes novel clinical decision support software (CDSS) to facilitate daily key quality indicators, process, and outcome metrics will improve patient safety, process adherence, and patient outcomes in a military intensive care unit and thus validate similar findings in civilian medical centers for the military. The study also aims to demonstrate that we can deploy similar technologies and virtual critical care support services to a combat support hospital during a simulated patient care exercise.

15. SUBJECT TERMS
Tele-critical care, combat casualty care, tele-medicine, intensive care unit

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1. INTRODUCTION:

In this project we intend to determine if using teleconsultation technologies and specialized software will improve patient safety, adherence to best medical practices, and improve patient outcomes in a military intensive care unit. These findings will validate civilian research findings in a military setting. We also intend to demonstrate that we can use similar technologies to facilitate critical care support during simulated patient care in a combat support hospital during a field training exercise.

2. KEYWORDS:

Tele-Critical Care, Combat Casualty Care, Tele-Medicine, Intensive Care Unit

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Timelines and progress are reported based on the most up to date SOW that had been approved. The tasks and the percentage of completion is as of 20 October 2020:

1. **Task 1.1:** Obtain Risk Management Framework (RMF) approval for the AWARE software package. (**Not Started**). Due to policy, AWARE software cannot interoperate with MHS Genesis.
2. **Task 1.2:** MAMC establishes a remote workstation for monitoring ICU beds. (**Complete**)
3. **Task 1.3:** Install VTC hardware in MAMC ICU rooms and establishes servers to host all necessary software. **(Initial install Complete, additional 5 rooms pending)**
4. **Task 1.4:** Purchase low cost, mobile devices and Omnicure Software for monitoring non-ICU patients from the TeleICU workstation. Test their function. (**Complete**)
5. **Task 1.5:** Develop remote physiologic monitoring solution that is usable on the DoD network **(75% Complete)**
6. **Task 2.1:** NMCSD Develops Clinical Practice Guidelines that include clinically meaningful process and outcomes metrics. **(90% Complete: 2 protocols completed, 2 still in development)**
7. **Task 2.2:** NMCSD and Mayo write and submit research protocol to submit to the IRB to evaluate impact of providing data to clinicians regarding quality metrics. **(Complete)**
8. **Task 2.4:** NMCSD clinicians monitor patients at the remote workstation and audit metrics, complete reports, and provide real-time feedback to bedside clinicians on performance (**Complete**)
9. **Task 2.5:** Analyze impact of these structural and process changes on clinician performance and patient outcome. (**75% Complete**)
10. **Task 3.1:** Mayo creates and implements research protocol to evaluate military clinician use of AWARE CDSS **(75% Complete)**
11. **Task 4.1:** Determine software and network solution(s) to connect combat support hospital to garrison clinical workstations **(Complete)**
12. **Task 4.2:** Scale project to support minimum bandwidth data transfer. This may involve reduced real-time physiologic monitoring, reduced frequency of data refresh rates, or other methods to diminish network demand and optimize remote clinician recommendations/monitoring. **(Complete)**
13. **Task 4.3:** Provide remote clinician support during a live and/or field training exercise.. **(Complete)**
14. **Task 5.1:** Determine software and network solution(s) to connect role 2 and MEDEVAC platform(s) to garrison clinical workstations **(Complete)**
15. **Task 5.2:** MAMC/ISR support a multi-role FTX demonstrating proof of concept for TeleCritical Service support during multi-casualty scenario from Role 2 to Role 3 **(Complete)**

What was accomplished under these goals?

1. **Task 1.1: Obtain Risk Management Framework (RMF) approval for the AWARE software package. (Not Started)**
    - *Subtask 1.1.1: Complete*
        - Software and documentation were provided to MAMC by Mayo on 15 December 2017.
    - *Subtask 1.1.2: MAMC Submits RMF Application*
        - MAMC completed the paperwork portion of the RMF process in the fall of 2017, but was required to re-submit/start over due to changes in the RMF process. The software validation testing and cybersecurity scanning were completed as part of the original submission and should be usable in the re-submission. The new packet was delayed for submission pending challenges with connecting AWARE to MHS GENESIS through an approved governance process and API.
        - Due to policy, AWARE software cannot interoperate with MHS Genesis.

2. **Task 1.2: MAMC establishes a remote workstation for monitoring ICU beds. (Original SOW Complete; pending implementation of DocBox ICU platform)**
    - *Subtask 1.3.1: Complete*
        - Equipment and hardware for the MAMC remote workstation has been obtained. This includes two single tier adjustable ergonomic desks, workstation monitors, Jabber cameras, and computers. Funding for this effort was a mixture of MTF and Grant.
    - *Subtask 1.3.2: Complete*
        - Remote workstation space at MAMC was renovated in anticipation of installation.
        - All equipment has been installed in this location.
        - Software components for the workstations to function completely include:
            - Remote Electronic Medical Record Access: tested and functional with MHS GENESIS.
            - Remote VTC: tested and functional with Cisco Jabber and VNC VTC.
            - Remote Imaging: tested and functional with PACS system.
            - Remote Vital Signs Monitoring: tested and functional using the SpaceLabs virtual application hosted on AVHE called CareAware. This interface will be updated after DocBox ICE platform completes RMF and can be used to virtualize remote visualization of bedside physiologic monitors).

3. **Task 1.3: Install VTC hardware in MAMC ICU rooms and establishes servers to host all necessary software. (Original SOW Complete, additional 5 rooms pending)**
    - *Subtask 1.3.1: GENEVA Purchases Equipment for MAMC*
        - Equipment purchase for all rooms is complete
    - *Subtask 1.3.2: MAMC Installs VTC Equipment in ICU Rooms*
        - Equipment installation has been completed 7 rooms according to the original SOW.
        - 5 additional rooms will be allocated to ICU East at MAMC for future Telehealth training and monitoring
            - Collaboration between MAMC and NMCSD is underway for allocation of 5 additional rooms to ICU east with Bernoulli
            - Command has agreed that TCC is an institutional priority and will likely be more supportive of additional installation
            - Implementation of additional rooms is currently under discussion with Madigan Facilities. Early disposition of some of the equipment has been

approved by the sponsor and is in process. This is expected to facilitate installation.

4. **Task 1.4: Purchase low cost, mobile devices and Omnicure Software for monitoring non-ICU patients from the TeleICU workstation. Test their function. (Complete)**
    - o Omnicure has completed integration SensoScan vital signs monitoring into their data display.
    - o Omnicure has provided requirements for mobile device platform and Geneva has purchased tablets as the mobile device solution to host the OmniCure application.
    - o Omnicure software application is complete and publicly available on the Android and iPhone platforms.
    - o The workflow between SensoScan continuous vitals data, bedside applications, and physician/provider monitoring via Omnicure has been successfully demonstrated during a simulated MASCAL event during the Navy's Fleet Week exercise in San Francisco (https://www.navy.mil/submit/display.asp?story_id=107325). This demonstration utilized the integrated OmniCure/Sensoscan platform to monitor and interact with 4 simulated and 20 synthesized patients through a web portal visible at Madigan Army Medical Center and Naval Medical Center San Diego.

5. **Task 1.5: Develop remote physiological monitoring solution that is usable on the DoD Network. (75% Complete)**
    - *Subtask 1.5.1: Obtain RMF for DocBox software and device*
        - **o** PIA for DocBox is completed and approved. RMF for Docbox is still backlogged
        - **o** DocBox RMF is being pursued as part of another effort (NETCCN). This is still being pursued as we work through the FEDRAMP processes for NETCCN.
        - **o The Docbox RMF will likely not be completed by the AWARE period of performance due to delays in government FEDRAMP planning and processes. The RMF will continue to be pursued within the FEDRAMP certification process through the National TeleCritical Care Network Project.**

    - *Subtask 1.5.2: Develop visualization software solution for real-time data.*
        - o Docbox will be the visualization software. Equipment was purchased and received on site.
        - o Docbox and Omnicure have integrated to provide visualization software for real time data at the bedside and in remote environments.
        - o The current capabilities are two-way video/audio**,** group-calling, team-messaging, remote physiology monitoring, file sharing, SOS alerts, creating care teams, and patient self-registration.

6. **Task 2.1: NMCSD develops Clinical Practice Guidelines that include clinically meaningful process and outcomes metrics. (90% Complete)**
    - *Subtask 2.1.1: NMCSD develops SOPs to integrate virtual critical care into daily patient care.*
        - o Draft version of this SOP has been completed. Final SOP is still undergoing revision pending additional nursing engagement.
        - o **The SOP has been complete.**

- *Subtask 2.1.2: NMCSD develops CPGs with local SME's, clinical champions, and critical care leadership*
    - The Blood Transfusion and Sepsis CPGs are complete. The ARDS CPG and vasopressor CPG are being circulated in draft form at present. They should be complete this year.
    - Jonas Carmichael has taken over for Konrad Davis which has caused a delay in finalizing the ARDS and Vasopressor CPG.
    - **Vasopressor CPG draft is complete and awaiting final approval at DHA level. In addition, a request has been submitted to Jonas Carmichael for both CPGs when complete and approved.**

7. **Task 2.2: NMCSD and Mayo write and submit research protocol to submit to the IRB to evaluate impact of providing data to clinicians regarding quality metrics (Complete)**
    - Protocol has been approved at NMCSD

8. **Task 2.4: NMCSD clinicians monitor patients at the remote workstation and audit metrics, complete reports, and provide real-time feedback to bedside clinicians on performance. (Complete)**
    - *Subtask 2.4.1: NMCSD monitors pre-TeleAWARE Process and Outcomes Metrics (retrospective and 3 months prospective) (Complete)*
        - The 3 months of prospective data collection is complete.
    - *Subtask 2.4.2: Run-in period. No data collection. Virtual presence established. (Complete)*
    - *Subtask 2.4.3: NMCSD monitors post- clinical data collection Process and Outcomes Metrics (3-6 months) (Complete)*
        - **This is complete and was accepted as an MHSRS poster, but the meeting was cancelled due to Covid-19. A virtual poster was submitted to the MHSRS website.**

9. **Task 2.5: Analyze impact of these structural and process changes on clinician performance and patient outcome. (75% Complete)**
    - *Subtask 2.5.1 MAMC analyzes data with Mayo for final report and demonstrates improved process adherence and patient outcomes post-implementation of virtual critical care service established compared to pre-implementation, and evaluates feasibility of CDSS on military clinician efficacy.*
        - **This will be considered complete once published.**
        - **We will be exploring publishing options depending on what available to us (MHSRS Military Medicine supplement, Military Medicine, or CCX)**

10. **Task 3.1: Mayo creates and implements research protocol to evaluate military clinician use of AWARE CDSS (75% Complete)**
    - *Subtask 3.1.1: Mayo creates synthetic environment consisting of actual critical care patient data evolving over simulated time and remotely viewable via AWARE CDSS (75% Complete)*
    - *Subtask 3.1.2: Mayo writes and gets approved IRB protocol to test clinician response in remote synthetic environment (75% Complete)*
        - Mayo Protocol has been received and must be adjusted for the MAMC environment before being submitted and approved by MAMC IRB
        - Dr. Colombo has reviewed the MAYO protocol and is currently reviewing the data sharing agreement to submit both to the IRB.

    - Will be implementing remotely due to Covid-19
- *Subtask 3.1.3: NMCSD recruits clinician subjects to participate in protocol (75% Complete)*
    - **Due delays from COVID-19, this is not a feasible part of the project. The protocol will be maintained in case it becomes usable in the future and can be submitted as work completed thus far.**
- *Subtask 3.1.4: Mayo and MAMC analyze data (Not Started)*

11. **Task 4.1: Determine software and network solution(s) to connect corresponding hospital to garrison clinical workstations (Complete)**
    - *Subtask 4.1.1: MAMC/NMCSD coordinates efforts with health IT principles (50% Complete)*
        - Multiple software and network solutions (TES, Omnicure software, Athena WVSM) have been integrated and tested for theoretical use to connect a combat support hospital to garrison clinical workstations

12. **Task 4.2: Scale project to support minimum bandwidth data transfer. This may involve reduced real-time physiologic monitoring, reduced frequency of data refresh rates, or other methods to diminish network demand and optimize remote clinician recommendations/monitoring. (Complete)**
    - *Subtask 4.2.1. MAMC works with CSH and tests IT support in preparation for FTX (Complete).*
        - Transportable Exam Station has been purchased and utilized due to low network requirements. Bandwidth readings have been captured during FTX's when possible.

13. **Task 4.3: Provide remote clinician support during a live and/or field training exercise. (Complete)**
    - *Subtask 4.3.1: MAMC provides remote continuous critical care support to CSH during FTX (Complete)*
        - MAMC has provided remote continuous care during four field exercises (Joint Warfighter Assessments, San Francisco Fleet Week exercise, Forward Surgical Team exercise, and the Army Best Medic Competition)
    - *Subtask 4.*3.2: *MAMC and CSH write after action review (AAR) of the event for inclusion in the final report. (Complete)*
        - A lessons learned/after action report that contains a review of each exercise was submitted with previous report.

14. **Task 5.1: Determine software and network solution(s) to connect role 2 and MEDEVAC platform(s) to garrison clinical workstations. (Complete)**
    - *Subtask 5.1.1: MAMC coordinates efforts with IT principles at 44 MB (Complete)*
    - *Subtask 5.1.2: MAMC coordinates with DocBox and Omnicure or other suitable vendor for software product that delivers VTC, real-time physiologic vital signs, and simple documentation solution. (Complete)*
        - Docbox and Omnicure have created a software product that delivers VTC, real-time physiology vital signs, and a simple documentation solution
        - MAMC has received a new and updated Docbox for continued simulations and data collection on-site.
    - *Subtask 5.1.3: TGF Purchases hardware (android mobile devices and TeleHealth carts) to support proof of concept demonstration (Complete)*

15. **Task 5.2: MAMC/ISR support a multi-role FTX demonstrating proof of concept for TeleCritical Service support during multi-casualty scenario from Role 2 to Role 3 (Complete)**
    - *Subtask 5.2.1: Develop casualty simulation scenarios (Complete)*
    - *Subtask 5.2.2: Conduct multi-casualty simulation FTX (Complete)*

- A multi-casualty simulation was conducted to demonstrate proof of concept for TeleCritical Services.

What opportunities for training and professional development has the project provided?

Telecritical care offers a new scope of practice for military critical care nurses, physicians, and medics. While none of the clinical decision making is new, the manner in which clinicians review data and communicate with local caregiver is a *skillset* that may be developed and trained. MAMC and clinical partners at NMCSD and BAMC are working to develop these training programs. **Lastly, MAMC has integrated telehealth into many large-scale exercises and will continue to do so based on positive feedback from nurses, physicians, and medics. Please see attached report.**

How were the results disseminated to communities of interest?

Thus far, we have three CPGs that will help standardize clinical practices across the Joint Tele-Critical Care Network after this project completes, a Telecritical Care SOP at MAMC that has been drafted and continues to undergo interactive development with other clinical partners, and training media/SOPs that are also undergoing development jointly with other clinical partners. These will all be made available to the Sponsor once the products are more fully developed and validated. **Please see a list of products in the “Products” section.**

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

Associated Task	
Major Task 1.5	• The Docbox RMF will continue to be pursued through the NETCCN FEDRAMP efforts.
Major Task 2.4	• We will be exploring publication methods for this task
Major Task 2.5	• We will be exploring publication methods for this task

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Clinical Impact:

- The installation of remote monitoring workstation equipment at MAMC has allowed the site to be a leader in the creation of the Joint Tele-Critical Care Network (JTCCN). The active JTCCN network includes MAMC, BAMC, and Naval Medical Center San Diego. The remote monitoring capabilities amongst these sites allow personnel burdens and responsibilities to be divided amongst all sites. This in turn has resulted in more active patient care with increased access to experienced providers. The JTCCN network has also been able to provide support for the established ADVISOR system.
- The increased momentum and visibility brought to virtual care has in part lead to tele-critical care being investigated by the MHS Tele-Health workgroup for program objective memorandum (POM) funding.
- The Virtual Critical Care Center (VC3) at MAMC has also provided proof of concept operations during a Joint Warfighter event in Yakima, WA.

What was the impact on other disciplines?

NOTHING TO REPORT

What was the impact on technology transfer?

- Tele-Critical Care (TCC) is a core component of the ADvanced VIrtual Support for OpeRational (ADVISOR) system that has now provided support for over 30 real world and over 100 training scenarios. TCC resources (i.e. the workstation and clinical support) offers a novel method to provide high fidelity, continuous consultation to operational forces during prolonged field care.

What was the impact on society beyond science and technology?

The proof of concept MASCAL demonstration at Fleet Week is a potential model for supporting a large scale (i.e. nation or multi-national) response to natural or man-made disasters that create 100s-1000s of casualties over short time periods. This model workflow could be combined with other technologies (like drone delivery of supplies and mobile ad hoc networking) to offer a highly flexible and scalable technology solution for humanitarian aid.

This project's posture on disaster medicine supported by technology, specifically 1) TCC from a garrison/academic setting 2) utilization of Docbox and Omnicure in separate pieces of the project led directly to NETCCN planning, collaboration and real life clinical support for COVID pandemic care in CONUS.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

NMCSD has been added to the SOW in order to utilize their Clinical Practice Guidelines that include clinically meaningful process and outcomes metrics. Moreover, NMCSD clinicians will monitor patients at the remote workstation and audit metrics, complete reports, and provide real-time feedback to bedside clinicians on performance. Moving these tasks to NMCSD will expedite the process of analyzing data and collecting information; efficiently utilizing time and resources.
Please see updated GANTT chart (Appendix I).

Since the beginning of COVID-19, we have had to implement a large portion of the tasks remotely. One of these tasks was 3.1. The delays were larger than expected though which caused a halt in progress for that task.

Actual or anticipated problems or delays and actions or plans to resolve them

The VTC hardware for the 5 additional rooms will be utilized by installing them into the MAMC ICU East rooms. This will depend on how ICU East is being utilized for the future. Once the equipment is installed into ICU East rooms, it will be used for Telehealth monitoring and training.

The DocBox PIA has been received by DHA and is being processed. The ATO will be discussed by CyberLog on 29 Sep to determine if it will be added to the prioritization list. We are still waiting for their final decision. Future work with Omnicure will be devoted to using their software platform for two-way Communications between a rapid response nurse and a floor nurse. This proved to be successful for providing communications during a simulated physical therapy patient interaction.

Covid-19 has delayed all non-Covid research heavily. Efforts and deliverables have been coordinated between the NETCCN project and the AWARE project to complete tasks effected by the heavy delays. A no cost extension is expected to be required and will be requested in Q4.

The no cost extension was implemented, and we are continuing to explore options to complete the final tasks that were extremely delayed by Covid-19. These specific tasks require a higher degree of problem solving due to the nature of the work needed to consider them complete. Unfortunately, Task 3.2 does not seem feasible to complete during PoP. We will be following up with the Science Officer soon to discuss possible SOW revisions.

Changes that had a significant impact on expenditures

Due to the delays mentioned above, spending on the project has been slower than anticipated. However, this will allow the team to finish the deliverables during **the extension period which has been approved and utilized.**

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

NOTHING TO REPORT

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

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

Journal publications.

11. Ieronimakis KM, Cain JA, Switzer MS, Deacy TK, Odineal DD, Stein MTO, Colombo RE, **Colombo CJ**, , Leveraging Tele-Critical Care Capabilities for Clinical Trial Consent Crit Care Explor. 2020 Jun 25;2(7):e0167. PMID: **32766563**

Jeremy C. Pamplin, Konrad L. Davis, Jennifer Mbuthia, Steve Cain, Daniel J. Yourk, Sean J Hipp, **Christopher J. Colombo**, Ron Poropatich, Military Telehealth: a model for delivering expertise to the point of need in austere and operational environments, Health Affairs, 2019 Aug;38(8):1386-1392. PMID: **31381391**

The Trifecta of Tele-Critical Care: Intrahospital, Operational, and Mass Casualty Applications. Ieronimakis KM, **Colombo CJ**, Valovich J, Griffith M, Davis KL, Pamplin JC.Mil Med. 2021 Jan 25;186(Suppl 1):253-260. doi: 10.1093/milmed/usaa298.PMID: 33499446

Books or other non-periodical, one-time publications.

NOTHING TO REPORT

Other publications, conference papers and presentations.

Impact of Tele-Critical Care implementation in a remote and isolated critical care environment within the DOD. *Jakob Kerns, BA, Jonas Carmichael, MD FCCM, USN, MC*, *Konrad L. Davis, MD FCCP FCCM CAPT MC USN (Retired)*, *Roland Champagne, MPH, MBA, RN*, *Jeremy C. Pamplin, MD*, *Christopher J. Colombo, MD.* Accepted as a 2021 MHSRS abstract.

Military Tele-Critical Care: Intra-Hospital, Operational, and Mass Casualty Applications Kristina Ieronimakis, Mark Griffith, Konrad Davis, Jeremy Pamplin, **Christopher Colombo.** Critical Care Medicine volume 48 number 1(supplement) January 2020 presented at SCCM Annual Congress Feb 2020.

Virtual Health in a Graduate Medical Education Prolonged Field Care Exercise, A Pilot Intervention **Christopher Colombo**, Lindsay Grubish, Jillian Phelps, Deanna Musfeldt, Mohamad Haque. Critical Care Medicine volume 48 number 1(supplement) January 2020 presented at SCCM Annual Congress Feb 2020.

Pilot Surgical Telementoring Utilizing Novel Telestration Technology: Lessons Learned **Christopher Colombo**, Justin Valovich, Drew Thomas, Mohamad Haque. Critical Care Medicine volume 48 number 1(supplement) January 2020 presented at SCCM Annual Congress Feb 2020.

- **Website(s) or other Internet site(s)**

Virtual Health expands at Madigan Suzanne Ovel May 20, 2019
https://www.army.mil/article/222059/virtual_health_expands_at_madigan

Virtual Care puts Madigan experts in the mix by Kirstin Grace-Simons Oct 11, 2018
https://www.army.mil/article/212292/virtual_care_puts_madigan_experts_in_the_mix

Testing out the Tech by Kirstin Grace-Simons June 2, 2020
https://www.army.mil/article/236144/testing_out_the_tech

- **Technologies or techniques**

NOTHING TO REPORT

- **Inventions, patent applications, and/or licenses**

NOTHING TO REPORT

- **Other Products**

Three Abstracts submitted and accepted for presentation:

- Abstract accepted and presented at the 2019 Military Health Systems Research Symposium (MHSRS) Conference. Ieronimakis, et. Al., "The Trifecta of Tele-Critical Care: Intra-hospital, Operational and Mass Casualty Applications" (Appendix II)
    - Also submitted and accepted as a manuscript to a supplement to Military Medicine (Journal)
- Abstract presented at the Society of Critical Care Medicine. Colombo, et. Al., "Virtual Health in a Graduate Medical Education Prolonged Field Care Exercise" (Appendix III)
- Abstract presented at the Society of Critical Care Medicine. Ieronimakis, et. Al., "Military Tele-Critical Care: Intra-hospital, Operational and Mass Casualty Applications" (Appendix IV)

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

NAME	LTC Christopher Colombo (no change)
NAME	COL Jeremy Pamplin (no change)
NAME	Mary McCarthy (no change)
NAME	LTC Cristin Mount (no change)
NAME	Brian Pickering (no change)
NAME	Vitaly Herasevich (no change)
NAME	Kevin Ross (no change)
NAME	Justin Valovich (no change)
NAME	Stacie Barczak (no change)

NAME	Drew Thomas (no change)
NAME	CAPT Konrad Davis
PROJECT ROLE	Co-Investigator
NEAREST PERSON MONTH WORKED	0.6 calendar months
CONTRIBUTION TO PROJECT	He is responsible for assisting the Principal Investigator in guiding the protocol through IRB, HRPO, and other regulatory approval processes, coordinating activities from across participating study sites, and facilitating necessary data analysis and reporting requirements.
NAME	Jakob Kerns
PROJECT ROLE	Clinical Data Specialist
NEAREST PERSON MONTH WORKED	12 calendar months
CONTRIBUTION TO PROJECT	He is responsible for data analysis and management, quality control assurance, report generation, and operations of the day to day study responsibilities.
NAME	CDR Jonas Carmichael
PROJECT ROLE	Co-Investigator
NEAREST PERSON MONTH WORKED	3 months effort
CONTRIBUTION TO PROJECT	He is responsible for assisting the Principal Investigator in guiding the protocol through IRB, HRPO, and other regulatory approval processes, coordinating activities from across participating study sites, and facilitating necessary data analysis and reporting requirements.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

None.

What other organizations were involved as partners?

Organization Name: Mayo Clinic
Location of Organization: Rochester, MN
Partner’s contribution to project: Collaboration (Mayo staff worked with the research team to initiate the RMF process for incorporating the AWARE system with MHS Genesis)

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS: *Attached*

9. APPENDICES

Appendix I

Updated GANTT Chart

		2017	2018				2019				2020				2021				2022
		Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1
Aims & Tasks	**Months after award**	3	6	9	12	15	18	21	24	27	30	33	36	39	42	45	48	51	54
1	Install hardware and software for virtual monitoring in the adult intensive care unit and non-ICU patients at Madigan Army Medical Center.																		
1.1	Obtain a RMF for the AWARE software package.							1											
1.2	MAMC establishes a remote workstation for monitoring ICU beds.		2																
1.3	Install VTC hardware in MAMC ICU rooms and establish servers to host all necessary software.		3																
1.4	Purchase low cost mobile devices and Omnicure Software for monitoring non-ICU patients from the TeleICU workstation. Test their function.																		
1.5	Develop remote physiologic monitoring solution that is usable on the DoD network.							4											
2	To test the hypothesis that implementing a virtual critical care service in a military adult intensive care unit that utilizes novel decision support software (CDSS) to audit quality indicators, process, and outcome metrics on a daily basis and to review that data with bedside clinicians, we can improve patient safety, process adherence, and patient outcomes.																		
2.1	NMCSD develops Clinical Practice Guidelines that include clinically meaningful process and outcomes metrics.																		5,6
2.2	NMCSD and Mayo write and submit research protocol to submit to the IRB to evaluate impact of providing data to clinicians regarding quality metrics.					7,8													
2.4	NMCSD clinicians monitor ICU patients at the remote workstation and audit metrics, complete reports, and provide real-time feedback to bedside clinicians on performance.														9				
2.5	Analyze impact of these structural and process changes on clinician performance and patient outcome.																		
3	To test the hypothesis that military clinicians can utilize a novel clinical decision support software (CDSS) to facilitate recognition of decompensating patients and speed intervention.																		
3.1	Mayo creates and implements research protocol to evaluate military clinician use of AWARE CDSS.																		
4	Demonstrate proof of concept that this virtual service can be deployed during live and/or field training exercise.																		
4.1	Determine software and network solution(s) to connect corresponding hospital to garrison clinical workstations																		
4.2	Scale project to support minimum bandwidth data transfer. This may involve reduced real-time physiologic monitoring, reduced frequency of data refresh rates, or other methods of diminishing network demand and optimize remote clinician recommendations/monitoring.										10								

4.3	Provide remote clinician support during a live and/or field training exercise.													▲ 11					
5	Demonstrate proof of concept that this virtual service can support combat casualty care evacuation and monitoring from a role 2 to, and in a role 3 facility.													▲	▲				
5.1	Determine software and network solution(s) to connect role 2 and MEDEVAC platform(s) to garrison clinical workstations																		
5.2	MAMC/ISR support a multi-role FTX demonstrating proof of concept for TekeCritical Service support during multi-casualty scenario from Role 2 to Role 3												▲ 12	▲ 13					

	Milestones and Events		
1	**Approved RMF and GENESIS Connection for AWARE Software**	**9**	**Pre-Post Implementation Data**
2	**Functioning Workstation**	**10**	**AWARE Integrates with JOMIS if available**
3	**Functioning ICU Monitoring Equipment in 10 ICU Beds**	**11**	**AAR of virtually supported FTX**
4	**Advanced Monitoring Solutions for ICU Beds**	**12**	**Multi-casualty FTX Simulation Scenario**
5	**SOPs for Virtual Critical Care**	**13**	**Proof of concept software and network solution outlined**
6	**CPGs for clinical practice that Virtual Critical Care Supports**		
7	**Research Protocol Approved by IRB(clinical data)**		
8	**Research Protocol Approved by MAYO and MAMC IRB (synthetic clinical environment)**		
	Quarterly Status Report		**Final Report**

Appendix II

The Trifecta of Tele-Critical Care: Intra-hospital, Operational and Mass Casualty Applications

Kristina M. Ieronimakis, BSN, RN; CCRN, TNCC; Mark Griffith RN, BSN, CCRN, MCPO, USN, Ret.;Christopher J. Colombo MD, MA, FACP, FCCM; Konrad L. Davis, MD FCCP FCCM, Jeremy C. Pamplin, MD FCCM, FACP TATRC, USUHS

Background: Tele-Critical Care (TCC) has the capacity to simultaneously improve patient outcomes in military treatment facilities, in deployed environments and mass casualty events. TCC leverages technology to extend the reach of critical care physicians and nurses beyond geographic boundaries. Tele-consultative services (TCS) are not limited to traditional hospital settings; the military leverages telemedicine in operational environments to provide expert consultative support to deployed providers. TCC reduces patient mortality by enhancing quality of care, patient safety, process adherence, and reduce costs. Madigan Army Medical Center's (MAMC) new Virtual Critical Care Center (VC3) has been integrated into the military's Joint Tele-Critical Care Network (JTCCN) and is designed to support both hospital and field based TCC. The varied and unpredictable census of garrison ICU's, operational patient needs and mass casualty events lends itself to overwatch being provided for all of these applications by a single intervention (TCC), ideally by a networked solution that provided the TCC system resiliency and redundancy.

Methods: The VC3, staffed by a critical care trained physician and nurse, offers TCS to ICU bedside nurses at MAMC and consultative support to field medical personnel. Two recent exercises demonstrate this flexibility. The first was a pilot introduction of TCC nursing for the monitoring of six patients in the MAMC ICU over the course of a week. The VC3 physician teamed with the TCC nurse to provide multidisciplinary care via virtual means. Additionally, the physician was scheduled to be available for operational telementoring for prolonged field care (PFC). In the second instance, the VC3 supported a military medical exercise by concurrently monitoring the MAMC ICU and a mass casualty exercise in a remote location. The VC3 physician closely monitored a recently extubated high risk ICU patient while the VC3 nurse provided over-watch on vital signs of 24 simulated casualties. This supported multiple parallel goals: intervention by the critical care physician to prevent hypoxia and reintubation in the ICU, unburdening of the teaching attending in the ICU to facilitate training of housestaff in critical care, and augmenting the mass casualty response allowing a separate group of remote physicians to focus on procedural tele-mentorship.

Results: VC3 support in the ICU resulted in anecdotal improvement in clinical practice guideline adherence by allowing for real-time education and guidance to bedside nurses. The VC3 nurse was a critical member of the bedside healthcare team, improving patient outcomes by clarifying physician orders, coordinating and communicating with ancillary services and documenting bedside interventions, thus freeing the task saturated bedside nurse to complete vital direct patient care. All the while, the VC3 physician was able to provide TCC guidance to a field medic in a complex prolonged field care medical simulation scenario, including procedural and cognitive tele-mentoring. The VC3 physician and nurse continued to collaborate with each event occurring simultaneously, thus enriching the quality of care and interventions being provided to all recipients of the TCS. Throughout the mass casualty exercise while the VC3 nurse successfully maintained remote overwatch on the vital signs trends of 24 simulated casualties, the VC3 physician was able to directly observe hypoxia in the recently extubated patient, and quickly intervene,

successfully treating the hypoxia and lowering the risk of reintubation. Overall, informal feedback was positive and enthusiastic during this pilot phase of VC3 implementation. Participants commented that the VC3 enhanced the quality and safety of bedside care. Families expressed deep appreciation for the “second set of eyes” watching their loved one. Responses from the military exercise were positive and indicated the application of TCS can expand multi-patient monitoring during a mass casualty event.

Conclusion: Monitoring capabilities of the VC3 continue to evolve with technological improvements. Currently, TCS are offered in traditional hospital settings. However, the opportunity to support the ICU-without-walls (i.e. “critical care anywhere”) concept and participate in pre-hospital care has military and civilian relevance in the acute management of natural disaster and mass casualty events. Fully leveraging capacity in the VC3 to simultaneously support ICU and operational patient scenarios can lead to improvements in safety, outcome, maintenance of critical war time medical skills and continuity of care for military casualties. Future directions include formal measure of efficacy and processes adherence metrics, simultaneous monitoring of garrison ICU patients at multiple sites, leveraging TCC in the assistance of triage and treatment for operational field exercises beginning at point of injury thru evacuation. Additionally, there is a focus on interoperability and rapid expandability given the possible overwhelm of a single TCC provider covering multiple responsibilities. TCC has the potential to expand the capacity and capability of pre-hospital caregivers to increase their ability to optimize care for one or many patients. This capability should be further developed as a possible solution for managing the large volume of casualties anticipated in future peer/near-peer conflicts or MASCAL events, civilian or military.

Appendix III

Virtual Health in a Graduate Medical Education Prolonged Field Care Exercise: A Pilot Intervention

Authors: Christopher Colombo, Lindsay Grubish, Jillian Phelps, Deanna Musfeldt, Mohammed Haque

Introduction/Hypothesis:

Military, mass casualty and disaster medicine may require less expert providers to care for critically ill patients in austere environments for extended time. Virtual Health (VH) capability brings remote expertise to these prolonged field care (PFC) providers. Graduate medical education (GME) provides minimal experience with VH, but it is a vital skill for austere PFC providers. We utilized an existing VH capability in concert with a planned military GME field exercise to determine attitudes and gain feedback about VH in PFC.

Methods:

An initial baseline survey measured 70 graduating military resident's VH experience and perception of value of VH in PFC. All participants attended a brief didactic session on utilizing the synchronous voice VH service. During the field exercise, participants in a critically ill trauma PFC simulation scenario were provided a cellular phone to utilize VH. Critical care physician staffed the VH line and provided advice. Post exercise anonymous surveys measured VH experience, perception of value of VH, and impact of VH on knowledge, stress and confidence in PFC. Free text observations were also solicited anonymously.

Results:

67 pre and 59 post surveys were returned (88%). Pre-exercise, likert scale ratings of perception of VH experience was low (mean 1.8/5, SD 0.9) and perception of value was just above neutral (mean 3.7/5 SD 0.8). Post- exercise perception of VH experience (mean 3.0/5 SD 1.05) and value of VH in PFC (Mean 4.12/5 SD 0.65) showed a statistically significant increase (student's T-test, $p < 0.05$). Perceived impact on knowledge (4.08/5), confidence (4.33/5) and stress (4.17/5) were positive. 11% of subjects rated all impacts non-positive (< or = 3/5), citing connectivity issues preventing effective VH utilization. Comments focused on connectivity; many suggesting a more complicated/challenging simulation scenario to provide more opportunity to use VH.

Conclusions:

A simple, synchronous voice VH service was successfully utilized by graduating physicians with little prior VH experience. Brief exposure to the service increased perception of the value of VH to PFC in military providers. Many felt the value would extend to a more complex clinical scenario. The feedback will aid in improving VH training and implementation in military GME.

Appendix IV

Military Tele-Critical Care: Intra-hospital, Operational and Mass Casualty Applications

Kristina M. Ieronimakis, BSN, RN; CCRN, TNCC; Mark Griffith RN, BSN, CCRN, MCPO, USN, Ret.;Christopher J. Colombo MD, MA, FACP, FCCM; Konrad L. Davis, MD FCCP FCCM, Jeremy C. Pamplin, MD FCCM, FACP TATRC, USUHS

Background: Military Tele-Critical Care (MTCC) has the potential to fulfill unique roles in addition to those fulfilled by civilian TCC, to include support for deployed medical providers. Full development of this capability may simultaneously improve patient outcomes in military treatment facilities, in deployed environments and mass casualty events. In order to fully optimize limited human clinical resources (ICU physicians and nurses), military MTCC needs to be flexible and adaptable to rapid changes in demand. The varied and unpredictable census of garrison ICU's, operational patient needs and mass casualty events lends itself to overwatch being provided for all of these applications by a single intervention (TCC), ideally by a networked solution that provided the TCC system resiliency and redundancy.

Methods: We performed three pilot feasibility exercises in which a MTCC center was simultaneously utilized to monitor hospital based ICU patients, and support a field training exercise. First was a pilot introduction of TCC nursing for a hospital ICU over the course of a week with a physician and ICU nurse teamed to provide multidisciplinary TCC. Additionally, the physician was providing cognitive and procedural telementoring for a military medic performing prolonged field care (PFC). Second, MTCC concurrently monitored ICU and a disaster mass casualty exercise in a remote location. The MTCC physician monitored a recently extubated high risk ICU patient while the nurse provided over-watch on vital signs of 24 simulated casualties. Third, the MTCC nurse simultaneously monitored the hospital ICU while providing reachback support to nurses training in a simulation scenario of a deployed field hospital ICU.

Results: We were able to demonstrate the feasibility of multiple iterations of simultaneous multi role MTCC, including the physician and nurse alternating operational and hospital support roles, and the ICU nurse managing both simultaneously. Informal feedback obtained from ICU staff commented that MTCC enhanced the quality and safety of bedside care. Families expressed deep appreciation for the "second set of eyes" watching their loved one. Positive responses from the field exercise participants indicated the application of MTCC can expand multi-patient monitoring during a mass casualty event and enhance training via expert reachback availability.

Conclusion: MTCC is unique in the opportunities to extend the ICU-without-walls concept to field, disaster and mass casualty settings, while simultaneously performing tradition tele critical roles. Interoperable and rapidly expandable systems must be developed given the possible overwhelm of a single MTCC provider covering multiple responsibilities.. Lessons learned from the development of this capability should have applicability for managing mass casualty events whether deriving from military (war) or civilian (disaster) events.

Implementation of the AWARE system to support virtual critical care in a MEDCEN and CSH.

W81XWH-17-C-0253

PI: LTC Christopher Colombo, MD **Org:** The Geneva Foundation **Award Amount:** $1,760,756

Study/Product Aim(s)

Using a combination of novel analytics and visualizations of electronic medical data, local workgroup-initiated process improvement projects, virtual audits of quality metrics, and daily review of process and outcomes reports by bedside and virtual clinician's, rapidly improve process adherence and patient outcomes in an adult intensive care unit. Demonstrate that this technology and approach to ensuring high quality patient care can be used in a deployed setting.

Approach

We will use the paradigm of structure, process, and outcome standardization and metric monitoring to improve care in the intensive care unit using teleICU technologies that have recently advanced to the point they are ready for supporting clinical medicine in a fixed and deployed facility.

AWARE Unit Level Interface

AWARE Patient Level Interface

Timeline and Cost

Activities CY	17	18	19	20	21
Install virtual monitoring capability at Madigan Army Medical Center.					
Develop CPGs, implement virtual critical care service, and measure impact on associated processes and outcomes					
Test capability with CSH during FTX					
Estimated Budget ($1,761K)	**$52K**	**$556K**	**$425K**	**$459K**	**$269K**

Updated: 29 October 2021

Goals/Milestones

CY17-18 – Installation Phase

☑ Submit AWARE/DocBox software to Risk Management Framework (RMF)
☑ Establish Telecritical Care Workstations
☑ Install VTC hardware in ICU rooms; Purchase low cost, mobile telecritical care (TCC) solution; Connect DoxBox solution to TCC workstations
☑ Develop Clinical Practice Guidelines & Submit IRB Protocol

CY18 – Operation Phase

☑ Develop CPG's to integrate VCC into daily patient care
☐ Implement research protocol to evaluate military clinician use of AWARE
☑ Work with CSH to test virtual support during FTX.

CY19 – Fielding Phase

☐ Measure impact of TCC on clinician performance & patient outcomes
☑ Test virtual presence during FTX
☑ Determine network solution to support scenario from Role 2 to Role 3

Comments/Challenges/Issues/Concerns

- No rapid ATOs, DocBox RMF is in standby for system integration

Budget Expenditure to Date

Projected Expenditure:$1,693,750 Actual Expenditure: $1,635,062