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

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CONTRACTING ORGANIZATION: Uniformed Services University
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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.

Major findings in this reporting period include establishing the novice learning curve to achieve expert performance criteria for a surgical cricothyroidotomy in an en route care environment. Expert performance was previously defined as 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.

The learning curve for all novices:

- 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.

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Standard Form 298 (Rev. 8-98)

Table of Contents

Page

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 1-3 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, 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:
    - Subtasks 2 -3 complete.
    - All recruitment has been completed for the CRIC learning curve and Durability study.
        - A total of 93 subjects were enrolled in this study; 4 subjects were excluded as recruitment strategy changed to only include medics/corpsmen/air force technicians and medical students and exclude nurses. All 4 subjects included were nurse, which we would not have been able to recruit high enough numbers to do a sub analysis of learner type. These subjects have all been informed by the study team of the investigators decision. No rights were violated and subjects still received potential benefit of training. USU IRB was informed and approved decision to change recruitment targets.
        - Final n=89.
    - Subtask 4 in progress. All subjects were randomized to return for durability study at 6 months, 12 months, and 24 months. Durbability study in progress, no results to report.
        - 6 month fol1ow up will be complete in NOV 2019.
        - 12 month follow up beginning AUG 2019
    - Subtask 5 in progress for learning curve.

- CRIC-Learning Curve Results and Key Findings
  - Total 89 novice subjects enrolled in the CRIC Learning curve study.
    - Demographics of corpsmen and navy reservists (n=35)
      - 26 males, 9 females
      - Average age of 29.7 years (SD=9.24)
      - 20 (57%) currently have a high school degree, 15 (43%) 4-year degree or greater
      - All corpsmen (100%) had previous training in CRIC but no experience performing it in real life
    - Demographics medical students (n=54)
      - 33 males, 21 females
      - Average age of 25.2 years (SD= 3.63)
      - All subjects had a 4-year degree (93%) or greater (7%)
      - Only 18 (33%) medical students have reported receiving previous training in CRIC, the remaining 36 (66%) reported having no previous training. None has experience performing CRIC in real-life.
  - Number of practice attempts to reach expert level all novices: $\bar{x}$ = 7.9, SD=2.74
    - Medics/Corpsmen: $\bar{x}$ =7.14, SD=3.27
    - Medical Students: $\bar{x}$ =8.39, SD=2.19
  - Time (seconds) per practice iteration for all novices: $\bar{x}$ =35.75, SD=5.31
    - Medics/Corpsmen: $\bar{x}$ =37.50, SD=4.79
    - Medical Students: $\bar{x}$ =34.61, SD=5.33
  - Number of attempts in En Route Care environment for all novices $\bar{x}$ =2.40, SD=.63
    - Medics/Corpsmen: $\bar{x}$ =2.57, SD=.69
    - Medical Students: $\bar{x}$ =2.30, SD=.57
  - 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.
    - 19 of 35 (54%) of medics/corpsmen met expert criteria on the first 2 consecutive attempts in the en route care environment.

        - 41 of 54 (76%) met expert criteria on the first 2 consecutive attempts in the en route care environment
        - Only 7 (8%) participants of all novices needed 4 attempts in the en route care environment to meet expert criteria.
    - 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:
    - Subtask 1:
        - Complete
    - Subtask 2: Test simulations from Subtask 1 for effectiveness, feasibility and realism; repeat after any modifications
        - Currently piloting curriculum and scenarios and making adjustments as needed.
- Major Task 3a:
    - Subtask 1:
        - Protocol creation has been completed, IRB submission pending Data collection plan and data analysis plan which is currently underway with stat consults.
        - Verbal discussions with IRB to expedite approval process.

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:
    - Complete Major Task 2
    - Complete Major Task 3a, subtasks 1 – 3
    - Begin Major Task 3a, subtask 4 -5
    - 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.

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

CRIC-LC (learning curve) and Durability study changed eligibility criteria from medics/corpsmen/technicians, nurses, physician extenders, and medical students to only medics/corpsmen/technicians and medical students. Recruitment for CRIC-LC increased from 40 to 90 in order to reuse subjects for durability study. Fasciotomy LC (n=100) and Project 4 (n-80) will also include the same subjects to save expenditures on materials and time to train.

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

Major delays caused by lack of fasciotomy curriculum designed specifically for novice learners. Extensive work with SMEs and the Co-PI Mark Bowyer. Piloting of nearly finalized curriculum underway with plans to begin recruitment in fall 2019.

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, Dr. Craig Goolsby replaced by Dr. Tyler Harris for project 2 and project 4.
- No change: Research Coordinator, Rachael Dampman
- Change: addition of Sim educator, Christen Phillips

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 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				
Testing of novices in enroute care contexts				
Testing of telementoring technologies				
Handover tool testing and evaluation				
Estimated Budget ($K)	**$750K**	**$750K**	**$750K**	**$750K**

Updated: Jul 2019

Goals/Milestones

CY17 Goal – IRB approval and expert testing

☑ Determine expert level in four procedures

CY18 - 19 Goals – Novice Testing

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

CY19 Goal – Telementoring

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

CY20 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

EIRB Protocol Template (Version 1.11)

1.0 General Information

***Please enter the full title of your study:**

Validation of select procedures, consultation and handovers in a simulated en route care environment

***Please enter the Protocol Number you would like to use to reference the protocol:**

En Route Care
* This field allows you to enter an abbreviated version of the Protocol Title to quickly identify this protocol.

Is this a multi-site study (i.e. Each site has their own Principal Investigator)?

No

Does this protocol involve the use of animals?

○ Yes ◉ No

2.0 Add Site(s)

2.1 List sites associated with this study:

Primary Dept?	Department Name
◉	**P and R** - Uniformed Services University of the Health Sciences (USUHS)

3.0 Assign project personnel access to the project

3.1 *Please add a Principal Investigator for the study:

Joseph O Lopreiato MD, MPH, MD

Select if applicable

☐ Student ☑ Site Chair
☐ Resident ☐ Fellow

3.2 If applicable, please select the Research Staff personnel:

A) Additional Investigators

Bowyer, Mark
Co-Investigator
Goolsby, Craig A, MD, MEd

Co-Investigator
Liu, Alan V
Co-Investigator

B) Research Support Staff

Dampman, Rachael G, BS
Research Coordinator
Reyes, Julissa Isabel
Team Member
Voelkel, Maria L
Research Coordinator

3.3 *Please add a Protocol Contact:

Dampman, Rachael G, BS
Lopreiato, Joseph O MD, MPH, MD
Reyes, Julissa Isabel

The Protocol Contact(s) will receive all important system notifications along with the Principal Investigator. (i.e. The protocol contact(s) are typically either the Protocol Coordinator or the Principal Investigator themselves).

3.4 If applicable, please select the Designated Site Approval(s):

Add the name of the individual authorized to approve and sign off on this protocol from your Site (e.g. the Site Chair).

4.0 Project Information

4.1 Is this a research study?

(•) Yes ( ) No

4.2 What type of research is this?

- [ ] Biomedical Research
- [ ] Clinical trial (FDA regulated)
- [ ] Behavioral Research
- [x] Educational Research
- [ ] Psychosocial Research
- [ ] Oral History
- [ ] Other

4.4 Is this human subjects research (Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Activities covered by 32 CFR 219.101(a) (including exempt research involving human subjects) and DoDI 3216.02)?

(•) Yes ( ) No

4.5 Do you believe this human subjects research is exempt from IRB review?

(•) Yes ( ) No

4.6 Identify the category(ies) into which you believe your study falls:

Exempt Categories

Category	Description
[x] 1	Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
[x] 2	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
[ ] 3	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter
[ ] 4	Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
[ ] 5	Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services

	under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs
☐ 6	Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii)if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

5.0 Personnel Details

5.1 Will you have a Research Monitor for this study?

- ○ Yes
- ○ No
- ◉ N/A

Research Monitor Role:

If applicable, you may nominate an individual to serve as the Research Monitor:

No Users have been selected.

6.0 Data/Specimens

6.1 Does the study involve the use of existing data or specimens only (no interaction with human subjects)?

○ Yes ◉ No

7.0 Funding and Disclosures

7.1 Source of Funding:

Funding Source	Funding Type	Amount

: Congressionally Directed Medical Research Program (CDMRP)	: Research Development Testing and Evaluation (RDT&E) funds	3750000

Total amount of funding:

3750000

7.2 Do you or any other Investigator(s) have a disclosure of a personal interest or financial nature significant with sponsor(s), product(s), instrument(s) and/or company(ies) involved in this study?

○ Yes ◉ No

8.0 Study Locations

8.1 List any Research Team members without EIRB access that are not previously entered in the protocol:

Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Harris, Julia Role on Protocol: Student Research Assistant		Julia.Harris@usuhs.edu	Uniformed Services University of the Health Sciences (USUHS)
Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Jaffe, Edward Role on Protocol: Student Research Assistant		edward.jaffe@usuhs.edu	Uniformed Services University of the Health Sciences (USUHS)
Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
McMurray, Haana Role on Protocol: Student Research Assistant		haana.mcmurray@usuhs.edu	Uniformed Services University of the Health Sciences (USUHS)
Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:
Kraemer, Laura Role on Protocol: Student Research Assistant		laura.kraemer@usuhs.edu	Uniformed Services University of the Health Sciences (USUHS)
Name: (Last, First, M.I.)	Phone Number:	Email Address:	Associated Institution:

Phillips, Christen Role on Protocol: Research Staff Support/Sim Educator		Christen.Phillips.ctr@usuhs.edu	Uniformed Services University of the Health Sciences (USUHS)/ HJF
Name: (Last, First, M.I.) Capo-Dosal, Gerardo Role on Protocol: Student Research Assistant	Phone Number:	Email Address: gerardo.capo-dosal@usuhs.edu	Associated Institution: Uniformed Services University of the Health Sciences (USUHS)

8.2 Has another IRB reviewed this study?

○ Yes ◉ No

IRB Name	Review Date	Determination
No records have been added		

8.3 Is this a collaborative or multi-site study? (e.g., are there any other institutions involved?)

◉ Yes ○ No

8.4 Study Facilities and Locations:

Institution	Site Name	Site Role	FWA or DoD Assurance Number	Assurance Expiration Date	Is there an agreement?	IRB Reviewing for Site
Army	WAMC	Performance site				WAMC IRB

Other:

Other Institution Site	Site Role	FWA or DoD Assurance Number	FWA or DoD Expiration Date	Is there an agreement?	IRB Reviewing for Site
No records have been added					

8.5 Are there international sites?

Attach international approval documents, if applicable, when prompted. Note: Ensure local research context has been considered

○ Yes ◉ No

8.6 Is this an OCONUS (Outside Continental United States) study?

○ Yes ◉ No

Select the area of responsibility:

Have you obtained permission from that area of responsibility? (This is a requirement prior to study approval)

○ Yes ○ No

9.0 Study Details

9.1 Abstract/ Summary:

Summarize the proposed study in 500 words or less, to include the purpose, the subject population, the study's design type, and procedures

This study will provide a blueprint for setting the standards for determining skill specific "expert" readiness and proficiency; test the feasibility and potential benefits to casualty en route care using remote mentoring and decision support tools; and improve patient safety by implementing a joint patient handoff curriculum to standardize patient handoffs throughout the military trauma system.
Participants will be made up of multi-disciplinary providers such as surgeons, non-surgeon physicians, medics, and physician assistant novices (defined as never seen or performed the procedures) undergoing training for en route care.

Our approach utilizes mixed-methods comparison group study and randomized controlled trials to measure the performances of novices in select life-saving procedures to the performance of experts and effectiveness of new training techniques in comparison with the current techniques used at the USUHS Simulation Center and WOMACK, Ft. Bragg. As a result, this effort will focus on three major outcomes:

1. Defining expert performance levels in the skills of Cricothyroidotomy (CRIC), Fasciotomy, REBOA, and axillary artery exposure in a combat medical, en route care scenario. During the prototype phase, an expert group of experienced military medical professionals will be asked to perform CRIC, Fasciotomy and axillary artery exposure and REBOA in a static (well-lit room without distractions) environment on part-task trainers and tested in a dynamic environment (simulated en route care enviornment). Performances will be scored by blinded evaluators using currently available and validated metrics.
    - Multi-disciplinary providers such as surgeons, non-surgeon physicians, medics, physician assistants, and medical student novices (defined as never seen or performed the procedures) will undergo training with validated physical models followed by mentored practice in a static environment. All subjects will then be "tested" by asking them to perform these procedures in the dynamic environment while being scored using the currently validated and to be developed metrics.
2. Assessing the effectiveness of remote mentorship and decision support during en route care. Subjects will be randomized to "remote mentorship" and "Decision Support" groups. Study PIs will record the time to decision, time to perform procedures, deviations from protocols or standard practices, recognition/prevention of complications and effectiveness of patient handoff at end of event.
3. Assessing a military-specific handoff curriculum for en route care subjects will be randomized into two groups: control group with no standardized handoff instruction and intervention group with standardized handoff instruction. All subjects will have their handoff performance tested in a simulated en route care environment. Outcome measures will be the rate of errors, omissions and quality of the handoff between control and intervention groups using a validated checklist.

9.2 Key Words:

Provide up to 5 key words that identify the broad topic(s) of your study

en route care, simulation

9.3 Background and Significance:

Include a literature review that describes in detail the rationale for conducting the study. Include descriptions of any preliminary studies and findings that led to the development of the protocol. The

background section should clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. This section establishes the relevance of the study and explains the applicability of its findings

The care rendered to a casualty in the pre-hospital and en-route care settings is vitally important to ultimate survival. Most combat related deaths occur in the pre-hospital or en-route setting before the casualty reaches a military medical facility [1-4]. The en-route care doctrine requires the care for and movement of initially potentially unstable patients (from point of injury (POI) to higher level (role 1 to 3) or "stabilized" but not always stable patients from the role 1 or 2 to the role 3 or from the role 3 to role 4 facilities. These patients may have to be cared for in environments for variably long periods of time in which access to subspecialty or physician care is not available and they are at risk for rapid decompensation which must be identified and promptly acted upon to assure optimal outcomes. As such individuals from a variety of disciplines and levels of training must be able to perform invasive life and limb saving procedures that may well fall outside of traditional practice roles.

Combat first responders are currently trained to provide trauma care in the tactical environment using the principles of Tactical Combat Casualty Care (TCCC), and these principles and guidelines serve as the basis for pre-deployment training for operational medical and combat personnel. This project is designed to further evaluate within a simulated En-Route Environment for skills needed of all En Route Care Providers: 1. What defines expert performance; 2. What is the learning curve required to teach novices to perform at "expert" level; and 3. What is the durability of the skill over time and how often should it be refreshed/retaught to maintain currency.

Surgical Airway (Cricothyroidotomy)

Airway obstruction ranks third as a preventable cause of death on the battlefield following severe hemorrhage and tension pneumothorax [2]. Review of modern military conflicts suggests that airway compromise accounts for 1-2% of total combat fatalities [4-6]. In a study by Adams et al [7], from Operation Iraqi Freedom, 5.8% of 293 casualties needing advanced airways received a cricothyroidotomy (CRIC). Other data from Mabry [8] indicate that 18 of 982 battlefield casualties had airway compromise as the most likely primary cause of death. Of these 18 all had traumatic injuries to the face and neck and 9 had multiple injuries to major vascular structures with significant hemorrhage. Airway management is not only a top priority in initial and ongoing resuscitation of these casualties – it is quite literally the difference between life and death [9]. Airway control is one of the few procedures in pre-hospital emergency care that significantly affects outcome [10].

One of the vital skills that must be mastered along the entire continuum of care is the management of the airway and the ability to recognize the need for and to perform a surgical airway or Cricothyroidotomy in a rapid and competent fashion. TCCC guidelines recommend the aggressive use of surgical airway when maxillofacial trauma makes the use of non-invasive airway techniques inadequate to open the airway [11], and surgical CRIC is one of the essential skills taught to combat first responder. Unfortunately the current training of military providers for this skill and ultimate measures of successful training are far from standardized, and there are no evidence based standards for when this skill should be refreshed or retrained. CRIC has been used for many years by civilian first responders as well and published studies reveal that it can be performed successfully in 40-60 seconds when effective training frequency is combined with ideal airway simulation models [12]. Success rates for pre-hospital providers (paramedics and flight nurses) range from 88 to 100% with complication rates ranging from 4 to 27% comparing well to physicians in emergency departments. Hubble et al conducted an extensive meta-analysis of pre-hospital airway control techniques and in 18 studies with a pooled total of 485 patients the success rate reported for surgical CRIC was 90.5% [13].

Unsuccessful surgical CRIC in both the civilian and combat environment can be attributed to a number of factors to include lack of familiarity with the procedures, inadequate teaching of the underlying anatomy, limited hands-on training with human anatomical landmarks, inadequate human training simulation models, and a low refresher training frequency [14]. Elliott et al [15] state that one of the main reasons for CRIC failure is the lack of clinical experience, and therefore regular refresher training is required for skill maintenance. Walls [16] relates two major problems when performing an emergent CRIC that affect success rates: 1) the stress of the operator owing to the life-threatening nature of the situation; and 2) anatomical distortions caused by injury. The combat first responder may also find that correct identification of the landmarks needed to perform a successful CRIC can be exceedingly difficult in austere environments owing to limitations of sensory perception, poor lighting, lack of equipment, and added environmental stressors [9]. There is no literature that specifically addresses the impact of environments such as one is likely to encounter in the En route care continuum on the ability to competently preform this procedure, nor is there any evidence of as to how to best train such individuals to proficiency. A recent civilian study [24] showed that the time needed to perform a CRIC (needle) was significantly greater in a simulated OR setting than in a classroom with a higher failure rate, lending credence to the aforementioned statement that the environment may affect ones' ability to perform a vital skill and likely in a negative fashion.

How do military providers currently perform? In a recent review [5] of 11,492 patients in the Joint Trauma Tracking Registry (JTTR), 72 patients were found to have pre-hospital CRIC (PC). In this review PC was documented as successful in 68% of cases, unsuccessful in 21% and unknown in 6%. Medics performed 62% of the PCs at the point of injury and had a **failure rate of 33%.** The remainder were performed by physicians or physician assistants with a **failure rate of 15%.** A complication rate of 21% was reported. The failure rate in civilian literature reported in multiple reviews, is between 6 and 12% with a complication rate between 4 and 38% [10, 17-21]. It is clear that there is room for improvement in how we prepare military (and civilian) providers how to perform this vital life-saving procedure. Given that as currently prepared, military medics have a failure rate at least three to five times that reported in the civilian setting, it is important to critically evaluate current training paradigms, with an eye on the environment specific skill set needed, the number of repetitions needed to master the skill, and the durability and degradation of the skill (currency) once learned.

Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)

The leading cause of death in both in both civilian [1-3] and wartime [3-5] trauma is bleeding from vascular disruption. Broadly classified hemorrhage occurs from either compressible sites (controllable with either direct pressure or tourniquet) and non compressible (Not controllable with direct pressure or tourniquet) from the torso. Non Compressible Torso Hemorrhage (NCTH) is responsible for the majority of deaths following otherwise survivable (no lethal head or cardiac injury), accounting for up to 70% of mortality in civilian studies [6, 7, 42] and up to 80% in studies of combat injured patients[4,8,9]. Contemporary classifications of NCTH describe bleeding from one of four anatomic sites: Large axial vessels, Complex pelvic fractures, Solid organ injuries, and pulmonary parenchymal injuries [10].

Analysis of recent military casualties has shown that NCTH was the cause of death in 50% of patients judged to have sustained potentially survivable injuries [8]. Kelly and colleagues [4] reported that the leading cause of death in otherwise survivable injuries sustained in combat (during two time periods-2003-2004, and 2006) was hemorrhage, accounting for 87% and 83% of deaths during these respective period with airway problems, head injury, and sepsis constituting the remaining causes of death. Within the hemorrhage group, 50 % were due to NCTH and 33% to extremity hemorrhage (amenable to tourniquet application). This study also introduced the concept of "junctional vascular injury" which is hemorrhage from the proximal femoral or axillobrachial vessels not amenable to direct pressure or application of a tourniquet. Kelly et al found that 20% of deaths from hemorrhage occurred from injuries in these junctional zones [4]. Other reviews of potentially survivable injuries on the battlefield [11,12] have confirmed the high and early lethality of NCTH in those who could have otherwise survived their injuries.

The recent emphasis on pre-hospital management of compressible hemorrhage has resulted in significant decreases in mortality [7], but there has to date been no similar result in the setting of NCTH. This is an area that is amenable to increased emphasis in an attempt to further improve survival from potentially survivable injuries. Traditionally the management of NCTH has required the resources of the hospital setting ideally in the operating room by a surgeon. If we are to improve the survival from these wounds, we must look at moving the initial control of NCTH further forward in the en-route care environment and potentially expanding the role of non-surgeon providers. The management of NCTH from solid organs and pulmonary parenchymal bleeding is currently not practical or feasible in the pre-hospital setting. NCTH from complex pelvic injuries and from "junctional injuries" of the axillary or proximal femoral arteries are injuries that have the potential to be managed in the en-route care environment by a variety of providers not traditionally trained to manage these injuries.

One of the significant advances in the management of vascular injuries from combat has been the incorporation of endovascular capabilities [13-16]. When implemented early, selected catheter-based techniques have been shown to have decreased morbidity and mortality rates compared to open vascular procedures [17]. The recent experience with catheter based management of vascular injuries has sparked a growing and enthusiastic interest in the use of balloon occlusion of the aorta as a mechanism achieving initial control of NCTH.

The history of intra-aortic balloon occlusion (IABO) of the aorta for trauma dates back to the Korean conflict where it was used (unsuccessfully) in three moribund patients [18]. In the 1970s [19] and 1980s [20] series of resuscitative thoracotomy with cross clamping of the descending aorta in the setting of massive hemoperitoneum led to a widespread acceptance of this as the procedure of choice for patients with NCTH supplanting significant interest in the use IABO in trauma. Sporadic reports have appeared in the literature since that time describing the use of IABO for trauma [21], as well as for the treatment of massive post-partum hemorrhage [22], and gastrointestinal bleeding [23]. With the increasing use of endovascular techniques there has been a significant resurgence in the use of IABO as a potential tool to gain initial control of non-compressible hemorrhage. There is a significant interest in using balloon occlusion as an alternative to resuscitative thoracotomy and the contemporary term for this has become Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA) [24].

REBOA as an alternative to resuscitative thoracotomy has recently garnered significant interest by military authors in the setting of extrathoracic blunt or penetrating trauma [3, 24-26]. A recent small series described six successful cases of REBOA deployment in a variety of civilian clinical scenarios in Houston and Baltimore [27] has led to increased enthusiasm for learning and applying this technique in civilian centers [28]. Additionally, reports from other centers in North America [29, 30, 43], and Japan [31-33] have fueled the interest in the increasing use of this procedure. As with any new procedure the optimal training regimen, modality, and method of skill maintenance have yet to be determined [34]. To address this issue there have been two curricula developed to teach this skill. The Endovascular Skills for Trauma and Resuscitative Surgery (ESTARS) course, developed with input from the U.S. military in Ann Arbor, Michigan, is a two day course that seeks to provide fundamental endovascular training for trauma surgeons [35]. The ESTARS course includes the use of an endovascular simulator and a live animal model and has been shown to be an effective curriculum to teach basic endovascular skills [35]. An alternative one day course, the Basic Endovascular Skills for Trauma (BEST) course was developed in Baltimore (also with military surgeon input) and initially included training only on an endovascular simulator [36] but has more recently added a perfused cadaver model [37].

The U.S. Military has incorporated the potential use of REBOA as an alternative to resuscitative thoracotomy in the management of combat casualties with profound shock and post-traumatic cardiac arrest as codified in a June 2014 Joint Theatre Trauma System Clinical Practice Guideline (CPG) [38]. The current CPG as written is intended for REBOA to be performed only at surgically capable facilities, by surgeons with the "optimal management strategy best determined by the surgeon at the bedside" and dependent on the "casualty's physical location, mechanism and pattern of injury, and the experience level of the surgeon" [38]. The standards for training, credentialing, and competency for this procedure have yet to be determined [28]. While the majority of REBOA procedures done in the US have been performed by Vascular or Trauma/Acute care surgeons [27], in Japan this procedure is in the realm of emergency room physicians, who can become credentialed after performing REBOA three times during residency [33]. As the use of REBOA has gained increasing interest, there has been a discussion of the potential use of this technology in the pre-hospital environment by first responders [39] and proponents suggest that there may be a role for the selected use of such interventions in cases of long transit times. It is essential that prior to pushing this promising technology farther forward that a critical assessment of who should be doing it, how they should be trained, how competency will be assessed, and how often these skills will need to be refreshed in order to maintain currency.

Given the potential for long transit times or periods of time during which a surgeon is not available in the en-route care environment, there may be a role for teaching non-surgical (as well as non-vascular trained surgical) members of military en-route care teams to perform REBOA or to expose and control the named arteries at junctional areas, specifically the axillary artery below the clavicle and the femoral artery below the inguinal ligament. It will be extremely important to determine the feasibility of providing these interventions in the Joint En Route Care environment and to define the skill set required to perform these procedures, the ideal curriculum, the standards required to meet proficiency, the durability of the skill once learned, and the level of provider that can expected to competently perform them.

This project will look specifically at the feasibility of training members of the En-route care team to perform cut-down on the axillary artery below the clavicle to control junctional bleeding and the performance of the REBOA procedure. As REBOA is a relatively new procedure there is a significant paucity of information as to what constitutes successful training. It is anticipated that this study will help determine standards for training and assessing proficiency with this procedure as well. We have had significant experience with teaching the exposure of the axillary artery below the clavicle as the PI for this project is the originator of the Advanced Surgical Skills Exposures in Trauma (ASSET) having conducted the course more than 100 times in the past 5 years, and is also currently involved in an ongoing validation of the course to include the durability of the skills as well as comparing whether a physical model (simulator) is adequate to teach this skill as compared to a cadaver model. The prototype simulator developed as part of this ongoing validation study is a high fidelity physical model of the right upper chest and upper arm that allows for practice and testing of the exposure of the axillary artery below the clavicle, as seen in the figures below:

The ASSET course has become the de-facto Cadaver pre-deployment course for U.S. military surgeons and is taught as part of the Emergency War Surgery course. Our research team has had significant experience with creating and validating performance metrics for several of the skills that are taught in the ASSET course to include exposure of the axillary artery below the clavicle [40, 41]. In this effort we have developed a validated "trauma readiness index" (TRI) which assesses a trainees performance versus that of an idealized expert for the exposures of the axillary, brachial, and femoral arteries, as well as fasciotomy of the lower extremity [41]. Validated metrics (checklist for cognitive and technical skills) have also been developed for several of the skills taught in the ASSET course to include the exposure of the Axillary Artery (included in the supplementary materials). Additionally we have compared the use of prototype high fidelity physical models to the cadaver model (see figures above) to teach these procedures and have found them to be comparable (unpublished data) to the cadaver. The availability of a physical model with comparable ability to teach/assess axillary artery exposure enables conducting this training outside of a cadaver lab and as such can be used in the simulated en-route environment.

Compartment Syndrome and En route Fasciotomy

Compartment syndrome (CS) is a limb-threatening and potentially life-threatening condition. Long bone fractures and vascular injuries are the most frequent antecedent events. Burns, crush injury, bleeding in enclosed spaces, external compression of the limb, and blast injury have all been implicated. The extremity wounds caused by improvised explosive devices in the current conflicts in Iraq and Afghanistan are at very high risk for the development of CS. Current knowledge unequivocally reflects that if you fail to identify and treat compartment syndrome properly, you will have a patient with tissue necrosis, permanent functional impairment, and potentially renal failure and death. The leg (calf) is the area that is most commonly affected, followed by the forearm and the thigh. The duration of time that increased pressures from compartment can be tolerated before irreversible damage occurs is reported to be six hours but is probably less in the multiply injured patient with likely hypotension

The definitive treatment of compartment syndrome is **early and aggressive fasciotomy.** It is imperative that surgeons caring for trauma and combat casualties understand the anatomy of the extremity compartments and the technique of fasciotomy for each. In one large civilian series reported by Feliciano et al, 75% of amputations of the lower extremity were related to a delay in performing, or performing an incomplete fasciotomy. In a recent series of combat wounded patients admitted to Landstuhl Regional Medical Center in Germany (Ritenour et al), 15.7% had a fasciotomy performed either in theatre or at Landstuhl. In the Ritenour study 17 % of patients who had Fasciotomy performed in theatre required a revision of that Fasciotomy in Landstuhl. This translated into a muscle excision rate of 35% and a mortality rate of 20% in patients who required revision of their fasciotomy which was much higher than the 9% muscle resection and 6% mortality rates in those who did not. Likewise patients who underwent fasciotomy after evacuation (delayed) had much higher rates of muscle excision (25% vs 11%), amputation (31% vs 15%), and mortality (19% vs 5%).

Currently the US theatre of operations enjoys "air superiority" and casualties are usually transported to advanced surgical care in a timely fashion. There are circumstances currently in which timely transport to a higher eschelon of care may not be possible and there is no guarantee of air superiority in future conflicts resulting in the certainty of casualties who will need life and limb saving procedures performed farther forward in the en route care environment by providers who may be asked to do procedures not within their traditional skill set. Given the consequences in terms of limb salvage and potential loss of life for untreated or delayed treatment of compartment syndrome, a critical evaluation of the feasibility of performing fasciotomy in the early en-route care environment by both traditional and non-traditional providers is required to ensure that our wounded heroes receive the best care possible.

In spite of efforts to train surgeons on this essential skill prior to deployment through the Extremity War Surgery course, there has been an unacceptably high rate of delayed fasciotomy, or improperly performed Fasciotomy (as detailed in the Ritenour paper) requiring revision at the next level of care leading to higher rates of muscle excision, amputation and death. This suggested that the current curriculum and model for teaching this essential skill is inadequate. We have previously shown that the typical surgeon who is being deployed has not been adequately trained to perform the type of fasciotomy that is required in the management of these complex combat wounds. Additionally we have shown (presented but unpublished data) that successful implementation of the physical model based multi-media curriculum that teaches the anatomy, landmarks, indications, and proper technique of this procedure impacts on what is truly a preventable loss of muscle, limb and life.

Given this backdrop, Dr. Bowyer has spent considerable time to develop multimedia curricula to teach this procedure and has published widely on the proper performance of the optimal technique. A video that demonstrates the proper technique for performing a two incision four compartment lower extremity fasciotomy on a cadaver model was developed by Dr. Bowyer and widely disseminated by the Joint Theatre Trauma Consultants to military surgeons in theatre during deployment as "just-in-time" training and has been reported anecdotally (unpublished results) to have improved outcomes. Concurrently, Dr. Bowyer began working in close collaboration with Operative Experiences, Inc (OEI) to develop a realistic model of the lower extremity upon which Fasciotomy skills could be taught, practiced and evaluated. Through an Army funded small business initiative grant, OEI, under the direction of founder and trauma surgeon Robert F. Buckman, MD has developed a highly realistic physical model of the lower extremity which can be used to teach two incision four compartment Fasciotomy.

Using the physical model as the basis, and in consultation with military and civilian SMEs, Dr. Bowyer developed a comprehensive curriculum to teach this skill. This curriculum is a multimedia product that is based on video of the anatomy, landmarks and surgical technique of lower extremity fasciotomy as demonstrated and performed on the physical model, human cadaver, and actual operative footage. The physical model is a component of the complete curriculum and provides a platform for practice and evaluation of this vital wartime readiness skill. The standardized nature of the model also allows for an improved ability to assess adequacy of the skills at both baseline and after completion of the curriculum. A procedural checklist (See supplementary materials) was developed via a consensus opinion of both military and civilian subject matter experts based on task deconstruction and agreement on the key correct (and incorrect) steps for the procedure and has been used to evaluate trainees in initial and

ongoing validation of the model and it's curriculum. The curriculum that was developed has also been included into the Advanced Surgical Skills for Exposure in Trauma (ASSET) course, which is the current de-facto pre-deployment training platform for deploying military surgeons. Our research team has an ongoing study to validate the ASSET course looking specifically at lower extremity fasciotomy as one of the included procedures (Shackelford et al). As part of this study we have further matured and validated a check list metric (see supplemental materials for fasciotomy checklist) that enable assignment of a "Trauma Readiness Index" (TRI) which scores trainees compared to an idealized "expert" performance. Likewise we have compared the use of the physical model with a fresh cadaver model for training this procedure and have found it to be comparable (presented but unpublished data). Additionally we are looking at the durability of the skill once learned in an ongoing study of surgeons who have been trained with the physical model based curriculum

En Route Remote Mentorship

The deployed Military Health System over the last 15 years has demonstrated the lifesaving impact of a robust and well developed theater trauma system.[1] Military operations in Anti-Access/Area Denial military environments, as well as medical support to deployed special operations forces, are expected to require a greater dependence on field medics to provide direct care to casualties for significantly longer time periods than were routinely experienced during OEF/OIF. One of the conclusions of the recently published USAF/SG3 "Medical Operations in Denied Environments Operational Concepts" paper is the need to incorporate advanced technologies to support casualty care during prolonged field care and en route care.[2]

Multiple studies based on data from the Joint Trauma Registry have demonstrated a survival benefit in casualties evacuated by medical personnel with advanced training[3-6]. The sentinel Eastridge studies on preventable deaths in the early years of OEF/OIF showed that 51% of Died of Wounds and 24 % of Killed in Action deaths were potentially survivable if required interventions had been performed earlier.[4-5] Mabr y's study on the positive impact of using Emergency Medical Technician (EMT))-Paramedic DUSTOFF flight medics on casualty survival resulted in the US Army accepting EMT-Paramedic as the standard for all DUSTOFF flight medics.[6-7] Similarly, comparisons of the survival outcomes of critically injured combatants based on evacuation capability (EMT-Paramedic or British Physician led teams) showed statistically significant survival when physician led teams were managing casualties during evacuation from the point of injury.[3-5, 8] Positioning of DOD Role 2 resuscitative surgical facilities within the "golden hour" flight radius of DUSTOFF in Afghanistan was able to demonstrate significant improvement in Case Fatality Rate.[9] Finally, a Joint Trauma System relook at the "TACEVAC Golden Hour" study that incorporated Killed in Action as well as Wounded in Action showed that being able to reduce the time it takes to provide the required lifesaving intervention is the most critical factor in reducing preventable combat deaths. Combined, the body of literature from OIF/OEF supports the hypothesis that projection of advanced trauma care closer to the point of wounding reduced casualty mortality. In future conflicts with a less robust medical support system, it is critical that the deployed military health system explore alternative ways to project advanced medical care and procedures forward.[2]

One alternative concept being explored is the use of remote and autonomous management of casualties by advanced care providers in support of field medical personnel[10-11.] A critical hurtle to this concept has been a lack of scientific evaluation demonstrating the impact and limitations of remote mentorship during staging and en route care. Experience in the civilian medical system with virtual intensive care units implies that the physician's physical presence may not be required to provide meaningful improvement in the casualty's management during staging and en route care. It may turn out that compared to working within the hectic en route care platform; the advanced provider in a quiet remote environment may be better able to effectively guide the assessment and treatment of the casualty. This project will explore and identify the extent to which advanced care providers can assess casualty injuries, guide interventions and manage post procedure critical care in a realistic military en route care environment.

Military-Specific Handoff Curriculum

The military trauma system is characterized by multiple handoffs of critically injured casualties,[1-2] at times involving up to 10 handoffs in the care of a single casualty. Each handoff event carries the potential for loss of critical information that may contribute to delays in treatment of critical injuries or medical errors.[3-5] The problem of communication errors was recognized as a factor in a majority of patient safety events and in 2007, the Joint Commission established standardization of patient handoffs as a National Patient Safety Goal to improve communication to prevent omissions.[6-7] Previous investigations of Emergency Medical Services (EMS) handoffs found that physicians accurately recalled only 36% of the paramedic verbal report relating to pre-hospital care of trauma patients[8] and that only 73% of key prehospital data points were documented by receiving staff.[9] Structured handoff training has been shown to reduce medical errors in civilian hospital settings involving transfers within the hospital, such as from the ED to admitting team and from the OR to the ICU.[4,6,10-11] While much of the

published handoff literature has focused on within-unit handoffs (which occur during change shift), unique challenges specific to between-unit handoffs (which occur when patients are moved between different institutions) have been described.[12] Such challenges include communication between different specialties, lack of established relationships between sending and receiving individuals, and lack of awareness of each units' current status. Such between-unit challenges are typical of military en route care handoffs. Additionally, previous civilian research has focused mostly on the handoff between the sending and receiving facility, with little focus on the en route care portion of the handoff.

A previous systematic review of handoffs in hospitals and in other high risk environments such as space (NASA) and Submarines (US Navy) have yielded a framework that can help in reducing errors by preventing or recovering from an adverse event. Cheung,[13] et al have described a framework for effective handoffs as involving 1) Data transfer; 2) Illness scripts: concise summaries of patient problems and concerns; 3) Social interaction: a shared mental model of what is wrong with the patient and what to do if the patient status worsens; and 4) Resilience: cross checking data, assumptions and the plan for the patient.[13] O'Brien et al[14] conducted a qualitative study of handoffs during hospital shift changes and noted the importance of questioning as a necessary adjunct to the data transfer that occurred in handoffs. She concluded that handoffs are highly transactional events between giver and receiver and that time for questions should be encouraged both to detect errors and correct faulty plans.

To date, only limited efforts have occurred to improve patient handoffs within the military trauma system. An SBAR (Situation-Background-Assessment-Recommendation/Request) checklist was implemented in the USAF Aeromedical Evacuation system in 2012 with a goal of reducing information loss and improving patient safety.[15] However, SBAR and another mnemonic, DeMIST (Details, Mechanism, Injuries, Signs/Symptoms and Observations, Treatment given) have not been shown to yield clinically relevant outcomes in several studies, primarily because they involved only data transfer without regard to the social interaction (questioning) and resilience (check back).[16-19]

The I-PASS mnemonic and associated training curriculum[20-21] was developed after an exhaustive literature review of handoffs by Starmer et al that incorporates the framework of a handoff as a complex transactional experience. It incorporates all of the framework elements: data transfer and an illness script, an action plan, a contingency plan, time for questions and synthesis/repeat back by receiver. Specifically I-PASS represents five crucial steps or types of information that must be conveyed during a successful patient handoff: 1) Illness Severity 2) Patient Summary 3) Action List 4) Situation Awareness and Contingency Planning 5) Synthesize by Receiver. The multi-institutional I-PASS study demonstrated[10] that medical errors decreased by 23% and preventable adverse events decreased by 30% suggesting that the I-PASS methodology has the potential to greatly improve patient handoffs in a hospital setting. Cheung[13] and colleagues have suggested measures of handoff outcomes that will be useful in this project. These include 1) Knowing the narrative and illness state; 2) Knowing significant events; 3) The number of questions asked by the receiver; 4) Understanding of the action plan; 5) Understanding of the contingency plan; and acknowledgment of understanding and transfer of control. The SBAR mnemonic (Situation, Background, Assessment, Recommendation) has also been widely implemented as a handoff tool,[22] although originally identified as a situation report rather than a handoff structure within the TeamSTEPPS teamwork training structure.[23]

Our review suggests that the key components contributing to improved communication during handoffs include minimizing distractions, organized structure, and active listening by receiver with questioning and repeat-back. These components, integrated into a curriculum that includes evaluated practice sessions and memory aids, are representative of the I-PASS handoff system. This system represents much more than a specific mnemonic and have significantly reduced medical errors in civilian hospital settings. We plan to implement a similar handoff system within the military en route care setting.

9.4 Objectives/Specific Aims/Research Questions:

Describe the purpose and objective(s) of the study, specific aims, and/or research questions/hypotheses

Our approach utilizes mixed-methods comparison group study and randomized controlled trials to measure the performances of novices in select life-saving procedures to the performance of experts and effectiveness of new training techniques in comparison with the current techniques used at the USUHS Simulation Center and Wilford Hall. As a result, this effort will focus on three major objectives:

1. Defining expert performance levels in the skills of Cricothyroidotomy (CRIC), Fasciotomy, REBOA, and axillary artery exposure in a simulated en route care environment. For each procedure, our aims are to determine:

a. What defines expert performance of these skill? Can Medics, Emergency Physicians, Physician Extenders, and Surgeons perform at the same level?
b. Do Experts perform as expected in simulated combat en-route environment?
c. Can medics, physician extenders, non-surgical physicians, and surgeons perform at same level?
d. What is the learning Curve for Novices? How many repetitions does it take to be able to perform at expert level (able to perform at expert level) on two consecutive attempts?

2. Assessing the effectiveness of real-time remote mentorship and decision support during en route care. Specifically, can emerging technologies in medical decision support and medical communication expand en route care medical personnel capability to assess and treat complex casualties in areas where advanced care providers are not permitted or not available?
    a. What is the impact on quality of assessment, treatment and post procedure care?
3. Assessing a military-specific, standardized, handoff curriculum for en route care and the impact on patient outcomes. To do this, the study aims to:
    a. Develop and implement a standardized patient handoff training curriculum to be used during simulated en route care casualty exercise involving handoffs of patients between providers.
    b. Validate a handoff evaluation tool (the I-PASS military handoff tool) for assessing patient handoffs from MEDEVAC to military treatment facility (MTF) and MTF to an en route care team in a simulated combat environment.
    c. Determine the effect of standardized handoff training on patient handoff performance during simulated en route care using the I-PASS military handoff tool.

9.5 Study Design:

Describe study design in one to two sentences (e.g., prospective, use of existing records/data /specimens, observational, cross-sectional, interventional, randomized, placebo-controlled, cohort, etc.). Specify the phase – Phase I, II, III, or IV – for FDA-regulated investigational drug research

This study will provide a blueprint for setting the standards for determining skill specific "expert" readiness and proficiency; test the feasibility and potential benefits to casualty en route care using remote mentoring and decision support tools; and improve patient safety by implementing a joint patient handoff curriculum to standardize patient handoffs throughout the military trauma system. Our approach utilizes mixed-methods comparison group study and randomized controlled trials to measure the performances of novices in select life-saving procedures to the performance of experts and effectiveness of new training techniques in comparison with the current techniques used at the USUHS Simulation Center and Wilford Hall.

9.6 Target Population:

Describe the population to whom the study findings will be generalized

The target population will be multi-disciplinary providers of all skill levels (surgeons, non-surgeon physicians, medics/corpsmen/technicians, and physician assistant novices) within the military health system.

9.7 Benefit to the DoD:

State how this study will impact or be of benefit to the Department of Defense

The military trauma system involves en route care and multiple handoffs of critically injured patients within a short time span. Critical skills such as proper management of emergency airways, extremity injuries and non-compressible torso hemorrhage are tantamount to the survival of combat wounded casualties. There has been very little research on how to best train military health care providers to perform as advertised in the multitude of environments they may encounter in the modern era of en route care. We believe that the results of this study will provide a blueprint for setting the standards for determining skill specific "expert" readiness and proficiency. Additionally this study will help determine the skill specific learning curve, the training needed to attain proficiency in an en-route environment and the appropriate time interval for retraining. These tools will help to produce ready proficient military health care providers who can perform as advertised optimizing outcomes along the along the continuum of en-route care.

10.0 Study Procedures and Data management

10.1 Study Procedures:

Describe step-by-step how the study will be conducted from beginning to end

En Route Study Procedures

CRIC/Fasciotomy/Axillary Artery Exposure and REBOA Simulations

Expert Performance Studies

Experts will be evaluated for performance on static and dynamic simulators for CRIC, fasciotomy, and axillary artery exposure in order to develop evaluation criteria for the novices that will be undergoing training.

- The "expert" performance level for surgical CRIC will be determined by experienced providers – Surgeons, Emergency Room Physicians, Anesthetic Providers, and Combat Medics. Eligible participants are medical professionals in the military healthcare system. Ten experts will be recruited for each of these groups for a sample size of 10-12.
- The "expert" performance levels for two incision four compartment fasciotomy of the lower extremity, and axillary artery below the clavicle have been previously determined via our ongoing validation study of the ASSET course. To specifically address the dynamic en route environment, ten "experts" in each procedure will be asked to participate. These experts will be made up of experienced military surgeons with relevant deployment experience who have performed the technique and have attended an ASSET course.
- Each Individual will perform the procedure in the static (well lit room without distractions) environment and in the dynamic environment (simulated En-route environment).
- The performances will be video-captured via head mounted cameras that capture the POV. These performances will be scored by blinded evaluators who will be pre-trained to acceptable inter-rater reliability using currently available metrics we are using in another study to compare training on a simulator vs. an anesthetized pig.
- The "expert" performances will be utilized in conjunction with subject matter expertise to craft a refined evaluation instrument/metric tool and assign a "Trauma Readiness Index (TRI)" that will based upon an idealized expert performance.
- The results of this part of the study will be used to set the "expert" criterion for performance in a simulated en-route environment and used to evaluate achievement of proficiency by subsequent learner groups.

REBOA Expertise Establishment

- The "expert" performance level for REBOA will be determined via consultation with military and civilian SME/champions of this procedure. As this is a new procedure, little work has been done to determine what constitutes proficiency with this procedure and this project will offer an opportunity to develop robust assessment metrics, leveraging on our prior experience for developing and validating metrics for portions of the ASSET course.
- A separately funded study will soon be underway to compare training on a perfused cadaver model with that on a high fidelity physical model that is currently under development by Operative Experiences Inc. This model will be further validated and refined based on this ongoing work and when deemed ready will be introduced into this en-route care project.
- Twenty experienced providers, ten surgeons and ten emergency department physicians with deployment experience, who might be expected to be in a position to perform REBOA in a future deployment will be included for training to establish the "expert" criteria.
- These 20 subjects will be offered the BEST course as part of participation in the study and after completion of the best course will be asked to perform REBOA on the physical model in both a static environment a dynamic simulated combat en-route care environment (simulated helicopter with motion platform, noise and multiple distractors).
- The performances will be scored real time by a trained evaluator and will also be video-captured via head mounted cameras that capture the POV. These performances will be scored by blinded evaluators who will been pre-trained to acceptable inter-rater reliability using the metrics to be developed as part of this effort.

Novice Learning Curve Study (Cricothyroidotomy, Fasciotomy/Axillary Artery Exposure)

- Novices will be recruited from different learner groups to include Medical Students, Intern or Resident, Medics/Corpsmen/Technicians, and Nurses, PAs. Actual novice groups recruited are dependent on procedure being taught and likelihood of being asked to perform during combat or clinical emergencies. Eligible participants are medical professionals in the military healthcare system.
- Multiple learner groups were chosen in order to examine if the curriculum needs to be altered due to provider group or if a single comprehensive curriculum can meet the needs of all.
- Learners will undergo mentored practice in each procedure and measured for practice itteration and time to perform.
- Subjects will then be tested in an en route care environment.
- Each of the attempts will be scored real time using the aforementioned evaluation tool and video captured using head mounted point of view camera. These videos will be rendered anonymous and be de-identified and will be reviewed in a blinded fashion by evaluators pre-trained to acceptable inter-rater reliability.

Procedure Specific procedures
Cric:

- Novices recruited will include medical students, medics, corpsmen, and/or technicians.
- The novices will undergo training for the procedure using a standardized curriculum (narratedPowerPoint) that was developed via expert consensus as a significant expansion /refinement of the existing TCCC curriculum and is currently being validated as part of the expert portion of the study.
- Subjects will also complete a brief pre-test to review procedure knowledge before training on simulated models.
- Subjects will then undergo mentored practice using one of several possible commercially available part-task trainers (actual one to be determined). This practice will take place in a static environment.
- Students will then be "tested" by asking them to perform the procedure on the manikin which will be animated (bleeding and moving) while in the dynamic environment while being scored and timed by a real time evaluator for at least two attempts to measure if they can complete the procedure successfully meeting average "expert" performance.

Fasciotomy/Axillary Artery Exposure:

- Learner groups for Fasciotomy will include medical students, Physician assistants, and Special Forces medics/corpsman/technicians.
- Each subject will receive an standardized curriculum to review procedure prior to full participation in study.
- Subjects will complete a pre-and post-test based on knowledge followed by undergo mentored practice for the procedure.
- Once subjects have attained minimum criteria for performing procedure at expert level, subject will be tested in an en route care scenario.

Durability of Knowledge Study (Cricothroidotomy):

- In this portion of the study, 75 novices (medical students and medics/corpsmen/technicians) will be trained to proficiency as described and determined by the learning curve results described above using the standardized curriculum, mentored practice and performance to the standard on two consecutive trials.
- All subjects in the Durability of Knowledge study will perform the same procedures of the Learning Curve Study for Cricothyroidotomy. Subjects will then be assigned to return at 6 months (n=25), 1 year (n=25), or 2 years (n=25) to retest their skillset for cricothyroidotomy within a 3 month window of availability.

Remote Mentorship vs. No Mentorship Just-in-Time (JiT) decision support during En Route Care

This is a two-arm, randomized trial. This phase of the study will look to see if there is significant difference in assessment, decision to treat, and procedure performance among test subjects who receive real time remote mentoring and a control group that does not receive mentoring but low-tech decision support materials also known as Just-in-Time training. This structure will allow us to determine if mentoring impacts performance. This study will utilize the subjects and procedures used in the En Route learning curve portion of the FAS curriculum protocol to assess the impact of mentoring and monitoring on casualty en route care. The time to assess casualty injuries and to initiate required treatments will be

tracked as well as the number of deviations from Clinical Practice Guidelines and other indicators of standard of care. Post event surveys with both the remote provider and en route care medic will provide feedback as to what additional training might have improved performance during the event.

All test subjects for this protocol will be individuals that have completed participation in fasciotomy learning curve portion of this protocol. Therefore, all subjects will have received standardized training to perform fasciotomy. Test subjects will then wait approximately 6 to 9 months after concluding participation in FAS Learning curve (initial training) portion to enter into this phase of the study. This fixed delay is proposed to simulate a time between initial procedure training in garrison and application of a skill in the field. Subjects will be brought back for a second visit and randomized to "remote mentorship" and "no mentorship, JiT" groups to perform the previously trained procedures during simulated en route environments using mannequins and task trainers. The simulated en route environments will be MEDEVAC to MTF.

During en route care, subjects in the mentored group will be provided mentorship in a manner that most effectively delivers required care to the casualty as opposed to maximizing training for the volunteer. Mentors will be advanced practice mentors seated in a separate location from the subjects. Mentors will be provided with a computer with monitors that can display full motion video from the casualty care site, mirrored view of all electronic monitoring displayed to the test subject and two way audio communications via headset with the en route care provider (participants). During remote mentoring events, feeds from cameras (Go-Pro or similar device) will available to the remote mentor. Immediately prior to the initiation of the scenario, all subjects in the remote mentored group will have five minutes to communicate with mentors to confirm communication devices are working.

Mentors may make notes or use references during the study but must use material that would be appropriate to their respective settings (ie, computer based references at remote site or "pocket" books for on-site mentors). A display of the mentor's face/upper body will be available for the en-route care study participants. Noise can be a significant limitation to communicating in an en-route care environment, and hand gestures and facial expressions may facilitate improved communication between mentor and study participant.

Subjects in the control group will perform procedures and treat patients and receive no mentoring except a JiT decision support tool. All groups will be challenged with identical scenarios from the Learning Curve studies and perform fasciotomy with usage of the JiT decision support tool. Investigators will record the time to decision, time to perform procedures, deviations from protocols or standard practices, recognition /prevention of complications and effectiveness in each of the procedures defined above.

Following the procedure, participants will complete a questionnaire about their comfort and opinions of their experiences. This data will be collected utilizing standard Likert scales. Both mentors and subjects will be surveyed at completion of an event on an array of questions concerning qualitative impressions of the effectiveness of mentoring provided.

The primary outcome will be the proportion of successful procedures performed as measured by checklist criteria for that medical procedure. Secondary outcomes include time measurements to initiate and complete the procedure as well as participants' qualitative impressions about their comfort and experience.

We plan to use a chi square test to compare the proportion of remote mentored (test) to non-mentored participants/low tech (control) who successfully completed the procedure. Our sample size estimate is based on a 5% two-tailed significance level, with a power of 80% and an equal allocation ratio. We will require a minimum sample size of 40 participants for each of the two arms in this phase to show a difference in success of 87.5% (remote mentorship) vs. 60% (no mentorship, Jit).

The anticipated number of subjects in an estimated and is subject to a reasonable modiication as we gain experience and gather data.

I-PASS Curriculum

Experienced investigators from C-STARS Baltimore and USUHS/WRNMMC Bethesda have modified the I-PASS handoff observation tool for use during military combat casualty care scenarios based on the collaborative input of expert instructors and review of previously published handoff metrics. The handoff curriculum is currently being modified for military use by the PIs in this project and consists of a 20 minute video demonstrating idealized handoffs, a one hour practice exercise, and handoff "cards" to serve as memory aids to a structured handoff.

The quality and consistency of handoff training will be evaluated by an expert instructor from the I-PASS study group (a co-investigator on this study) who will travel to the training sites to conduct train-the-trainer sessions. These new instructors will then conduct the training for students at the two study sites (USUHS and DMRTI) as an instructor candidate under the observation of the expert instructor. The

handoff training will be integrated into the current training curriculum at each site, adding approximately 80 minutes of training to the overall trauma training curriculum.

Multi-trauma scenarios involving handoffs in a simulated combat environment

The Val G. Hemming Simulation Center of the Uniformed Services University, Bethesda, MD and the Defense Medical Readiness Training Institute, San Antonio, TX will collaborate to develop identical multi-trauma scenarios involving handoffs from MEDEVAC to MTF and from MTF to an en route care team (e.g. a Critical Care Air Transport team).

Scenarios developed from the learning curve portion of this protocol will be formatted for integration into the I-PASS tool using a standard case creation template to include patient demographics, mechanism of injury, medications given, allergies, treatments rendered and patient illness severity.

Test subjects will manage and handoff multi-casualty patients in simulated en route case scenarios developed in the learning curve portion of the study. The I-PASS military handoff tool as described in Aim 3 will be used to compare handoff outcomes between two groups: (1) A group of military providers (physicians, medics, or nurses) with no handoff training (control group); and (2) providers receiving form al handoff training with the I-PASS curriculum (intervention group).

The I-PASS military handoff evaluation tool incorporates the transactional framework described previously that was shown to reduce medical errors in a multi-institutional study. We will use this tool and the video/audio recordings of all handoffs in this study to measure these variables: presence or absence of I-PASS elements in the handoff, questioning frequency, prioritization of injuries, distractions, handoff errors (defined as clinically significant discrepancies between information in the verbal handoff and the case scenario script), handoff omissions (clinically significant findings and treatments in the case scenario script that were excluded from the verbal handoff), and suggestions for improvement.

10.2 Data Collection:

Describe all the data variables, information to be collected, the source of the data, how the data will be operationally measured, and approvals needed for use of information from DoD databases

No data will be collected from DoD databases.

Expert Performance Studies

The performances will be video-captured via head mounted cameras that capture the POV. These performances will be de-identified and scored by blinded evaluators who will be pre-trained to acceptable inter-rater reliability. Data regarding timing of performance in select procedures will be recorded in real-time and video for accuracy. Subjects complete a demographic form including age, gender, career status, and prior experience levels in select procedures; a task trainer usability form to determine best simulator to use, and post procedure form. Data collected will be analyzed descriptively as well as a Pearson's r to measure for interrater reliability of score performances and later compared to novice performances.

Novice Learning Curve

Each of the attempts will be scored real time using the aforementioned evaluation tool and video captured using head mounted point of view camera. These videos will be rendered anonymous and be de-identified. Data collected includes number of attempt itterations and timing of performance in select procedures; demographic form including age, gender, career status, prior experience levels in select procedures; brief pre knowledge test; and post procedure form. Data collected will undergo statistical analysis utilizing Wilcoxon matched-pairs signed rank test, Student T-test, and ANOVA testing as appropriate with α set at $p < 0.05$.

Durability of Knowledge

Each of the attempts will be scored real time using the aforementioned evaluation tool and video captured using head mounted point of view camera. These videos will be rendered anonymous and be de-identified. Data collected includes number of attempt itterations and timing of performance in select procedures; demographic form including age, gender, career status, prior experience levels in select procedures; brief pre knowledge test; and post procedure form. Data collected will undergo statistical analysis utilizing Wilcoxon matched-pairs signed rank test, Student T-test, and ANOVA testing as appropriate with α set at $p < 0.05$.

Remote Mentorship

Investigators will record the time to decision, time to perform procedures, deviations from protocols or standard practices, recognition/prevention of complications and effectiveness in each of the simulated procedures.

The primary outcome will be he proportion of successful procedures performed as measured by the checklist criteria for that medical procedure. Secondary outcomes include time measurements to initiate and complete the procedure, as well as the participants' qualitative impressions about their comfort and experience.

We plan to use a chi square test to compare the proportion of mentored and remote mentored (test) to non-mentored participants (control) who successfully completed the procedure. Our sample size estimate is based on a 5% two-tailed significance level, with a power of 80% and an equal allocation ratio. We will require a minimum sample size of 30 participants for each of the three arms in this phase to show a difference in success of 40% vs. 75%.

Both mentors and subjects will be surveyed at completion of event on an array of questions concerning qualitative impressions of the effectiveness of mentoring provided. Control group survey will provide subjective questions concerning at what points, if any, during the event they felt they would have benefited from input from a mentor.

Impact of Mentorship in Order to Perform Unfamiliar Procedures

Each attempted procedure will provide data on time to completion, successful completion and adherence to standards of practice. Both mentors (when participating) and subjects will be surveyed at completion of event on an array of subjective questions concerning the effectiveness of care provided and mentoring if provided.

The primary outcome will be the proportion of successful REBOA procedures performed by prior-trained participants (control) vs. the proportion of successful procedures performed by JiT mentored participants (test) as measured by objective criteria for REBOA success. Secondary outcomes include time it takes to initiate and complete the procedure, as well as qualitative feedback about the participants' experiences.

Our sample size estimate is based on a 5% two-tailed significant level, power of 80% and an allocation ratio of 1 to 1, treatment to controls. We will require a minimum sample size of 30 participants for each of the groups in this phase to show a difference in success of 40% vs. 75%.

Impact of Mentorship from Decision Support /Semi-Autonomous Technology

Investigators will record the time to decision, time to perform procedures, deviations from protocols or standard practices, time to recognition of physiologic abnormalities, appropriateness of interventions and effectiveness of patient handoff at end of event.
The primary outcome will be the proportion of successful management of complications between those subjects provided decision support vs. no decision support as measured by a checklist. Variables included in the checklist will include time to assess, initiate, complete, and manage complications in the casualty. Secondary outcomes include participants' feedback about their comfort and experiences with or without decision support.

Volunteers will be surveyed at completion of event on an array of subjective questions concerning the effectiveness of care provided and mentoring if provided.
We plan to use a two-sample z-test to compare the proportions. Our parameters will be a 5% two-tailed significant level, a power of 80% and an allocation ratio of 1 to 1, treatment to controls. We will require a minimum sample size of 30 participants for each of the groups in this phase to show a difference in success of 40% vs. 75%.

I-PASS Curriculum

The I-PASS military handoff evaluation tool incorporates the transactional framework described previously that was shown to reduce medical errors in a multi-institutional study. We will use this tool and the video/audio recordings of all handoffs in this study to measure these variables: presence or absence of I-PASS elements in the handoff, questioning frequency, prioritization of injuries, distractions, handoff errors (defined as clinically significant discrepancies between information in the verbal handoff and the case scenario script), handoff omissions (clinically significant findings and treatments in the case scenario script that were excluded from the verbal handoff), and suggestions for improvement.

10.3

At any point in the study, will you request, use, or access PII from the Military Health System (MHS)?

○ Yes ◉ No

10.4 Have you consulted with an MHS data expert to determine the data elements to be extracted or the information system(s) to access?

Consulting with a data expert often saves time later in the compliance process because the data expert can advise on the data available in the numerous MHS information systems, the quality of that data and the methods for encrypting and collapsing data. To schedule a consult with an MHS data expert, send an email to: (**dha.ncr.pcl.mbx.privacyboard@mail.mil**)

○ Yes, then complete the questions below according to the data consult

◉ No, then complete the questions below according to the best of your knowledge (NOTE: It is highly recommended that you work with an MHS data expert)

10.5 Indicate whether you plan to receive a data extract from the MHS or plan to access an information system directly to create a data set:

A data extract is when the MHS or a contractor provides the data set directly to the researcher. When receiving a data set through data extract, the researcher may indicate whether the data elements should be provided as is, encrypted or collapsed. In contrast to a data extract, access to an information system means that the researcher may directly access an MHS information system and create a data set for the research study

☐ Data Extract

☐ Access

10.6 Do you intend to use only de-identified data from the MHS in your research study?

There are different two methods for de-identifying data pursuant to HIPAA:
1) Safe Harbor Method: Removing all of the identifiers listed in Table 1 below, provided that the researcher does not have actual knowledge that the remaining data can be used alone or in combination with other information to identify the individual who is the subject of the information
2) Statistical Method: An expert, with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable, determines that the data is not individually identifiable

○ Yes ◉ No

10.7 If your research study requires access to an MHS information system, please indicate the system to obtain data:

If you do not know which system(s) contain the data elements you need, refer to the Guide for DoD Researchers on Using MHS Data or seek guidance from an MHS data expert:

PHI Systems:

MHS Information System	Requesting Data
No records have been added	

PII-Only Systems:

MHS Information System	Requesting Data
No records have been added	

De-Identified Data & Other Systems:

Information System	Requesting Data
Expense Assignment System	
List other system(s):	
List other system(s):	

10.8 Do you intend to merge or otherwise associate the requested data with data from any sources outside of the MHS, including other DoD systems that are not part of the MHS?

- ○ Yes, will merge data
- ◉ No, will not merge data

10.9 Indicate the categories of data that you will request from MHS systems or MHS health care providers about research participants or relatives, employers, or household members of the research participants.

Data Element(s)	MHS	Non-MHS Systems
1. Names	☐	☐
2. Postal address with only town, city, state and zip code	☐	☐
3. Postal address with all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of Census: 1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and 2) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000	☐	☐
4. Dates including all elements (except year) directly related to an individual, including birth date, admission date, discharge date, and date of death	☐	☐
5. Ages over 89 and all elements of dates (including year) indicative of such age, unless you will only request a single category of "age 90 or older"	☐	☐
6. Telephone numbers	☐	☐

7. Fax numbers	☐	☐
8. Electronic mail addresses	☐	☐
9. Social Security numbers (SSNs)	☐	☐
10. Medical record numbers	☐	☐
11. Health plan beneficiary numbers	☐	☐
12. Account numbers	☐	☐
13. Certificate/license numbers	☐	☐
14. Vehicle identifiers and serial numbers, including license plate numbers	☐	☐
15. Device identifiers and serial numbers	☐	☐
16. Web Universal Resource Locators (URLs)	☐	☐
17. Internet Protocol (IP) address numbers	☐	☐
18. Biometric identifiers, including finger and voice prints	☐	☐
19. Full-face photographic images and any comparable images	☐	☐
20. Any other unique identifying number, characteristic, or code (DEERs ID, EDIPN, Rank)	☐	☐

If you are obtaining SSNs, provide a justification as to why and explain why a substitute cannot be used

10.10 Is it possible that the data will become identifiable because of triangulation, a small cell size, or any unique data element(s)?

Triangulation means using different data elements that are not themselves identifiable but that when combined can be used to identify an individual. For example, triangulation would be using rank and race together to determine the identity of an individual with a particular health condition
Small cell size means that there are only a small number of eligible individuals that satisfy the category description. Guidance for acceptable cell size is available from the Centers for Medicare and Medicaid Services. For example, the rank category of four star generals with a particular diagnosis may be less than 30 so the rank category may need to be expanded to include lower ranks

A unique data element includes any unique features that are not explicitly enumerated in the categories of data in rows 1 – 19 of Table 1 above, but that could be used to identify an individual. Examples of unique data elements include: 1) a unique number, such as a medical record number or EDIPN; 2) a unique code, such as a diagnosis code or a bar code on an electronic health record; and 3) any unique characteristic, such as the rank of general or admiral, or a race or gender combined with another unique characteristic

- ○ Yes, there is a reasonable possibility the data will become identifiable
- ◉ No, there is no reasonable possibility the data will become identifiable

10.11 HIPAA Privacy Rule and Use of Protected Health Information in Research:

- ◉ N/A – will not use or disclose protected health information (PHI)
- ○ HIPAA Authorization will be obtained
- ○ Use of a limited data set where a data use agreement will be obtained
- ○ Waiver/alteration of HIPAA Authorization is being requested

10.12 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for this Study:

Include in this section the plan for acquiring data (both electronic and hard copy), access during the study, data/specimen storage and length of time stored, shipment/transmission, and the plan for storage and final disposition at the conclusion of the study. Describe any data agreements in place for accessing data within and/or outside of your institution (e.g., Data Sharing Agreement, Data Use Agreement, Business Agreements, etc.)

No personally identifying data or biological specimens will be collected for this study.

Video-Captured Performance Data

The performances will be video-captured via head mounted cameras that capture the POV. These videos will be rendered anonymous and be de-identified and will be reviewed in a blinded fashion by evaluators pre-trained to acceptable inter-rater reliability.

Recorded Data

Investigators will record the time to decision, time to perform procedures, deviations from protocols or standard practices, recognition/prevention of complications and effectiveness in each of the simulated procedures. Both mentors and subjects will be surveyed at completion of event on an array of questions concerning qualitative impressions of the effectiveness of mentoring provided.

All surveys and observable data will not contain personally identifying information for the subject.

I-PASS Curriculum

The I-PASS military handoff evaluation tool incorporates the transactional framework described previously that was shown to reduce medical errors in a multi-institutional study. We will use this tool and the video/audio recordings of all handoffs in this study to measure these variables: presence or absence of I-PASS elements in the handoff, questioning frequency, prioritization of injuries, distractions, handoff errors (defined as clinically significant discrepancies between information in the verbal handoff and the case scenario script), handoff omissions (clinically significant findings and treatments in the case scenario script that were excluded from the verbal handoff), and suggestions for improvement.

10.13 Managing Data (Data Management and/or Sharing Plan) and/or Human Biological Specimens for Future Research:

If the study involves collecting, storing, or banking human specimens, data, or documents (either by the Investigator or through an established repository) for FUTURE research, address. How the specimens /data will be used, where and how data/specimens will be stored (including shipping procedures, storage plan, etc.), whether and how consent will be obtained, procedures that will fulfill subjects' request as stated in the consent, whether subjects may withdraw their data/specimens from storage, whether and how subjects may be recontacted for future research and given the option to decline, whether there will be genetic testing on the specimens, who will have access to the data/specimens, and the linkage, the

length of time that data/specimens will be stored and conditions under which data/specimens will be destroyed

No personally identifying information or biologic specimens will be collected during this study.

Data collected via video or recorded data will be stored without personal identifiers throughout the duration of this study, and after the study.

11.0 Statistical/Data Analysis Plan

11.1 Statistical Considerations:

List the statistical methods to be used to address the primary and secondary objectives, specific aims, and/or research hypotheses. Explain how missing data and outliers will be handled in the analysis. The analysis plan should be consistent with the study objectives. Include any sub-group analyses (e.g., gender or age group). Specify statistical methods and variables for each analysis. Describe how confounding variables will be controlled in the data analysis

ANOVA Pairwise
Mann-Whitney U
Krusal Wallis
Fisher and chi-square tests
Student's t-tests
z-tests

11.2 Sample Size Estimation:

The number of experts recruited to establish "expert criterion" will be 10 for each of the skills and specialty types, plus 2-5 depending on if PI deems "not expert" based on performance. Novices of learning curve studies will require minimum of 40 subjects. May vary depending on follow-up study needs.

Project 1 Cricothyroidotomy Learning Curve: Approximately n=30 within each learner group with a total N of approximately 90 to meet follow-up needs of Durability Study (see below).

Project 1 Durability: The cricothyroidotomy durability study is seeking to have a total of 75 subjects, n=25 subjects in each follow-up group (60 mo, 1 yr, and 2 yr). In order to achieve that sample size by the conclusion of the project it is projected we will need to recruit approximately 90 subjects during Learning Curve to achieve a retention rate >80%. Subjects in CRIC learning curve will also be asked to follow-up in the Durability of knowledge portion.

Project 2 Fasciotomy: Approximate total N=100 with two learner groups approximately 50 in each. Subjects will asked to follow up for Project 4 (see below for necessary sample sizes).

Project 3, REBOA, will require an approximate sample size of n=20.

Project 4 (Mentoring) will require approximately 40 subjects per an arm (two arms, total N= 80). All subjects for this study will be carried over from the Fasciotomy (FAS) learning curve portion anticipating a maximum 20% attrition rate from the initial 100 subjects recruited/trained to retain at least 40 subjects in each arm.

Project 5, I-PASS curriculum will need n=60 subjects.

Total projected subjects recruited for study is approximately, N=270.

11.3 Data Analysis Plan:

For each of the projects where expert performance will be established, the number of trials necessary to increase the skill of a novice to that of an expert will be compared to a normal distribution and the log of the number of trials will also be compared. Whichever one fits the normal distribution better, will be used to calculate mean and standard distribution. At the mean + 2 standard deviations, we expect that 98% of the novices will be performing at expert levels. That information will be used for adding that number of trials to each of the study groups as indicated.

The number of experts recruited to establish "expert criterion" will be ten for each of the skills and specialty types. This number is based upon our previous work where we have shown that ten expert performances provided a sample size sufficient to account for individual variability and to establish a replicable mean expert mean and a standard distribution.

Inter-evaluator reliability for review of the video performances will be measured with Cronbach's α, the standard method of estimating the reliability of a psychometric test and assessing reliability of the rating scales we have and will develop to measure performance on the individual skills. We will set the reliability at an α of greater than 0.8 as the standard for this high stakes assessment of a trauma readiness vital skill. Non-parametric tests (Mann-Whitney U or Krusal Wallis) will be used to ensure that performance metric samples are from the same distribution and will be used to assess construct validity. Sub-group differences will be tested by analysis of the covariance. The longitudinal analysis technique will be used for evaluating and quantitating skills degradation. Logistical regression and mixed models will be used in sub group analyses with $p < 0.05$ considered a significant difference.

The sample size of 75 Novices chosen for the skills durability cricothroidotomy study is predicated on the assumption that the novices can be trained to expert proficiency (achieve within one SD of the Expert mean) with a target time (one of the several parameters that will be measured) of 45 seconds (+/- 5 seconds) and an anticipated degradation of skills of at least 10% giving a mean performance time of 49.5 seconds (+/- 5 seconds) on follow-up. Using a one way ANOVA Pairwise with two sided equality a power of .80 and a type one error rate of 5%, the sample size needed at each of the follow-up intervals of 6 months, 1 year, and 2 years expert is calculated at 20, with 25 chosen to account for possible attrition.

For each of the procedures novices will be enrolled to evaluate performance improvement before and after training to proficiency by testing the skills in a dynamic (simulated en-route environment). For continuous outcome measures, this sample size will provide 80% and 90% power to detect differences between estimated pre and post training Standard Deviations (SDs) based on a two-tailed t-test with 5% type I error. For binary outcomes, this sample size will provide at least 80% power to difference in proportions, between two groups, based on a chi-square test with 5% type I error.

Project 4:
The primary outcome will be the proportion of successful management of complications between those subjects provided decision support vs. no decision support as measured by a checklist. Variables included in the checklist will include time to assess, initiate, complete, and manage complications in the casualty. Secondary outcomes include participants' feedback about their comfort and experiences with or without decision support. We plan to use a two-sample z-test to compare the proportions. Our parameters will be a 5% two-tailed significant level, a power of 80% and an allocation ratio of 1 to 1, treatment to controls. We will require a minimum sample size of 40 participants for each of the groups in this phase to show a difference in success of 60% vs. 87.5%.

12.0 Participant Information

12.1 Subject Population:

Participants will be made up of multi-disciplinary providers such as experienced surgeons, non-surgeon physicians; Novice providers such as non-surgeon physicians; medics/corpsmen/technicians, medical students from Uniformed Services University School of Medicine; advance practice registered nursing students from the Graduate school of Nursing at Uniformed Services University; military nurses, and physician assistants.

12.2 Age Range:

- ☐ 0-17
- ☑ 18-24
- ☑ 25-34

- [x] 35-44
- [x] 45-54
- [x] 55-64
- [ ] 65-74
- [ ] 75+

12.3 Gender:

- [x] Male
- [x] Female

12.4 Special categories:

- [ ] Minors /Children - "You must also consider the requirements of 45 CFR 46 Subpart D and DoDI 3216.02, Enclosure 3, paragraph 7.d."
- [ ] Students
- [ ] Employees - Civilian - "You must also consider the requirements of DoDI 3216.02, paragraph 7.e."
- [ ] Employees - Contractor
- [x] Resident/trainee
- [ ] Cadets /Midshipmen - "You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraphs 7.e. and 12."
- [x] Active Duty Military Personnel - "You must also consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e."
- [ ] Wounded Warriors - "Depending on your intended subjects' status, you may also need to consider the requirements of DoDI 3216.02, Enclosure 3, paragraph 7.e."
- [ ] Economically Disadvantaged Persons - "You must also consider the requirements of 32 CFR 219.111 (b)."
- [ ] Educationally Disadvantaged Persons - "You must also consider the requirements of 32 CFR 219.111 (b)."
- [ ] Physically Challenged (Physical challenges include visual and/or auditory impairment)
- [ ] Persons with Impaired Decisional Capacity - "You must also consider the requirements of 10 USC 980."
- [ ] Prisoners - "You must also consider the requirements of 45 CFR 46 Subpart C and DoDI 3216.02, Enclosure 3, paragraphs 7.b. and 7.c."
- [ ] Pregnant Women, Fetuses, and Neonates
- [ ] Non-English Speakers
- [ ] International Research involving Foreign Nationals - Headquarters Review is necessary

12.5 Inclusion Criteria:

Order Number	Criteria
1	Individuals are eligible to participate as long as they are able to participate in en route care training. This population is over the age of 18, and includes both men and women.
1	All subjects must be over 18 years of age.
3	Experts in projects 1-2 defined as faculty level physicians within any surgical, emergency medicine, and anesthesia specialties who have performed select procedure at least one time in real life clinical situation.
3	Novices defined as above mentioned populations who are not faculty level providers and have never before performed select procedures in real-life clinical environment.

12.6 Exclusion Criteria:

Order Number	Criteria
1	Individuals who are not part of the en route care training. Individuals who participate in this training are over the age of 18, which excludes children from this study.
2	Experts will be excluded if they do not meet performance criteria as determined by PI.
2	Novice subjects will be excluded if they have performed select procedures in real-life clinical situation.

13.0 Recruitment and Consent

13.1 Identification and Selection of Subjects:

Multi-disciplinary providers within the military health system were selected for this study to measure training/skill differences between groups on select procedures in en route care environment. Selection was also based on subject availability for decay projects in which subjects are asked to return at a later date.

13.2 Recruitment Process:

Recruitment will be completed in a variety of methods in order to best adapt to the variability in the subjects schedules:

- Via approved advertisement flyers/email blast (brief study descriptions) through email by program directors/administrators, flyers placed on university bulletin boards, or Val G Hemming Simulation Center website
- Trained student volunteers/research staff that have completed all eIRB requirements will approach potential students or interested subjects in informal settings on campus using approved flyers and information sheets.
    - Subjects who are interested will complete a referral form allowing them to be contacted by study coordinator or provided an information sheet to contact study directly
- Potential subjects may also contact study directly if interested in participation
- Groups coming to Val G Hemming Simulation center for training may also be approached to participate in the en route care study with verbal permission from supervisors.

Upon recruitment, subjects will be screened for eligibility. If subject has been deemed eligible, study coordinator/research assistant will contact participation for scheduling.

Potential subjects are volunteers and are no way obligated to participate.

13.3 Compensation for Participation:

Participants will not be compensated for their participation.

13.4 Eligibility Assessment Process:

Subjects will be asked screening questions prior to scheduling for enrollment. If deemed eliligible, they will be asked to schedule. Screening questions may change for each project as they have distinct goals.

13.5 Consent Process:

Are you requesting a waiver or alteration of informed consent?

○ Yes ◉ No

Please explain the consent process:

This study is human subjects research that uses established educational setting and tools, does not involve children, and the information collected is neither identifiable nor does it place the participants at any risk. Based on this, this project should be exempt under 45 CFR 46.101(b)(2), and should not require a consent form. (see information sheet)

13.6 DoDI 3216.02 requires an ombudsman to be present during recruitment briefings when research involves greater than minimal risk and recruitment of Service members occurs in a group setting. If applicable, you may nominate an individual to serve as the ombudsman.

◉ N/A
○ Propose ombudsman

13.7 Withdrawal from Study Participation:

Explain the process for withdrawal and specify whether or not the subjects will be given the opportunity to withdraw their data their data/specimens in the event they wish to withdraw from the study

No data will be linked to personal identifiers. If a participant would like to cease participation, they will inform the study personnel, and no longer be included in the study portion of the training. If the potential volunteers do not want to participate, it will have no bearing on their simulation training.

14.0 Risks and Benefits

14.1 Risks of Harm:

Identify all research-related risks of harm to which the subject will be exposed for each research procedure or intervention as a result of participation in this study. Consider the risks of breach of confidentiality, psychological, legal, social, and economic risks as well as physical risks. Do not describe risks from standard care procedures; only describe risks from procedures done for research purposes

No risks are anticipated in this study. All participants will be volunteers who are already attending simulation training at either the Val G. Hemming Simulation Center The activities outside of the standard training include additional handouts, simulated motion, remote mentorship via phone or video conferencing, briefings on volunteer impressions of the training, and questionnaires that will allow us to better mitigate demographic variables when analyzing the data.

14.2 Measures to Minimize Risks of Harm (Precautions, safeguards):

For each research procedure or intervention, describe all measures to minimize and/or eliminate risk of harms to subjects and study personnel

All participants will be volunteers who are already attending simulation training at either the Val G. Hemming Simulation Center or at Wilford Hall Ambulatory Surgical Center. Prior to training, all participants will be asked if there is anything that could keep them from being able to participate in a simulated en route procedure.

14.3 Confidentiality Protections (for research records, data and/or specimens):

Describe in detail the plan to maintain confidentiality of the research data, specimens, and records throughout the study and at its conclusion (e.g., destruction, long term storage, or banking). Explain the plan for securing the data (e.g., use of passwords, encryption, secure servers, firewalls, and other appropriate methods). If data will be shared electronically with other team members/collaborators outside the institution, describe the method of transmission and safeguards to maintain confidentiality. Explain whether this study may collect information that State or Federal law requires to be reported to other officials or ethically requires action, e.g., child or spouse abuse

Subject confidentiality will be maintained by any data being linked to a unique identifier, and not to any protected health information.

We are not collecting any protected health informaton.

14.4 Potential Benefits:

Describe any real and potential benefits of the research to the subject and any potential benefits to a specific community or society

If the individuals in the research are considered experimental subjects (per 10 USC 980), and they cannot provide their own consent, the protocol must describe the intent to directly benefit all subjects

14.5 Privacy for Subjects:

Describe the measures to protect subject's privacy during recruitment, the consent process, and all research activities, etc.

Subject confidentiality will be maintained by any data being linked to a unique identifier, and not to any protected health information.

We are not collecting any protected health information.

14.6 Incidental or Unexpected Findings:

Describe the plan to address incidental findings and unexpected findings about individuals from screening to the end of the subject's participation in the research. In cases where the subject could possibly benefit medically or otherwise from the information, state whether or not the results of screening, research participation, research tests, etc., will be shared with subjects or their primary care provider. State whether the researcher is obligated or mandated to report results to appropriate military or civilian authorities and explain the potential impact on the subject

No incidental findings are expected in this study due to the observational/educational nature of the project.

15.0 Study Monitoring

15.1 Data Monitoring Plan:

Describe the plan to monitor the data to verify that data are collected and analyzed as specified in the protocol. Include who will conduct the monitoring, what will be monitored and the frequency of monitoring

The PI and co-investigators will monitor the data after each stage of collection to verify that it has been collected as outlined in the protocol.

15.2 Safety Monitoring Plan:

Describe the plan to monitor the data to ensure the safety of subjects

Participants will be in simulated environments that are routinely used for educational purposes. The safety procedures in place for the educational courses in these environments will be used during this study.

15.3 Does your study require independent data and safety monitoring?

○ Yes ◉ No

16.0 Reportable Events

16.1 Reportable Events:

Consult with the research office at your institution to ensure requirements are met
• Describe plans for reporting expected adverse events. Identify what the expected adverse events will be for this study, describe the likelihood (frequency, severity, reversibility, short term management and any long term implications of each expected event)
• Describe plans for reporting unexpected adverse events and unanticipated problems. Address how unexpected adverse events will be identified, who will report, how often adverse events and unanticipated problems will be reviewed to determine if any changes to the research protocol or consent form are needed and the scale that will be used to grade the severity of the adverse event

There are no expected adverse events as described in the risks section.

Serious Adverse Events: The PI, within one working day, will report all serious adverse events (SAE) occurring in subjects enrolled at USU by submitting an adverse event report memorandum to the IRB office. Serious adverse events will be reported even if the PI believes that the adverse events are unrelated to the protocol.

Unexpected (but not serious) adverse events occurring in subjects enrolled at USU which, in the opinion of the PI, are possibly related to participation in the protocol will be reported by the PI within 10 (ten) working days to the IRB using the same procedure.

A summary of all serious or unexpected side effects also will be included in the Continuing Review Report.

17.0 Equipment/non-FDA Regulated Devices

17.1 Does the study involve the use of any unique non-medical devices/equipment?

◉ Yes ○ No

Please describe:

Educational simulators

18.0 FDA-Regulated Products

18.1 Will any drugs , dietary supplements, biologics, or devices be utilized in this study?

- [ ] Drugs
- [ ] Dietary Supplements
- [ ] Biologics
- [ ] Devices
- [x] N/A

18.5 Sponsor (organization/institution/company):

- [x] N/A

If applicable, provide sponsor contact information:

19.0 Research Registration Requirements

19.1 ClinicalTrials.gov Registration:

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

19.2 Defense Technical Information Center Registration (Optional):

- (•) Registration is not required
- ( ) Registration pending
- ( ) Registration complete

20.0 References and Glossary

20.1 References:

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Compartment Syndrome and En route Fasciotomy

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20.2 Abbreviations and Acronyms:

Abbreviations/Acronyms

Abbreviation	Definition
ANOVA	Analysis of Variance
ASSET	Advanced Surgical Skills Exposure for Trauma
BEST	Basic Endovascular Skills for Trauma
C4	Combat Casualty Care Course
CPG	Clinical Practice Guideline
CRIC	Cricothyroidotomy
CS	Compartment Syndrome
C-STARS	Center for Sustainment of Trauma and Readiness Skills
CV	Coefficient Variances
DeMIST	Details, Mechanism, Injuries, Signs/Symptoms, Treatment
DMRTI	Defense Medical Readiness Training Institute
DOD	Department of Defense
DUSTOFF	Dedicated Unhesitating Service to Our Fighting Forces
ED	Emergency Department
EMS	Emergency Medical Services
EMT	Emergency Medical Technician
ESTARS	Endovascular Skills for Trauma and Resuscitative Surgery
FY16	Fiscal Year 2016
IABO	Intra-Aortic Balloon Occlusion
ICC	Intraclass Correlation Coefficients
ICU	Intensive Care Unit
I-PASS	Illness, Patient, Action, Situation, Synthesis
J-ERC	Joint En Route Care
JiT	Just in Time
JTTR	Joint Trauma Tracking Registry
MDW	Medical Wing
MEDEVAC	Medical Evacuation
MERT	Medical Emergency Response Team
MTF	Military Treatment Facility
NASA	National Aeronautics and Space Administration
NCTH	Non Compressible Torso Hemorrhage
OEF	Operation Enduring Freedom
OEI	Operative Experiences, Inc.
OIF	Operation Iraqi Freedom
OR	Operating Room
PC	Pre-hospital CRIC
POI	Point of Injury
POV	Point of View
REBOA	Resuscitative Endovascular Balloon Occlusion of the Aorta
SBAR	Situation, Background, Assessment, Recommendation/Request
SD	Standard Deviation
SME	Subject Matter Expert
TACEVAC	Tactical Evacuation
TCCC	Tactical Combat Casualty Care
TRI	Trauma Readiness Index
USAF	United States Air Force
USUHS	Uniformed Services University of the Health Sciences
WAVE	Wide Area Virtual Environment
WRNMMC	Walter Reed National Military Medical Center