CONTRACT NUMBER: W81XWH-18-F-0426

TITLE: Prehospital Airway Control Trial (PACT)

PRINCIPAL INVESTIGATOR: Jason Sperry

CONTRACTING ORGANIZATION: University of Pittsburgh, Pittsburgh, PA

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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
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Unclassified	Unclassified	Unclassified	Unclassified	18	19b. TELEPHONE NUMBER *(include area code)*

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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 2,009 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.

- The 50% enrollment milestone was reached in OCT-2022!
- CCC/DCC continued to hold monthly Study Monitoring Committee (SMC) & Site Coordinator calls.
- EMS newsletters were distributed to study personnel quarterly.
- DCC distributed nine Operation Memos to all study personnel over the last year.
- IDSMB interim analysis (861 patients – reached 19-JUL-2022) review was conducted on 07-OCT-2022 – final letter received on 11-NOV-2022.
  - The Board voted for the study to continue without modification and to meet again in approximately 6 months (APR-2023).
- OHRO Continuing Review Acceptance Memo was received on 14-NOV-2022.

- FDA/IDE protocol modification (V6) was submitted to the University of Pittsburgh's IND & IDE Support (IIS) office on 08-NOV-2021. FDA approval received on 09-DEC-2022.
- Protocol modification (V6) was submitted to the IRB on 16-DEC-2022.
  - Committee review was held on 20-JAN-2023 and determined a modification was required to secure approval.
  - Response was submitted on 13-FEB-2023 and IRB approval was granted on 18-FEB-2023.
    - Protocol V7 modification included updates to clarify the process for obtaining primary endpoint (24-hour mortality) for patients enrolled and transported to non-participating hospitals).
- CCC sent quarterly consent monitoring reports to IRB on 01-DEC-2022 as per the IRB's response to the Corrective And Preventive Actions plan following continuing serious noncompliance related to participant notification and consent.
  - Committee review held on 09-DEC-2022. 16-DEC-2022 Committee Determination – Committee reviewed the quarterly site monitoring reports, identified no issue of concern, and considered this RNI closed.
- Successful virtual In Progress Review (IPR) meeting held on 13-DEC-2022!
  - CCC/DCC worked on/finalized the PPT presentation in preparation for the DEC IPR meeting.
- Notification Letter for LAR Refusal was created and distributed to sites on 15-DEC-2022.
  - Sites should use this letter to notify subjects of their enrollment should their LAR decline continued participation but the subject themselves end up getting discharged with the capacity for consent.
  - This letter is only to be sent when a subject is discharged with the capacity for consent but for some reason was not able to be notified before discharge.
  - This letter is only to be sent if the subject's legal authorized representative (LAR) refused study participation for the subject.
- Notification of IDE Change (protocol modification V7) was submitted to the University of Pittsburgh's IND & IDE Support (IIS) office on 27-FEB-2023, and FDA confirmation of receipt obtained on 01-MAR-2023.
  - 5-Day Notice (Protocol Change) Review Complete: notified by the FDA on 31-MAR-2023 – approved, no further action required.
- In response to the FDA/IDE annual report (submitted 30-JAN), the FDA sent a request for information on 03-MAR-2023 RE: an increase in rates of aspiration/suspected aspiration and incorrect airway placement (from 2022 to 2023).
  - Response submitted on 04-APR-2023 and FDA letter of acknowledgment was received on 06-APR-2023.
    - Aspiration rates: The original numbers recorded in the 2022 annual FDA report were the result of under-reporting by the sites. The coordinating center recognized under-reporting was occurring at the time of IRB annual renewal and initiated site re-training for recognizing and documenting aspiration. The numbers reported in the 2023 annual FDA report are more accurate and reflect the aspiration rates reported in the literature for this population.
    - Misplaced airways: The frequency of misplaced airways included radiographic evidence that an endotracheal tube is too deep or shallow. This reflects reported literature as sites improved their surveillance and reporting practices.
  - On 13-APR-2023, a letter from the FDA was received confirming the annual report review is complete and no further information is required.
- COA Request for Cost Modification and PoP was submitted to the DoD on 28-FEB-2023.
  - The Government completed their initial review of the proposal and provided a list of items for Pittsburgh to address on 22-MAR-2023.
  - COA letter clarifications and budget spreadsheet sent to the DoD on 28/29-MAR-2023.
- IDSMB interim review reports were sent to the DoD COR.
  - IDSMB open report was sent to the DoD on 21-MAR-2023.
  - The DCC worked with the COR to deliver the remaining files: the closed report, raw data, and the related data dictionary. Confirmation of receipt obtained!
- IRB Continuing Review was submitted on 12-MAY-2023.
  - Committee review date: 06-JUN-2023 – approval was granted on 06-JUN-2023.
- COA Request for Cost Modification and PoP was submitted to the DoD on 28-FEB-2023.

- COA letter clarifications and budget spreadsheet sent to the DoD on 28/29-MAR-2023.
- The fully executed amendment to add/re-allocate new funds was received on 17-MAY-2023.

- Funds to facilitate the transfer of prehospital monitor data to the Coordinating Center.
  - COR approval was obtained on 19-MAY-2023.
  - Approximately 900 cardiac monitor files have been collected and sites have been paid.
- OHRO continuing review documents were submitted on 21-JUN-2023. Continuing review acceptance memo was received on 14-SEP-2023.
- The IDSMB review meeting was held on 11-MAY-2023.
  - On 19-JUL, the Board instructed the CCC/DCC to stop study enrollment immediately – Sites/EMS agencies were notified.
  - On 08-AUG, DSMB voted to change study status from closed to suspended. Additional data analysis conducted.
    - LITES DCC statistician met with the DSMB to examine additional data and add context – the before-step (standard care) SGA use may be driving the mortality difference.
  - CCC has communicated with all sites via email, monthly all-sites call, and Op Memo.
    - Newsletter was sent to all sites and EMS services explaining the DSMB process and next steps.
  - On 17-AUG, the DSMB voted to lift the suspension and allow enrollment to resume.
- USAMRAA completed de-obligation of additional funds.
- A request to resume suspended study was submitted to the University of Pittsburgh's IND & IDE Support (IIS) office on 31-AUG-2023, and FDA confirmation of receipt obtained on 01-SEP-2023.
  - On 13- SEP, the FDA sent a request for additional information and on 15-SEP, CCC sent a response to the FDA information request.
  - On 29-SEP, the FDA voted to lift the suspension and allow enrollment to resume.
- A modification was submitted to the University of Pittsburgh IRB on 03-OCT-2023.
  - Request to resume suspended study – Committee review date is scheduled for 11-OCT-2023.
- CCC developed a communication plan for re-opening.
  - Notifying regulatory bodies is underway (FDA, IRB, OHRO). Pending necessary approvals required prior to resuming.

The University of Pittsburgh IRB received an anonymous complaint RE: STAT MedEvac's involvement in the supraglottic airway (SGA)-first arm.

- The IRB notified the CCC on 28-NOV-2022 and requested a response to the complaints, information on successful SGA placement during the study, the most recent DSMB closed report, and a response directly from the DSMB.
  - Response to IRB provided in advance of Committee review date on 09-DEC-2022.
  - 15-DEC-2022 IRB Executive Committee Determination – the Committee had no additional concerns and considers this matter closed.

ENROLLING SITES

- On 15-MAR-2023, three EMS services switched to the SGA-first arm of the study (step 4): Grady EMS, ECU-Lenoir County, and City of Pittsburgh EMS

- LITES finance team is working to extend sites subcontracts until 2025 (due to extension of period of performance). All sites with the exception of Chicago have been extended at this time.

- CCC notified OHRO of the change in subject status when a previously enrolled human subject became a prisoner:
  - The prisoner status of three enrolled subjects changed. OHRO was notified on 23-NOV-2022 and OHRO acknowledgment was received on 23-NOV-2022.
  - The prisoner status of one enrolled subject changed. OHRO was notified on 16-DEC-2022.
    - Report of Subject Incarceration Acknowledgement received on 19-DEC-2022.
    - The prisoner report will be placed in the OHRO protocol file. No further action related to this event is required.
  - The prisoner status of one enrolled subject changed. OHRO was notified on 22-MAR-2023.
    - Report of Subject Incarceration Acknowledgement received on 28-MAR-2023.

○ The prisoner report will be placed in the OHRO protocol file. No further action related to this event is required. *Note: No IRB determination is available as this event does not meet the definition of reportable to the University of Pittsburgh sIRB. Per enrollment guidelines under EFIC, the data for this subject will be retained.*	
▪ Enrollment suspended as of 19-JUL-2023. For information surrounding the suspension, see details above noted under bullet: "The IDSMB review meeting was held on 11-MAY-2023".	
Pittsburgh	*(Presby, Hamot, Altoona, Williamsport)*
	Nothing to Report.
AGH	Nothing to Report.
OHSU	Metro West Ambulance will not enroll after 01-AUG-2023 due to losing contract with Washington County. ▪ AMR will take over their enrollment area and have been onboarded.
Vanderbilt	Site identified a new PI and started the onboarding process. ▪ Change in PI was approved by the Pitt sIRB on 02-NOV-2022. ▪ Documents were submitted and local IRB approval was obtained on 13-DEC. ▪ Documents were submitted to OHRO on 22-DEC-2022 and approval was received on 26-JAN-2023.
	Training to onboard the new PI & Medical Director was conducted on 01-MAR-2023.
	Re-activation memo sent and approval to restart enrollment was granted on 01-MAR-2023.
Louisville	Nothing to Report.
East Carolina	EMS Medical Director for Lenoir County completed training in JAN-2023 and resumed enrollment.
WashU	Air Evac Missouri bases – new EMS Medical Director was onboarded, and services were reactivated for enrollment on 10-APR-2023. ▪ AirEvac had to close one base due to staff; three bases are still active.
Tulane	Nothing to Report.
Emory	Nothing to Report.
Chicago – Cook County	Nothing to Report.
Chicago – Northwestern	Nothing to Report.
Chicago – U of Chicago	Nothing to Report.
Chicago – Mount Sinai	LITES monitoring core is meeting bi-weekly with site staff to verify timely compliance with subject consent and notification procedures.

Enrollment: *suspended as of 19-JUL-2023*	
University of Pittsburgh (Presby, Hamot, Altoona, Susquehanna)	364
AGH	20
Oregon Health & Science University	123
Vanderbilt University	55
University of Louisville	71
East Carolina University	112
Washington University	16
Tulane University	149
Emory University	64
Chicago – Cook County (Stroger)	102
Chicago – Northwestern	72
Chicago – U of Chicago	103
Chicago – Mount Sinai	50

TOTAL (goal: 2,009)	1,301

DATA & CONSENT MONITORING

Remote Consent Monitoring:

- Reviews are conducted quarterly, and reports are distributed to sites upon completion.
  - Individual site calls are being held to discuss finding and provide additional guidance.

Interim Monitoring Visit (IMV):

- Continued conducting remote IMVs with participating sites/trauma centers (schedule below).
  - Post IMV calls are being held with the PI and lead CRC to discuss findings.

Note: The University of Pittsburgh Education and Compliance Support for Human Subject Research (ECS-HSR) conducts interim monitoring visits, reviews consents/notifications, and regulatory documents for the Pittsburgh sites (Presby, Hamot, Altoona, Williamsport).

SITE	IMV-04	IMV-05	IMV-06	IMV-07	IMV-08
AGH	27-MAR-2023	*TBD*	*TBD*	*TBD*	*TBD*
Oregon Health & Science University	30-JAN-2023	12-JUN-2023	*TBD*	*TBD*	*TBD*
Vanderbilt University	27-FEB-2023	AUG-SEP-2023	*TBD*	*TBD*	*TBD*
University of Louisville	16-JAN-2023	20-JUN-2023	*TBD*	*TBD*	*TBD*
East Carolina University	16-FEB-2023	13-JUL-2023	*TBD*	*TBD*	*TBD*
Washington University	15-MAY-2023	*TBD*	*TBD*	*TBD*	*TBD*
Tulane University	17-APR-2023	*TBD*	*TBD*	*TBD*	*TBD*
Emory University	13-MAR-2023	*TBD*	*TBD*	*TBD*	*TBD*
Chicago – Cook County (Stroger)	20-MAR-2023 03-APR-2023	*TBD*	*TBD*	*TBD*	*TBD*
Chicago – Northwestern	26-JUN-2023	26-JUN-2023	*TBD*	*TBD*	*TBD*
Chicago – U of Chicago	10-APR-2023	*TBD*	*TBD*	*TBD*	*TBD*
Chicago – Mount Sinai	18-JUL-2023	*TBD*	*TBD*	*TBD*	*TBD*

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.

- LITES prepared for and attended an Investigator Meeting on 26-JAN-2023 to coincide with NAEMSP conference.
  - The goal of the meeting was to provide study updates, conduct study-wide training for EMS Medical Directors and education staff, and to promote study engagement.
- LITES booth held at the EMS West Update conference on 23-24-MAR-2023 for continued PACT outreach.
- To assist with advanced airway training, LITES facilitated the purchase of mannequins for enrolling EMS agencies. COR approval was obtained on 21-APR and the mannequins were purchased on 30-MAY-2023.
  - All mannequins were delivered to each EMS service in AUG-2023.
- Produced a second EMS engagement video in JUN/JUL-2023.

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.

- Prepare In-Progress Review (IPR) presentation for NOV-2023 meeting.
- Resume study enrollment once necessary approvals have been obtained.
- Continue to hold monthly coordinator & SMC teleconferences.
- Continue conducting remote data and consent monitoring.
- Continue implementing CAPA to ensure timely consent/notification.
- Obtain fully executed sites subcontracts (due to extension of period of performance).
- Reach interim analysis (1,434 subjects).
- Step 5 of the Step-Wedge Design (1435 subjects).
- Prepare for NAEMSP conference in JAN-2024 to collaborate with PACT EMS Medical Directors in attendance.
- LITES/Pitt's Office of Sponsored Programs submit budget and justification to request more funds.

Travel Reporting

Travel conducted:

- LITES prepared for and attended an Investigator Meeting on 26-JAN-2023 to coincide with NAEMSP conference.
  - The goal of the meeting is to provide study updates, conduct study-wide training for EMS Medical Directors and education staff, and to promote study engagement.
- CCC held an Investigator Meeting on 26-JAN-2023 to coincide with the NAEMSP conference.
  - Approximately 60 individuals attended from PACT sites, prehospital services, PACT educators and Clinical Coordinating Center.
- Investigator and Medical Director training at Vanderbilt was conducted on 01-MAR-2023.
  - Attendees: Rachel Molinaro and Elizabeth Gimbel
- On-site training at Altoona was conducted 22-FEB-2023.
  - Attendees: Rachel Molinaro and Hannah Hayes
- LITES booth held at the EMS West Update conference on 23-24-MAR-2023 for continued PACT outreach.
- On-site EMS training at Emerycare (Erie, PA) was conducted 06-APR-2023.
  - Attendee: Wesley McLaughlin
- On-site EMS training at Louisville Metro (Louisville, KY) was conducted on the following dates:
  - 15-16-MAY-2023 | Attendees: Wesley McLaughlin and Caroline Levin
  - 22-23-MAY-2023 | Attendee: Wesley McLaughlin
- On-site EMS training at OHSU (and all 7 EMS services) was conducted on 02-06-JUL-2023.
  - Attendee: Wesley McLaughlin
- On-site cardiac monitor training at Vanderbilt (Nashville, TN) was conducted 09-23-MAY-2023.
  - Attendee: Wesley McLaughlin

- One LITES personnel (Rachel Molinaro) attended the 2023 MHSRS conference in Kissimmee, FL – TO5 abstract accepted and poster presented on 15-AUG-2023.
- On-site EMS training at EmergyCare was conducted on 19-SEP-2023.
  - Two EMS trainers attended.
  - *This was not previously reported as it was not planned/scheduled at the time of reporting last quarter.*

Travel anticipated: see below table.

- Note: some details are still being solidified.

Cumulative to Billing Period: **30-SEP-2023**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**

Upcoming Travel for Quarter: **OCT-2023 to DEC-2022**	**Traveler Name**	**Destination/ Purpose**	**Estimated Date of Travel**
	Youngsville Fire Department		
	LITES expects 1-2 EMS Trainers to attend.	Youngsville, PA EMS Training	03-OCT-2023
			16-NOV-2023
	EmergyCare Education Center		
	LITES expects 1-2 EMS Trainers to attend.	Erie, PA EMS Training	10-OCT-2023
			17-OCT-2023
			07-NOV-2023
	EmergyCare Greenville Station		
	LITES expects 1-2 EMS Trainers to attend.	Greenville, PA EMS Training	19-OCT-2023
			31-OCT-2023
	Wilson County (ECU)		
	LITES expects 1-2 EMS Trainers to attend.	EMS Training	NOV-2023 - TBD
	Pitt County EMS		
	LITES expects 1-2 EMS Trainers to attend.	EMS Training	NOV-2023 - TBD

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.

- Changes: as part of the study-wide CAPA, an individual was hired to track enrollments in real time for consent/notifications.
- Staff removal: Logan Owens (Data Entry – last day with LITES was on 02-JUN-2023).
  - Partial effort charged to TO5-PACT (50%).
- Staff removal: Hannah Hayes (promoted to Assistant Project Manager for TO10 in AUG-2023).
- Staff addition: Emily Kelly (promoted to Assistant Project Manager for TO5 in SEP-2023).

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.

Enrollment rate may be affected due to the IDSMB study suspension placed on 20-JUL-2023.

- We expect this to cause an approximate 4-month pause, and estimate resuming enrollment in late-OCT/early-NOV-2023.
- LITES CCC is in the process of notifying the appropriate regulatory bodies (IRB & OHRO) and awaiting necessary approvals required prior to resuming.
- If an extension is needed, a request will be submitted closer to the end of the study's period of performance (which ends in SEP-2025).

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.

Same as above under "Actual or anticipated problems or delays and actions or plans to resolve them".

One EMS services for WashU is currently not enrolling: St. Louis Fire is not enrolling due to staffing issues (lack of paramedics).

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.*

- Study Design and Implementation of the Prehospital Airway Control Trial (PACT)
  - Abstract accepted and poster presented at MHSRS on 15-AUG-2023.

- **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 17

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 5 Quad Chart: see page 18

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, Ronnie Sanford
Email: ronald.s.sanford2.civ@health.mil

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

Personnel Listing (as of 30-SEP-2023)

W81XWH-16-D-0024 / W81XWH-18-F-0426			
Department	**Personnel Name**	**UPitt Role**	**T0 % Effort**
Surgery	Basile, Andrew J.	Temp Employee	8%
Surgery	Brown, Joshua B	Co-PI	38%
Epidemiology (GSPH)	Chaudhary, Prasanna	Data Scientist	100%
Computing and Information	Frisch, Adam N	Physician Researcher	8%
Surgery	Gimbel, Elizabeth	Assistant Project Manager	42%
SCI	Gupta, Abhibha	Graduate Student Researcher	33%
Emergency Medicine	Guyette, Francis X III	Co-PI	15%
Surgery	Hayes, Hannah E	Clinical Researcher II	56%
SCI	Luo, Zhimeng	Language GSR	67%
Epidemiology (GSPH)	Macey-Kalcevic, Melody	Research IV	100%
Emergency Medicine	Martin-Gill, Christian	Co-Investigator	16%
Surgery	Molinaro, Rachel	Project Manager	69%
Emergency Medicine	Patel, Ravi	Data Analyst II	17%
Epidemiology (GSPH)	Pattison, Angela Dawn	Research IV	100%
Surgery	Rayman, MaryAnne	Research II	47%
Surgery	Rogers, Natalie	Research Coordinator (CRC)	7%
Emergency Medicine	Salcido, David D	Co-Investigator	7%
Epidemiology (GSPH)	Silfies, Laurie N	Systems Engineer IV	100%
Surgery	Sperry, Jason L	PI	8%
Surgery	Stephenson, Joshua Paul	Data Entry Assistant	100%
Surgery	Vincent, Laura Everett	Program Administrator	8%
Emergency Medicine	Weiss, Leonard S	Co-Investigator	12%
Epidemiology (GSPH)	Wisniewski, Stephen R	Co-PI	2%
Emergency Medicine	Zikmund, Chase	Data Analyst	7%
SCI	Zou, Ning	Graduate Student Researcher	33%

YEAR 5 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: $11,884,444 to $7,651,106**

STUDY AIMS

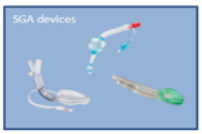
Compare strategies of definitive airway management of endotracheal intubation to supraglottic airways in trauma patients within the prehospital setting.

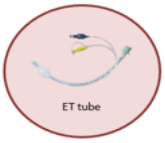
I. To compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on 24-hour survival after traumatic injury.

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

- ✓ Enrollment N (as of SEP-2023) = 1,301
- ✓ The 50% enrollment milestone was reached in OCT-2022!
- ✓ Step 4 of the Step-Wedge Design were reached and a total of three agencies stepped.

Timeline and Cost

Activities CY	SEP-18	19	20	21	22	23	24	25
Startup, Hiring, IRB approval, Contracts, Single IRB, Database creation, site selection								
5-year (4-year enrollment), 2009 pts.								
Step wedge – first interim analysis								
Step wedge – second interim analysis								
Data analysis and publication								
Estimated Budget	$11,884,444					$7,651,106		

Updated: (University of Pittsburgh 13-OCT-2023)

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 & first step of the Step-Wedge Design reached

CY22 Goal – Patient enrollment 600-1100
- ✓ 3 of 7 groups of agencies will be implemented to SGA first strategy.
- ✓ Interim Analysis (861 patients)

CY23 Goal – Patient enrollment (goal = 2009)
- ❑ 4 & 5 of 7 groups of agencies will be implemented to SGA first strategy.
- ❑ Request No Cost Extension (NCE)
- ❑ 6-7 groups of agencies will be implemented to SGA first strategy.
- ❑ Interim Analysis

Budget Expenditure compared to Actual thru 30-SEP-2023
- Actual Expenditure: $7,174,119.70
- Scheduled Expenditures: $5,598,370.02