CONTRACT NUMBER: W81XWH-16-D-0024-001

TITLE: A prospective, multicenter, observational study to characterize the presentation, management and outcomes of moderate and severe physical injury in the United States

PRINCIPAL INVESTIGATOR: Jason Sperry

CONTRACTING ORGANIZATION: University of Pittsburgh
Pittsburgh, Pennsylvania 15213

REPORT DATE: OCT-2021

TYPE OF REPORT: Annual – Year 5

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

REPORT DOCUMENTATION PAGE

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OCT-2021	Annual Report	23-SEP-2020 to 22-SEP-2021

4. TITLE AND SUBTITLE

A prospective, multicenter, observational study to characterize the presentation, management and outcomes of moderate and severe physical injury in the United States

5a. CONTRACT NUMBER

5b. GRANT NUMBER
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5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Pittsburgh
Pittsburgh, Pennsylvania 15213

8. PERFORMING ORGANIZATION REPORT NUMBER

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

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

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

13. SUPPLEMENTARY NOTES

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.

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

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
Unclassified	Unclassified	Unclassified	Unclassified	14	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.

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.

Network Highlights:

- Successful virtual In Progress Review (IPR) meeting held on 01-DEC-2020!
- 4 new sites were accepted into the Network between SEP-2010 & SEP-2021.
  - There is a total of 35 sites in the LITES Network.
- The DCC distributed the LITES Quarterly Update newsletters to network personnel:
  - 2021 Q2 on 15-APR-2021
  - 2021 Q3 on 06-JUL-2021

Task Order 0001

- Network sites received Annual IRB Renewal approval and HRPO Continuing Review Acknowledgment.
- Interim Analysis Report (data through 2019 Q2) was sent to the DoD on 10-APR-2021.
- No Cost Extension (NCE) approval received and extends the research end date to 22-SEP-2023.
- No patients will be enrolled after 30-JUN-2021. The CCC/DCC requested sites to have all three sources of data uploaded through the end of 2021 Q2 by 30-SEP-2021.
- Op Memo #10 was distributed to sites on 08-JUN-2021: Close of Data Collection
- Generated and distributed weekly site status emails.
- CCC/DCC held quarterly calls with the Cerner & Epic sites.
- Continued to work directly with individual clinical site personnel to get data files set up in appropriate format for transfer and to resolve issues identified in transferred data.
- Spreadsheets summarizing each site's status for Cause of Death and PPM determinations were distributed by the DCC.
- Continued to monitor and hold Potentially Preventable Mortality (PPM) consensus calls with individual sites.

TOTAL UNIQUE IDs 68,633 | TOTAL RECORDS 171,294

TQIP DATA: 7/8 sites have uploaded TQIP data through 2021 Q1!

- 2021 Q1 outstanding: Louisville
- 2021 Q2: 5/8 sites have uploaded data

IN-HOSPITAL DATA: 7/8 sites have uploaded in-hospital data through 2021 Q1.

- 2021 Q1 outstanding: Louisville
- 2021 Q2: 4/8 sites have uploaded data

PRE-HOSPITAL DATA: 2017 Q1 through 2020 Q2 data submission have been received from all agencies!

- 2021 Q1: 12/17 sites have uploaded agency data
- 2021 Q2: 9/17 sites have uploaded agency data
- See table below for outstanding agency quarters
- BAYLOR: currently having a contract dispute w/ Houston Fire and it is unclear when they will get their 2020 Q3-Q4 & 2021 Q1-Q2 data.
- Oregon LifeFlight (EMS Charts): submissions are outstanding for all quarters; it is unlikely that we will obtain this query due to the study is reaching the end of its five-year contract.

SITE	SOURCE	2020 Q3 | 2020 Q4	2021 Q1 (due 01-AUG-2021)	2021 Q2 (due 30-SEP-2021)
Pittsburgh	STAT MedEvac	UP TO DATE	UP TO DATE	OUTSTANDING
	Pgh. EM			
	MutualAid Ambulance			
	St. Clair			
	Fayette EMS			
Houston	Houston Fire	UP TO DATE	Received - pending upload to main database	OUTSTANDING
	Life Flight	UP TO DATE	OUTSTANDING	OUTSTANDING
Arizona	Tucson Fire	UP TO DATE	UP TO DATE	Received - pending upload to main database
	AMR	UP TO DATE	UP TO DATE	Received - pending upload to main database
	LifeNet (AirMethods)	UP TO DATE	UP TO DATE	UP TO DATE
Louisville	LOU Metro	UP TO DATE	Received - pending	OUTSTANDING

			upload to main database	
	AirMethods	UP TO DATE	OUTSTANDING	OUTSTANDING
	Air Evac	UP TO DATE	OUTSTANDING	OUTSTANDING
Denver	Denver Health	UP TO DATE	Received - pending upload to main database	Received - pending upload to main database
	AirLife Denver	UP TO DATE	OUTSTANDING	OUTSTANDING
Oregon	AMR	UP TO DATE	Received - pending upload to main database	Received - pending upload to main database
	Metro West	UP TO DATE	Received - pending upload to main database	Received - pending upload to main database
Vanderbilt	Nashville Fire	UP TO DATE	UP TO DATE	Received - pending upload to main database
	LifeFlight	UP TO DATE	UP TO DATE	Received - pending upload to main database
	Air Evac	UP TO DATE	UP TO DATE	Received - pending upload to main database
Baylor	Houston Fire	OUTSTANDING	OUTSTANDING	OUTSTANDING
	Harris Co-Corps/Dist. 1	UP TO DATE	OUTSTANDING	OUTSTANDING

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to report.

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Nothing to report.

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

- Continue to hold quarterly calls with Cerner and Epic sites.
- Continued to hold Potentially Preventable Mortality (PPM) Teleconferences with TO1 Investigators.
- Continue to work directly with individual clinical site personnel to get data files set up in appropriate format for transfer and to resolve issues identified in transferred data.
- DCC to continue cleaning & harmonizing the data from all 3 sources for the final analysis dataset.
- Prepare In-Progress Review (IPR) presentation

Travel Reporting

Base: travel is anticipated for the next quarter (OCT-2021 to DEC-2021)

- In-Progress Review (IPR) Meeting (see table below)

TO1: no travel is anticipated for the next quarter (OCT-2021 to DEC-2021).

- Close-out visits will be conducted once data has been cleaned and harmonized.
- We anticipate these visits happening once the COVID-19 pandemic restrictions are lifted.

Cumulative to Billing Period: **30-SEP-2021**	**Travel Funds Budgeted**	**Cumulative Actual Spent**	**Remaining Balance**
	$122,125.00	$36,539.63	$85,585.37
Upcoming Travel for Quarter: **OCT-2021 to DEC-2021**	**Traveler Name**	**Destination/ Purpose**	**Estimated Date of Travel**
	Jason Sperry	Bethesda, MD/ IPR	17-DEC-2021
	Frank Guyette	Bethesda, MD/ IPR	17-DEC-2021
	Steve Wisniewski	Bethesda, MD/ IPR	17-DEC-2021
	Barbara Early	Bethesda, MD/ IPR	16-DEC-2021 to 17-DEC-2021
	Laura Vincent	Bethesda, MD/ IPR	16-DEC-2021 to 17-DEC-2021
	Meghan Buck	Bethesda, MD/ IPR	16-DEC-2021 to 17-DEC-2021
	Laurie Silfies [tentative]	Bethesda, MD/ IPR	16-DEC-2021 to 17-DEC-2021
	Michelle Dubovecky [tentative]	Bethesda, MD/ IPR	16-DEC-2021 to 17-DEC-2021

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.

- Centralizing data capture from individual site that use multiple methods of data collection.
- Inconsistencies in data submission formats.
- Linkage issues.
- Harmonization has taken longer than anticipated.

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.

- Prehospital agencies Patient Care Records (PCR) are transitioning so the CCC/DCC will need to validate data that's been uploaded from the new PCR.
- Prehospital agencies QI contacts change and identifying replacements cause major delays.

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.)*

Personnel listing: see page 13

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 14

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), Sandy Snyder
Email: sandy.j.snyder.civ@mail.mil

Personnel Listing (as of 31-AUG-2021)

Department	Pesonnel Name	Government Used Labor Category	UPitt Role	T0 % Effort
Surgery	Ardolino, Michelle	Financial Analyst I	Financial Administrator II	100%
Surgery	Desantes, Lisa	Central IRB Coordinator	Central IRB Coordinator	100%
Surgery	Dubovecky, Michele	Financial Analyst IV	Financial Administrator III	100%
Computing and Information	Frisch, Adam N	Physician Rsearcher	Physician Rsearcher	2%
Emergency Medicine	Guyette, Francis X III	Clinical Research Director	Co-PI	11%
Surgery	Hayes, Hannah E	Clinical Researcher II	Clinical Researcher II	10%
Computing and Information	He, Daquing	Physician Rsearcher (Natural Language)	Physician Rsearcher	20%
Critical Care Medicine	Huang, David Tom	Clinical Research Director	CO-Investigator	3%
Surgery	Jackson, Alan Richard	Database Adminstrator III	Data Manager	100%
Epidemiology (GSPH)	Kania, Michael A	Systems Developer III	Systems Developer III	40%
Epidemiology (GSPH)	Knopf, Steven Paul	Systems Engineer IV	Systems Engineer IV	100%
Computing and Information	Luo, Zhimeng	System Developer I (Web Applications Developer I)	GSR-PHD Regular Earnings	50%
Epidemiology (GSPH)	Luther, James Francis	Biostatistican IV	Biostatistican IV	25%
Emergency Medicine	Martin-Gill, Christian	Clinical Research Director	CO-Investigator	7%
Surgery	Merti, Alexandra K	Clinical Research Coordinator	Health Professional I	100%
Neurosurgery	Okonkwo, David O	Clinical Research Director	CO-Investigator	3%
Epidemiology (GSPH)	Over, Lisa Ann	Clinical Data Manager III	Clinical Data Manager III	50%
Epidemiology (GSPH)	Silfies, Laurie N	Systems Engineer IV	Systems Engineer IV	20%
Surgery	Sperry, Jason L	Clinical Research Director	PI	12.5%
Epidemiology (GSPH)	Stewart, Kathleen Mary	Administrative Assistant IV	Administrative Assistant IV	10%
Surgery	Vincent, Laura	Program Administrator	Program Administrator	100%
Computing and Information	Wang, Zhendong	System Developer I (Web Applications Developer I)	GSR-PHD Regular Earnings	100%
Epidemiology (GSPH)	Weller, Alison N	Clinical Data Manager III	Clinical Data Manager III	5%
Epidemiology (GSPH)	Wisniewski, Stephen R	Epidemologist	Co-PI	3%
Epidemiology (GSPH)	Zadorozny, Eva Vladi	Data Analyst	Temporary Employee	100%

YEAR 5 QUAD CHART

Linking Investigations in Trauma and Emergency Services – TO1

17052001-TO1/W81XWH-16-D-0024-0001 LITES Task Order 0001

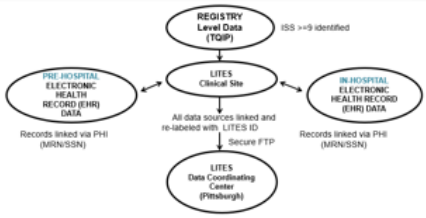
PI: Jason Sperry MD MPH **Org:** University of Pittsburgh **Award Amount:** $10,842,112

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.

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.



ACCOMPLISHMENTS

✓ No patient data to be collected after 30-JUN-2021; sites instructed to upload all three sources of data through the end of 2021 Q2 ASAP

Data count as of SEP-2021

Total unique IDs: 68,633 | Total records: 171,294

Timeline and Cost

Activities CY	17	18	19	20	21	22	23
Startup, Hiring, IRB approval, Contracts, IRB organization, Initiation of data procurement & extraction							
Enrollment 3-5 years							
Interim analysis							
Characterization of regional variation and potentially preventable mortality							
Data analysis and publication							
Estimated Budget ($M)	1.7	1.7	1.7	1.7	1.7	1.1	1.1

Updated: (University of Pittsburgh 06-OCT-2021)

Goals/Milestones

CY17 Goals – Network Startup and Data procurement/extraction
✓ Base Hiring; TO1 IRB approval; 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 | CY20 Goal – Patient enrollment 30,000
✓ Patient enrollment; interim analysis reached
CY21 Goal – Patient enrollment 40,000
✓ Interim Data Tables and Exec Summary submitted
CY22 | CY23 Goal
☐ Characterization of regional variation and potentially preventable mortality
☐ Data analysis and publication

Budget Expenditure to Date

- Actual Expenditure To-Date: $8,681,858 (reflects level reports up to 31-AUG -21).
- Current Month Expenditures: $225,301 (reflects account through AUG-2021 period).