

AWARD NUMBER: CDMRPL-16-0-DM167045

TITLE: VALIDATION OF SELECT PROCEDURES, CONSULTATION, AND HANDOVERS IN A SIMULATED EN ROUTE CARE ENVIRONMENT

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REPORT DATE: July 2018

TYPE OF REPORT: Annual Report

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

DISTRIBUTION STATEMENT: Approved for Public Release;
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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 July 2018			2. REPORT TYPE Annual		3. DATES COVERED 01 July 2017 to 30 June 2018	
4. TITLE AND SUBTITLE VALIDATION OF SELECT PROCEDURES, CONSULTATION, AND HANDOVERS IN A SIMULATED EN ROUTE CARE ENVIRONMENT					5a. CONTRACT NUMBER	
					5b. GRANT NUMBER CDMRPL-16-0-DM167045	
					5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Joseph Lopreiato, MD; Mark Bowyer, MD, Craig Goolsby, MD; Alan Alan Liu, PhD, Stacy Shackelford, MD E-Mail: Joe.Lopreiato@simcen.usuhs.edu					5d. PROJECT NUMBER	
					5e. TASK NUMBER	
					5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Uniformed Services University 4301 Jones Bridge Rd. Bethesda MD 20814					8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012					10. SPONSOR/MONITOR'S ACRONYM(S)	
					11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited						
13. SUPPLEMENTARY NOTES						
14. ABSTRACT This multi project study aimed to demonstrate what constitutes expert performance in an en route care environment for the skills cricothyroidotomy, fasciotomy, axillary artery exposure, and REBOA (Aims 1-2); what the is learning curve and durability of cricothyroidotomy and fasciotomy skill sets for non-surgical novices (EMTs, medical students, nurses) to be able to perform at expert levels (Aim 3); and establish protocol for tele mentoring and handover criteria in en route care scenarios (Aim 4-5). Aims 1-3 for this study are in progress. Major findings of this aim include establishment of expert performance criteria for a cricothyroidotomy in an en route care environment is a mean time for performance of 2 consecutive, successful cricothyroidotomies is approximately 40 seconds (SD=5 sec.) and meeting at least 9 of 10 criteria on the developed skill checklist which is currently being used as the proposed Trauma Readiness Index (TRI) in novice studies of Aim 3. Comparative analysis for "expert" and "novice" performance of select procedures will occur following competition of all projects within Aims 1-3.						
15. SUBJECT TERMS en route care, cricothyroidotomy, lower extremity fasciotomy, axillary artery, REBOA, telementoring, patient handoff curriculum, surgery, trauma, education,						
16. SECURITY CLASSIFICATION OF:				17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE	USAMRMC			
Unclassified	Unclassified	Unclassified	Unclassified		10	19b. TELEPHONE NUMBER (include area code)

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1. INTRODUCTION:

This multifaceted research program includes 5 distinct, yet related projects. Projects 1, 2 and 3 aim to determine the level of expert performance for select lifesaving procedures: cricothyroidotomy, lower extremity fasciotomy, axillary artery exposure / control, and resuscitative endovascular balloon occlusion of the aorta (REBOA) in an en route care environment. These projects will explore whether medics, physician extenders, non-surgical physicians and surgeons can perform these procedures at the same level. The aim of project 4 will be to determine whether nurses, physicians and enlisted personnel can be directly mentored, remotely mentored and/or trained using “just in time” training in some of these procedures. Project 5 will implement and test a standardized patient handoff curriculum in an en route environment and measure effectiveness. Projects 1-3 are now underway with testing subjects with experience in these procedures to determine the expert level. Projects 4 and 5 will begin once projects 1-3 are nearing completion.

2. KEYWORDS:

en route care, cricothyroidotomy, lower extremity fasciotomy, axillary artery, REBOA, telementoring, patient handoff curriculum, surgery, trauma, education, training.

3. ACCOMPLISHMENTS:

What were the major Goals of this project?

SPECIFIC AIMS (PROJECT) 1-3: VALIDATE THE FEASIBILITY DURING EN ROUTE CARE FOR SELECT INTERVENTIONS AND TREATMENT.

- Major Task 1: Develop/modify simulation procedures for an En Route care model for select interventions and treatment
 - Subtask 1: Develop En Route cricothyroidotomy simulation
 - Subtask 2: Develop En Route fasciotomy simulation
 - Subtask 3: Develop En Route Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) simulation
- Major Task 2: Test simulations to determine feasibility of performance En Route
 - Subtask 1: Test simulations from Major Task 1 against SIM Center for effectiveness, feasibility and realism; repeat after any modifications
 - Subtask 2: Measure feasibility based on skill sets (e.g. physicians, EMTs, nurses)

What was accomplished under these goals?

- Subtasks 1 and 2, under Major Task 1, have been completed. Subtask 3 is delayed until the near completion of project 1 and 2 (cricothyroidotomy and fasciotomy learning curve).
- Major Task 2 is on-going until completion of Projects 1-3.
 - All “expert” subjects for cricothyroidotomy and fasciotomy projects have completed participation in study. From expert population data, we generated performance criteria (trauma readiness index, TRI) for novice studies, defined below:
 - Cricothyroidotomy (cric): Ideal performance time is an average of 40 seconds (SD=5 seconds). Subjects must meet at least 9 items on TRI with 2 critical items in an en route care environment (simulated helicopter) to be considered to perform at “expert” level en route.
 - TRI developed via blinded video review of expert performances in en route care environment. Scores were then analyzed for interrater reliability to validate the cricothyroidotomy TRI checklist with a Pearson’s r test ($\alpha=0.05$). The interrater scores were found to have a high correlation ($r=0.86$), thus establishing the checklist for use with novice cric projects.
 - Fasciotomy: Approximate time to perform is 8 minutes with a standard deviation of 1.7 minutes. Fasciotomy TRI is currently being developed.
 - Recruitment and testing of novices for cricothyroidotomy projects (learning curve and durability) are in progress. Fifteen out of 40 of learning curve subjects enrolled and completed participation. Some learning curve subjects will be included in the durability portion of study.

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

This study has recruited and trained Medical Candidates from the Uniformed Services University to help administer/lead military trauma-based surgical curriculums. Students are also be afforded the opportunity to gain research skill sets and develop own research questions within defined protocol.

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?

Within the next reporting period we plan to accomplish the remainder of Major Task 2, excluding the REBOA project which is anticipated to begin approximately 1 year from now. Preparations for Projects 4 (Validate Tele-mentoring) methods for select procedures during en route care to more definitely care) are underway goals hoping to be accomplished within the next reporting period define below:

- Major Task 1: Develop effective teleconsultation network between sites 1 and 2
 - Subtask 1: Install teleconsultation equipment/supplies
 - Subtask 2: Establish teleconsultation SOP and model for En Route scenarios - including simulation/testing
 - Subtask 3: Test teleconsultation SOP and model for utility and feasibility
 - Subtask 4:Modify SOP/model for effectiveness

4. IMPACT:

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

- From expert population data, we generated standard performance criteria (trauma readiness index, TRI) for novice studies, defined below:
 - Cricothyroidotomy (cric): Ideal performance time is an average of 40 seconds (SD=5 seconds). Subjects must a meet at least 9 items on TRI with 2 critical items in an en route care environment (simulated helicopter) to be considered to perform at “expert” level en route.

- TRI developed via blinded video review of expert performances in en route care environment. Scores were then analyzed for interrater reliability to validate the cricothyroidotomy TRI checklist with a Pearson's r test ($\alpha=0.05$). The interrater scores were found to have a high correlation ($r=0.86$), thus establishing the checklist for use with novice cric projects.
 - Fasciotomy: Approximate time to perform is 8 minutes with a standard deviation of 1.7 minutes. Fasciotomy TRI is currently being developed.
 - Timing of cricothyroidotomy procedure in consistent previous research literature. On-going goals will determine skill sets of non-surgical medical providers in the combat military trauma setting for select procedures.

What was the impact on other disciplines?

None to report.

What was the impact on technology transfer?

None to report.

What was the impact on society beyond science and technology?

None to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for changes

Instead of randomizing “expert” subjects to static and dynamic conditions. “Experts” were asked only to perform in the dynamic (en route care simulation) scenario twice, to demonstrate 2 consecutive performances of successful cricothyroidotomy. All novices are receiving mentored practice in the static condition and being tested on skill sets in dynamic condition based on criteria established from expert studies.

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

Protocol was approved at the institution, Uniformed Services University, on 4 April 2017. The previous research associate for projects ended employment end of July 2017. Due to lapse in staffing, project stalled until replacement employee was hired and trained to continue project. Further delays

were caused by Wide Area Virtual Environment (WAVE) was closed to usage due to maintenance and repairs for an unspecified amount of time. Study team created an alternate en route care testing environment to meet the requirements originally intended in study proposals.

Changes that has significant impact on expenditures

None to report.

Significant changes in use of human Subjects, vertebrae animals, biohazards, and/or select agents.

Significant Changes in use or care of human subjects

Does not apply.

Significant changes in use or care of vertebrate animals.

Does not apply.

Significant changes in use of biohazards and/or select agents

Does not apply.

6. PRODUCTS:

None to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATION:

What individuals have worked on this project?

- No change: Primary investigator, Dr. Joseph Lopreiato
- No change: Co-Investigator, Dr. Mark Bowyer
- No change: Co-Investigator, Dr. Craig Goolsby
- Change: Research Associate, Kristina Pugh
 - No longer employed. Did not contribute to project during this reporting period.
- Change: Research Assistant, Rachael Dampman
 - Replacement of Kristina Pugh
 - Contribution 8/14/17 - present

What other organizations were involved as partners?

No other organizations are involved as partners

8. SPECIAL REPORTING REQUIREMENTS:

(SEE PAGE 10)

9. APPENDICES:

No appendices to attach

Validation of Select Procedures, Consultation, and Handovers in a Simulated En Route Care Environment

DM167045

PI: Joseph Lopreiato MD, MPH

Org: Uniformed Services University Award Amount: \$3.5 million



Study/Product Aims

- What constitutes Expert Performance for the skill Cricothyroidotomy (CRIC), Fasciotomy, REBOA and axillary artery exposure? Can Medics, ED Docs and Surgeons perform at same level?
- Compare the performance of en route care medics in performing specific procedures in one of three situations – 1) alone without mentorship, 2) with onsite mentorship from an advanced care provider and 3) with remote mentorship from an advance care provider.
- Determine the effect of standardized handoff training on patient handoff performance during simulated en route care using the I-PASS military handoff tool.



Using the advanced virtual environment theater at USU, we can re-create many enroute care environments for testing.

Timeline and Cost

Approach

Activities	CY	16	17	18	19
IRB approval and Expert testing		█		█	
Testing of novices in enroute care contexts				█	█
Testing of telementoring technologies				█	█
Handover tool testing and evaluation					█
Estimated Budget (\$K)		\$750K	\$750K	\$750K	\$750K

Updated: April 2018

Goals/Milestones

CY16 Goal – IRB approval and expert testing

- Determine expert level in four procedures

CY17 Goals – Novice Testing

- Test novices and compare to expert performance during enroute care environments

CY18 Goal – Telementoring

- Test and evaluate telemedicine technologies to augment the operator performing the four skills

CY19 Goal – handovers

- Test whether a handover protocol for enroute care reduces medical errors.

Comments/Challenges/Issues/Concerns

- Awaiting USU HPRO approval to begin research

Budget Expenditure to Date

Projected Expenditure: \$75,000 for a research assistant

Actual Expenditure: \$75,000