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: OCTOBER 2022

TYPE OF REPORT: Annual

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

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University of Pittsburgh
Pittsburgh, Pennsylvania 15213

8. PERFORMING ORGANIZATION REPORT NUMBER

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U.S. Army Medical Research and Development Command
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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
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	16	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 2,009 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.

Clinical Coordinating Center/ Data Coordinating Center

- Successful In Progress Review (IPR) meeting held on 17-DEC-2021!
- EMS newsletters were distributed to study personnel quarterly.
- Continued to hold monthly Study Monitoring Committee (SMC) & Site Coordinator calls.
- DSMB meeting was held on 12-NOV-2021 (final letter received 07-DEC-2021) and the Board voted for the study to continue without modification.
  - DSMB voted to postpone the next DSMB meeting until 07-OCT-2022, when the Interim Analysis Data would be available for review.
- CCC recorded and distributed a "one-year-mark video" to EMS providers.
- First interim reached 19-JUL-2022 (861 patients)!
- Florence system set-up throughout 2022 for regulatory document management and monitoring.
  - PACT sites received Florence training in JUL-2022 with full launch of system in SEP-2022.
- In preparation for Step 2 & 3 of the Step-Wedge Design, the CCC/DCC provided new training resources, training video, and enrollment/reminder materials were distributed to sites.
- DCC finalized MATRIX updates to increase reporting functions and improve error identification.
- Secondary QR code designed and distributed as a back-up QR code for EMS services.
- Data lock for patient enrollment payments occurred quarterly.
- CCC submitted FDA/IDE Annual Renewal Report on 31-JAN-2022.
  - Notification was received on 22-FEB-2022 that the FDA reviewed the report and determined that we have met the reporting requirements and no further information is required at this time.
- sIRB Continuing Review (incorporating PI change at the Northwestern enrolling site) approval was granted on 21-JUN-2022.
- OHRO continuing review for E00589 Series was submitted on 12-JUL-2022 – pending acknowledgment.

EFIC Trial Audit:

- USAMRDC, CDMRP, and ORP HRPO conducted a successful site visit of the PACT study at the University of Pittsburgh on 21-22-JUN-2022.
- Site Assessment Visit (SAV) – routine monitoring visit report received 28-JUL-2022.
  - No regulatory deficiencies or concerns
  - Commended us on monitoring, CC/PD toolkit, PMs w/ comprehensive knowledge to execute TOs, thorough process for reviewing AEs, external sites SOP review for onboarding, implementation of Florence.

Chicago-Mount Sinai Corrective And Preventative Action Plan (CAPA):

- Deficits were noted at the Mt. Sinai site during the first Interim Monitoring Visit (IMV-01) in NOV-2021.
  - There were significant delays in the consent/notification process for subjects enrolled by the Mt. Sinai site. This was due to the late identification of enrollments by the study team. Notification of study enrollment was significantly delayed for ten subjects.
  - Additionally, the study team's consent/notification documentation was not sufficient per LITES standards.
- Initial monitoring corrective action items were communicated to the site with instructions to resolve and/or respond to queries by mid-JAN-2022.
  - In response to these deficiencies, Mt. Sinai began addressing the action items. They also started onboarding residents to assist with the consent/notification process.
  - CCC reviewed Mt. Sinai's responses to the queries and distributed their monitoring report on 28-FEB-2022. The report outlined documentation issues that had since been corrected and remaining items to be addressed (i.e., ongoing insufficient research staffing).
- In response to the confirmed delays in the consent/notification process for subjects identified during the IMV-01, the CCC submitted a Reportable New Information (RNI) event to notify the sIRB. The RNI was submitted to the sIRB on 03-MAR-2022
  - sIRB deemed notification delays as Serious Non-Compliance. IRB representative notified DoD OHRO and the FDA in APR-2022.
    - DoD OHRO acknowledged receipt on 04-APR-2022.
    - FDA acknowledged receipt on 11-APR-2022.

- The CCC implemented the Corrective And Preventive Action Plan (CAPA) for the Mt. Sinai site on 07-APR-2022.
  - Enrollments were suspended and the site was not permitted to enroll until the CAPA had been completed.
  - CCC will oversee all new enrollments in collaboration with the Chicago PI. Upon notification that an enrollment occurred, the CCC will communicate with Mt. Sinai's research team to ensure the following items are addressed in a timely manner:
    - Patients must be entered in MATRIX (electronic DCF) within 24 hours.
    - Designated staff must approach/follow-up with the patient/LAR (as early as feasible, but at least within 72 hours of the participant's arrival) to conduct the consent/notification process.
- Corrective action items were re-evaluated in JUN-2022 and found to be satisfactorily addressed. The CCC submitted a request for approval to the sIRB to allow Mt. Sinai to reopen to enrollment.
  - Staff was established and trained on the importance of timely consent/notification and procedures to ensure confidentiality of all subjects.
  - A dedicated coordinator was assigned to ensure all aspects of study compliance are being followed.
  - sIRB Committee accepted the Mt. Sinai corrective action plan and approved the re-opening of the site on 19-JUL-2022.
  - Mt. Sinai resumed enrollment on 20-JUL-2022.
- Post reinstatement, the below steps are being followed:
  - The CCC meets weekly with site personnel to ensure that all proper documentation is provided for each subject enrolled; this includes notification letters, consents, narrative notes, consent logs, etc.
  - The EMS Director is following up to identify any possible enrollments transported to Mt. Sinai by Chicago Fire to help facilitate the timely initiation of the consent/notification process.
  - The CCC will continue to monitor progress and will communicate any concerns to regulatory authorities.

Study-wide Corrective and Preventative Action Plan (CAPA)

- Significant delays in the consent/notification process for several patients from various participating sites were discovered during routine interim monitoring visits.
  - Delays in the consent/notification process were found to be due to various, often site-specific reasons, including late identification of enrolled subjects by the study teams, staffing issues due to COVID, natural disasters, and software issues.
- CCC met with Pitt IRB to obtain guidance for delayed notification on 20-JUL-2022.
  - To prevent future occurrences, a study-wide CAPA was discussed. The IRB expressed that expedient consent and/or notification is in keeping with respect for person and autonomy of human research participants.
- CAPA to resolve both site-specific and study-wide issues of non-compliance was submitted to the sIRB on 05-AUG-2022.
  - Guidelines on consent/notification expectations were explicitly stated.
    - Late identification of subject enrollments is not permitted
    - Consent/notification efforts must be started within 3 business days
    - All notifications efforts must be documented, and first notification success must be documented for all subjects
    - Any consent/notification effort greater than 30 days must be justified in a Deviation form for CCC review.
  - Rapid Escalation Plan was developed to ensure timely intervention by the CCC for any non-compliance issues that may present at enrolling sites.
  - The sIRB approved the CAPA on 23-AUG-2022. IRB representative notified DoD OHRO and the FDA.
    - DoD OHRO acknowledged receipt on 25-AUG-2022.
- The CAPA was distributed to all sites on 08-SEP-2022 and discussed at length on an all-site call on 09-SEP-2022.

Enrolling Sites:

- Enrollment N (574) for the second step was reached and 2 agencies stepped on 03-JAN-2022.
  - Vidant Eastcare and all OHSU EMS services
- Enrollment N (861) for the third step was reached and 4 agencies stepped on 20-JUL-2022.
  - STAT MedEvac, Chicago Fire, Air Evac St. Louis, and Susquehanna Regional EMS
- University of Pittsburgh performance site continued daily tasks for recruitment & enrolled subjects.
  - CCC implemented training with a newly hired PM on back-up responsibilities for capturing enrollments, AEs, and consents.
  - New Data Entry Assistant hired and trained on PACT data entry.
- CCC implemented centralized tracking of all enrollments to ensure timely documentation.

Enrollment: 974 Enrollments (as of 29-SEP-2022)

University of Pittsburgh (Presby, Hamot, Altoona, Susquehanna)	259
AGH	17
Oregon Health & Science University	76
Vanderbilt University	49
University of Louisville	50
East Carolina University	89
Washington University	16
Tulane University	116
Emory University	51
Chicago – Cook County (Stroger)	93
Chicago – Northwestern	48
Chicago – U of Chicago	77
Chicago – Mount Sinai	33
TOTAL	**974**

Data & Consent Monitoring

Interim Monitoring Visit (IMV):

- Continued conducting remote IMVs with all participating sites/trauma centers (schedule below).
  - Post IMV calls are being held with the PI and lead CRC to discuss findings.
  - If noncompliance is discovered, the CCC will implement the Rapid Escalation Plan detailed in the study-wide CAPA.

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.
  - CCC conducted remedial consent training with all enrolling sites on 09-SEP-2022 as a result of discussions with IRB representatives RE: study-wide CAPA implemented in SEP.
  - If noncompliance is discovered, the CCC will implement the Rapid Escalation Plan detailed in the study-wide CAPA.

	IMV-01	**IMV-02**	**IMV-03**
University of Pittsburgh (Presby, Hamot, Altoona, Susquehanna)	10-MAY-2021	09-AUG-2021	08-NOV-2021
AGH	28-JUN-2021	07-MAR-2022	19-SEP-2022
Oregon Health & Science University	26-MAY-2021	10-JAN-2022	25-JUL-2022
Vanderbilt University	02-AUG-2021	11-APR-2022	*17-OCT-2022*
University of Louisville	30-AUG-2021	09-MAY-2022	11-JUL2022
East Carolina University	07-JUL-2021	02-FEB-2022	24-AUG-2022
Washington University	26-JUL-2021	28-FEB-2022	03-SEP-2022
Tulane University	16-AUG-2021	18-APR-2022	*31-OCT-2022*
Emory University	09-AUG-2021	28-MAR-2022	12-SEP-2022
Chicago – Cook County (Stroger)	12-JUL-2021	21-MAR-2022	26-SEP-2022
Chicago – Northwestern	13-DEC_2021	18-JUL-2022	*TBD*

Chicago – U of Chicago	23-AUG-2021	04-APR-2022	*24-OCT-2022*
Chicago – Mount Sinai	09-NOV-2021 to 28-FEB-2022	18-MAY-2022	*TBD*

DCC distributed Operation Memos to all study personnel		
An updated Data Manual and Variations of the Manual of Operations (MOP) were distributed over the last year & posted in the Document Library on the study website		
#14	**CRT Data Form update**	**05-OCT-2021**
#15	**Updated MOP**	**11-NOV-2021**
#16	**MATRIX Updates & Holiday Coverage**	**14-DEC-2021**
#17	**MATRIX Updates & MOP**	**05-JAN-2022**
#18	**Notification letter updates**	**26-APR-2022**
#19	**Delayed Notification of Enrollments**	**25-JUL-2022**
#20	**MATRIX Consent Form**	**05-AUG-2022**
#21	**CAPA & Rapid Escalation Plan**	**08-SEP-2022**
#22	**Note to File (NTF) Form update**	**29-SEP-2022**

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.

- DSMB meeting on interim analysis dataset
- Prepare In-Progress Review (IPR) presentation for 14-NOV-2022
- Continue enrollment
- Continue to hold monthly coordinator & SMC teleconferences.
- Continue to distribute quarterly EMS newsletters.
- Continue conducting remote data and consent monitoring.
- Continue implementing CAPA to ensure timely consent/notification

Travel conducted:

- EMS West Update 2022
  - Seven Springs, PA | 23-26-MAR-2022 | 1 LITES personnel
- Chicago Fire EMS update session and Mt. Sinai Site Visit
  - Chicago, IL | 16-20-MAY-2022 | Attendees: 4 LITES personnel & 3 EMS trainers
- Louisville IMV-03
  - Louisville, KY | 11-12-JUN-2022 | Attendees: 3 LITES personnel
- Chicago Site Visit at Cook County enrolling site
  - Chicago, IL | 21-23-SEP-2022 | Attendees: 1 LITES personnel

Travel Reporting: No travel is anticipated for the next quarter.

Cumulative to Billing Period: **30-SEP-2022**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**
	$313,657.52	$56,291.69	$257,365.83
Upcoming Travel for Quarter: **OCT-2022 to DEC-2022**	**Traveler Name**	**Destination/ Purpose**	**Estimated Date of Travel**
	N/A	N/A	N/A

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

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

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

Nothing to Report.

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

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

Nothing to Report.

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

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

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

Nothing to Report.

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

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

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

Nothing to Report.

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

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

Nothing to Report.

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

Multiple sites have reported staffing shortages. CCC temporarily implemented a 'data entry assistance' program. ▪ This allows sites that are falling behind in data entry due to staffing issues, to enter data on a paper DCF, and the CCC provides transcription data entry assistance into MATRIX.
Turn-over has made it difficult to continue to keep the EMS providers engaged in the research study. ▪ CCC recorded and distributed a "one-year-mark video" to encourage EMS provider engagement and provided PACT branded "zipper pulls" as reminder. ▪ CCC facilitating re-training/education to EMS services as-needed. ▪ Site contracts were amended with the proper CLIN end date of 2023 and to distribute EMS training monies.

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.

Multiple sites and EMS services have reported staffing shortages which are impacting their participation in the study and have contributed to deficits during monitoring visits.

- Mt. Sinai:
  - Details surrounding their CAPA are noted above on page 5.
  - Data Entry Assistant identified, and training conducted in DEC-2021.
- New medical directors named at Vidant Eastcare and Wilson Co, NC.
- Site PI changes at Cook Co and Northwestern.
- PI left at Wash U and Vanderbilt.
- Coordinators replaced at Wash U and ECU.

Two EMS services for Wash U are currently not enrolling:

- St. Louis Fire is not enrolling due to lack of paramedics. Held conversations to determine if assistance can be provided to keep service in the study during their staffing crisis. At this time, it's unlikely that this agency will resume enrollments.
- Air Evac Missouri bases are not enrolling as they still have not onboarded a new EMS Medical Director. Medical Director was identified in SEP-2022 and enrollment will commence once they have been trained.

Vanderbilt closed to enrollment due to PI/EMS Medical Director not renewing the contract.

- Site will reopen when new PI is onboarded.

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

Delayed consents/notifications were found at one institution, and later, at several enrolling sites.

- See "Chicago-Mount Sinai Corrective And Preventative Action Plan (CAPA)" on page 5 for a full description of the issue.
  - LITES notified sIRB via an RNI on 03-MAR-2022.
  - sIRB notified DoD OHRO and the FDA.
- Delays in the consent/notification process for several patients enrolled at various sites were discovered during routine interim monitoring visits (additional details noted on page 6).
  - LITES notified sIRB via an RNI 05-AUG-2022
  - sIRB notified DoD OHRO and the FDA.
- Additional details on notification, approval and/or acknowledgment dates are noted above on page 5-6.

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 16

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

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

Nothing to report.

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

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

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

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

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

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

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

Year 3 Quad Chart: see page 16

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

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

AND
One Copy: Contract Specialist, 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-2022)

W81XWH-16-D-0024 / W81XWH-18-F-0426			
Department	**Personnel Name**	**UPitt Role**	**T0 % Effort**
Surgery	Gimbel, Elizabeth	Assistant Project Manager	65%
Emergency Medicine	Guyette, Francis X III	Co-PI	14%
Surgery	Hayes, Hannah E	Clinical Researcher II	29%
Emergency Medicine	Martin-Gill, Christian	Co-Investigator	53%
Surgery	Molinaro, Rachel	Project Manager	100%
Surgery	Owens, Logan	Data Mgmt. Coord.	33%
Surgery	Rayman, MaryAnne	Research II	33%
Epidemiology (GSPH)	Silfies, Laurie N	Systems Engineer IV	18%
Surgery	Skroczky, Hunter L	Health Professional III	50%
Surgery	Sperry, Jason L	PI	5%
Surgery	Stephenson, Joshua Paul	Data Entry Assistant	33%
Emergency Medicine	Weiss, Leonard S	Co-Investigator	28%
Epidemiology (GSPH)	Wisniewski, Stephen R	Co-PI	2%

YEAR 4 QUAD CHART

Linking Investigations in Trauma and Emergency Services – TO5

17052001-TO5/W81XWH-16-D-0024, W81XWH18F0426
Prehospital Airway Control Trial (PACT) - LITES Task Order 0005

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

STUDY AIMS

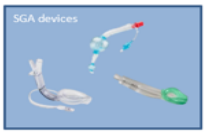
Compare strategies of definitive airway management of endotracheal intubation to supraglottic airways in trauma patients within the prehospital setting.

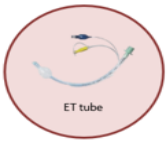
I. To compare the effect of initial endotracheal intubation (ETI) vs. initial supraglottic airway (SGA) on 24-hour survival after traumatic injury.

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

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

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





ACCOMPLISHMENTS

- ✓ Enrollment N (as of SEP-2022) = 974
- ✓ First interim reached 19-JUL-2022 (861 patients)!
- ✓ Step 2 & 3 of the Step-Wedge Design were reached and a total of six agencies stepped.
- ✓ USAMRDC, CDMRP, and OHRO conducted a successful site visit of the PACT study in JUN-2022.

Timeline and Cost

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

Updated: (University of Pittsburgh 14-OCT-2022)

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-2022
- Actual Expenditures: $3,863,752.93
- Scheduled Expenditures: $6,713,404.10