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TITLE: Validation of select procedures, consultation and handovers in a simulated En route care environment

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14. ABSTRACT This multi project study aimed to demonstrate what constitutes expert performance in an en route care environment for the skills cricothyroidotomy, fasciotomy, lateral canthotomy and cantholysis, 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. Additionally, project 5, the study in Patient Handovers Major accomplishments in this reporting period include: <ul style="list-style-type: none"> • Project 1: Ensuring subject return for the Cricothyroidotomy Durability study • The learning curve for all novices: <ul style="list-style-type: none"> • Number of practice attempts to reach expert level \bar{x}= 7.9, SD=2.74 • Time (seconds) per practice iteration \bar{x}=35.75, SD=5.31 • Number of attempts in En Route Care environment \bar{x}=2.40, SD=.63 • 67% of novices were able to perform at expert level in the first 2 consecutive attempts, all novices were able to perform at expert level within 4 attempts. A statistical analysis evaluating our secondary aims in the Cric-Learning curve study comparing medics and medical students is underway. No other major findings at this time.						
15. SUBJECT TERMS en route care, cricothyroidotomy, lower extremity fasciotomy, axillary artery, REBOA, telementoring, patient handoff curriculum, surgery, trauma, education, training.						
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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, lateral canthotomy and cantholysis, 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 1-5 are now underway with testing subjects with experience in these procedures to determine the expert level.

2. KEYWORDS:

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

3. ACCOMPLISHMENTS:

What were the major Goals of this project?

- Specific Aims (Projects) 1-3: Validate the feasibility during en route care for select interventions and treatment.
 - Major Task 1: (Project 1) Develop/modify/test simulation procedures for an En Route care model for Cricothyroidotomy Learning Curve and Durability
 - Subtask 1: Develop En Route cricothyroidotomy simulation
 - Subtask 2: Test simulations from Subtask 1 for effectiveness, feasibility and realism; repeat after any modifications
 - Subtask 3: Measure feasibility based on skill sets (e.g. physicians, EMTs, medical students, nurses)
 - Subtask 4: Repeat test simulations at 6 months, 1 year, and 2 year intervals after initial training; measure for skill decay.
 - Subtask 5: Analyze data, draw conclusions and make recommendations for future improvements on Learning curve and Durability projects

- Major Task 2: (Project 2) Develop/modify/test simulation procedures for an En Route care model for Fasciotomy Learning
 - Subtask 1: Develop En Route Fasciotomy simulation
 - Subtask 2: Test simulations from Subtask 1 for effectiveness, feasibility and realism; repeat after any modifications
 - Subtask 3: Measure feasibility based on skill sets (e.g. learner groups)
 - Subtask 4: Analyze data, draw conclusions and make recommendations for future improvements
- Major Task 3a: (Project 3) Develop/modify/test simulation procedures for an En Route care model for Lateral Canthotomy
 - Subtask 1: Develop En Route Lateral Canthotomy protocols and simulation regarding change to procedure
 - Subtask 2: Submit/obtain for Regulatory approval (IRB)

What was accomplished under these goals?

- Major Task 1: Cricothyroidotomy Learning Curve and Durability Studies
 - A Total of 85/89 subjects were eligible for the Durability study. They were randomized to return at either 6 months post training, 12 months, or 24 months. Each group has a 3 month window to return.
 - Subjects that were scheduled for a 6 month performance redo were impacted by COVID19.. To mitigate this, we will try to bring them in within the next time period (12 or 24 months) in order to keep consistent retention of participants.
 - Blinded review of the 6 months performances are currently being graded by pre-trained (to expert level) reviewers. Results of follow up are currently being analyzed.
 - 12/30 subjects in 1 year cohort have completed participation. 9 subjects were not able to return due to being out of the area within their return window. The project is expected to get at least 7 more subjects to finish participation in the cohort.
 - Final n=89.
 - Subtask 4 in progress. All subjects were randomized to return for durability study at months, 12 months, and 24 months. Durability study in progress, no results to report quite yet.
 - 6 month follow up complete
 - 12 month follow ups are ongoing
 - 24 month follow ups are ongoing

- Subtask 5 in progress for learning curve.
 - CRIC-Learning Curve Results and Key Findings
 - A statistical analysis for significance in difference between Medics/corpsmen and Medical students is currently being conducted to prepare for reporting results in publications.
- Major Task 2: Fasciotomy Learning Curve
 - IRB amendment completed on 25-OCT-2019 approving new study forms, changes to protocol and procedures, and the addition of Ft. Bragg during multisite conversion. No changes to protocol affect the rights of participants in the study.
 - A new measurement tool to measure fasciotomy performance was created with expert consensus when interrater reliability of minimum .80 could not be achieved on previous version. This involved a restructuring of the checklist, minor changes to content to provide clarity, and the development of grading rules. New expert performances to set baseline performance standards will be conducted at the end of JAN-2020.
 - Pilot complete and curriculum finalized. Enrollment at USU will was ongoing, however, due to delays with COVID19, we were unable to continue bringing in participants for the training, as this was against University guidance due to issues with capacity and safety.
 - A new Research Assistant was added, on-boarded, and trained in order to run participants at our secondary site. Data collection is currently ongoing.
 - Data collection with students is underway, and nearly complete – 16 students and enrolled and completed from USUHS, 36 additional students (at USUHS) were enrolled to participate in the study throughout the month of March, but all student data collection was temporarily suspended due to COVID19 Pandemic in MAR 2020 – and JPC-6 was notified.
 - The secondary site for this study, Ft. Bragg North Carolina, has recruited ~40 Army Physician Assistants. IRB Amendment summary- Amendment submitting 12 AUG 2019, waiting for approval. Changes included administrative updates, minor protocol language changes, updates to forms, and multisite conversion. No changes to protocol affect the rights of participants in the study.
 - A total of 60 subjects were enrolled in this study. 16 of the 60 are USUHS medical students, the remaining 44 participants are physician assistants at Ft. Bragg, North Carolina (our Secondary Site), under the supervision of Co-PI Dr. Tyler Harris.
 - 50 of the enrolled participant subjects have taken the training, assessments, and initial testing for the fasciotomy curriculum.

- Final n for this project = 60.
- Project 3a: Develop/modify/test simulation procedures for an En Route care model for Lateral Canthotomy and Cantholysis, Subtasks 1 – 3
 - Subtasks 1 and 2: IRB Submission was submitted and approved in MARCH 2020.
 - Addition of Co-PI: Dr. Eva Chou, Oculoplastic Surgeon was added to our protocol officially in APRIL 2020, in order to help with the study due to Dr. James Zimmerman’s TDY relocation to Naval Medical Center San Diego. He continues to help with the study remotely.
 - Initiation of curating the curriculum/official training to be provided to participants by our Co-PIs/SMEs.
- Project 3b: Develop/modify/rest simulation procedures for an En Route care model for Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) Simulation
 - New Co-Investigator identified, officially added to protocol
 - REBOA Protocol modifications were completed with Co-PI Carmen Spalding – the eIRB approved the modifications submitted in MAY 2020, including a study posttest, participant forms, and clarifications to the REBOA protocol for the En Route Care study.
 - Due to COVID19 we had issues procuring cadavers at the University, due to the added complexity of cadaveric specimen testing to ensure no COVID contamination. We are currently working to figure out the next steps of this study, at NMCS D.
- Project 4: Validate Tele-mentoring/Teleconsultation methods for select procedures during En Route to more definitive care
 - No Progress
- Project 5: Test and Validate the modified MIST/SBAR systems to reduce communication errors in patient handovers during En Route Care
 - Subtask 1: Develop and implement Handover protocol, SOP, and model for En Route Care
 - Changes to protocol have been finalized and are ready to move forward
 - Subtask 2: Provide training to users and trainers on use of the Handover protocol, SOP and model for utility and feasibility.
 - Successfully ran a systems test/Pilot run on a virtual platform to test feasibility of the current curriculum/training. Additional feedback given from student participants, SMEs, and instructors will govern the next iteration of the training to be given in the early fall.

- Second iteration of the curriculum is currently underway
- Due to COVID19, we could not bring in participants to take the training in person, hence the virtual pilot. We are planning to bring in TCCC Instructors to take the training first, before then becoming our instructors for the training with study novices in the fall.

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 – results upcoming.

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

- Within the next reporting period we plan to accomplish:
 - Complete Major Task 1, Subtask 4: : Repeat test simulations at 6 months, 1 year, and 2 year intervals after initial training; measure for skill decay.
 - Complete Major Task 2, subtasks 3 and 4: Continue collecting data for the Fasciotomy training, as well as analyzing data, draw conclusions and make recommendations for future improvements.
 - Complete Major Task 3a, Subtasks 3-5: Test simulations from Subtask 1 for effectiveness, feasibility and realism, Test simulations from Subtask 1 for effectiveness, feasibility and realism; repeat after any modifications, as well as data analysis, drawing conclusions, making future recommendations.
 - Begin Major Task 3b
 - Begin Aim 4 (Project 4): validate tele-mentoring (teleconsultation) methods for select procedures during en route to more definitive care. And progress on the following aims:

- 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
- Major Task 2: Validate utility of teleconsultation v treatment as usual in En Route care
 - Subtask 1: Measure teleconsultation model/SOP and job aid impact on En Route care scenarios (e.g. speed, knowledge, delays) SPRING- WINTER 2020
 - Subtask 2: Analyze data, draw conclusions and make recommendations for future improvements

4. IMPACT:

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

This study examined the minimum training needs to get novices to perform at expert level in an en route care environment after first establishing the criteria for expert performance in cricothyroidotomy. The completion of on-going goals will determine the decay period for cricothyroidotomy in novices, as well as training criteria in procedures fasciotomy, and lateral canthotomy and cantholysis.

A major issue with this reporting period is due to COVID19 – much of our project planning was delayed/pushed further in our performance period due to limitations given the University’s guidance, and the health and safety of our staff, students and participants.

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

A major issue with this reporting period is due to COVID19 – much of our project planning was delayed/pushed further in our performance period due to limitations given the University’s guidance, and the health and safety of our staff, students and participants. In order to mitigate this, the following changes were made:

- Major Task 2/Project 2: En Route Care Model for Fasciotomy
 - Ft. Bragg was still able to onboard and test participants for this study, therefore, we decided to move forward with them as our primary site of enrollment and testing. We were unable to bring in cohorts to USU due to safety precautions put in place.
 - There were limitations to this study for most of Q3 due to lack of supplies- COVID19 directly impacted the manufacturers of the Fasciotomy legs we use for this study, therefore our timeline was put on pause because we were unable to obtain the refurbished legs needed
- Major Task 3b/ Project 3: En Route Care REBOA
 - Due to COVID19 we had issues procuring cadavers at the University, due to the added complexity of cadaveric specimen testing to ensure no COVID contamination. We are currently working to figure out the next steps of this study, at NMCS D.
 - We plan on using NMCS D as a primary site for this study, and have contingency plans to run extra sessions at USUHS – we are working closely with the USUHS Anatomical Lab to ensure this.

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

Major delays were caused by COVID19, because we were unable to bring in individuals to test/retest on a few of our projects. Additionally, extensive work with SMEs and Co-PIs Dr. James Zimmerman/Dr. Eva Chou have brought us closer to a nearly finalized curriculum underway with plans to begin recruitment in fall 2020.

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
- Change: Co-Investigator added, Dr. Eva Chou to aid with LCC Project
- Change: Co-Investigator added, Dr. Carmen Spalding for the REBOA Project
- Change: Research Coordinator, Rachael Dampman left in February 2020.
- Change: Addition of Research Coordinator, Theepica Jeyarajah, M.S.

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 lateral canthotomy/cantholysis? 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 ECCCHO method/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	17	18	19	20
IRB approval and Expert testing		[Green bar]			[Purple bar]
Testing of novices in enroute care cricothyroidotomy			[Green bar]		[Purple bar]
Testing of novices in FAS, LCC, and REBOA				[Green bar]	[Purple bar]
Handovers				[Green bar]	[Purple bar]
Estimated Budget (\$K)		\$750K	\$750K	\$750K	\$750K

Updated: JUN 2020

Goals/Milestones

CY17 Goal – IRB approval and expert testing

- ☑ Determine expert level in four procedures

CY18 - 20 Goals – Novice Testing

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

CY20 Goal – REBOA

- ☑ Prepare IRB modification, onboard new PI, conduct prep.

CY20 Goal – Fasciotomy

- ☑ Recruit and complete subject testing for the Fasciotomy study protocol to teach expert performance to novices.

CY20 Goal – Handovers

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

Comments/Challenges/Issues/Concerns

- ☑ **Current subject testing delayed due to COVID-19 .**

Budget Expenditure to Date

Burn rate furnished upon request