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TITLE: Medical Surgical Technical Assistance Tool (mSTAT) Development and Testing

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CONTRACTING ORGANIZATION: University of Maryland, Baltimore, MD

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6. AUTHOR(S)
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13. SUPPLEMENTARY NOTES

14. ABSTRACT

We propose to evaluate the efficacy of a video-based step-by-step approach (medic Surgical Technical Assistance Tool, mSTAT) to enable medics to perform more advanced surgical interventions. We have previously shown that this approach significantly improves the performance of selected vascular and fasciotomy procedures by trained surgeons.

Aim 1: To test if medics using a similar tool, redesigned to target individuals whose surgical procedural skill level is that of the combat medic, will allow for effective advanced vascular and fasciotomy procedures.
Aim 2: To analyze medic cognition and reasoning as they undertake each of the procedures in comparison to available surgeon data to inform development of effective training/forward knowledge interventions.

15. SUBJECT TERMS
Trauma, hemorrhage, video training, vascular control, fasciotomy

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1. INTRODUCTION:

A substantial fraction of medical care in combat environments involves medics providing field stabilization, followed by aeromedical evacuation to a forward medical facility. Potential delays in aeromedical evacuation requires advancing medical capabilities closer to the point of injury. The objective of this proposal is to provide a knowledge- and skills-based tool that a medic could use to improve performance of more advanced surgical stabilization interventions in austere environments and/or situations in which advanced telecommunications are unavailable. We propose to evaluate the efficacy of a video-based step-by-step approach (medic Surgical Technical Assistance Tool, mSTAT) to enable medics to perform more advanced surgical interventions.

2. KEYWORDS:

Trauma, hemorrhage, video training, vascular control, fasciotomy

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: To test if medics using the mSTAT, video-based tool, can effectively perform advanced vascular and fasciotomy procedures.

Major Task 1: IRB submission, Sub-Contract negotiations, Didactic Curriculum, mSTAT Video development, pilot testing.

1.1 Kick–off meeting of research staff, consultants and Sub-Contractors.
1.2 Complete Sub-Contract negotiations.
1.3 Develop didactic curriculum and teaching videos with input from trauma, military, and medic experts.
1.4 Obtain IRB & HRPO approval
1.5 Test didactic curriculum and teaching videos on pilot subjects; Additional input from experts; finalize curriculum and videos; develop introductory materials for potential subjects; pilot procedures with medics (n=10 medics and 10 cadavers)

Major Task 2: Subject enrollment

2.1 Send Introductory Materials to potential medic subjects; Begin Study Enrollment of medics (after IRB approvals and Informed consent obtained). Assignment into study groups: n=20 per group, 3 groups; 60 participants total.
2.2 Evaluation of medics performing 4 ASSET procedures on unpreserved cadavers (n=60) using didactic education 3-6 months before testing only, the video tool only, or didactic education plus video too.
2.3 Mid-term review meeting with investigators and consultants
2.4 Complete recruitment of subjects testing the efficacy of the didactic curriculum and the video tool for medic procedural performance

Major Task 3: Data analysis

3.1 Analyze metrics of performance to determine efficacy of the didactic curriculum and/or video tool. Correlate performance metrics against think-aloud cognitive analysis. Compare project dataset with previous surgeon performance data from W81XWH-13-2-0028 and W81XWH-17-2-0011 on the same procedures.
3.2 Draft papers; present results; and Prepare Final report.

Specific Aim 2: To analyze medic cognition and reasoning during the procedures in comparison to available surgeon data to help development of effective training/forward knowledge interventions.

1.1 Evaluation of 'think-aloud' from the medic audio recordings for content (planning, procedural narratives, anatomical references) and affective metrics (metacognition, stress)
1.2 Evaluate medics' self-reported survey of subjective factors of perceptions of self-confidence/helpfulness from the didactic curriculum and/or the video tool.

What was accomplished under these goals?

Specific Aim 1: To test if medics using the mSTAT, video-based tool, can effectively perform advanced vascular and fasciotomy procedures.

Major Task 1: IRB submission, Sub-Contract negotiations, Didactic Curriculum, mSTAT Video development, pilot testing.

1.1 Kick–off meeting of research staff, consultants and Sub-Contractors.
We have met with research staff, consultants, and sub-contractors.
1.2 Complete Sub-Contract negotiations.
Subcontract negotiations with WSU are complete. We are working with the Geneva Foundation and Womack and received the Womack IRB reliance and command approvals.
1.3 Develop didactic curriculum and teaching videos with input from trauma, military, and medic experts.
We have completed shooting, revising/reshooting and editing the principal videography for the procedural videos to use in both the mSTAT and Didactic components of the project. Post-production for all of the proposed procedures is completed. We have continued to draft assessment scripts for the procedure scenarios and training materials for the medic didactic training sessions.

Procedure	Shot raw footage	Video post-production	Scripts drafted	Finalized scripts
Axillary artery exposure	✓	✓	✓	
Femoral artery exposure	✓	✓	✓	
Lower extremity fasciotomy	✓	✓	✓	
Upper extremity fasciotomy	✓	✓	✓	
Carotid artery exposure	✓	✓	N/A*	
Brachial artery exposure	✓	✓	N/A	
Hand fasciotomy	✓	✓	N/A	
Lateral canthotomy	✓	✓	N/A	

*These procedures will be introduced to the participants as part of the didactic curriculum, but will not be tested in the cadavers. Therefore, scripts will not be needed. By including additional procedures in the didactic curriculum that won't be tested, we hope to decrease the chances that the participants will actively prepare ahead of time for performing the procedures.

1.4 Obtain IRB & HRPO approval

We have approval from the University of Maryland, Baltimore, Institutional Review Board. We have an IRB Institutional Agreement between WSU and UMB. We have approval from the Womack Army Medical Center Human Research Protection Program.

All approvals have been submitted to the Army HRPO. We are currently awaiting their approval to initiate testing phases.

1.5 Test didactic curriculum and teaching videos on pilot subjects; Additional input from experts; finalize curriculum and videos; develop introductory materials for potential subjects; pilot procedures with medics (n=10 medics and 10 cadavers)

Not yet initiated.

Major Task 2: Subject enrollment

2.1 Send Introductory Materials to potential medic subjects; Begin Study Enrollment of medics (after IRB approvals and Informed consent obtained). Assignment into study groups: n=20 per group, 3 groups; 60 participants total.

Not yet initiated.

2.2 Evaluation of medics performing 4 ASSET procedures on unpreserved cadavers (n=60) using didactic education 3-6 months before testing only, the video tool only, or didactic education plus video too.

Not yet initiated.

2.3 Mid-term review meeting with investigators and consultants

Not yet initiated.

2.4 Complete recruitment of subjects testing the efficacy of the didactic curriculum and the video tool for medic procedural performance

Not yet initiated.

Major Task 3: Data analysis

3.1 Analyze metrics of performance to determine efficacy of the didactic curriculum and/or video tool. Correlate performance metrics against think-aloud cognitive analysis. Compare project dataset with previous surgeon performance data from W81XWH-13-2-0028 and W81XWH-17-2-0011 on the same procedures.
Not yet initiated.
3.2 Draft papers; present results; and Prepare Final report.
Not yet initiated.

Specific Aim 2: To analyze medic cognition and reasoning during the procedures in comparison to available surgeon data to help development of effective training/forward knowledge interventions.

1.1 Evaluation of 'think-aloud' from the medic audio recordings for content (planning, procedural narratives, anatomical references) and affective metrics (metacognition, stress)
Not yet initiated.
1.2 Evaluate medics' self-reported survey of subjective factors of perceptions of self-confidence/helpfulness from the didactic curriculum and/or the video tool.
Not yet initiated.

DESCRIBE THE REGULATORY PROTOCOL AND ACTIVITY STATUS

PROTOCOL (1 of 1 total):

HRPO Protocol: E01511.2a

Title: Medical Surgical Technical Assistance Tool (mSTAT) Development and Testing

Target required for statistical significance: 60

Target approved for statistical significance:

SUBMITTED TO AND APPROVED BY:

- University of Maryland, Baltimore, Institutional Review Board
  - Submitted 3/19/20
  - Approved 6/24/20
- Wright State University Institutional Review Board Authorization Agreement
  - Submitted 12/17/20
  - Approved 4/5/21
- US Army Human Research Protection Office
  - Submitted 9/16/21
  - Approval pending

ENROLLMENT TABLE:

			Enter information regarding number of subjects					
HRPO Protocol Number	**Protocol PI Name**	**Organization (Site)**	**# Target**	**# Screened**	**# Recruited**	**# Enrolled**	**# Completed**	**Other**
E01511.2a	Tisherman/Puche	UMB						
This annual reporting period								
Cumulative								

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

Nothing to report.

How were the results disseminated to communities of interest?

Nothing to report.

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

We will continue to work with the Army HRPO to obtain approval to begin subject recruitment. The initial recruitment will be for pilot subjects to assist with finalizing the didactic curriculum, video scripts, and any final editing of the videos.

We will work with the Geneva Foundation and the staff at Womack to plan specific logistics for subject recruitment, as well as the logistics for the didactic curriculum, and initiate medic subject enrollment.

4. IMPACT:

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

Nothing to report.

What was the impact on other disciplines?

Nothing to report.

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

No changes to report.

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

There was a prolonged delay in obtaining approval from the Womack IRB. The approval has now been forwarded to the US Army HRPO. This delay has prevented us from moving forward with pilot testing or subject recruitment. Once we have HRPO approval, we will begin pilot testing.

Changes that had a significant impact on expenditures

COVID-19 restrictions on research and the delay in approvals initially limited our ability to develop the didactic curriculum and videos. As such, we did not initially deploy our full FTE staffing to ensure fiscal health of the project during the restriction period. As ongoing COVID-19 restrictions are reducing, and we anticipate regulatory approvals in the near future, we are deploying our FTE staffing.

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

Significant changes in use or care of human subjects

Nothing to report.

Significant changes in use or care of vertebrate animals

N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

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

Journal publications.

Nothing to report.

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

Nothing to report.

Other publications, conference papers and presentations.

Nothing to report.

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

Nothing to report.

- **Technologies or techniques**

Nothing to report.

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

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project

Name	Project Role	Researcher Identifier	Nearest Person Month Worked	Contribution to Project
Samuel A. Tisherman, MD	Co-PI	0000-0003-3810-3729	1	Project oversight and management, directs and mentors staff
Adam Puche, PhD	Co-PI	eracommons 'apuche"	1	Project oversight and management, directs and mentors staff
Kristy Fuller, MS	Research Lead Specialist		3	Coordinates project and manages data collection, development of project materials and data collection and analysis
Lorreen Agandi, MS	Research Assistant		3	Assists with participant scheduling and data analysis

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

Dr. Tisherman:

- Grant number W81XWH-17-2-0011 (Co-PI; 5% effort), "Emergency Refreshing of Combat Surgical Skills" has been closed.
- Grant number PR191560 (Co-I, 2% effort), "Cooling to Help Injured Lungs (CHILL) Phase IIB Randomized Control Trial of Therapeutic Hypothermia in Patients with ARDS" has been funded.

Dr. Puche:

- Grant W81XWH-17-2-0011 (Co-PI; 5% effort), "Emergency Refreshing of Combat Surgical Skills" has been closed.

What other organizations were involved as partners?

Organization Name: Wright State University
Location of Organization: Dayton, OH
Partner's contribution to the project: Will analyze medic cognition and reasoning during the procedures
Key personnel: Valerie Shalin, PhD

Organization Name: Womack Army Medical Center
Location of Organization: Fort Bragg, NC
Partner's contribution to the project: Will recruit subjects for the project and assist with logistics for the didactic curriculum and the procedures (which will be performed at the Maryland State Anatomy Board.
Key personnel: COL Tyler Harris, MD

8. SPECIAL REPORTING REQUIREMENTS

QUAD CHARTS:

9. APPENDICES: