

CONTRACT NUMBER: W81XWH-16-D-0024

TITLE: Linking Investigations in Trauma and Emergency Services (LITES)

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Pittsburgh, PA 15213

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14. ABSTRACT Task Order 0001 is a prospective observational cohort that will have a limited data set from trauma registry data and electronic health records. Specific Aim one is to characterize the epidemiology of moderate and severe physical injury in the U.S. and across the LITES network and investigate regional variations of presenting characteristics, management practices and attributable outcomes. Specific Aim two is to determine and characterize injury related factors, management practices and trauma system factors resulting in or associated with preventable mortality.					
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1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

Task Order 0001 is a prospective observational cohort that will have a limited data set from trauma registry data and electronic health records. Specific Aim one is to characterize the epidemiology of moderate and severe physical injury in the U.S. and across the LITES network and investigate regional variations of presenting characteristics, management practices and attributable outcomes. Specific Aim two is to determine and characterize injury related factors, management practices and trauma system factors resulting in or associated with preventable mortality.

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

Trauma; Intensive/granular data: registry, pre-hospital, and in-hospital; linkage; ISS; surveillance

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 0001 is to characterize traumatic injury, current treatment, and outcomes, particularly for the moderate and severely injured in the US.

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.

- LITES Network website was developed and published live, including password protected research side; information about joining the LITES network as a clinical site was also added to the website.
- Successful kick-off meeting and three Expert Panel meetings/teleconferences held.
- All 8 network sites received initial IRB approval.
- 7 of the 8 participating sites were submitted to HRPO for initial approval.
- 5 of the 8 participating sites received initial HRPO approval.
- University of Pittsburgh participating site is currently collecting data from patients that meet inclusion criteria. There are currently 366 patients in the data set (JAN-MAR-2017). Patients will be added quarterly, with Quarter 2 data due to the DCC by 01-NOV-2017.

- Individual site pre- and in-hospital teleconferences were held. CCC/DCC discussed the pre-hospital variable list, identification, abstraction, and linkage across data sources.
 - There have been approximately 31 teleconferences held between all participating sites.
- There are several different EHRs utilized across EMS services. Dr. Frank Guyette has been working with all 7 pre-hospital EHRs to obtain sample queries to assist the networks participating sites. He has held approximately 22 calls.
 - 1 query is built and can be shared.
 - 5 queries are currently being built.
- Sample Cerner code (in-hospital EHR) developed.
- The Data Coordinating Center (DCC) analyzed, tested, purchased, and installed the reporting software.
- The DCC finalized the file transfer protocol and began transfer set up at sites.
 - 2 of the 8 participating sites have completed the test, others in various phases of progress.
- 5 of the 8 participating sites have fully executed contracts.

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 work with network sites to obtain fully executed contracts.

- Continue to work with HRPO to obtain remaining sites initial approval.
- Continue to work with clinical sites to set up secure data transfer. Three sites completed, others in various phases of progress.
- Continued review and refinement of data files received for content and format. Two quarters of data have been received from one site with additional sites pending only regulatory approvals before being able to make their initial data transfers..
- Setup of death causation and PPM determination modules on secure area of study website.
- Continued development of TO1 specific reports.
- Work with CCC to identify topics and associated data fields for preliminary analyses.
- Distribute LITES newsletter to all study personnel on a quarterly basis.
- Continue holding site & pre-hospital EHR teleconferences. CCC/DCC will discuss pre-hospital codes, data collection and linking across sources, and transfers.

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).

The linking of intensive pre-hospital and in-hospital granular data represents an innovative accomplishment which will promote further insight into trauma care and associated outcomes not available prior to this undertaking.

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.

- | |
|--|
| <ul style="list-style-type: none">▪ Centralizing: continue 1-on-1 site calls, quarterly data calls with all sites, FAQ on website.▪ Contracting delays: implement master contract scenario but unable to do at this time. |
|--|

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.

- | |
|--|
| <ul style="list-style-type: none">▪ Behind in expenditures due to the delay in activating sites.<ul style="list-style-type: none">- IRB approvals took longer than anticipated at some sites.- Delay in fully executed contracts so some sites cannot invoice for effort to-date. |
|--|

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

Not applicable to TO 0001

Significant changes in use or care of vertebrate animals

Not applicable to TO 0001

Significant changes in use of biohazards and/or select agents

Not applicable to TO 0001

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.)

See page 12

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), Dr. Shelley Jorgensen

Email: shelley.c.jorgensen.civ@mail.mil

LITES Project Personnel

	Department	Last Name	First Name	Middle Initial	Role	Current Effort Infrastructure	Current Effort TO1
1	Surgery	Early	Barbara	J	Program Administrator	85%	
2	Epidemiology (GSPH)	Fabio	Anthony		CO-Investigator	5%	
3	Emergency Medicine	Guyette	Francis	X	PI	20%	13.4%
4	Critical Care Medicine	Huang	David	T	CO-Investigator	2.5%	
5	Epidemiology (GSPH)	Kania	Michael	A	Systems Developer III	40%	
6	Epidemiology (GSPH)	Knopf	Steve	P	Systems Engineer IV	100%	
7	Epidemiology (GSPH)	Luther	James	F	Biostatistician IV	40%	
8	Emergency Medicine	Martin-Gill	Christian	H	CO-Investigator	10%	
9	Surgery	Mazzella	Carolyn	A	Financial Administrator	100%	
10	Neurosurgery	Okonkwo	David	O	CO-Investigator	2.5%	
11	Epidemiology (GSPH)	Rosario-Rivera	Bedda	L	CO-Investigator	5%	
12	Epidemiology (GSPH)	Silfies	Laurie	N	Systems Engineer IV	25.0%	
13	Surgery	Sperry	Jason	L	PI	5%	2.5%
14	IRB	Thomas	Carey	J	Central IRB Coordinator	50%	
15	Epidemiology (GSPH)	Wanovich	Renee		Administrative Assistant (temp)	50%	
16	Epidemiology (GSPH)	Wisniewski	Stephen	R	PI	2.5%	
17	Surgery	Zhu	Ying		Data Manager	50%	50%
	Epidemiology (GSPH)	Fair	Janet	A	Administrative Assistant IV	Retired DEC 31, 2016	
	Surgery	Fleck	Tyler	C	Research Administrator	Removed June 30, 2017	
	Epidemiology (GSPH)	Stillwell	Emily	E	Administrative Assistant IV	Removed May 31, 2017	

Running Personnel Updates:

Fullfilled TBN Financial position (DEC-16)

Fullfilled TBN IRB position (Jan-2017)

Fullfilled Data Manager position (Feb-17)

Janet Fair retired and replaced by E. Stillwell

Laurie Silfies reduced effort, Steve Knopf increase effort

Renee Wanovich will replace Emily Stillwell tempoary to support GPSH administratively

Tyler Fleck no longer on study (JUN-17)

Linking Investigations in Trauma and Emergency Services - T.O.#1

17052001-01/W81XWH-16-D-0024-001 LITES Task Order 001



PI: Jason Sperry MD MPH

Org: University of Pittsburgh Award Amount: \$10,842,112

Study Aims

- I. To characterize the epidemiology of moderate and severe physical injury in the U.S. and across the LITES network and investigate regional variations of presenting characteristics, management practices and attributable outcomes.
- II. To determine and characterize injury related factors, management practices and trauma system factors resulting in or associated with preventable mortality.

Approach

The LITES network will perform an inaugural, large, national, 5 year, prospective, multicenter observational cohort study. The study will consist of an initial 3 year initiative (6 month lead in, 2 year enrollment, 6 month analysis) followed by an interim analysis with the potential for data collection redirection.



- I. Epidemiology of Injury for Network
- II. Regional Variation
- III. Potentially Preventable Mortality

Patient Data Procurement for DCC from Jan 2017

n=366 1st quarter, n=588 2nd quarter

TOTAL= 954
(Pittsburgh data)

Accomplishments 4th quarter: Site IRB approvals; Sub Contract completion (majority); Site data extraction testing and execution; Central IRB organization

Timeline and Cost

Activities	CY	17	18	19	20
Startup, Hiring, IRB approval, Contracts, Central IRB organization, Initiation of data procurement/extraction					
0 thru 2 year enrollment, Interim analysis – 25,000 patients					
Enrollment 3-5 years – 50,000 patients					
Characterization of regional variation and potentially preventable mortality					
Estimated Budget (\$K)		\$2.2M	\$2.2M	\$2.2M	\$2.2M

Goals/Milestones

CY17 Goals – Network Startup and Data procurement/extraction

- ☒ Base Hiring; T.O.#1 IRB approval (Pittsburgh); Central IRB organization, sub-contract initiation
- ☒ Data extraction and procurement planning; Pittsburgh data capabilities
- ☒ Final site HRPO / IRB approval; Final sub-contract execution
- ☒ Site data extraction and procurement

CY18 Goals – Patient enrollment 10,000-15,000

- ☒ Begin characterization of regional variation and preventable mortality

CY19 Goal – Patient enrollment 30,000

- ☐ Characterization of regional variation and potentially preventable mortality

CY20 Goal – Patient enrollment 40,000

- ☐ Characterization of regional variation and potentially preventable mortality

Comments/Challenges/Issues/Concerns

- Progressing on schedule

Budget Expenditure to Date

Actual Expenditure To-Date: \$877,095.88 (reflected level reports up to 9/31/17)

Projected Expenditures: \$37,047.29 (reflects current known encumbrances on account for October period)

Updated: (University of Pittsburgh 10/19/17)