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14. ABSTRACT
U.S. military units are increasingly organized into smaller elements and operating in remote areas leading to longer evacuation times. This necessitates increased medical care by inexperienced clinical providers beyond doctrinal timelines, a concept coined "prolonged field care" (PFC). Early entry medical operations planning anticipate similar challenges during future engagements. Our research project proposes to use an off-the-shelf device that is capable of two-way audio/video streaming that can be used for expert medical consultation. We will develop PFC scenarios that are realistic along with a training program for novice physicians and medics to test. We will then evaluate the clinicians on what decisions were made, the timing of those decisions, their mental workload, confidence in their performance, and evaluation of the impact of their daily clinical practice on PFC performance. In this research study, we will determine if virtual critical care consultation (VC3) is beneficial in a PFC. Our research aligns with focus area 3 in which we will provide scientific knowledge on optimizing management of critically ill patients during PFC, the impact of virtual critical care consultation and how to provide it during PFC, and how to optimize tele-medical support technology.

15. SUBJECT TERMS
Trauma, simulation training, telemedicine, prehospital emergency care

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TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

The purpose of this study is to measure military caregiver performance related to critical care management in prolonged field care (PFC). We have created a PFC testing platform, developed and validated simulation scenarios, and are actively recruiting subjects to measure their performance during PFC simulation scenarios both with and without support from a telementor. The telementor groups use synchronous and asynchronous communication technologies and is divided into partial and comprehensive telemedicine support to better approximate current military telemedicine capabilities supporting operational environments. Partial support uses phone and e-mail; comprehensive support uses phone, e-mail, and videoteleconferencing (VTC) during procedural telementoring (i.e. placement of tube thoracostomy).

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Telemedicine; Critical Care; Simulation; Technology; Virtual Health; Prolonged Field Care (PFC); Telecritical Care; Tactical Combat Casualty Care (TCCC); Telementoring

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

1) Major Task 1: Identify a commercial off the shelf product that is sustainable and deployable. (**Complete**)
2) Major Task 2: Install telemedicine workstations at collaborating sites. (**Complete**)
3) Major Task 3: Identify ideal, critical care clinical scenarios for testing. (**Complete**)
4) Major task 4: Write PFC scenarios (**Complete**)
5) Major Task 5: Pilot test and validate scenarios with subject matter experts. (**Complete**)
6) Major Task 6: Recruit and conduct just in time training. (In progress)
7) Major Task 7: Test subject performance in PFC scenarios at MAMC and ISR. (In progress)
8) Major Task 8: Statistical Analysis, publications, and final report. (**Starts** December 2018)

What was accomplished under these goals?
For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) Major Task 1: Identify a commercial off the shelf product that is sustainable and deployable. (**Complete**)
    - Following further testing of COTS products on low bandwidth networks, none of the original solutions (Global Med or HoloSkype) have been reliable enough for high quality research and data collection. Facetime, WhatsApp, Google Hangout, and Skype have all functioned sufficiently on low bandwidth communication networks (cell signal) for this project and we have chosen to use a combination of Facetime and Google Hangout. We will continue to pursue other first-person/heads-up-display (HUD) type technologies in year two as the augmented reality HUD technologies are evolving rapidly.

2) Major Task 2: Install telemedicine workstations at collaborating sites. (**Complete**)
    - Subtask 2.1: Laboratory Use Protocol approved locally.
        - **Milestone A:** All necessary core and local protocols have been approved.
    - Subtask 2.2: Verification of telemedicine equipment platform and workstation connectivity.
        - MAMC & BAMC telemedicine workstations are installed and functioning.
        - **Milestone B:** We conduct **ongoing** connectivity tests with each scenario to ensure optimal telemedicine consults. We have found that despite high bandwidth cellular signals an wi-fi connectivity that videoteleconferencing (VTC) applications will often fail (i.e. loose video signal). Without dedicated network analysis, it is difficult to determine what causes these failures, however it is a MAJOR finding in this ongoing effort. Namely, that COTS VTC solutions used by the "average" customer, fail to maintain continuous video signal without interruption during all encounters. This has implications for military planning. A list of our VTC technologies are listed below. Back-up for VTC (i.e. comprehensive telementoring) is first to re-start the VTC (effective >90% of the time) and then to switch the subject to partial telementoring. Voice calls (phone and/or voice over internet protocol [VOIP]) have also had occasional problems with dropped call and/or poor signal quality, but this problem is much less common than with VTC technology. We have made these observations during our pilot testing. Data regarding frequency of these problems will be obtained as part of subject testing.

VTC Technology	Near Connection	Far Connection	Result
HoloLens	Cellular Hotspot (3G & LTE)	Cellular Connection on Smartphone or Laptop	Not functional
HoloLens	Hospital "Guest" WiFi	Cellular Connection on Smartphone or Laptop	Intermittent function
ODG R7	Cellular Hotspot (3G & LTE)	N/A	Not Functional
HoloLens	Hospital "Guest" WiFi	Hospital "Guest" WiFi	Functional 100% (or near to)

FaceTime	Cellular Hotspot (3G & LTE)	Cellular Connection on Smartphone or Laptop	Functional > 90%
Google Hangouts	Cellular Hotspot (3G & LTE)	Cellular Connection on Smartphone or Laptop	Functional > 90%
Skype	Cellular Hotspot (3G & LTE)	Cellular Connection on Smartphone or Laptop	Functional > 90%

3) Major Task 3: Identify ideal, critical care clinical scenarios for testing. (**Complete**)
   - Subtask 3.1: USAISR/MAMC develops and submits protocol to train and test subjects.
     - USAISR submitted a CORE protocol and a site-specific addendum to MRMC IRB. MAMC's RHC-P IRB deferred to MRMC IRB and a site-specific addendum for MAMC was subsequently submitted to the MRMC IRB.
     - The CORE protocol and USAISR site specific addendum were approved by the MRMC IRB on 6 June 2018.
     - The MAMC site specific addendum was approved by the MRMC IRB on 18 June 2018.
     - **Milestone C: Is complete. A human use protocol and site-specific addendums were submitted to and approved by the MRMC IRB.**
   - Subtask 3.2: MAMC and USAISR will work with subject matter experts (SME) to identify appropriate number of scenarios and type of scenarios for study.
     - Four scenarios were initially identified to develop as representative of some of the most difficult challenges that could be faced by caregivers in PFC. While hemorrhage is a major cause of death on the battlefield, it is NOT in PFC; casualties must survive the initial insult to reach a PFC scenario. Consequently, caregivers in PFC manage the consequence of major trauma or life-threatening DNBI. Some of the most difficult issues faced by caregivers in PFC are problems that they rarely experience, have only received limited exposure to during training, and are usually evacuated rapidly in recent conflicts. Some of these challenges are: non-hemorrhagic fluid resuscitation, management of sepsis/septic shock, management of organ dysfunction (pulmonary, renal, cardiac), management of life threatening electrolyte abnormalities. Give this context, the study team selected the following scenarios to further develop as cases that illustrate these challenges, and were likely to be *unfamiliar* to most subjects: large (40%) thermal injury, severe pneumonia with hypoxia and respiratory distress, crush injury, and closed head injury.

4) Major task 4: Write PFC scenarios (**Complete**)
   - Subtask 4.1: Write PFC description including situation, mission, training, execution, and data collection systems. Improve scenarios with SME.
     - The team created the overall case backgrounds and general case progression for each of the scenarios above (burns, pneumonia, crush, head injury). We

quickly realized that each scenario took a tremendous amount of time to script and practice so that subjects at both sites would receive nearly identical case scenarios. The burn and pneumonia scenarios have each undergone over 200 hours of development, refinement, and practicing administering. Due to this extensive time and our desire for the two research sites to administer nearly identical scenarios, we have elected to only administer the severe pneumonia case during the first year of testing. We selected the pneumonia scenario because it had the most clearly identifiable and differentiated tasks that subjects should complete thus providing more data elements for comparison between groups and it is a *medical* case, a scenario that few warfighters consider during training but equally as important to trauma in PFC. We will revisit adding additional scenarios in year two.

5) Major Task 5: Pilot test and validate scenarios with subject matter experts. (**Complete**)
   - Subtask 5.1: APTIMA will train research teams on how to use the ACLAMATE systems and data collection platform.
     - Two members of the APTIMA team visited MAMC to install software and instruct the research team on how to apply and use the ACLAMATE system in late April 2018.
   - Subtask 5.2: MAMC and ISR team will travel between each other's respective site to pilot test the scenarios. Will conduct iterative improvements on the scenario testing with subject matter experts.
     - In late February 2018, the MAMC team traveled to ISR for one week for initial testing and development of Scenario 1.
     - In late April 2018, the ISR team traveled to MAMC for one week of pilot testing of both scenarios.
     - In June 2018, the MAMC team traveled to ISR for one week of final testing for both scenarios.
     - **Milestone D: Both teams have run through and tested the SME validated pneumonia scenario. Minor changes to scenario administration will be addressed by the sites during regularly scheduled synchronization calls to ensure the scenarios to run smoothly, realistically, and remain consistent between sites.**

6) Major Task 6: Recruit and conduct just in time training. (**In Progress**)
   - Fundamentals of Critical Care Support (FCCS) courses were conducted at both MAMC and BAMC sites in June 2018.
   - Following the FCCS course, the ISR recruited and consented 14 individuals to participate in the study. MAMC has recruited and consented 3 individuals.
   - FCCS was an unsuccessful recruiting platform. Both sites are working to mitigate this problem by changing inclusion criteria for the protocols. Initial inclusion criteria included completion of the FCCS course and focused on junior medical *providers* (i.e. physicians trainees). While this provides a more consistent subject population from which we analyze results and demonstrate differences between groups more reliably, it is a very small population from which to recruits subjects and not necessarily representative of the majority of caregivers who will provide PFC.

Consequently, we plan to broaden the subject population by including other physician trainees from non-surgical specialties and medics at large.

7) Major Task 7: Test subject performance in PFC scenarios at MAMC and ISR. (**In Progress,** 1% Complete)
    - In late July 2018, the MAMC team ran their first subject through the scenario. This subject unfortunately was unable to complete the full scenario due to a family emergency.
    - **Milestone E: Is 1% Complete. The ISR team is actively working to coordinate time with their consented subjects and are currently scheduled to run one subject in November 2018. The MAMC team is actively recruiting additional subjects. Protocol amendments to change inclusion criteria are underway.**

8) Major Task 8: Statistical Analysis, publications, and final report. (**In Progress**)
    - Case review forms were created for compiling data collection elements for both scenarios and for end-points for inter-rater reliability.
    - Scenario statistical analysis will be ongoing and performed periodically between subject testing according to protocol.
    - Publications:
        i. Abstract accepted and podium presentation at the Special Operations Medical Assembly (SOMSA) Conference. Veazey et. Al., "Developing a Prolonged Field Care Human Performance Training and Testing Platform." Podium presentation May 16, 2018. (Appendix I)
        ii. Abstract submitted and accepted for poster presentation to Military Health Systems Research Symposium Conference. Veazey et. Al., "Developing a Validated Simulation Platform for Testing Telemedicine's Impact on Clinician performance During Prolonged Field Care". (Appendix II)
        iii. Proceedings submitted to the Journal of Translational Medicine. Fahy et. al., "Developing Semi-Reusable Training Models for Use in Prolonged Field Care Medical Simulations to Test Clinical Decision Making". Proceedings as part of the USAISR Summer Research Program 2018. (Appendix VI)

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Under this award, we have had the opportunity to send research team members and collaborators to various conferences related to our field of study. Conferences have provided advanced knowledge of topics such as prolonged field care, innovative medical technologies, mobile health solutions, and telemedicine.

Conference travel supported by this grant:

Date	Conference	Attendees
26-30 Aug 2017	2017 Military Health System Research Symposium (MHSRS) Kissimmee, FL	Principle Investigator* Project Manager Research Coordinator
25-28 Feb 2018	Society of Critical Care Medicine's (SCCM) 47th Critical Care Congress San Antonio, TX	Principle Investigator Research Nurse
13-17 May 2018	2018 Special Operations Medical Association Scientific Assembly (SOMSA) Charlotte, NC	Principle Investigator* Research Nurse
15-20 Jul 2018	Human-Computer Interaction International (HCII) 20th International Conference Las Vegas, NV	Principle Investigator*

*Denotes presentation

Additionally**,** scenario development and pilot testing has offered advanced medical training to 16 medics and physician trainees. Feedback from these individuals has been that the scenarios and telementoring have helped them grow as medical providers and better prepare them for future patient care. When research is completed with these scenarios, they could provide outstanding opportunities for training caregivers.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

At a local level, effort has been made to bring knowledge of this project to an expanding cohort of divisions within the medical center and joint-bases as a whole. Madigan Army Medical Center's Senior Medical Council has been briefed to spread awareness and garner further support. Additionally, presentations have been made at the Delayed Evacuation Casualty Management Course (DECM), to the 1st Special Forces Group, and to the Enlisted Board of Directors. The project has been presented to graduate students at UT San Antonio as one of the research efforts conducted through the Clinical Decision Support Research Branch. Poster presentation of this project and the simulation trainers were presented at the USAISR Summer internship poster day session. Additional dissemination activities will occur as study results become available.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Associated Task	
Major Task 4	• We intend to use additional scenarios during year two of our subject recruitment. We will further develop, refine, and validate at least one other scenario for use in year two.
Major Task 5	• Kevin Ross, Katy Cohen, and Stacie Barczak of the MAMC group plan to visit the ISR in September 2018 to ensure both sites run simulations in the same way. Site visits of this sort may continue if/as needed to ensure both sites function similarly. • Continue developing inter-rater reliability for study endpoint analysis through editing and coding of simulation data.
Major Task 6	• Submit amendments to broaden recruitment population. • Continue ongoing recruitment.
Major Task 7	• Continue to test consented subjects as available at both sites.
Major Task 8	• Christopher Colombo, Sena Veazey, Maria Serio-Melvin, and Katy Cohen will travel to the Military Health System Research Symposium (MHSRS) in August 2018 where Ms. Cohen will present on the development of study simulations.

4. IMPACT: D*escribe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:*

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Thus far, this project has developed several tools that are likely to support military operational medical training and technology development and testing:

- Methodology for developing, validating and sharing through documentation high fidelity *military relevant* prolonged field care simulation scenarios
- Methodology for time compressing prolonged field care scenarios so that subjects or trainees could, when appropriate/desired, complete the scenarios in less time. This includes a *new software application* that manages simulation vs. real time.
- Methodology for standardizing groups so that it is possible to compare differences between caregiver performance with and without use of different technologies. Performance in key decisions and tasks is a surrogate marker for patient outcome.
- Low cost task trainers for tube thoracostomy, escharotomy, and tracheostomy.
- Pilot database of annotated audio, video, and "casualty" physiology that could be used for machine learning purposes.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

It is possible that the Dragon Skin and low-cost task trainers could be "transitioned" to industry. These tools would be beneficial for the simulation community and could be developed more fully to production and minimum cost.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to report.

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:*

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

No change to overall methodology. As discussed above, we will expand our subject population by changing inclusion criteria.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

ACTUAL:
Initial delays were experienced in acquiring both Hexoskin and Aptima devices due to manufacturing delays. All equipment has since been received and incorporated into the simulations.

Connectivity issues were identified at MAMC with software that required higher bandwidth. The decision has been made to remove augmented reality devices for the first year of scenario testing and retain only mobile video teleconferencing software that's easily accessible by mobile phone or tablet. Bandwidth capabilities will be re-evaluated in the second year of the project to determine viability of augmented reality devices. Limited bandwidth has also hindered data transfer and accessibility between sites. To mitigate this issue, we have minimized the amount of data transfer required by developing an auditing strategy with planned site data checks.

BAMC simulation laboratory was removed as a performance site because of potential scheduling, storage, and connectivity issues. This constraint was resolved by acquiring new laboratory space at USAISR dedicated to this project's simulation study and approved by the Chief of Clinical Decision Support and Automation Research Branch.

Location and infrastructure challenges have also contributed to schedule delays at MAMC. The team has gained room in the local simulation center and is actively working to resolve remaining scheduling and network constraints.

As a split site study, additional time has been required to strengthen communication channels and team development strategies between sites.

Staff turnover and the need to hire and train new staff has caused significant time delays. The simulation tech position at MAMC was replaced by a research assistant who has assumed the duties of the simulation tech and is currently learning additional administrative duties. Learning to program the complex scenarios for the sim manikin has taken longer than anticipated and we continue to troubleshoot challenges with the support of Laerdal.

Recruitment and scheduling of study subjects has proven to be more challenging than initially anticipated. The abovementioned amendments for both sites will help address this by allowing ISR to resume recruitment activities and broaden the subject population at MAMC.

ANTICIPATED:
Dr. Pamplin has been transferred to TATRC. At this time, with the support of CDMRP, we have decided to leave him on as PI of this grant. A replacement site PI at MAMC has been identified as LTC Christopher Colombo, MD. We will re-evaluate this fall to ensure that this continues to be a feasible solution. A memo was provided to CDMRP stating this intention.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

The original negotiated budget underestimated travel requirements necessary for developing and training seamless scenarios between sites. Funds have been repurposed from personnel and equipment allocations.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

None.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. **PRODUCTS:** *List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."*

Publications, conference papers, and presentations
Report only the major publication(s) resulting from the work under this award.

Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

i. Abstract presented at the Special Operations Medical Assembly (SOMA) Conference. Veazey et. Al., "Developing a Prolonged Field Care Human Performance Training and Testing Platform." Podium presentation May 16, 2018.
ii. Abstract submitted and accepted to Military Health Systems Research Symposium Conference. Veazey et. Al., "Developing a Validated Simulation Platform for Testing Telemedicine's Impact on Clinician performance During Prolonged Field Care".
iii. Proceedings abstract submitted (In Progress) to the Journal of Translational Medicine under "Proceedings of the 6th Annual United States Army Institute of Surgical Research Summer Undergraduate Research Internship Program 2018" – subsection Fahy et al., "Developing Semi-Reusable Training Models for Use in Prolonged Field Care Medical Simulations to Test Clinical Decision Making"

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

SIM CLOCK: Initial invention disclosure of the SimClock was submitted to MRMC on February 26, 2018. The patent committee meeting was held on June 13, 2018. The committee agreed the software is not patentable but copyrightable. Contracting company Ciconix LLC (Sena Veazey is the employee) has interest in technology transfer of this software. Woodbury LLC (David Luellen is the employee) has waived copyright rights. A simulation clock application was developed in order to be able to track the condensed time used for these scenarios (15 minutes of real time equates to 1 hour of simulation time). The clock also has the ability to transition out of simulation time to allow for real time tracking during procedures. The research team relies on this clock and the ability to pause/restart according to simulation breaks to track the amount of time a subject takes to reach individual decision points.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to report.

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*

- *audio or video products;*
- *software;*
- *models;*
- *educational aids or curricula;*
- *instruments or equipment;*
- *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
- *clinical interventions;*
- *new business creation; and*
- *other.*

CHEST TUBE TRAINER:
A standalone simulated chest trainer was developed for use with both needle decompression and chest tube procedures. The trainer is a unique combination of components that allows the subject to visualize and feel for correct anatomical landmarks as well as get realistic feedback for correctly performed procedures. The chest tube trainer was developed for use with both scenarios. (Appendix III)

ESCHAROTOMY TRAINER:
The escharotomy trainer was refined for use in scenario 1. This trainer is put in place around the leg of the manikin and provides visual and tactile feedback to the subject as the escharotomy task is performed. The design of the trainer allows the procedure to be performed "on" the manikin without risk of harm to the manikin itself. We are continuing to refine this trainer and the finalized version will be used with the completed scenario 1. (Appendix IV)

DRAGON SKIN for SKIN SIMULATION:
Dragon Skin® is a commercially available off the shelf product that creates a fast curing silicone rubber intended for making high performance molds along with a variety of industrial applications. With the assistance of an intern at ISR, the research team developed a method of creating realistic "skin" and anatomical features such as the nipple for the chest tube trainer. By adjusting the thickness and pigment of the "skin", the research team was able to enhance the original design of the chest tube trainer and create a very realistic outer "skin" layer. This layer is thin enough that anatomical landmarks such as ribs can still be felt through it. (Appendix IV)

SIMULATION VIDEO DATABASE:
We are currently developing the framework and determining the most appropriate method for both storing and sharing the videos which will be amassed from this study. Each scenario is recorded in-full from two different camera angles; one angle is that of the entire room for a comprehensive view of events and the second angle is from a chest mounted camera worn by the subject. These videos are used for coding and verification of analysis once the scenario is complete. The research team also hopes that these videos will be able to be used for future research to assist with machine learning capabilities. There is currently 1 scenario recording stored to be part of this database. (Appendix V)

PHYSIOLOGICAL COMPONENT DATABASE:
In collaboration with Aptima, the research team is finalizing the ACLAMATE software platform that is used to collect and store all subject physiological components recorded during simulations.

These components include continuous EEG and EKG readings collected by the Aptima cap and Hexoskin shirt. The ACLAMATE software then factors these elements to produce real-time cognitive load and stress models. The software is currently fully functional as a storage and collection platform, but the ease of use and display layout is undergoing continued improvements to ensure the most user-friendly and efficient model is available to the research team.

EXTENDED TRACK MODEL FOR PFC SIMULATION:
The simulation scenarios developed by the research team are unique in that they model a full prolonged field care environment. Many simulations are only based around trainers that have a subject perform a known set task. Our scenarios include the circumstances around these tasks and most importantly, capture the decision points that the subject reaches and has to make in the care of the simulated patient.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:
Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*

Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

NAME	LTC Jeremy Pamplin
PROJECT ROLE	Principal Investigator
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Leads project, scenario development, budget management, experimental design, lead meetings, meet with subject matter experts.

NAME	Sena Veazey
PROJECT ROLE	CO-Principal Investigator
NEAREST PERSON MONTH WORKED	8 months effort
CONTRIBUTION TO PROJECT	Project management, experimental design of simulations, administer tasks to other investigators, assist in CRADA approvals, lead meetings, write protocols, simulation role

	development, meet with stakeholders for recruitment and simulation experiments.

NAME	David Luellen
PROJECT ROLE	Associate Investigator, Biomedical Software Engineer
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Write security plan and work with USAISR IMD, identifying device and software integration solutions, simulation role development, assist in CRADA approvals, attends all meetings.

NAME	Stacie Barczak
PROJECT ROLE	Research Coordinator
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Facilitates administrative aspects of the project (regulatory support, simulation role development, coordination, document preparation, etc.) assist with recruitment and consenting of subjects, and data collection.

NAME	Katy Cohen
PROJECT ROLE	Research Nurse
NEAREST PERSON MONTH WORKED	10 months effort
CONTRIBUTION TO PROJECT	Assist with project management, write, edit and contribute to simulation scenarios, assist with protocol creation, simulation role development, assist with recruiting and consenting of subjects.

NAME	Deana Apple
PROJECT ROLE	Research Coordinator
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Assist with project, edit and contribute to case review forms, data analysis, simulation role development, assist and recruit consenting of subjects.

NAME	Maria Seriomelvin
PROJECT ROLE	Associate Investigator, Research Coordinator
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Assist with project management, edit and contribute to simulation scenarios, assist with protocol creation, simulation role development, assist with recruiting and consenting of subjects.

NAME	Kevin Ross
PROJECT ROLE	Program Manager
NEAREST PERSON MONTH WORKED	4 months effort
CONTRIBUTION TO PROJECT	Project management at MAMC, administer task to other team members, facilitate meetings, engage with stakeholders for recruitment and simulation experiments.

NAME	Joanne Kunze
PROJECT ROLE	Research Assistant
NEAREST PERSON MONTH WORKED	2 months effort
CONTRIBUTION TO PROJECT	Assist with project, edit and contribute to case review forms, data analysis, simulation role development, and simulation programming.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to Report

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*

- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name	Aptima
Location of Organization	Woburn, MA
Contribution to the project	Collaboration; Aptima's staff worked with the research team to train, install, and deploy the ACLAMATE software platform. The research team is currently working with Aptima staff to finesse the software for ease of use.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ers.amedd.army.mil*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

APPENDIX I
SOMSA Scientific Assembly and Exhibition 2018

Sena Veazey[1], Doug Powell, MD[2], Ramey L. Wilson[3], MSG Kaleb J. Twilligear[4], LTC Christine M. Vaccaro, MD[4], LTC Jeremy C. Pamplin, MD[4,5]

Title: Developing a Prolonged Field Care Human Performance Training and Testing Platform.

Introduction: Military medical providers at all levels may experience discordance between their garrison medical practice and the medical care they provide while deployed to operational settings. Consequently, clinicians may have limited experience in combat casualty care, particularly of complex, critically ill casualties in resource-limited environments. The military provides extensive training for medical providers, but training – usually a combination of didactics and simulation – may not help clinicians when nuanced care requires judgment gained through experience. This is especially true when pre-hospital providers –contextually advanced practice medics in the special operations forces (SOF) – must provide prolonged field care (PFC) of critically ill/injured casualties.

Methods: We intend to develop a methodology that tests human performance during PFC and to investigate how new technology solutions, particularly telemedicine, impacts performance. This testing platform should allow the testing of various technology solutions and determine if they improve human performance before fielding. Demonstrating the value of new technology to enhance human performance and piloting its use in simulated conditions increases the likelihood that it will be accepted by users and avoid the potential of doing harm.

Results: We will establish a standardized training program that addresses key critical care skills that all subjects experience before testing. Subjects will then record their daily medical care in their garrison work environment. Subjects will be randomized to PFC simulation scenarios with/without telemedicine consultation. Both groups will have access to internet-based information and paper references typical of a deployed environment. We will measure subject performance including efficiency, accuracy, and reliability of medical decisions as well as cognitive work measured by validated surveys and physiologic measurements. Subjective experiences will be measured by custom surveys and interviews.

Discussion: This methodology will better identify useful and clinically beneficial technology that will improve combat casualty care more effectively than methods currently in use.

Acknowledgement: (Funding/COI) - We have applied for grant funding from the Joint Program Committee 6 Prolonged Field Care request for proposals. We have no conflicts of interest to report. This information has not previously been presented.

[1] US Army Institute of Surgical Research, Joint Base San Antonio, Fort Sam Houston, TX
[2] Third Special Forces Group (Airborne) and Womack Army Medical Center, Fort Bragg, NC
[3] First Special Forces Group (Airborne), Joint Base Lewis-McChord, WA
[4] Madigan Army Medical Center, Joint Base Lewis-McChord, WA
[5] Uniformed Services University, Bethesda, MD

APPENDIX II
Military Health System Research Symposium 2018

Authors: S. Veazey, MS[1], K. Cohen, RN[2], M. Serio-Melvin, MSN, RN[1], S. Barczak, BA[2], D. Luellen, BS, MBA[1], E. Weidemann, BSN, RN[1], K. Ross[2], D. Powell, MD[3], J. Salinas, PhD[1], J. Pamplin, MD[2]

Title: Developing a Validated Simulation Platform for Testing Telemedicine's Impact on Clinician Performance During Prolonged Field Care

Background:
Prolonged field care (PFC) is identified as a critical capability gap that requires research and development of knowledge and material products in order to enhance combat casualty care within the medical field context. Multi-prong approaches to address how to take care of casualties in austere environments will require additional training, resources, technology, and personnel. One approach to address clinician knowledge and potential skill gaps is to deliver expert consultation using telemedicine technologies when network communication resources are available. Teleconsultation is currently used by Special Operations Forces (SOF) during PFC; position papers describe the SOF unit needs to develop and train using a telemedicine plan called PACE (primary, alternate, contingency, and emergency), to obtain expert consultations when caring for complex, critically ill or injured patients. Telemedicine technology is a flexible toolset that uses asynchronous and synchronous systems to deliver information to, and recommendations from, remote experts. The optimum combination of these tools has not been defined.
However, in order to understand the spectrum of telemedicine and the capabilities and limitations of this tool, thorough research must be conducted to answer some of these questions: What is the minimum technology platform needed for appropriate communication during full and limited connectivity; what procedures benefit from telemedicine and which do not; what level of medical training is minimally required; how does this impact clinical decision making in terms of accuracy and reliability compared to standard of care, and ultimately, does it affect mortality outcomes? These questions have driven our research project to answer these basic questions. This project entails a two year multi-center site, prospective, human study. We are developing a validated, high-fidelity simulation platform that resembles PFC of critically ill patients to test subjects on clinical performance.

Methods:
We developed PFC scenarios involving treatment of critical illnesses or injuries that were identified by subject matter experts (SME). Scenarios were designed to evolve over an 8-24 hour period of time but are compressed into a 2-5 hour simulation experiment. Simulation scripts consist of: a storyline for the subject that reflects the type of care environment, casualty history and physical examination findings, hourly casualty vital signs, ins and outs fluids, potential patient response, and physical exam findings. The data mimics the pathophysiology of the illness/injury, casualty verbalizations, telementor timings and script, and confederate roles and capabilities.
Key procedures that subjects must perform during the simulated patient care have additional scripting, are not time-compressed when analyzed for efficiency, and require definitive and identifiable start and stop points. The simulated vitals are affected when key procedures are performed to add additional fidelity. Casualty vital signs for background clinical progression and procedure time were pre-programed into the SimMan 3G^{TM} (Laerdal, Stavanger, Norway), a high fidelity manikin used as our simulated "patient", that reflects the care provided by the subject

during each scenario. We developed and validated, with SME support, detailed supply lists including medications and medical supplies. Simulations were administered by a proctor (research lead), a simulation technician (that runs the manikin's programing and interacts with the subject through the manikin), a confederate (a research team member that works with the subject within the scenario helping to maintain realism), and a trained telementor. We have three telemedicine technology groups: comprehensive capabilities (phone, e-mail, and Video TeleConference), partial capabilities (phone and e-mail only), and no capability (paper clinical practice guidelines). Subject performance is measured in terms of accuracy, reliability, efficiency of clinical care, quality of care, and cognitive work measured using physiologic data and the National Aeronautics and Space Administration Task Load Index (NASA TLX). Retrospective data analysis and tagging of key events were done through a customized software, the Automated Cognitive Load Assessment for Medical Staff Training and Evaluation (ACLAMATE) system (Aptima Inc, Woburn, MA).

Results:
Four scenarios were identified and two multi-site research study teams were established for prospective human research. We conducted pilot testing of the scenarios in February of 2018 and plan iterative improvements until subject enrollment in June 2018. A novel simulation clock was developed to track simulation-time and real-time of the simulation experiment to maintain data synchronization. Additional surveys were designed to collect data about possible confounding variables (e.g. subject experience with tested procedures, familiarity with clinical practice guidelines). The ACLAMATE system enables all data sources including time, video feeds, checklist forms, NASA-TLX, and subject physiology – to be combined into a singular dataset that allows data review and adjudication.

Conclusions:
Establishment of validated, repeatable, simulation scenarios to test telemedicine and other technologies is necessary to answer basic questions about clinical performance in the PFC environment. We recognize that measuring clinical performance, cognitive work, and stress is not equivalent to directly measuring patient outcome however, improvements in these measurements are associated with improved patient outcomes. Consequently, the resources, personnel, and funding to support this type of research are necessary to evaluate technologies during PFC and to determine their benefits and limitations. We propose to re-use this validated platform, share our experiences with other researchers, and use the results from this study to guide operational needs.

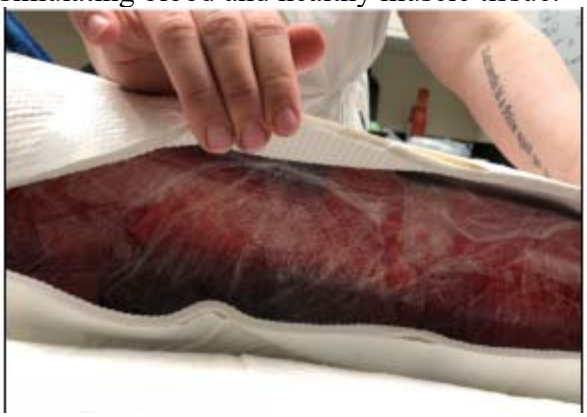
[1] US Army Institute of Surgical Research, Joint Base San Antonio, Fort Sam Houston, TX
[2] Madigan Army Medical Center, Joint Base Lewis-McChord, WA
[3] Ft. Bragg, Fayetteville, NC

APPENDIX III

Captured stills from chest camera video recording showing the chest tube trainer having been used for needle decompression and the subject preparing for a chest tube. These images also display the realistic appearance gained through use of Dragon Skin® for creation of the outer skin later and nipple.

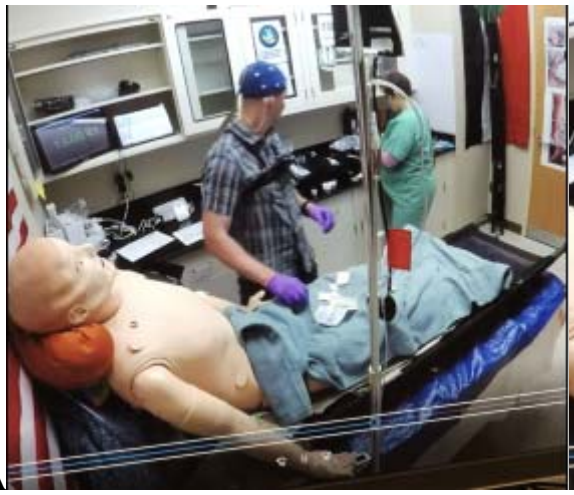
APPENDIX IV

Escharotomy trainer showing flayed outer dermis and subcutaneous tissue with internal layers simulating blood and healthy muscle tissue.

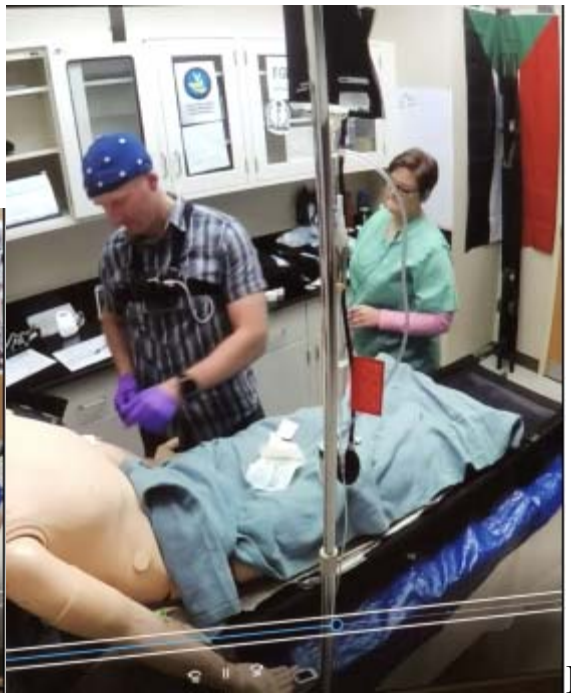


APPENDIX V

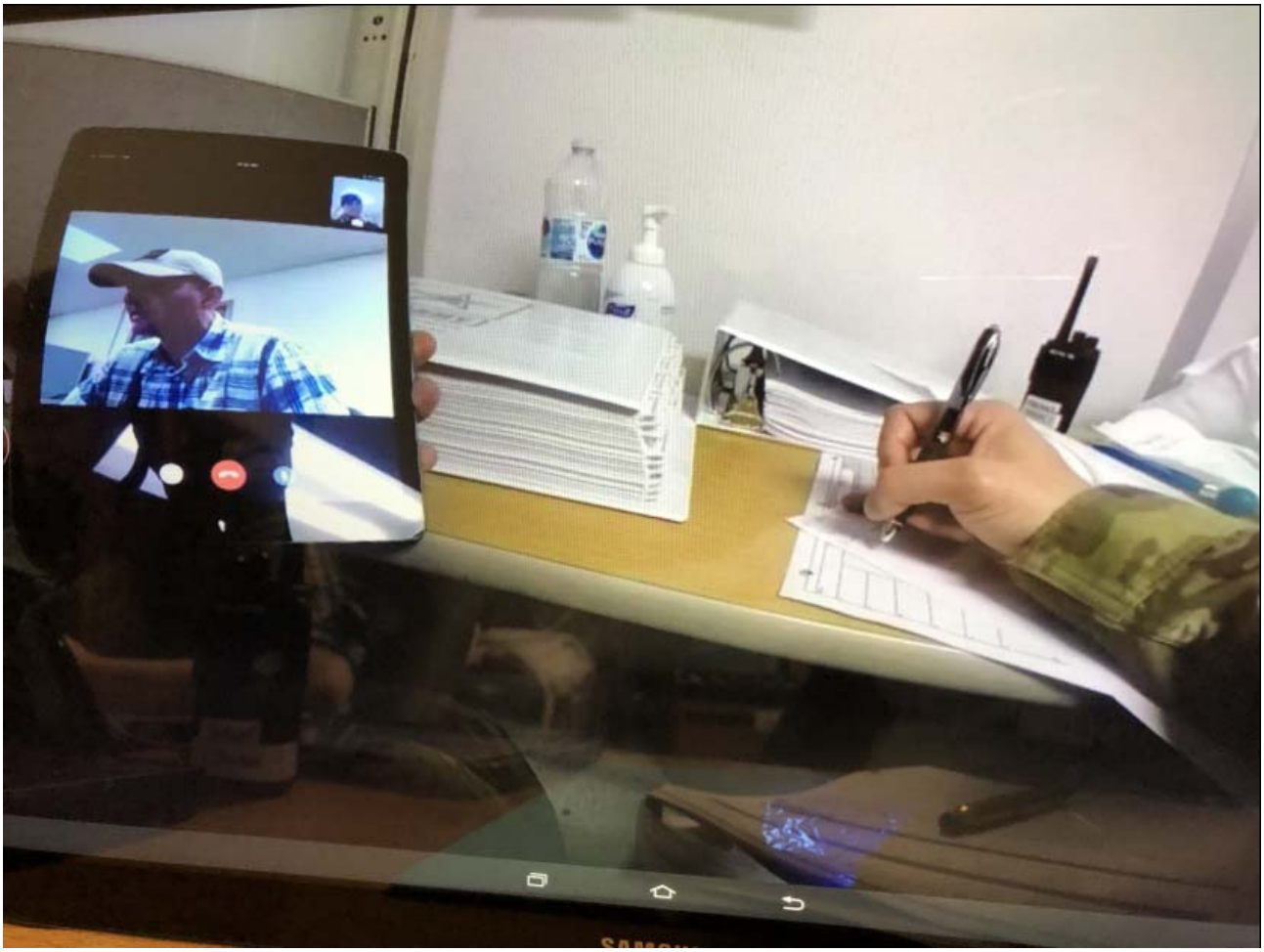
Image A and B are still from the room camera set up that captures whole room activity.



A



B



The above photo is a screenshot of chest camera video displaying a sample of what can be viewed and captured from this angle.

APPENDIX VI

Developing Semi-Reusable Training Models for Use in Prolonged Field Care Medical Simulations to Test Clinical Decision Making

Joshua A. Fahy[1, 2], Deana A. Apple[2], PhD, Katy Cohen[2], RN, Jeremy Pamplin[2], MD, Maria Serio-Melvin[2], RN, MSN, Sena R. Veazey[2], MSc.

[1]University of Arkansas, Fayetteville, AR 72701, USA
[2]US Army Institute of Surgical Research, JBSA Fort Sam Houston, TX 78234, USA

Background

High-fidelity simulation (HFS) is the reproduction of medical scenarios through the use of a computerized manikin that is programmed to recreate clinical conditions and react to the caregivers' actions [1]. Using high fidelity manikins as procedural task trainers is limited by cost and realism. Using models repeatedly to reduce costs reduces realism and impacts clinical decision making within the scenario because used manikin skins show indications of previous interventions. The objective of this study was to develop cost effective, realistic manikin skins that could be used to test caregiver decision and performance related to procedures commonly encountered during combat casualty care.

Materials and Methods

Dragon Skin® (Smooth-On, Macungie, PA, USA) products are mixed to form a silicone elastomer. The elasticity, color, and texture are varied to suit specific tissue types (skin, muscle, adipose, etc.) We made cricothyrotomy replacement neck skins using single layer sheets cut to size and needle decompression (NDC)/chest thoracostomy (CT) skins using two layered-sheets made to wrap around a plastic rib-cage. For the NDC/CT model, we placed balloons and sponges inside the skeleton. Procedural success penetrated the balloons, releasing air, and expanding the sponge. We assessed the realism of our skins using a paper survey that compared the tactile properties of our models and the standard manikin skin to our subjects' recollection of human tissue during past procedures using a Likert Survey with 1 – 5 rating scales where 1 = Not Alike and 5 = Alike.

Results

Our models were reviewed by six clinicians (critical care intensivists, nurses, and medics). The models were deemed more realistic than the standard manikin skin (2.50 ± 0.22 vs. 3.83 ± 0.16, $p < 0.0001$). Our cricothyrotomy skins were less expensive than the commercial models: Laerdal $47.33/skin/use [2], Syndaver $62.40/skin/use [3], ours $3.00/skin/use. Our NDC/CT skin was also less expensive than commercial models. Cost for Laerdal's trainer is $1,260.00 with reusable parts ranging from $20.30 – $106.00/procedure [4] whereas ours is estimated $85.00 ($15.00 for the skin, $5.00 for reusable materials like tape, and a one-time $65.00 cost for the skeleton rib-cage). Our models reduced costs/procedure by >90%.

Conclusions

Our Dragon Skin® models provide superior clinical fidelity at less cost than similar commercial products. These advantages facilitate increased realism for procedural simulation training or assessment at a price point that allows increased frequency task performance.

References

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2. "Neck Skin Kit (6)." Trachlight™ End of Life Announcement, Laerdal Medical, www.laerdal.com/us/item/212-21050.
3. "Adult Cric Trainer." SynDaver Labs, syndaver.com/shop/synatomy/deluxe-cric-trainer/
4. "Pneumothorax Trainer." Trachlight™ End of Life Announcement, Laerdal Medical, www.laerdal.com/us/doc/983/Pneumothorax-Trainer.

Development of a Simulation Model to Test Technologies that Improve Human Performance During Prolonged Field Care

W81XWH-17-2-0023

PI: LTC Jeremy Pamplin, MD **Org:** The Geneva Foundation **Award Amount:** $1,109,809

Study/Product Aim(s)

- Aim 1: Identify a technology platform that supports real-time telemedicine in during PFC.
- Aim 2: Develop simulation training scenarios that test critical decision making during PFC.
- Aim 3: Test subject performance in PFC scenarios after standardized training with and without use of telementoring

Approach

The purpose of this study is to measure clinician performance related to critical care management in prolonged field care (PFC). We will create a PFC testing platform, develop and validate simulation scenarios, recruit clinicians to complete "just-in-time" training, and then measure their performance during PFC simulation scenarios with/without telementoring. We hypothesize that patient care provided to critically ill or injured patients during PFC by clinicians following standardized training will be inferior to patient care provided following standardized training and supported by real-time telementoring.

Figure 1: Example of telemedicine consultation using device to inform military clinician.
Accomplishment: NA

Timeline and Cost

Activities / CY	18	19	20
Establish telemedicine platform			
Develop simulation training scenarios			
Pilot test and validate scenarios			
Test subject performance in PFC scenarios			
Data analysis and manuscript writing.			
Estimated Budget ($K)	**$646K**	**$348K**	**$115K**

Updated: 30 August 2018

Goals/Milestones (Example)

CY 18 Goal – Establish technology platform, Pilot test simulations

☑ Identify commercial off the shelf product to use as telemedicine device.

☑ Install telemedicine workstations/hubs at collaborating sites (SAMMC and MAMC)

☑Develop simulation training scenarios

☑Identify and write PFC scenarios (95% complete)

CY 19-20 Goal – Test subject performance in simulated PFC scenarios.

☑Pilot test and validate scenarios using subject matter experts

❑Complete just in time training & recruit subjects

❑Test subject performance of critically injured patients using validated testing platform with or without telemedicine consult

CY 20 Goals – Data analysis and manuscript writing

❑ Statistical analysis

❑Publication (abstracts and manuscripts)

Comments/Challenges/Issues/Concerns

None.

Budget Expenditure to Date

Projected Expenditure: $646,027

Actual Expenditure: $413,621.10