CONTRACT NUMBER: W81XWH-18-F-0426

TITLE: Prehospital Airway Control Trial (PACT)

PRINCIPAL INVESTIGATOR: Jason Sperry

CONTRACTING ORGANIZATION: University of Pittsburgh

REPORT DATE: OCT-2021

TYPE OF REPORT: Annual – Year 3

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

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Prehospital Airway Control Trial (PACT)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

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

University of Pittsburgh
Pittsburgh, Pennsylvania 15213

8. PERFORMING ORGANIZATION REPORT

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

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14. ABSTRACT
PACT is a proposed 5-year, open label, multi-center, stepped-wedge randomized trial to compare standard strategies of definitive airway management to a strategy of initial supraglottic airways in trauma patients within the prehospital setting.
PACT aims to compare different methods of trauma airway management in the prehospital setting.

Specific Aim one is to compare the effect of a standard strategy of airway management vs. a strategy of first attempt with supraglottic airway (SGA) on 24-hour survival after traumatic injury. Specific Aim two is to compare the effect of a standard strategy of airway management vs. a strategy of first attempt with supraglottic airway (SGA) on hospital survival after traumatic injury. Specific Aim three is to compare the effect of a standard strategy of airway management vs. a strategy of first attempt with supraglottic airway (SGA) on major adverse events.

15. SUBJECT TERMS
Trauma; Prehospital; Airway Management; Supraglottic Airways (SGA); Surgical Airway (SA); Endotracheal Tube (ET)

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRDC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
Unclassified	Unclassified	Unclassified	Unclassified	16	

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

PACT is a proposed 5-year, open label, multi-center, stepped-wedge randomized trial comparing airway management strategies of prehospital trauma patients. The initial airway attempt will be randomized to either usual care (control) or a supraglottic airway management approach (intervention). The primary outcome will be 24-hour survival, with secondary outcomes to include survival to hospital discharge, expected clinical adverse events, airway management performance, ICU length of stay, ventilator days, incidence of ARDS, and incidence of ventilator associated pneumonia. Subjects will be enrolled across approximately 20 prehospital agencies at select LITES Network sites and will enroll a total of 2,040 subjects.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

Trauma; Prehospital; Airway Management; Supraglottic Airways (SGA); Surgical Airway (SA); Endotracheal Tube (ET)

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

The purpose of Task Order 0005 to compare standard strategies of definitive airway management to a strategy of initial supraglottic airways in trauma patients within the prehospital setting.
PACT aims to compare different methods of trauma airway management in the prehospital setting.

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

Clinical Coordinating Center (CCC)

- Successful virtual In Progress Review (IPR) meeting held on 01-DEC-2020!
- CCC/DCC continued to hold monthly site coordinator calls.
- CCC scheduled first meeting of Study Monitoring Committee (will occur 10-SEP-2021).
  - Study Monitoring Committee data tables were redeveloped.
- Contract/budgets for renewals have been completed for 8 of the external sites.
- Developed and distributed new training slide deck for all EMS providers to complete.
- CCC/DCC conducted remote Site Initiation Visits (SIV) with all participating sites/trauma centers in MAR-2021.
- CCC hired an administrative assistant student to assist with study start.

- Ordered & distributed reminder materials to sites for participating EMS providers.
- In preparation for commencing enrollment, each participating site was sent an Activation Memo on 31-MAR-2021. Chicago sub-sites will be activated upon IRB/HRPO approval.
- CCC updated forms to ensure remote SIV compliance with Part 11.
- Data lock for Q2-2021 patient enrollment payments was on 30-JUN-2021

Data Coordinating Center (DCC)

- CCC/DCC testing data entry system:
  - Tables have been developed to collect repeating variables.
  - Testing has continued for the utility tables designed.
  - Testing continued with complicated patient scenarios.
- DCC working on development of queries and reports.
  - Developed 'snapshot' for patients who will be included in monitoring visits.
- DCC set up server and processes for secure transfer of cardiac monitor files from EMS agencies and began testing site uploads.
- DCC set up storage for cardiac monitor files and is working to finalize transfer processes from various monitoring systems.
- CCC/DCC continued the development of the ePCR notification system.
- DCC prepared data training materials and finalized reference materials.
- DCC uploaded final versions of study documentation and training materials to the website.
  - An animated education video explaining QR codes for study enrollment finalized and distributed to EMS providers.
- DCC developed server for collecting and analyzing sample cardiac monitor files for PACT patients from key services. Collection and analyzing is on-going.
- DCC developed a plan to reach out to each agency to adjust monitor data collection settings.
- QR code notification was tested and finalized.
- CCC conducted calls to assist sites with the development of ePCR notifications.
- MATRIX (electronic data capture system) accounts were developed and distributed to all research staff.
- DCC uploaded final versions of study documentation and training materials to the website.
- CCC developing payment plan for patient enrollments for Q2-2021 to account for form changes during Q2.
- DCC updated MATRIX (electronic data capture system):
  - Adjusted for data discrepancies.
  - Reports were created for sites.
  - Adjusting the system to account for multiple EMS agencies treating patients at the same time.
  - Creation of new form to capture summary information for those patients who end up at a non-participating trauma center
  - Drafted new form to consolidate information about EMS agencies other than then PACT-enrolling agency.
  - Adding options to forms for unexpected data.

FDA/IDE

- FDA approval of protocol supplement changes was obtained on 23-DEC-2020.
- CCC Submitted the FDA/IDE annual report to the University of Pittsburgh Office for Investigator-Sponsored IND and IDE Support (O3IS) on 29-JAN-2021.
- A Supplemental IDE Application was submitted to the FDA on 21-MAY-2021. Changes included:
  - Modification to the randomization scheme from time-based stepping (every six months) to enrollment-based stepping (every 281 pts.). This change will allow for more balanced enrollment in control vs. intervention groups & reduce the effect of seasonal variation in trauma volumes.

- Clarification that subjects who need advanced airways but do not receive an ET or SGA prior to hospital arrival will be retained as intent to treat.
- Addition of contingency for subjects that may be transported to a non-participating hospital.

- On 24-JUN-2021, the FDA approved the supplemental IDE application regarding the change of the randomization scheme to enrollment based (vs time based), consolidation of Oregon prehospital agencies into one unit, clarification for intention to treat and contingency for subjects transported to a non-participating hospital.
  - FDA has determined that there are no subject protection concerns that preclude continuation of the investigation and has approved us to implement the above changes to our study.
  - Investigation is limited to 17 US institutions and 2009 US subjects.

University of Pittsburgh Institutional Review Board (sIRB)

- University of Chicago's plan for CC/PD was approved on 23-NOV-2020. Pitt sIRB has approved the University of Chicago to rely on Cook County's in-person survey results.
- CCC and Tulane University completed a second round of modified community consultation (due to COVID-19), and results were submitted to the IRB on 16-OCT-2020.
  - sIRB approval was obtained on 23-NOV-2020.
  - Resolution of Tulane's results will solve the delay for the IRB approval of 3 other sites that were included in the same submission.
- University of Chicago implemented their CC/PD plan in DEC-2020.
  - Community consultation results were submitted to Pitt IRB in FEB-2021.
- sIRB application was transitioned to the University of Pittsburgh's new platform called PittPRO (previously known as OSIRIS).
- University of Pittsburgh IRB approved protocol revisions (protocol version 3) on 18-FEB-2021.
- University of Pittsburgh IRB approved the Chicago sub-sites on 29-MAR-2021.
- Northwestern and Mt. Sinai will be reviewed by their local IRB in APR-2021
- IRB conducted annual renewal on 14-JUL-2021; the changes to step-wedge design in protocol were approved (based on volume rather than time).
- IRB modification approval was obtained on 27-JUL-2021 for including email and other communication with subjects in the data security section.

DoD HRPO

- CCC worked with external sites to obtain materials for their initial HRPO submission.
  - Required documents for East Carolina University were submitted to HRPO for initial approval on 19-OCT-2020
  - Oregon Health and Science University and their 8 EMS services received initial HRPO approval on 29-OCT-2020.
  - Required documents for Tulane were submitted to HRPO for initial approval on 09-DEC-2020.
  - Required documents for the University of Chicago were submitted to HRPO for initial review/approval on 30-MAR-2021.
- Initial HRPO approval for two sites was obtained in JAN-2021 (Tulane & ECU).
- Initial HRPO approval for 4 sites was obtained in FEB-2021 (Cook County, Wash U, Vanderbilt, & Louisville).
- CCC held a conference call with HRPO in APR-2021 to discuss enrollments at sites that were submitted to HRPO but not yet approved.
  - HRPO agreed that sites should keep these patients since sIRB/local IRB approval had already been obtained.
- E00589 series received HRPO Continuing Review approval on 23-AUG-2021.

Enrolling Sites

- A new Emergency Medicine PI was identified at Wash U.
  - Required documents were collected by and all necessary agreements have been executed.
  - Project Manager held a virtual call to review the study.
- All participating EMS services have fully executed FWA and IAA.
- CCC decided to remove Greenville Fire Department from ECU as an enrolling agency.
  - Their administrative office would not comply with the execution of an IAA.
- Enrollment commenced on 01-APR-2021.
  - Individual site calls conducted to touch-base on start-up and data entry support.
  - FAQ document created to address issues/questions arising during study start.
  - Data walkthrough/MATRIX training was conducted with sites in MAY-JUN-2021.
- CCC developing and implementing EMS training on Stepping; Step 1 will occur when enrollment reached 287.
  - EMS agencies assigned for at Step 1 were St. Matthews Fire, Emergycare, and St. Louis Fire.
  - CCC created & distributed training slide deck/communication guide for the 3 EMS agencies assigned at Step 1.
  - EMS providers participated in CRC-led EMS training per agency need in Lunch & Learn format.
- Enrollment N (287) for the first step was reached and 3 EMS agencies (St. Matthews Fire, Emergycare, and St. Louis Fire) stepped on 09-AUG-2021.
- CCC reviewed and distributed 2021 Q2 informed consent reports to individual sites.
  - Calls will be arranged in OCT-2021 with each site to reviews findings & provide additional consent training.
- EMS portal added to LITES website to allow distribution of protocols, training, and resources for EMS services within the network. Portal password was distributed to the EMS medical directors and trainers.
- Sites uploaded their misses and screen fails.

Acting CRC at the University of Pittsburgh performance site continued daily tasks for recruitment & enrolled subjects:

- Identify enrollments & reviewing eligibility
- Screening for potential missed enrollments & identifying screen fails
- Following subjects for consent & assist the physicians with the consent process
- Maintaining proper consent documentation
- Reviewing subjects for Adverse Events
- Maintaining deviation logs & submitted reportable events to the IRB
- Assisting with data input & management of data team
- Upload misses and screen fails for previous month
- Writing enrollment reports for the internal monitor
- Completed Interim Monitoring Visit.

Enrollment: 389 Enrollments (as of 30-SEP-2021)	
University of Pittsburgh (Presby, Hamot, Altoona, Susquehanna)	104
AGH	11
Oregon Health & Science University	23
Vanderbilt University	27
University of Louisville	23
East Carolina University	34
Washington University	14
Tulane University	42
Emory University	15
Chicago – Cook County (Stroger)	54

Chicago – Northwestern		2	
Chicago – U of Chicago		30	
Chicago – Mount Sinai		10	
TOTAL		**389**	
Initial & Interim Monitoring Visit Schedule	**IMV-01**	**IMV-02**	**IMV-03**
CCC/DCC developed and implemented the remote monitoring plan - Initial Monitoring Visits were conducted between MAY-SEP 2021 at all sites except Chicago-Northwestern and Chicago-Mount Sinai. IMV-01 for these two sites will be scheduled in 2021 Q4			
University of Pittsburgh (Presby, Hamot, Altoona, Susquehanna)	10-MAY-2021	09-AUG-2021	08-NOV-2021 *(tentative)*
AGH	28-JUN-2021		
Oregon Health & Science University	26-MAY-2021		
Vanderbilt University	02-AUG-2021		
University of Louisville	30-AUG-2021		
East Carolina University	07-JUL-2021		
Washington University	26-JUL-2021		
Tulane University	16-AUG-2021		
Emory University	09-AUG-2021		
Chicago – Cook County (Stroger)	12-JUL-2021		
Chicago – Northwestern	*Pending*		
Chicago – U of Chicago	23-AUG-2021		
Chicago – Mount Sinai	*Pending*		

DCC distributed Operation Memos to all study personnel		
Several variations of the Manual of Operations (MOP) were distributed over the last year & posted in the Document Library on the study website		
#5	Data Form and Report Changes.	28-MAY-2021
#6	Data Form and Report Changes and Adverse Event/Complications Update	11-JUN-2021
#7	Protocol and Consent Changes	14-JUN-2021
#8	Data Form Changes	21-JUN-2021
#9	Continuing review, revised protocol approval, form updates, report updates, and general updates (updated MOP, download option in SecureShare, and consent reference guide).	15-JUL-2021
#10	Data Form Changes and EMS resource material info EMS resource materials will soon be available on the LITES website	16-AUG-2021
#11	Data Form Change and update to AEL PDF Fillable form	31-AUG-2021
#12	Updated Manual of Operations (version 2) Documentation reminder for when subjects become prisoners after enrollment.	10-SEP-2021
#13	Data Form Changes: ADV Form: Description box now available for all complications and AEs on the AER form/ CLO Form: Hospice options added to disposition tab	20-SEP-2021
Three documents were posted in the Document Library on the study website: - New notification letter for subjects taken to non-LITES hospitals - Updated version of notification letter for discharged subjects - Updated version of notification letter for deceased subjects.		

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

If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to Report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Continue enrollment
- Continue to hold monthly coordinator teleconferences.
- Continue to hold quarterly EMS teleconferences.
- Investigate & purchase reminder materials for EMS crews
- Prepare for next step & distributing training materials

Travel Reporting: no travel is anticipated for the next quarter (OCT-2021 to DEC-2021).

Cumulative to Billing Period: **30-SEP-2021**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**
	$313,658.00	$35,385.26	$278,272.74
Upcoming Travel for Quarter: **OCT-2021 to DEC-2021**	**Traveler Name**	**Destination/ Purpose**	**Estimated Date of Travel**
	N/A	N/A	N/A

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report.

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report.

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report.

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Nothing to Report.

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change

Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Nothing to Report.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Executed IAAs took longer than anticipated due to difficulty navigating city/county legal issues with data sharing.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

It was difficult to determine when enrollment would begin due to the following:

- COVID pandemic interruptions
  - Research resources and staffing at each university
  - Standard community consultation efforts were difficult for some sites
- DoD HRPO approval for each of the 8 external sites
- Remote training/ re-training at EMS services

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report.

Significant changes in use or care of vertebrate animals

Not applicable to TO 0005

Significant changes in use of biohazards and/or select agents

Not applicable to TO 0005

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report.

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report.

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report.

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Nothing to Report.

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance

progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

Nothing to Report.

- **Other Products**

  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:

  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

<u>Example:</u>

Name:	*Mary Smith*
Project Role:	*Graduate Student*
Researcher Identifier (e.g. ORCID ID):	*1234567*
Nearest person month worked:	*5*
Contribution to Project:	*Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support:	*The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Personnel Listing: see page 15

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Nothing to report.

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

Year 3 Quad Chart: see page 16

9. APPENDICES: Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

Annual and final reports are submitted to: https://ers.amedd.army.mil/

AND
One Copy: Contract Specialist, Mr. Paul Martha
Email: paul.m.martha.civ@mail.mil

One e-Copy: Contracting Officer's Representative (COR), Rene Smith
Email: rene.k.smith.civ@mail.mil

Personnel Listing (as of 31-AUG-2021)

Department	Pesonnel Name	Government Used Labor Category	UPitt Role	TO % Effort
Emergency Medicine	Guyette, Francis X III	Clinical Research Director	Co-PI	5%
Surgery	Hayes, Hannah E	Clinical Researcher II	Clinical Researcher II	20%
Epidemiology (GSPH)	Macey-Kalcevic, Melody	Data Aanalyst R IV	Research IV	100%
Emergency Medicine	Martin-Gill, Christian	Clinical Research Director	CO-Investigator	30%
Surgery	Molinaro, Rachel	Project Manager	Project Manager	100%
Surgery	Phillips, Kaitlin Nicole	FICA-Paying Student	FICA-Paying Student	50%
Epidemiology (GSPH)	Silfies, Laurie N	Systems Engineer IV	Systems Engineer IV	10%
Surgery	Skroczky, Hunter L	Health Professional III	Health Professional III	20%
Surgery	Sperry, Jason L	Clinical Research Director	PI	5%
Emergency Medicine	Weiss, Leonard S	Clinical Research Director	CO-Investigator	30%
Epidemiology (GSPH)	Wisniewski, Stephen R	Epidemologist	Co-PI	2%

YEAR 3 QUAD CHART

Linking Investigations in Trauma and Emergency Services – TO5

17052001-TO5/W81XWH-16-D-0024, W81XWH18F0426

Prehospital Airway Control Trial (PACT) - LITES Task Order 0005

PI: Jason Sperry MD MPH **Org:** University of Pittsburgh **Award Amount: $8,811,343**

STUDY AIMS

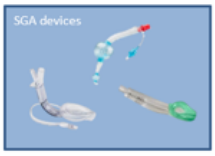
Compare strategies of definitive airway management of endotracheal intubation to supraglottic airways in trauma patients within the prehospital setting.

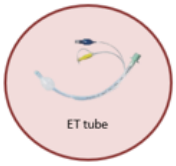
I. To compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on 24-hour survival after traumatic injury.

II. To compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on hospital survival after traumatic injury.

III. To compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on major adverse events

Open label, multi-center, stepped wedge cluster randomized trial comparing ETI and SGA for airway management of prehospital trauma patients





ACCOMPLISHMENTS

N = 389 (as of 30-SEP-2021)

- ✓ Enrollment N (287) for the first step was reached & 3 EMS agencies (St. Matthews Fire, Emergycare, & St. Louis Fire) stepped in AUG-2021.
- ✓ Initial Monitoring Visits conducted at all sites except Chicago-Northwestern and Chicago-Mount Sinai.

Timeline and Cost

Activities CY	SEP-18	19	20	21	22	23
Startup, Hiring, IRB approval, Contracts, Single IRB organization, Database creation, site selection						
5-year (4-year enrollment), 2009 pts.						
Step wedge interim analysis						
Step wedge interim analysis						
Data analysis and publication						
Estimated Budget	438K	438K	438K	438K	3.5M	3.5M

Updated: (University of Pittsburgh 06-OCT-2021)

Goals/Milestones

CY19 Goal – Study Startup & Site Selection

- ✓ Base Hiring; Central IRB organization; IRB approval; Sub-Contract organization.

CY20 Goal –

- ✓ Data base creation and CRF completion, data dictionary

CY21 Goal – Patient enrollment (500-600) and Data procurement/extraction

- ✓ Remote Site Initiation Visits and virtual training.
- ✓ SecArmy EFIC waiver approval
- ✓ HRPO approval
- ✓ Begin Patient enrollment
- ❑ 1 & 2 of 7 groups of agencies will be implemented to SGA first strategy.
- ❑ Begin Characterization compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on 24-hour survival, hospital survival, and major AEs after traumatic injury.

CY22 | CY23 Goal – Patient enrollment 600-1100

- ❑ Request No Cost Extension (NCE)
- ❑ 3 & 4 of 7 groups of agencies will be implemented to SGA first strategy.

Budget Expenditure to Date

- Actual Expenditures To-Date: $1,751,195 (reflected level reports up to 31-AUG-2021)
- Current Month Expenses: $23,041 (reflects account through AUG-2021 period)