

AWARD NUMBER: W81XWH-21-C-0119

TITLE: Connected and Autonomous Procedure Support Tools for Combat Trauma and Mass Casualty Management

PRINCIPAL INVESTIGATOR: Christopher Colombo

CONTRACTING ORGANIZATION: The Geneva Foundation, Tacoma, WA

REPORT DATE: October 2022

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE
October 2022

2. REPORT TYPE
Annual

3. DATES COVERED
30Sep2021 - 29Sep2022

4. TITLE AND SUBTITLE

Connected and Autonomous Procedure Support Tools for Combat Trauma and Mass Casualty Management

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-21-C-0119

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Christopher Colombo, MD
Kyle Couperus, MD

Email: ccolombo@genevausea.org Kcouperus@gmail.com

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Geneva Foundation
Tacoma, WA

8. PERFORMING ORGANIZATION REPORT NUMBER

Year 1 Annual Report
2022

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)
USAMRAA

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Annual report reviewing progress on the “Connected and Autonomous Procedure Support Tools for Combat Trauma and Mass Casualty Management” project. This report covers work to date and reviews the current collaborators, participants, and overall accomplishments during year one. This report describes a process to develop an offline decisional support tool for facilitation of trauma resuscitative care. This application will leverage procedural video datasets, machine learning, and feedback from subject matter experts to provide guidance to medical personnel attempting advanced critical care procedures.

Disclaimer: The views expressed are those of the author(s) and do not reflect the official policy of the Department of the Army, the Department of Defense, or the US Government.

15. SUBJECT TERMS

Prolonged Casualty Care, Emergency Medicine, Decisional Support Tools, Procedural Guidance, Artificial Intelligence, Machine Learning

16. SECURITY CLASSIFICATION OF:

a. REPORT

Unclassified

b. ABSTRACT

Unclassified

c. THIS PAGE

Unclassified

17. LIMITATION OF ABSTRACT

Unclassified

18. NUMBER OF PAGES

34

19a. NAME OF RESPONSIBLE PERSON
USAMRDC

19b. TELEPHONE NUMBER *(include area code)*

Standard Form 298 (Rev. 8-98)

Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

	<u>Page</u>
1. <u>Introduction</u>	<u>5</u>
2. <u>Keywords</u>	<u>6</u>
3. <u>Accomplishments</u>	<u>6-17</u>
4. <u>Impact</u>	<u>17-19</u>
5. <u>Changes/Problems</u>	<u>19-20</u>
6. <u>Products</u>	<u>20-28</u>
7. <u>Participants & Other Collaborating Organizations</u>	<u>28</u>
8. <u>Special Reporting Requirements</u>	<u>33</u>
9. <u>Appendices</u>	<u>34</u>

1. INTRODUCTION:

U.S. military units are increasingly organized into smaller elements and operate in remote areas leading to longer evacuation times. This requires increased medical care by inexperienced clinical providers beyond doctrinal timelines, called "prolonged casualty care" (PCC). However, rapid deployment of clinicians who do not regularly work with trauma or critically ill patients to austere locations often results in limited knowledge, skills, and experience to optimally care for critically ill and injured casualties beyond initial Tactical Combat Casualty Care (TCCC). Consequently, it may result in worse patient outcomes for combat support hospitals during the early deployment portion. By implementing advanced telemedicine tools with audio-visual capabilities during PCC, we can enhance inexperienced clinicians' decision-making and, therefore, casualty care. We are collaboratively developing a phone-based application with AR/VR-guided intervention systems to be utilized as a clinical decision-support tool. We hypothesize that the use of this application by equipped medical professionals in simulated trauma scenarios will result in improved performance of medical interventions compared to equally-equipped unassisted professionals.

Our goal is to create an evidence-based interface based on connected clinical decision support systems. We seek to comprehensively evaluate procedural performance to establish a phone-based application with AR/VR guided intervention systems efficacy and explore the benefits it may offer within deployed environments. Management of critically ill patients prior to evacuation to higher echelons of care requires clinical expertise to make judgment-weighted decisions that successfully manage these nuances. Advanced telecommunication devices that enhance communication and situational awareness may provide essential critical care expertise in real-time, decrease mental task load, and comfort clinicians when faced with unfamiliar, challenging problems. In addition, the development of virtual health technology is rapidly increasing in the private sector.

This prospective study aims to facilitate focus group collaboration to achieve a consensus amongst SMEs regarding best practices, scripting strategies, and specific steps to develop a decisional support tool. We also aim to measure clinician performance related to simulated critical care interventions of complex casualties with one of the following groups; comprehensive guided decisional support or no support. The objective is to determine the "best" subject performance.

2. KEYWORDS:

Artificial Intelligence, Machine Learning, Procedural Video Data Registry, Decisional Support tool, Prolonged Casualty Care, Task Training, Military Medicine

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: Test the hypothesis that Scripting is a feasible/efficacious approach to fill capability/resource gaps in prolonged field care	Timeline	% Complete
Major Task 1: Develop and optimize scripts for mentors to guide operators to perform TCCC procedures	Months	
Subtask 1.1: Review Scripts already developed for efficacy Subtask 1.1.1 Submit overall project to IRB for determination and HRPO for review	1-3	60%
Subtask 1.2: Collect focus group input for at least 3 levels of end users from non-medical to credentialed provider (e.g. non-medical first responder, combat medic, Special Operations Medic nurse, physician)	1-3	25%
Subtask 1.3: Develop prototype mentoring scripts for end users from non-medical credentialed provider 1.3.1 at least 2 procedure scripts 1.3.2 at least two reference CPG selected	3-6	40%
Subject 1.4 Optimize script based on pilot testing of end user performance with script type and success at TCCC procedures Will require IRB determination and HPRO review	6-12	0%

Subtask 1.5: Develop Mentor Training knowledge product with the goal to train a mentor to effectively guide a remote provide using the scripts	12-18	10%
Milestone(s) Achieved: 1) >/=2 scripts for >/=2 training level of operator created for procedure mentoring of TCCC procedure 2) training knowledge product for mentor to present script created		Pending
Milestone(s) Achieved: 1) Submit project to IRB for exemption 2) Submit IRB protocols for project aims deemed HSR	3	Pending
Milestone(s) Achieved: Receive IRB determination and HRPO review	6	Pending
Major Task 2: Develop prototype automated script management software		
Subtask 2.1: Select high yield Clinical Practice Guidelines for initial use by prototype software	1-3	70%
Subtask 2.2: Focus group with intended end users (at least 3 levels of aforementioned non-medical to credentialed provider) to determine human use/user interface capabilities/requirements	1-3	30%
Subtask 2.3: Develop prototype of audio assistant	3-12	40%
Subtask 2.4: Test prototype assistant with end user community for feedback and optimization	9-18	0%
Milestone(s) Achieved: 1) Offline capable version of audio assistant prototype created 2) Audio assistant capable of utilizing procedure script 3) Audio assistant capable of utilizing CPG or other reference material		Pending
Specific Aim 2: Demonstrate proof of concept that audio assistance can be utilized by operators in non-connected environments		
Major Task 3: Integrate CPG and mentor script into automated assistant		
Subtask 3.1: Select multiple reference CPGs for incorporation into digital audio assistant	9-12	10%
Subtask 3.2: Select mentor scripts to incorporate into digital audio assistant	9-12	10%

Subtask 3.3: Present prototype assistant references and scripts to end user community for feedback and optimization	12-15	0%
Milestone(s) Achieved: 1) Automated assistant can replay audio of multiple CPG and procedure scripts while disconnected from a network 2) Successful use of automated assistant to assist in procedure completion in simulation lab		Pending
Major Task 4: Demonstrate proof of concept of the effectiveness of mentoring scripts via connected and autonomous delivery		
Subtask 4.1: Test scripts with multiple audience levels via autonomous and connected delivery to establish feasibility to perform procedures and solve clinical problems.	12-24	0%
Subtask 4.2: Perform initial proof of concept of utilizing scripts with augmented reality for procedural mentoring	12-24	0%
Subtask 4.3: Perform initial proof of concept to Integrate Automated Assistant with Augmented Reality and Machine learning capability	12-24	30%
Milestone(s) Achieved: Automated digital assistant demonstrated in field environment during simulated exercise		Pending
Milestone(s) Achieved: 1) Randomized comparative study of automated assistant vs remote connect mentor for procedure completion by local provider complete 2) Pilot demonstrations of AR/VR script utilization (using a mentor) 3) Pilot demonstration of AR/VR integration with automated assistant 4) Manuscript developed and submitted for publication for completed milestones		Pending

What was accomplished under these goals?

Specific Aim 1: Test the hypothesis that Scripting is a feasible/efficacious approach to fill capability/resource gaps in prolonged field care

Major Task 1: Develop and optimize scripts for mentors to guide operators to perform TCCC procedures

- Subtask 1.1: Review Scripts already developed for efficacy

- Subtask 1.1.1 Submit overall project to IRB for determination and HRPO for review (60% complete)
- Four IRB protocols are anticipated for this research effort. The first (regarding the formation of focus groups to establish best practices for application development) was submitted for regulatory review, however additional stipulations were requested. These stipulations were completed and the protocol is currently pending further regulatory review following resubmission. The second protocol (regarding video data collection of simulated procedures) was submitted for regulatory review, however additional stipulations were requested. The research team is currently editing the protocol to address these stipulations prior to resubmission. The third protocol (to evaluate the efficacy of the decisional support tool) is 50% drafted. The fourth protocol has not been drafted yet, but will aim to create a research repository for collecting and storing large quantities of video data from willing volunteers within the general public. Three tracks for this “public challenge” are proposed: (a) Algorithms, (b) Dataset of human performance (including sound if possible), (c) Dataset of robot Performance (in the Field). Please see P1, P2, P3, P4, P5, P6, P7, P8, P9, and P10.
- Subtask 1.2: Collect focus group input for at least 3 levels of end-users from non-medical to credentialed providers (e.g. non-medical first responder, combat medic, Special Operations Medic nurse, physician) (25% Complete)
- Zotero library group is created with more than 15 articles related to the chatbot and intelligence studies.
- Dr. Gorbalkin, Dr. Colombo, Dr. Kyle Couperus, Dr. Kirkpatrick, Dr. Candelore, Dr. Cody Couperus, Dr. Curlett, and Dr. Birch have reviewed additional literature on procedural task lists and grading criteria. They have used this information to collaboratively generate comprehensive task lists of required actions for the five procedures (chest tube, intraosseous access, tourniquet placement, needle decompression, and cricothyroidotomy). **Please see P11**
- Google Cloud Storage Platforms were created for preliminary storage and QA of video data. Purdue University Research Repository (PURR) page was created for subsequent data storage and annotation. Additional SOPs are drafted for secure upload and storage of procedural video data and annotations. **Please see P16**
- Geneva Research Team met with potential collaborators from John Hopkins University to discuss their data commons prototype and its potential use as a platform for data storage and analysis.
- Subtask 1.3: Develop prototype mentoring scripts for end-users from non-medical to credentialed providers (40% complete)
 - 1.3.1 at least 2 procedure scripts
 - Documentation created to capture parameters surrounding video data collection. **Please see P16**
 - Conducted weekly meetings with Mission First/Zulucare to discuss the overall user experience and functionality of the decisional support application. Recognized need for mobile application and a host website. Mission First/Zulucare has continued to develop mobile wireframes, and also conducted a preliminary internal release of the website for review by their quality assurance team.
 - In development meetings with Mission First/ Zulu Care, teams discussed how content would be displayed and the processes of how content is uploaded, reviewed and approved or denied. Discussion of multi-tier approval, built-in referral process and the addition of a one-time use link for external users to review and report on content and procedures.
 - Capabilities for mobile wireframes were confirmed and the option for a token-based timer on datasets was considered in which content data can be available for a specific amount of time or indefinitely. Token-types such as push and email notifications to notify users when content has not been sync for a predetermined amount of time was also discussed.
 - Credentialing and logging in for the mobile side was developed and the basic framework is present. This allows credentialing to be done through iPhones, Apple, Google and email.
 - Madigan team created a tag list of commonly used words and any acronyms or synonyms associated with them. This will be used to facilitate the users searchers. **Please see P19.**
- 1.3.2 at least two references CPG selected
- Subtask 1.4: Optimize script based on pilot testing of end-user performance with script type and success at TCCC procedures (Not Started)
- Subtask 1.5: Develop Mentor Training knowledge product with the goal to train a mentor to effectively guide a remote provider using the scripts (10% complete)
- Research staff performed literature review of best practices and grading criteria for each of the five procedures. These materials, in combination with the expertise of our physician collaborators, were used to create a comprehensive procedural task list outlining the necessary actions of each procedure. This will be used to guide mentor training.

Major Task 2: Develop prototype automated script management software

- Subtask 2.1: Select high yield Clinical Practice Guidelines for initial use by prototype software (70% Complete)
 - The Research Personnel have completely drafted a video data collection protocol which is currently pending IRB submission following acquisition of supplemental documents from our collaborating departments. This protocol will gather video data of simulated procedures, which will be annotated for task analysis. Annotations and video content will be sent to our collaborators at Purdue University where it will undergo machine learning analysis for task recognition, to facilitate development of a software which will manage scripts and procedural guidance. Please see P10
- Subtask 2.2: Focus group with intended end-users (at least 3 levels of aforementioned non-medical to credentialed provider) to determine human use/user interface capabilities/requirements (30% Complete)
 - The Research Personnel have completely drafted a focus group protocol which is currently pending IRB review following acquisition of supplemental documentation from our collaborating departments. This protocol will gather the collective feedback from SMEs in the field of trauma resuscitative care to assist in determining human use capabilities/requirements.
 - The Purdue team has continued to utilize procedural video annotations (using the annotator software and manual transcription) to facilitate landmark identification on a wide range of manikins. Thus far, video content has been provided only by the study's primary investigators. The videos are actively being used to 'train' a computer program on landmark identification and predictive analytics to identify 'next steps' for each procedure. These videos capture only the upper extremities of our research staff while completing procedures and include no human subjects, patients, or other individuals. These videos will not be used in 'research' but rather for the development of the 'computer program'. The Purdue team is currently working to address challenges with the manikin regarding action recognition and anticipation.
- Subtask 2.3: Develop prototype of audio assistant (40%)
 - The Mission First and Zulucare teams are currently developing the application and audio assistant prototypes. Meeting with developers is taken weekly to review the progress and provide feedback on the wireframes
 - Mission First/Zulucare provided further drafts of mobile application layout 'wireframes.' **Please see P12**
 - MAMC investigators reviewed the summary of application structure with Mission First/ Zulucare, which includes:
 - Voice-Activated/Controlled hands-free interaction (i.e., open menu, advance 15 seconds, etc.). This feature is currently under development by the Zulucare team, with an anticipated prototype ready for review within the next reporting period.
 - AI/ML Work with Purdue to evaluate using recordings/systems to automate script/content generation partially. This work is still ongoing as we gather further video data to refine the task recognition and predictive analytics.
- Subtask 2.4: Test prototype assistant with the end-user community for feedback and optimization (Not Started)

Specific Aim 2: Demonstrate proof of concept that audio assistance can be utilized by operators in non-connected environments

Major Task 3: Integrate CPG and mentor script into automated assistant

- Subtask 3.1: Select multiple reference CPGs for incorporation into digital audio assistant (10%)
 - Research team is reviewing multiple reference CPG to integrate into the digital audio assistant. The incorporation will take place once the IRB protocol is approved.
- Subtask 3.2: Select mentor scripts to incorporate into digital audio assistant (10%)
 - Mentor scripts for different procedures are in the process of development. Additional feedback from the Subject Matter Experts will be collected in the scripts once receiving the IRB and HRPO approval.
 - Previously created script from TelePFC is being used as a stand in to aid in app development. This script will be iterated upon during focus group sessions once IRB approved.
- Subtask 3.3: Present prototype assistant references and scripts to the end-user community for feedback and optimization (Not Started)

Major Task 4: Demonstrate proof of concept of the effectiveness of mentoring scripts via connected and autonomous delivery

- This project has been accepted for presentation at the following conferences **Please see P13, P14, and P15:**
 - Joint Services Symposium on Emergency Medicine (JSSEM).
 - Military Health System Research Symposium (MHSRS).

- Nato Training Technology Conference (NTTC).
- Subtask 4.1: Test Scripts with multiple audience levels via autonomous and connected delivery to establish feasibility to perform procedures and solve a clinical problem. (Not Started)
- Subtask 4.2: Perform initial proof of concept of utilizing scripts with augmented reality for procedural mentoring (Not Started)
- Subtask 4.3: Perform initial proof of concept to Integrate Automated Assistant with Augmented Reality and Machine learning capability (30%)
- Purdue collaborators built a machine learning algorithm to review procedural videos, identify what procedure/step is being done, and then predict the following step. Additional GoPro video content was recorded at MHSRS on various models/manikins for additional machine learning review.
- Dr. Kirkpatrick, Dr. Birch, Dr. Colombo, Dr. Kyle Couperus, and Dr. Candelore have collectively delivered 119 videos of simulated procedures (chest tube, intraosseous access, tourniquet placement, needle decompression, and cricothyroidotomy), and 44 of these videos were collected on manikins at MHSRS. All videos underwent annotation for task analysis. Videos and annotations were utilized by Purdue collaborators to further train the machine learning network. Please see P1, P2, P3, P4, P5, P6, P7, P17, P21, and P22***.
- The Purdue team has continued to utilize procedural video annotations (using the annotator software and manual transcription) to facilitate landmark identification on a wide range of manikins. Thus far, video content has been provided only by the study's primary investigators. The videos are actively being used to 'train' a computer program on landmark identification and predictive analytics to identify 'next steps' for each procedure. These videos capture only the upper extremities of our research staff while completing procedures and include no human subjects, patients, or other individuals. These videos will not be used in 'research' but rather for the development of the 'computer program'. The Purdue team is currently working to address challenges with the manikin regarding action recognition and anticipation
- Additionally, the Purdue team has developed a 'Functional Object-Oriented Network' (FOON) to visually track the objects and actions of each step for all 5 procedures. These subgraphs will be created for each video and merged to yield a collective web outlining unique and shared actions of each procedure. This will facilitate training of the machine learning algorithm. **Please see P20**

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state “Nothing to Report.”

(a) Human Use Regulatory Protocols

TOTAL PROTOCOLS: State the total number of human use protocols required to complete this project (e.g., “5 human subject research protocols will be required to complete the Statement of Work”). If not applicable, write “No human subjects research will be performed to complete the Statement of Work”

TOTAL PROTOCOLS:

3 human subject research protocols will be required to complete the Statement of Work

PROTOCOL (1 of 3 total):

Protocol [HRPO Assigned Number]: Pending

Title: Trauma Alexa: Developing Scripted Autonomous Decisional Support Applications for Medical Intervention During Prolonged Casualty Care.

Target required for clinical significance: Pending

Target approved for clinical significance: Pending

SUBMITTED TO AND APPROVED BY:

- The first protocol is completely drafted and has been submitted for regulatory review, however additional stipulations were requested. This protocol has been edited to address these stipulations, and is currently pending resubmission in the next quarter.

STATUS:

- (i) Number of subjects recruited/original planned target: Planned Target =36
Number of subjects screened/original planned target: Planned Target =36
Number of patients enrolled/original planned target: Planned Target =36
Number of patients completed/original planned target: Planned Target =36
- (ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:
- Nothing to report for this quarter
- (iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:
- Nothing to report for this quarter

PROTOCOL (2 of 3 total):

Protocol [HRPO Assigned Number]: Pending

Title: Trauma Alexa: Utilizing Focus Groups to Develop Scripted Autonomous Decisional Support Applications for Medical Intervention During Prolonged Casualty Care.

Target required for clinical significance: Pending

Target approved for clinical significance: Pending

SUBMITTED TO AND APPROVED BY:

- The second protocol is completely drafted with plans to submit for regulatory review next quarter pending acquisition of supplemental documents from collaborating departments.

STATUS:

(i) Number of subjects recruited/original planned target: Planned Target 15-30
Number of subjects screened/original planned target: Planned Target 15-30
Number of patients enrolled/original planned target: Planned Target 15-30
Number of patients completed/original planned target: Planned Target 15-30

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

- Nothing to report for this quarter

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

- Nothing to report for this quarter

PROTOCOL (3 of 3 total):

Protocol [HRPO Assigned Number]: Pending

Title: TBD

Target required for clinical significance: Pending

Target approved for clinical significance: Pending

SUBMITTED TO AND APPROVED BY:

- The third protocol is approximately 50% drafted. Additional content is dependent upon the information yielded by the first and second protocols.

STATUS:

(i) Number of subjects recruited/original planned target: TBD
Number of subjects screened/original planned target: TBD
Number of patients enrolled/original planned target: TBD
Number of patients completed/original planned target: TBD

(ii) Report amendments submitted to the IRB and USAMRMC HRPO for review:

- Nothing to report for this quarter

(iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation:

- Nothing to report for this quarter

Include & update enrollment chart, showing projected, actual, and cumulative enrollment.

Example			Enter information regarding number of subjects				
<u>HRPO Protocol Number</u>	<u>Protocol PI Name</u>	<u>Organization (Site)</u>	<u># Target</u>	<u># Screened</u>	<u># Enrolled</u>	<u># Completed</u>	<u>Other</u>
Pending	Chad Gorbatkin, MD	Madigan Army Medical Center	36	0	0	0	
Pending	Chad Gorbatkin, MD	Madigan Army Medical Center	15-30	0	0	0	
Pending	Chad Gorbatkin, MD	Madigan Army Medical Center	TBD	0	0	0	

(b) Use of Human Cadavers for Research Development Test & Evaluation (RDT&E), Education or Training

No RDT&E, education or training activities involving human cadavers will be performed to complete the Statement of Work (SOW)

(c) Animal Use Regulatory Protocols

No animal use research will be performed to complete the Statement of Work.

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

- Dr. Eleanor Birch (DEM Resident Y2) attended and presented at the Military Health System Research Symposium (MHSRS) in September 2022 under this effort.
- An abstract for this effort was submitted and accepted to NATO Training Technology Conference (NTTC) in August 2022
- Dr. Birch attended and presented at Joint Services Symposium on Emergency Medicine (JSSEM) in August 2022 under this effort.
- Madigan Research team received training on how to set up the Annotation/Machine Learning (ML) on Linux systems and are capable of tagging the procedural actions manually - this training helps to compare the accuracy of the ML during the development process.

How were the results disseminated to communities of interest?

To date (1 year into this effort), no specific publications have been completed. Posters for the project have been presented at MHSRS 2022 and JSSEM 2022. The abstract was also submitted and accepted at NTTC 2022 - we could not attend the conference due to high travel costs. **(Please see attachments P13, P14, and P15).**

In addition, this study is invited for manuscript submission to Military Medicine: Warfighters 2022 Supplement. Only research methodologies will be presented in this paper as no data is collected at this time. The manuscript draft is in progress - a copy of the draft will be submitted by the next quarterly report.

A few collaboration meetings with other partners, such as TARTC, ISR, and PTG programs, have taken place to discuss potential future collaboration. A project trailer is also created to support the community outreach - the videos are screened multiple times to make sure no identifiable information is present (**Please see P22**). The investigators are planning to organize a challenge in the future related to AI-based mentorship for life-saving skills on the battlefield. Once the plan is established, further information will be included in the next quarterly report.

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

The following annual report will complete:

By Y2Q1, the research team will obtain approved documentation for the focus group and video data collection protocols from the IRB and HRPO, respectively. Following HRPO approval, recruiting and enrolling study subjects for the focus group and video data collection protocols will commence.

The research team will continue developing prototype mentoring scripts and testing and validating the mobile and web-based applications.

By Y2Q2, the research team will draft the efficacy protocol and submit it to the IRB for approval. Based on performance feedback during pilot testing with the end user and the success of TCCC procedures, the script will undergo optimization at this time.

As testing and feedback collection from the end user community continues, Subject Matter Experts will be contacted for video data collection for 5 different procedures: chest tube, intraosseous access, tourniquet placement, needle decompression, and cricothyroidotomy. The SMEs will then be interviewed to identify priorities in medical intervention and establish best practices for each procedure.

By Y2Q3, the research team will obtain IRB-approved documentation and submit those to HRPO for approval while continuing prototype assistant testing and feedback collection with the end user community for further optimization.

By Y2Q4, following HRPO approval, the research team will begin recruiting study subjects for efficacy evaluation and perform an initial proof of concept utilizing the scripts with augmented reality for procedural mentoring. The procedural performance (chest tube placement) completed in an augmented reality simulation will then be compared using a decisional support tool versus no decisional support tool.

4. IMPACT:

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

This project supports developing a decisional support tool to guide medical personnel in complex critical care procedures. We hypothesize that this will improve the care provided to individuals injured through traumatic mechanisms (military and civilian), particularly when the advanced critical care procedures are outside of the traditional scope of practice for the medical personnel providing care. Extensive progress has been made to provide a strong foundation for application development. The collective expertise of collaborating SMEs on this project has yielded documentation outlining best practices (Please see P11), application content, and videos of investigators completing these critical care procedures. Collaborators at Purdue University are utilizing this video data to refine a machine learning system on procedural task recognition and subsequent task prediction. This machine learning system will play an integral role in the decisional support application by offering guidance in real-time, depending on the specific actions being completed. Additionally, Mission First and Zulucare are currently developing web and mobile interfaces for the application with continued collaboration by the research team. The focus group protocol has been resubmitted with supplemental information and is currently pending approval by Madigan IRB. Additional stipulations were requested for the video data collection protocol, which is actively being completed prior to resubmission to Madigan IRB.

What was the impact on other disciplines?

While this study primarily focuses on the end product (a decisional support tool), the process of refining the machine learning algorithm will provide additional benefits to the field of artificial intelligence. Using the collected video data and annotations, the Purdue team will develop a system capable of recognizing a large number of medical instruments and identifying hand-tracking patterns associated with each action. This could prove beneficial if the dataset is expanded to include other procedures and could provide a foundation for subsequent unrelated studies involving complex task recognition and predictive analytics.

In addition, our team has identified potential data registries where we could upload the collected procedural video data. This would ideally prove mutually beneficial. The data registry would provide our team with a secure storage platform, and we would contribute valuable video data that could aid in their support of prolonged casualty care.

What was the impact on technology transfer?

Once we have collected sufficient video data, we will issue a challenge to outside collaborators, requesting that they use the data to create an optimal algorithm for action prediction. Collaborators benefit from access to a large dataset, and our team benefits from their collective expertise regarding machine learning/predictive analytics.

What was the impact on society beyond science and technology?

Through the decisional support application, we aim to improve education and the practice of critical care medicine, particularly in deployed environments and prolonged casualty care scenarios. Procedural video data is also crucial for developing a machine learning algorithm capable of complex task recognition and predictive analytics. This could substantially impact subsequent and unrelated projects using task recognition.

5. CHANGES/PROBLEMS:

Nothing to report.

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

No anticipated problems at this time.

Changes that had a significant impact on expenditures

There has been no significant impact in the past year affecting the research performance. However, the fund request to travel to Purdue Laboratory isn't needed for this year because the Machine Learning workflow is performed virtually efficiently between the Purdue research team and the Geneva research team. We hope to use this travel for expenditures such as travel to conferences or purchasing equipment. The Geneva Contract team will follow up with more information.

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

Nothing to report.

Significant changes in use of biohazards and/or select agents

Nothing to report.

6. PRODUCTS:

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

Journal publications.

A manuscript is currently being drafted for the 2022 MHSRS Supplement to Military Medicine, also known as the Warfighters 2022 Supplement. The manuscript will focus on research methodologies used for this project. A copy of the draft will be included in the next quarterly report supplements.

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

Nothing to report.

Other publications, conference papers and presentations.

Abstract submitted and accepted to 2022 Joint Services Symposium on Emergency Medicine (JSSEM): Couperus et. al "Trauma THOMPSON: TeleHelper for Operational Medical Procedure Support and Offline Network". Please see P13.

Abstract submitted and accepted to 2022 Military Health System Research Symposium (MHSRS): Couperus et. al "Trauma Alexa: Clinical Decision Support for The Frontline Medic". Please see P14

Abstract submitted and accepted to 2022 NATO Training Technology Conference (NTTC): Couperus et. al "Trauma Alexa: Clinical Decision Support for The Frontline Medic". Please see P15.

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

<https://thompsonisat.github.io/ISAT-THOMPSON/> (this website is still in the development process and has not been finalized yet)
<https://youtu.be/WmKCYqww3Vc>

- **Technologies or techniques**

The research team is in the process of establishing a functional machine-learning algorithm capable of recognizing a specific task being performed in any of 5 procedures (chest tube, IO insertion, tourniquet, needle decompression, or cricothyroidotomy). Additionally, this algorithm will use the recognized task to predict the following steps. This is accomplished by collecting a large volume of procedural video data, annotating each task in the procedure, and presenting this data to the algorithm for “learning”. A small subsection of the data will be presented to the algorithm for “testing” to establish the accuracy of task recognition and prediction. While the accuracy has continually improved as the size of the dataset increases, this piece of technology is not final and we anticipate further data collection (as proposed in Trauma THOMPSON Protocol #3) is needed to yield a fully functioning machine learning algorithm.

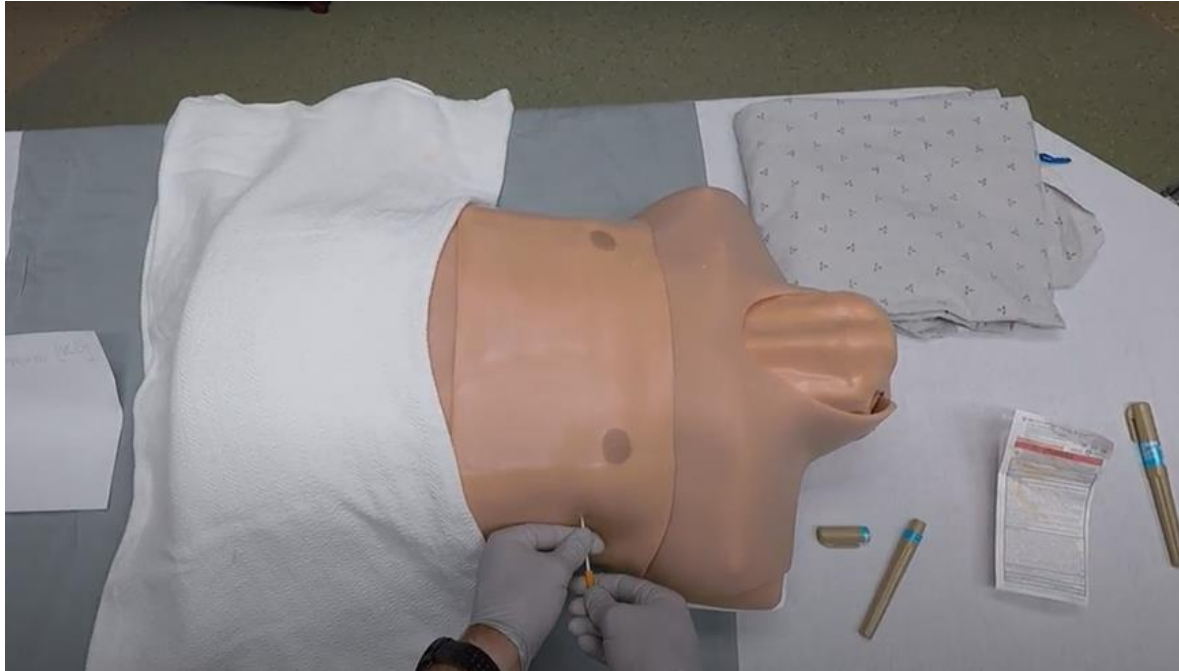
- **Inventions, patent applications, and/or licenses**

Nothing to report.

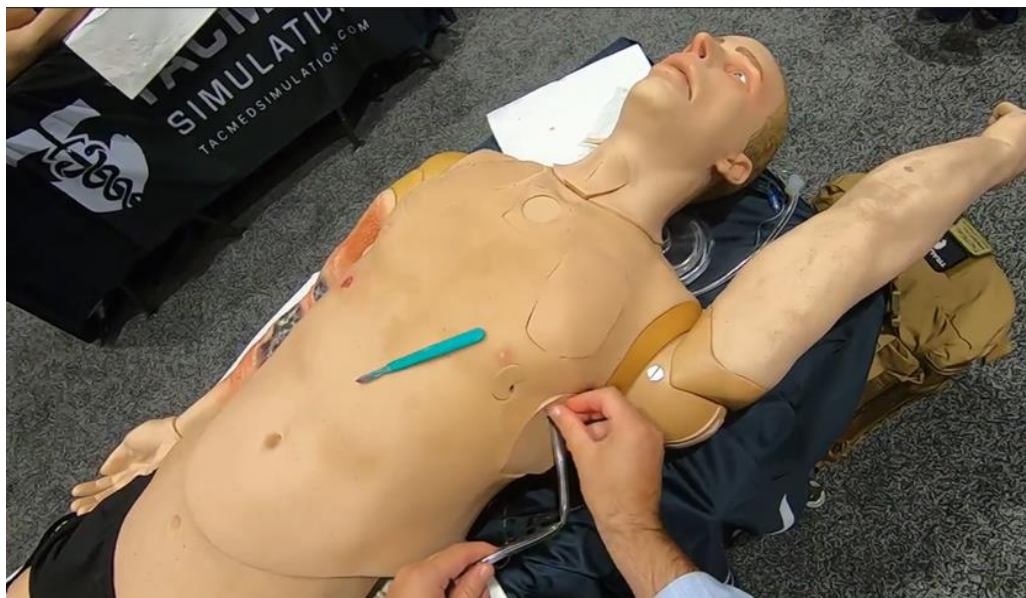
- **Other Products**



P1: Dr. Ross Candelore performing Needle Decompression in a field environment with manikin and medical equipment. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P2: Dr. Ross Candelore performing Needle Decompression on a stretcher with manikin and medical equipment. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P3: Chest tube insertion demonstrated at 2022 MHSRS on Manikin. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P4: Tourniquet placement performed at 2022 MHSRS using K-9 Manikin. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P5: Tourniquet placement performed at 2022 MHSRS using Manikin. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P6: Cricothyroidotomy performed at 2022 MHSRS using Manikin. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.



P7: Intraosseous Access performed at 2022 MHSRS using Manikin. Recording the videos in different environments and manikin models will help to train the Machine Learning (ML). The videos are collected for ML development purposes.

Tasks \ Results	Action recognition			Action recognition		
	Action	Verb	Noun	Action	Verb	Noun
Top1	18.85%	36.07%	28.69%	7.10%	25.72%	19.07%
Top5	34.43%	45.08%	40.98%	19.07%	37.69%	33.70%

P17: Current dataset from 17 videos and 478 actions to train Machine Learning - not a part of data collection.

	A	B	C
22	Take Kelly	2:09	
23	Insert kelly	2:13	
24	Expand kelly	2:14	
25	Expand kelly	2:15	
26	Insert kelly	2:16	
27	Expand kelly	2:17	
28	Remove kelly	2:40	
29	Drop kelly	2:42	
30	Take kelly	2:45	
31	Insert kelly	2:46	
32	Remove kelly	3:02	
33	Insert finger	3:02	
34	Insert kelly	3:22	
35	Remove finger	3:23	
36	Expand kelly	3:26	
37	Expand kelly	3:33	
38	Expand kelly	3:36	
39	Remove kelly	3:38	
40	Insert finger	3:41	
41	Sweep finger	3:45-3:54	
42	Remove finger	3:55	
43	Take kelly	3:57	
44	Take tube	3:59	
45	Attach Kelly and tube	4:02	
46	Insert finger	4:10	
47	Insert kelly/tube	4:11	
48	Detach kelly	4:18	
49	Advance tube	4:18	
50	Remove kelly	4:24	

P21: Manual annotation of tube thoracostomy for use in training the machine learning network.

	Tourniquet	IO Access	Cricothyroidotomy	Tube Thoracostomy	Needle Decompression
Number of videos from MHSRS:	17	3	4	5	15
Number of videos from investigators	2	6	5	40	22
Total videos:	19	9	9	45	37

P22: Current number of videos delivered by investigators. 44 of these videos were obtained on manikins/trainers at MHSRS.

- P8: Study Protocol Draft #1: Efficacy of Chest Tube Placement with and without a Decisional Support Tool - Please see supplemental attachment [S1]**
- P9: Study Protocol Draft #2: Trauma Alexa: Developing Scripted Autonomous Decisional Support Applications for Medical Intervention During Prolonged Casualty Care. - Please see supplement attachment [S2]**
- P10: Study Protocol Draft #3: Trauma Alexa: Procedural Video Data Collection for Task Analysis and Machine Learning Review - Please see supplement attachment [S3]**
- P11: Chest tube, Intraosseous access, Tourniquet Placement, Needle Decompression and Cricothyroidotomy Task List - Please see supplement attachment [S4]**
- P12: Server-Side Wireframes and Mobile Wireframes - Please see supplement attachment [S5]**
- P13: JSSEM 2022 Trauma THOMPSON Abstract - Please see supplement attachment [S6]**
- P14: MHSRS 2022 Trauma THOMPSON Abstract - Please see supplement attachment [S7]**
- P15: NTTC 2022 Trauma THOMPSON Abstract - Please see supplement attachment [S8]**
- P16: SOPs for Data Upload, Storage, and Deletion - Please see supplemental attachment [S9]**
- P18: Video Collection Parameters - Please see supplemental attachment [S10]**
- P19: Commonly Used Words, Acronyms, and Synonym Tag List - Please see supplemental attachment [S11]**
- P20: Functional Object-Oriented Network (FOON) Slides from Purdue - Please see supplemental attachment [S12]**
- P22: Trauma THOMPSON Trailer - Please see link: <https://youtu.be/WmKCYqww3Vc>**

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Name: Christopher J. Colombo, MD, FACP, FCCM

Project Role: Program Director/ Co-Principal Investigator

Researcher Identifier: ORCID ID 0000-0001-5499-3368

Nearest person month worked this quarter: 0.60

Contribution to Project: Dr. Colombo began the project as a Staff Intensivist and Director of Virtual Health and Telecritical Care at Madigan Army Medical Center, and following his retirement is now employed by the Geneva foundation specifically to work on projects like these. He will serve as the Principal Investigator and will dedicate 10% effort to this project. As the PI for this study, he will be responsible for the overall conduct and oversight of the study at MAMC. Specifically, Dr. Colombo will meet with the research team on a regular basis to review the planning and execution of the proposed project and support coordination and access to the user community for testing and validation. Dr. Colombo will also be responsible for the submission of technical reports and manuscripts generated by this study.

Name: Kyle Couperus, BSN, MD

Project Role: Co-Investigator

Researcher Identifier: N/A

Nearest person month worked this quarter: 0.36

Contribution to Project: Dr. Couperus began the project as Research Director in the Department of Emergency Medicine at Madigan Army Medical Center (MAMC) and following his leave from being active duty is now being employed by the Geneva Foundation and reservist at 75th Innovation Command. He serves as a Co-Investigator and will dedicate 3% effort to this project. He will support Dr. Colombo with the overall conduct and oversight of the study at Madigan. Specifically, Dr. Couperus will oversee the execution of simulation scenarios and scripts. He will also meet with the research team on a regular basis to review the experimental design and statistical analysis, as well as support the submission of technical reports and manuscripts

generated by this study.

Name: Chad Gorbatkin, MD

Project Role: Co-Investigator

Researcher Identifier: N/A

Nearest person month worked this quarter: 0.12

Contribution to Project: Dr. Gorbatkin began study project as Assistant Program Director of the Emergency Residency Program in the Department of Emergency Medicine (DEM) at Madigan Army Medical Center (MAMC) and is now Attending physician at DEM, MAMC. He serves as a Co-Investigator and will dedicate 1% effort to this project. Dr. Gorbatkin also serves as Principal Investigator on the IRB Research protocols at MAMC. He supports Dr. Colombo with the overall conduct and oversight of the study at Madigan. Specifically, Dr. Gorbatkin oversees the execution of simulation scenarios and scripts. He also meets with the research team on a regular basis to review the experimental design and statistical analysis, as well as support the submission of technical reports and manuscripts generated by this study.

Name: Ross Candelore, DO

Project Role: Co-Principal Investigator

Researcher Identifier: N/A

Nearest person month worked this quarter: 0.36

Contribution to Project: Dr. Candelore began the project as a Resident Simulation Director in the Department of Emergency Medicine at Madigan Army Medical Center (MAMC) and is now an attending physician at Brooke Army Medical Center (BAMC). He serves as a Co-Investigator and will dedicate 3% effort to this project. He supports Dr. Colombo with the overall conduct and oversight of the study. Specifically, Dr. Candelore oversees the execution of simulation scenarios and scripts. He also meets with the research team on a regular basis to review the experimental design and statistical analysis, as well as support the submission of technical reports and manuscripts generated by this study

Name: Grace DeVane

Project Role: Research Assistant II

Researcher Identifier: N/A

Nearest person month worked this quarter: 0.75

Contribution to project: Ms. DeVane has assisted with network and system administration including but not limited to the installation of equipment and software, training of other staff, and other technical requirements in support of the scope of work at Madigan Army Medical Center. She also works closely with Madigan IT and the study team to ensure the smooth operation of the system and resolve problems as needed.

Name Oanh Tran

Project Role: Program Manager

Researcher Identifier: N/A

Nearest person month worked this quarter: 0.25

Contribution to project: Ms. Tran has assisted Dr. Colombo and other investigators in serving as the direct interface with Madigan Army Medical Center for all study collaborators. Additionally, she is also responsible for oversight of all staff supporting the project

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

The Principal Investigators for this project have remained the same. However, due to their retirement and leave from active duty, Dr. Colombo and Couperus are now PI at the Geneva Foundation instead of Madigan Army Medical Center. The PI will provide an updated CV to the sponsors.

What other organizations were involved as partners?

Organization Name	The Geneva Foundation
Location of Organization	917 Pacific Ave Suite 600, Tacoma, WA 98402
Contribution to the Project	Financial support. The Geneva Foundation provided Research Assistant II and program manager contract services.

Organization Name	Purdue University
Location of Organization	610 Purdue Mall, West Lafayette, IN 47907
Contribution to the Project	Financial support and in-kind support. Purdue University team works with the research team on annotation and Machine Learning (ML) analysis.

Organization Name	University of Calgary
Location of Organization	Unit 32, 1359-69 Street SW, Calgary, Alberta, T3H 3W8
Contribution to the Project	Collaboration support. Worked with the research team to develop procedural guidelines and prototype mentoring scripts for end users from non-medical to credentialed providers.

Organization Name	Brooke Army Medical Center (BAMC)
Location of Organization	3551 Roger Brooke Dr, San Antonio, TX 78219
Contribution to the Project	Collaboration support. Worked with the research team to develop procedural guidelines and prototype mentoring scripts for end users from non-medical to credentialed providers.

Organization Name	Zulu Care Inc.
Location of Organization	1055 Stewart Ave, Suite 15, Bethpage, NY 11714
Contribution to the Project	Collaboration support and In-kind support. Work with the research team to develop a fully functional Android/Apple agnostic mobile application with core content areas.

Organization Name	Mission First Inc.
Location of Organization	8830 Stanford Boulevard, Suite 415, Columbia, MD 21045
Contribution to the Project	Collaboration support and In-kind support. Work with the research team to develop a fully functional Android/Apple agnostic mobile application with core content areas.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

[S1] Study Protocol Draft #1

[S2] Study Protocol Draft #2

[S3] Study Protocol Draft #3

[S4] Chest tube, Intraosseous Access, Tourniquet Placement, Needle Decompression and Cricothyroidotomy Task List

[S5] Server-side and Mobile Wireframes

[S6] 2022 JSSEM Abstract

[S7] 2022 MHSRS Abstract

[S8] 2022 NTTC Abstract

[S9] SOPs for Data Upload, Storage, and Deletion

[S10] Video Collection Parameters

[S11] Commonly Used Words, Acronyms, and Synonym Tag List

[S12] Functional Object-Oriented Network (FOON) Slides from Purdue