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CONTRACT NUMBER: W81XWH-16-D-0024, W81XWH18F0426

TITLE: Prehospital Airway Control Trial (PACT)

PRINCIPAL INVESTIGATOR: Jason Sperry

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TYPE OF REPORT: Annual – Year 1 (covering 23-SEP-2018 to 22-SEP-2019)

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

REPORT DOCUMENTATION PAGE

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5a. CONTRACT NUMBER

5b. GRANT NUMBER
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6. AUTHOR(S)

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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 NUMBER

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

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

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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		19b. TELEPHONE NUMBER *(include area code)*

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 with the following aims:
AIM #1: 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.
AIM #2: 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.
AIM #3: 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.

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.

- Site Selection Survey was developed and distributed to the Network sites in OCT-2018.
  - DCC developed a database to track/survey sites and pre-hospital providers.
- Selected 8 external LITES sites for study participation in JAN-2019.
  - 5 of the 8 participating sites have fully executed contracts.
  - Identified physicians for outlaying Pittsburgh site hospitals and have begun onboarding process.
  - Recruited two more EMS services for participation in study in Pittsburgh area.
- Worked with the University of Pittsburgh HR department to post study specific positions.
  - Hired 6 trainers to assist with protocol/airway training at each of the 30 EMS services potentially enrolling in this study.
  - Assistant Project Manager position was filled in JUN-2019.
- The University of Pittsburgh Clinical Coordinating Center (CCC) submitted a letter to request concurrence that PACT is exempt from IDE requirements to the FDA (via O3IS office) on 28-AUG-2018.
  - Th CCC worked directly with the FDA on the IDE application which was submitted to the University of Pittsburgh O3IS office on 21-DEC-2018.
  - Received FDA approval for Investigational Device Exemption (IDE) on 01-FEB-2019.
- CCC/DCC continued to hold monthly site teleconferences.
- First recurring quarterly call with EMS agencies was held on 18-SEP-2019.
- CCC/DCC finalized the PACT MOP in JUL-2019.
- DCC updated the LITES website to add EFIC & PACT information in MAY-2019.
  - DCC set up a PACT-specific email account to be used by the public to request information.
  - In JUL-2019, DCC updated LITES website to make PACT information public/EFIC friendly.
- Generated and released two PACT Operations Memos:
  - 04-SEP-2019 - #1 (Operations Memos).
  - 09-SEP-2019 - #2 (Registering for Accounts).
- Protocol, template consents, and EFIC (overall and Pitt site CC/PD plans):
  - Submitted to IRB for initial review on 25-MAR-2019.
  - Received IRB approval 29-MAY-2019.
- Presented consultation/disclosure results to the University of Pittsburgh IRB on 26-JUN-2019.
  - Received initial approval pending minor modifications on 03-JUL-2019.
  - Submitted requested modifications on 22-JUL-2019.
  - University of Pittsburgh received full IRB approval on 30-JUL-2019.
  - This also includes the approval of three sites Community Consultation/Public Disclosure Plans (Washington, Louisville, & Cook County).
- Negotiated a specialized IRB review board for the community consultation plans/results for participating sites.
- Initiated correspondence for DSMB selection and received a budget.
- Completed a monitoring plan detailing the oversight at the 8 sites.
- Built the Matrix system that will be used to capture the data (DCC side).
  - CCC/DCC working to refine/finalize data collection forms and corresponding data dictionary.

- DCC working with sites to obtain computer information for Matrix data system.
- Began building QxQ documentation.
- Incorporating "due" rules and edits.
- Began testing of the MATRIX system.

- Created scope of work for medical directors at EMS services participating in the study.
- Training for medical directors is required, however local IRBs may not recognize non-university staff so the research requirements must be fulfilled and reviewed outside of the local IRB.
  - Pitt has agreed to allow external EMS agencies to utilize Pitt CITI.
- Determined training required from EMS services.
  - Developing a training schedule for each of the EMS services identified.
  - Created public BOX site for EMS agencies to access training slides and protocol.
- Protocol training at EMS services began in JUL-2019.
  - Protocol training conducted at 3 EMS services in AUG-2019.
  - Protocol training conducted at 9 EMS services in SEP-2019.

Status of each sites IRB, Community Consultation/Public Disclosure Plans, and Agreement to Cede (as of 30-SEP-2019):

SITE	CC/PD PLAN APPROVAL	AGREEMENT TO CEDE	CC/PD PLAN APPROVAL TO START
TULANE	Review on 02-OCT-2019	*In process*	
ECU	*To be submitted*	*In process*	
WASH U	Approved 30-JUL-2019	Received 23-SEP-2019	Sent 26-SEP-2019
VANDERBILT	*To be submitted*	Received 25-SEP-2019	
LOUISVILLE	Approved 30-JUL-2019	*In process*	
EMORY	Approved 30-JUL-2019	*In process*	
COOK COUNTY	Approved 30-JUL-2019	Received 26-AUG-2019	Sent 16-SEP-2019
OHSU	*To be submitted*	Received 17-SEP-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 approval of remaining sites community consultation & public disclosure plans.
- Obtain Agreement to Cede from all remaining sites.
- Initiate community consultation & public disclosure plans at remaining sites.
- Continue to visit EMS agencies to verify airway training and conduct protocol training.

TO5 Travel Reporting:

- Between the 8 participating sites, approximately 25 EMS agencies will need protocol training and airway training verification. Initial training will be planned around each EMS agency's annual competency training times, which are scheduled to occur through JAN-2020.
- UPDATE FROM APR-2019 Quarterly Report:
  - Training was scheduled to be conducted at Vidant East Care for East Carolina University on 16-JUN-2019 to 18-JUN-2019 but it was cancelled.
- UPDATE FROM JUL-2019 Quarterly Report:
  - Training as reported at MetroWest EMS (OHSU), Lake Oswego (OHSU), and Louisville Metro (Louisville) occurred as planned!
  - Training was scheduled to be conducted at Wilson Co for East Carolina on 19-AUG-2019 to 22-AUG-2019 but it was rescheduled and is documented in the table below.

Cumulative to Billing Period: 30-SEP-2019			Travel Funds Budgeted	Cumulative Actual Spent	Remaining Balance
			$313,658.00	$12,846.77	$300,811.23
Upcoming Travel for Quarter: SEP-2019 to DEC-2019			Traveler Name	Destination/ Purpose	Estimated Date of Travel
		1	Rachel Molinaro	Canby Fire and Molalla Fire (OHSU)	03-SEP-2019 to 05-SEP-2019
		2	John Moss	Canby Fire and Molalla Fire (OHSU)	03-SEP-2019 to 05-SEP-2019
		3	Bob Hrabar	Air Evac (Wash U)	05-SEP-2019

		4	Josh Hutton	Air Evac (Wash U)	05-SEP-2019
		5	Rachel Molinaro	St. Louis Fire (Wash U)	13-SEP-2019 to 15-SEP-2019
		6	Rachel Molinaro	Pitt, Greenville Fire, Lenoir, Wilson, and EastCare (East Carolina)	22-SEP-2019 to 27-SEP-2019
		7	John Moss	Pitt, Greenville Fire, Lenoir, Wilson, and EastCare (East Carolina)	22-SEP-2019 to 27-SEP-2019
			Rachel Molinaro	EmergyCare (Erie)	10-OCT-2019 to 11-OCT-2019
		13	John Moss	EmergyCare (Erie)	10-OCT-2019 to 11-OCT-2019
		14	TBD	EmergyCare (Erie)	14-OCT-2019 to 15-OCT-2019
		15	Bob Hrabar	EmergyCare (Erie)	16-OCT-2019 to 17-OCT-2019
		16	Rachel Molinaro	Emory University	18-OCT-2019
		17	Kelsey Buchanan	EmergyCare (Erie)	18-OCT-2019 to 19-OCT-2019
		18	Peter Adams	OHSU Multiagency training	21-OCT-2019 to 22-OCT-2019
		19	Scott Everitt	EmergyCare (Erie)	23-OCT-2019 to 24-Oct-2019
		20	Bob Hrabar	EmergyCare (Erie)	30-OCT-2019 to 31-OCT-2019
		21	TBD	SREMS (Susquehanna)	19-NOV-2019 to 20-NOV-2019

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.

- It will be difficult to determine when enrollment will begin due to the following:
  - Unknown time frame for obtaining the Secretary of the Army's signature.
  - The community consultation/notification at each site will vary in time.
  - How we will start every site on the same day for the step wedge cluster.
- We need to identify the most appropriate means to notify sites of an enrollment and to send copies of LOT numbers for the SGAs.
- 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.

- Obtaining EMS data at each trauma center is done differently so our EDC must be amendable to the different ways that the data is being received; CCC/DCC are working to adapt to all the options.
- EMS Training:
  - EMS services have a wide range of requests as far as training, visits, and literature needed to inform their staff. Working with each service individually is tedious but necessary.
  - Training for the EMS services may have to be done in two steps. One step to verify airway training and another step to present the study and do ALL-HANDS training for the study protocol. This will increase our travel but ultimately provide more training time for the EMS which is beneficial.

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.

Nothing to Report

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.)*

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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.

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), Alexis Mosquera
Email: alexis.mosquera.mil@mail.mil

LITES Project Personnel - Task Order 0005 (PACT)

	Department	Last Name	First Name	Middle Initial	Role	Account #414625	Other Department Subaccounts
1	Emergency Medicine	Guyette	Francis	X	PI		30.0%
	Emergency Medicine	n/a	n/a		Health Professional II		50.0%
2	Emergency Medicine	Martin-Gill	Christian		PI		15.0%
3	Epidemiology (GSPH)	Silfies	Laurie	N	Systems Engineer IV		20.0%
4	Epidemiology (GSPH)	Wisniewski	Stephen	R	CO-Investigator		2.0%
	Epidemiology (GSPH)	n/a	n/a		Systems/Programmer III		50.0%
5	Epidemiology (GSPH)	Wolsk	Jenny		Research IV		50.0%
	Epidemiology (GSPH)	n/a	n/a		Research III (starts YEAR 2)		50.0%
6	Surgery	Sperry	Jason	L	PI	5.0%	
7	Surgery	Joshua	Hutton		Project Manager	50.0%	
Number of Budgeted Employees on TO5 =7							

Personnel named directly in budgets. Does not include MACRO personnel.

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

- ✓ Received FDA approval for Investigational Device Exemption (IDE).
- ✓ University of Pittsburgh received full IRB approval.
- ✓ 5 of the 8 participating sites have fully executed contracts.
- ✓ DCC built the Matrix system that will be used to capture the data.
- ✓ DCC updated the LITES website to add EFIC & PACT information.

Timeline and Cost

Activities / CY	18	19	20	21
Startup, Hiring, IRB approval, Contracts, Central IRB organization, Database creation				
1 year thru 4 year enrollment, 1050 patients; interim analysis at 50 % enrolled				
Characterize for variation of patient centered outcomes related to whole blood vs component therapy				
Characterization of bp and resusc endpoints for TBI in hemorrhagic shock ; prepare WB clinical practice guidelines				
Estimated Budget ($K)	**$1M**	**$2.5M**	**$2.5M**	**$1.5M**

Goals/Milestones

CY19 Goal – Study Startup & Site Selection
- ✓ Base Hiring; IRB approval; Central IRB organization, Sub-Contract organization.
- ❑ Data base creation and CRF completion, data dictionary
- ❑ Site Initiation Visits and hands on training.

CY20 Goal – Patient enrollment (500-600) and Data procurement/extraction
- ❑ 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.

CY21 Goal – Patient enrollment 600-1100
- ❑ 3 & 4 of 7 groups of agencies will be implemented to SGA first strategy.

Comments/Challenges/Issues/Concerns
- It will be difficult to determine when enrollment will begin due to the following:
  - Unknown time frame for obtaining the Secretary of the Army's signature.
  - The community consult at each site will vary in time, so it is difficult to determine exactly when to expect the study to start.
  - Approximately 30 EMS agencies will need protocol training & airway training verification.

Budget Expenditure to Date
- Actual Expenditures To-Date: $521,884.34 (*reflected level reports up to 30-SEP-19*).
- Projected Expenditures: $43,000 *(reflects current projections as of OCT-2019).*

Updated: (University of Pittsburgh 22-OCT-2019)