CONTRACT NUMBER: W81XWH-18-F-0426

TITLE: Prehospital Airway Control Trial (PACT)

PRINCIPAL INVESTIGATOR: Jason Sperry

CONTRACTING ORGANIZATION: University of Pittsburgh
Pittsburgh, Pennsylvania 15213

REPORT DATE: OCT-2020

TYPE OF REPORT: Annual – Year 2

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
OCT-2020	Annual Report	30-SEP-2019 to 29-SEP-2020

4. TITLE AND SUBTITLE

Prehospital Airway Control Trial (PACT)

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-18-F-0426

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Jason L. Sperry, Barbara Early, Meghan Buck, Laurie Silfies, Rachel

E-Mail: sperryjl@upmc.edu; earlybj@upmc.edu; buckml@upmc.edu; silfiesl@edc.pitt.edu; molinaror@upmc.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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)

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

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

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
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	15	19b. TELEPHONE NUMBER *(include area code)*

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.

CCC/DCC

- Continued to hold monthly site coordinator calls.
- DCC reviewed protocol and suggested modifications.
- Contract/budgets for renewal with the additional start-up sent out to all sites.
- The initial Institutional Data and Safety Monitoring Board (IDSMB) meeting was held on 20-MAR-2020.
  - The Board voted to begin the study without modification.

- CCC/DCC developed/distributed an annual survey to sites to capture changes at the EMS level (the number of patients receiving SGA, ETI or BVM-only in 2019 to stratify prior to randomization).
- CCC Submitted the FDA/IDE annual report to the University of Pittsburgh Office for Investigator-Sponsored IND and IDE Support (O3IS) on 31-JAN-2020.
- Notified by HRPO on 28-AUG-2020 that Sec Army waiver of informed consent has been granted.
  - The University of Pittsburgh Coordinating Center (E00589.1a) and Performance site (E00589.b-1) received initial HRPO approval on 02-SEP-2020.
- Established a Study Monitoring Committee: this committee will review study progress and benchmarks such as enrollment, compliance, and data entry across all sites.
- CCC is collecting SOPs (addressing logistical requirements) from external sites for study start-up.
  - SOPs from 3 sites have been collected and approved by the coordinating center.
  - 5 sites SOPs were returned for clarification.

Database Creation & Enrollment Notification (CCC/DCC)

- Worked with sites to obtain computer information and compatibility to DCFs.
  - All sites submitted information needed to begin access set-up.
- Developed Benchmark system to ensure site productivity and evaluation.
- Finalized adverse event reporting guidelines.
- DCC added data system information into the MOP and worked on finalizing development of the Data Management Manual.
- DCC continued building MATRIX system for capturing data electronically.
  - Determine final lab values.
  - Generated standardized reports.
  - Data entry system testing: sample patient testing revealed the need for utilities.
  - Utilities are being developed for repeating functions.
  - Developed method to capture monthly misses/screen fails.
- DCC continued to work on development of queries and reports to develop mechanisms for site oversight.
- DCC worked on system edits, data collection rules, and finalization of the data entry system.
- Creating QR code for automatic enrollment notification.
- Comparing REDCap and Qualtrics for auto email generation
- CCC/DCC continue to meet to finalize DCFs.

Medical Directors & EMS Training

- CCC continued to hold quarterly EMS calls.
- CCC held two Medical Director calls in MAY-2020.
- CCC collected EMS medical director agreements and HRPO addendums to document FWA/IAA agreements between services and sites.
- Finalizing quizzes and PPTs for the four services wishing to use on-line learning management system.
  - Going forward, we plan to conduct any training/retraining remotely.

Status of sIRB, Community Consultation/Public Disclosure Results, and HRPO submissions/approvals (as of 30-SEP-2020):

- CCC continued to work with external sites to obtain materials for their initial HRPO submission.

- Required documents for OHSU were submitted to HRPO for initial approval.

- Site Initiation Visits (SIV): TBD once timeline is solidified for study start.
- University of Pittsburgh received IRB annual renewal approval on 15-JUL-2020.
- Due to the COVID-19 pandemic, standard community consultation efforts were altered at Tulane. CCC worked with Tulane University to develop a mechanism to complete community consultation during social distancing. Developed an IRB approved script to allow for phone dialing consultation.
  - Tulane received IRB approval to move from in-person community consultation to increased digital surveys to meet their requirements.
  - CCC completed Tulane University's COVID-19 modified community consultation in AUG-2020. Results from random-digit dialing were insufficient to satisfy IRB requirements. CCC notified the site of the alternative consultation plan: recall unanswered numbers/new numbers & place paper surveys in the site's trauma clinic.
  - As of 30-SEP-2020, Tulane has 27 of the additional 50 surveys completed to meet IRB requirements.
- Resolution of Tulane's results will solve the delay for the IRB approval of 3 other sites that were included in the same submission.
- Chicago Sub-site hospitals:
  - University of Chicago received letter of support from Chicago Fire to continue with IRB process.
  - Northwestern formally approved using Cook County community consultation results.
  - Received conditional approval from Mt. Sinai (Chicago sub-site), to cede to Pitt IRB.

SITE	CC RESULTS RECEIVED	PITT sIRB APPROVAL OBTAINED	HRPO SUBMISSION	HRPO APPROVAL
TULANE	22-APR-2020	*Pending*		
ECU	29-FEB-2020	24-MAR-2020		
WASH U	21-APR-2020	*Pending*		
VANDERBILT	10-APR-2020	*Pending*		
LOUISVILLE	07-APR-2020	*Pending*		
EMORY	29-JAN-2020	19-FEB-2020	07-MAY-2020	*Pending*
COOK COUNTY	04-MAR-2020	24-MAR-2020		
OHSU	24-FEB-2020	24-MAR-2020	09-SEP-2020	*Pending*

Status of each sites IRB, Community Consultation/Public Disclosure Plans, and Agreement to Cede. All sites have agreed to cede review to Pitt IRB.

SITE	CC/PD PLAN APPROVAL	AGREEMENT TO CEDE	CC/PD PLAN APPROVAL TO START
TULANE	Approved 24-OCT-2019	Received 16-DEC-2019	Approved 29-FEB-2020
ECU	Approved 24-OCT-2019	Received 12-OCT-2019	Approved 24-OCT-2019.
WASH U	Approved 30-JUL-2019	Received 23-SEP-2019	Approved 26-SEP-2019
VANDERBILT	Approved 24-OCT-2019	Received 25-SEP-2019	Approved 24-OCT-2019
LOUISVILLE	Approved 30-JUL-2019	Received 09-JAN-2020	Approved 10-JAN-2020
EMORY	Approved 30-JUL-2019	Received 18-OCT-2019	Approved 24-OCT-2019
COOK COUNTY	Approved 30-JUL-2019	Received 26-AUG-2019	Approved 16-SEP-2019
OHSU	Approved 20-NOV-2019	Received 17-SEP-2019	Approved 06-DEC-2019

Enrollment: not yet recruiting.

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 to hold monthly coordinator teleconferences.
- Continue to hold quarterly EMS teleconferences.
- Obtain IRB approval of remaining sites community consultation & public disclosure results.
- Continued to work with external sites to obtain materials for their initial HRPO submissions/approvals.
- Cont. to develop protocol training materials for remote Site Initiation Visit (SIV).
  - Consenting, data collection, capturing enrollments; clinical certifications; training slide deck.
  - If feasible, conduct remote training/retraining at EMS agencies.
- Continued discussion and engagement with sites and agencies on regulatory matters throughout pandemic delay.

Travel Reporting: no travel is anticipated for the next quarter (OCT-2020 to DEC-2020).

- Between the 8 participating sites, ~24 EMS agencies required initial training which was planned around each EMS agency's annual competency training times.

- With the unknown time-table to start time retraining may be necessary if start date extends past the one-year mark from initial training.

- Due to the COVID pandemic, we have transitioned all training for both EMS and research sites to a remote-training model.

Cumulative to Billing Period: **30-SEP-2020**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**
	$313,658.00	$35,385.26	$278,272.74

OCT-2019 to DEC-2019	**Traveler Name**	**Destination/ Purpose**	**Estimated Date of Travel**
1	Rachel Molinaro	Emory University training	18-OCT-2019
2	Scott Everitt	Grady EMS airway observation	10-NOV-2019 to 11-NOV-2019
3	Rachel Molinaro John Moss	New Orleans airway observation & train-the-trainer	11-NOV-2019 to 12-NOV-2019
4	Rachel Molinaro	Hillsboro Fire training	18-NOV-2019 to 20-NOV-2019
5	Jason Cruz	Hillsboro Fire training	18-NOV-2019 to 23-NOV-2019
6	Rachel Molinaro	Washington County multi-agency training	20-NOV-2019
7	John Moss Ashley Harner	Susquehanna Regional EMS training	19-NOV-2019 to 20-NOV-2019
8	Frank Guyette Rachel Molinaro	Air Evac training in St. Louis	03-DEC-2019
JAN-2020 to MAR-2020			
1	John Moss	New Orleans EMS Training	13-JAN-2020 to 15-JAN-2020
2	Jason Cruz	New Orleans EMS Training	20-JAN-2020 to 22-JAN-2020
3	Kelsey Buchanan	New Orleans EMS Training	20-JAN-2020 to 22-JAN-2020
4	Scott Everitt	New Orleans EMS Training	27-JAN-2020 to 29-JAN-2020
5	Rachel Molinaro	Grady EMS training	04-FEB-2020 to 05-FEB-2020
6	Scott Everitt	Grady EMS training	10-FEB-2020 to 13-FEB-2020
7	Rachel Molinaro	Nashville Fire Train the Trainer	24-FEB-2020 to 25-FEB-2020
8	John Moss	Nashville Fire Training	24-FEB-2020 to 27-FEB-2020
9	Levi McLaughlin	Nashville Fire Training	24-FEB-2020 to 27-FEB-2020
10	Jason Cruz	Nashville Fire Training	09-MAR-2020
APR-2020 to JUN-2020	Due to the COVID-19 pandemic, we have transitioned all training for both EMS and research sites to a remote-training model. No travel occurred in this quarter.		
JUL-2020 to SEP-2020	Due to the COVID-19 pandemic, we have transitioned all training for both EMS and research sites to a remote-training model. No travel occurred in this quarter.		
OCT-2020 to DEC-2020	No travel is anticipated for this quarter.		

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.

- The IREx process requires IRB completion, therefore, reliance agreements between site IRBs and Pitt IRB will be done through written documentation to facilitate the community consultations at each site.
  - Once completed and with full IRB approval, each site will use IREx as a document repository.
- It will be difficult to determine when enrollment will begin due to the following:
  - COVID pandemic interruptions (issues w/ sites having resources/research available)
  - Each sites' CC/PD results must be submitted to Pitt IRB for approval. Upon Pitt IRB approval, each of the 8 external sites must be submitted to DoD HRPO for approval.
- Chicago Sub-site hospitals: difficulty communicating with busy COVID hospital sites.
- Continued to obtain and track FWA/IAAs from the EMS services. We have 4 pending IAA's due to difficulty navigating city/county legal issues with data sharing.
- Due to the study start-up delay, retraining for EMS services must be done prior to 01-JUN-2020 for agencies who were trained greater than 6 months ago.
  - Virtual training is being designed to accommodate this.
- All sites must start at the same time for the step-wedge design, therefore to accommodate a site initiation visit (SIV) for each site, we must begin scheduling those SIVs in advance.
  - Site Initiation Visits (SIV) are required for each site (including any sub-accrual hospitals).
  - This will require the coordination of approximately 18 SIVs.
  - Due to COVID, we are modifying our materials to accommodate remote SIVs.

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.

CCC/DCC discussed the impact of COVID-19 pandemic on the anticipated timeline for initiating the study and collected feedback from external sites on site-specific impacts of the pandemic response throughout MAY-2020.

- CCC/DCC distributed an Op Memo on 02-JUN-2020: notification to sites that PACT start-up would be delayed due to SARS-Cov-2 pandemic and we anticipate enrollment starting in Spring 2021.

- CCC continued to collected feedback from external sites on site-specific impacts of the pandemic response throughout JUN/JUL-2020.

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".

Example:

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 14

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 2 Quad Chart: see page 15

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 05-OCT-2020)

Department	Last Name	First Name	Government Used Labor Category	UPitt Role	PACT/5
Epidemiology (GSPH)	Wisniewski	Stephen	Epidemologist	Co-PI	2%
Surgery	Sperry	Jason	Clinical Research Director	PI	5%
Emergency Medicine	Martin-Gill	Christian	Clinical Research Director	CO-Investigator	15%
Epidemiology (GSPH)	Silfies	Laurie	Systems Engineer IV	Systems Engineer IV	20%
Emergency Medicine	Guyette	Francis	Clinical Research Director	Co-PI	25%
Epidemiology (GSPH)	Wolsk	Jenny	Database Adminstration Manager (R IV)	Research IV	100%

YEAR 2 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: $8,811,342.88**

STUDY AIMS

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

APPROACH

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

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

ACCOMPLISHMENTS

- ✓ Sec Army waiver of informed consent has been granted.
- ✓ University of Pittsburgh Coordinating Center (E00589.1a) and Performance site (E00589.b-1) received initial HRPO approval.
- ✓ Major progress made on building the MATRIX system for capturing data electronically.
- ✓ Testing the data entry system with sample pts.

Timeline and Cost

ACTIVITES	18	19	20	21	22
Hiring, Contracts, Central IRB organization					
Start-up, sIRB/HRPO approvals, Database creation					
Year 2 thru 4.5 > enrollment (2,040 pts.); analysis: two interim, one final (completion of the 2nd step & completion of the 5th step).					
Compare strategies of definitive airway management of endotracheal intubation to supraglottic airways in trauma patients within the prehospital setting					
Estimated Budget	**$1M**	**$2M**	**$2M**	**$2M**	**$1.5M**

Updated: (University of Pittsburgh 06-OCT-2020)

Goals/Milestones

CY19 Goal – Study Startup & Site Selection
✓ Base Hiring; IRB approval; Central IRB organization, Sub-Contract organization.
CY20 Goal – start-up delayed due to COVID pandemic
❑ Data base creation and CRF completion, data dictionary
CY21 Goal – Patient enrollment (500-600) and Data procurement/extraction
❑ Site Initiation Visits and hands on training.
❑ 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 Goal – Patient enrollment 600-1100
❑ 3 & 4 of 7 groups of agencies will be implemented to SGA first strategy.

Comments/Challenges/Issues/Concerns

- Anticipated timeline for initiating the study was delayed due to COVID pandemic.
- It will be difficult to determine when enrollment will begin due to the following:
  - Each sites' CC/PD results must be submitted to Pitt IRB for approval.
  - Upon Pitt IRB approval, each of the 8 external sites must be submitted to DoD HRPO for approval.
- All sites must start at the same time for the step-wedge design so this will require the coordination of approximately 18 SIVs.

Budget Expenditure to Date

- Actual Expenditures To-Date: **$1,194,403.87** (reflected level reports up to 31-AUG-20)
- Projected Expenditures: $29,234 *(reflects current projections as of AUG20).*