

CONTRACT NUMBER: W81XWH-16-D-0024-0001

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, PA

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PREPARED FOR: U.S. Army Medical Research and Development Command
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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.					
15. SUBJECT TERMS Trauma; Intensive/granular data: registry, prehospital, and in-hospital; linkage; ISS; surveillance					
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1. INTRODUCTION:

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:

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

3. ACCOMPLISHMENTS:

What were the major goals of the project?

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?

- LITES Network website was developed (including password protected research side and information about joining the LITES Network).
- 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.
- There are several different EHRs utilized across EMS services. CCC worked with all 7 prehospital EHRs to obtain sample queries. Approximately 22 calls were conducted.
- Computer codes to automatically query in-hospital EHRs for TO1 variables were created:
 - In MAR-2017, the code for Cerner EHRs was developed and uploaded to the Document Library for sites to utilize.
 - In NOV-2018, the code for EPIC EHRs was developed and uploaded to the Document Library for sites to utilize.
- Data collection started (retrospectively) 01-JAN-2017 and continued prospectively as codes for automatic queries were developed.
- DCC refined Cause of Death and Potentially Preventable Mortality applications for the website.
- The DCC generated and distributed weekly site status emails throughout the course of the project.
- CCC/DCC conducted monthly rotating calls with the Cerner & Epic sites (approximately 38 calls were held). In 2021, Cerner & EPIC site calls were transitioned to being held quarterly.
- Over the course of the project, the DCC distributed ten Operation Memos to all study personnel.
- Interim Analysis (JAN-2017 data through 2019 Q2):
 - DCC cleaned & harmonized the data from all 3 sources for the interim analysis dataset. Data was locked on 30-JUN-2020.
 - Interim Analysis Report was sent to the DoD in APR-2021.
- In JAN-2020, codes to automatically query prehospital Patient Care Records (PCRs) for TO1 variables were created. This was completed for all six PCRs (EMS Charts, ImageTrend, ESO, MEDS, & Golden Hour).
 - Reports were modified over the course of the project to run on older software versions or include

	<p>data elements that were not initially captured.</p> <ul style="list-style-type: none"> ▪ Received modification in MAR-2022 to update the period of performance and the Wide Area Workflow (WAWF) Payment Point Of Contact. ▪ Publication Proposal/Data Request Submission Form was developed and made available for all Investigators.
<p>Year One SEP-2016 to SEP-2017</p>	<ul style="list-style-type: none"> ▪ All 8 participating sites received initial IRB approval locally. ▪ 5 of the 8 participating sites received initial HRPO approval. ▪ 5 of the 8 participating sites have fully executed contracts. ▪ CCC/DCC held individual site calls to discuss the prehospital variable list, identification, abstraction, and linkage across data sources. Approximately 31 calls were conducted between all sites. ▪ Sites were activated and data collection initiated as sites completed the onboarding process
<p>Year Two SEP-2017 to SEP-2018</p>	<ul style="list-style-type: none"> ▪ Data collection continued. ▪ All 8 participating sites received initial HRPO approval by OCT-2017. ▪ All 8 participating sites were activated between JAN-2017 and OCT-2017. ▪ All 8 participating sites had fully executed contracts by 29-NOV-2017. ▪ Sites requiring Annual IRB Renewal approval and HRPO Continuing Review Acknowledgment were received. <ul style="list-style-type: none"> - Approvals for the change in PI at Vanderbilt University were obtained in FEB-2018. ▪ DCC worked 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 trained participating Network sites to use the new data transfer process via the LITES website/CloudShare.
<p>Year Three SEP-2018 to SEP-2019</p>	<ul style="list-style-type: none"> ▪ Data collection continued. ▪ Sites received Annual IRB Renewal approval and HRPO Continuing Review Acknowledgment. ▪ DCC 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.
<p>Year Four SEP-2019 to SEP-2020</p>	<ul style="list-style-type: none"> ▪ Data collection continued. ▪ Sites received Annual IRB Renewal approval and HRPO Continuing Review Acknowledgment. <ul style="list-style-type: none"> - Approvals for the change in PI at Baylor College of Medicine were obtained in OCT-2019. ▪ DCC 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.
<p>Year Five SEP-2020 to SEP-2021</p>	<ul style="list-style-type: none"> ▪ Data collection continued. ▪ Sites received Annual IRB Renewal approval and HRPO Continuing Review Acknowledgment. <ul style="list-style-type: none"> - In OCT-2020, there was a lapse in IRB approval for Baylor College of Medicine due to miscommunication regarding the number of subjects enrolled over the course of the study vs. the last year. No research related activities were conducted during the lapse. - In JUL-2021, there was a lapse in IRB approval for Denver Health Medical Center due to extended communication with the local IRB regarding the total numbers. No research related activities were conducted during the lapse. ▪ DCC continued to work directly with individual clinical site personnel to get data

	<p>files set up in appropriate format for transfer and to resolve issues identified in transferred data.</p> <ul style="list-style-type: none"> ▪ No Cost Extension (NCE) approval received and extends the research end date to 22-SEP-2023. ▪ In AUG-2021, subcontract agreements to extend the research end date were distributed to participating sites.
<p>Year Six SEP-2021 to SEP-2022</p>	<ul style="list-style-type: none"> ▪ Data collection continued and all remaining quarters of data were loaded into the master database by JAN-2022. ▪ Sites received Annual IRB Renewal approval and OHRO (formally HRPO) Continuing Review Acknowledgment. <ul style="list-style-type: none"> - Some sites no longer need to submit OHRO CR as their IRB decided to follow the 2018 revised Common Rule. ▪ Through JAN-2022, DCC 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. ▪ DCC was notified that the Arizona site inadvertently submitted duplicate data for 158 patients using different LITES IDs. <ul style="list-style-type: none"> - DCC worked with the site to identify and remove IDs submitted in error. All analysis datasets were updated appropriately. ▪ OHRO Protocol Closures Underway (POP ended in SEP-2022) <ul style="list-style-type: none"> - Pending OHRO closure memos for the following submissions: Pittsburgh, Vanderbilt, Houston, Louisville, Arizona, Denver - Pending submission to OHRO: Baylor, OHSU

Data collection was from 01-JAN-2017 to 30-JUN-2021 – all data submitted!

Annual data submission numbers by site: see page 19

Total Unique IDs:	77,575	Prehospital patients:	39,828
Total Records:	191,773	In-hospital patients:	74,370

Participating Sites, EMS Agencies, and Data Sources

Site	TQIP	In-Hospital	EMS Agency	Patient Care Record
PITTSBURGH	✓	Cerner	STAT MedEvac	EMS Charts
			Pgh. Emergency Med	EMS Charts
			Mutual Aid Ambulance	EMS Charts
			St. Clair	EMS Charts
			Fayette EMS	EMS Charts
UT HOUSTON	✓	Cerner	Houston Fire	ImageTrend
			Life Flight	RescueNet/Zoll
ARIZONA	✓	Cerner	Tucson Fire	RescueNet/Zoll
			AMR	MEDS
			AirMethods	EMS Charts
LOUISVILLE	✓	Cerner	LOU Metro EMS	ESO
			AirMethods	EMS Charts
			Air Evac	ImageTrend
DENVER	✓	Epic	Denver Health	ESO
			AirLife Denver	Golden Hour
OREGON	✓	Epic	AMR	MEDS
			Metro West	RescueNet/Zoll
			Life Flight	EMS Charts

VANDERBILT	✓	Epic	Nashville Fire	ImageTrend	
			LifeFlight	EMS Charts	
			Air Evac	ImageTrend	
BAYLOR	✓	Epic	Houston Fire	ImageTrend	
			Harris County	ImageTrend	
Cause of Death (COD) and Potentially Preventable Mortality (PPM)					
<ul style="list-style-type: none"> ▪ DCC distributed Cause of Death/Potentially Preventable Mortality reports to clinical sites. <ul style="list-style-type: none"> - PPM consensus calls with TO1 Investigators were held as COD determinations were submitted. - To date, approximately 59 calls have been conducted. ▪ Sites are working on final Cause of Death determinations and PPM consensus calls will be held when Cause of Deaths have been completed. 					
▪ Pending COD and PPM determinations:			Pittsburgh, Vanderbilt		
▪ Pending PPM determinations:			Houston		
▪ COD and PPM determinations complete:			Louisville, Denver, Oregon, Baylor, Arizona		
COD	Not Reviewable	Reviewable	Preventable	Not Preventable	Pending
6,305	5,346	959	165	628	166
DCC is curating and analyzing data from all three data sources (TQIP, Prehospital, In-hospital)					
<ul style="list-style-type: none"> ▪ CCC/DCC continue to prioritize manuscript proposals submitted by Co-Investigators. ▪ Writing groups working on manuscripts (see “Publication Topics” below) <ul style="list-style-type: none"> - Different writing groups, depending on which co-I have the research question; sometimes collaborative across institutions if the same research question. - LITES DCC is doing statistical analyses. 					
TO 0001	Publication Topics			Status/Progress	
Primary Manuscript	Epidemiology of trauma/Pragmatic and early prediction of survival after trauma (Mortality Model)			Analysis on-going, manuscript under development	
Planned Analyses	Change in Shock Index			Finalizing Analysis, drafting manuscript	
	Pelvic Binders			Analysis on-going	
	Prehospital Time - Transfusion and Mortality			Analysis complete, finalizing manuscript	
	Tourniquets and transfusion requirements			Analysis on-going	
	Health Disparities			Analysis on-going	
	Time on Scene Impact in Penetrating Trauma			Analysis on-going	
	Intraosseous vs IV access			Under Development	
Prehospital Trauma Patient Volume & Outcomes			Finalizing Analysis, drafting manuscript		

What opportunities for training and professional development has the project provided?

Nothing to report.

How were the results disseminated to communities of interest?

See presentations below; additionally, publications forthcoming

What do you plan to do during the next reporting period to accomplish the goals?

<ul style="list-style-type: none"> ▪ Hold remaining Potentially Preventable Mortality (PPM) calls with Investigators. ▪ DCC to continue curating and analyzing the data from all 3 sources for the final analysis dataset. ▪ TO1 technical data to be sent to the DoD per Contract Data Requirements Lists (CDRLs) ▪ CCC/DCC continue to prioritize manuscript proposals submitted by Co-Investigators. ▪ Writing groups to continue working on manuscripts. ▪ Upon completion of the following, official closure memos will be distributed: <ul style="list-style-type: none"> - Data has been cleaned and harmonized. - PPM consensus calls have concluded. 			
Travel Reporting: No travel funds remaining for this Task Order			
Cumulative to Billing Period: 31-DEC-2022	Travel Funds Budgeted	Cumulative Actual Spent	Remaining Balance
Upcoming Travel for Quarter: JAN-2023 to MAR-2023	Traveler Name	Destination/ Purpose	Estimated Date of Travel
	N/A	N/A	N/A
Travel conducted over the course of the project:			
Year One SEP-2016 to SEP-2017	N/A	N/A	N/A
Year Two SEP-2017 to SEP-2018	Laurie Silfies Barbara Early Peter Adams Meghan Buck	Portland, OR SIV and IMV-01	16-JUL-2018
	Laurie Silfies Barbara Early Peter Adams Meghan Buck	Denver, CO SIV and IMV-01	30-JUL-2018
	Laurie Silfies	Houston, TX SIV and IMV-01	14-AUG-2018
Year Three SEP-2018 to SEP-2019	Laurie Silfies	Houston, TX SIV and IMV-01	12-DEC-2018
	Laurie Silfies	Tucson, AZ SIV and IMV-01	08-FEB-2019
	Laurie Silfies Elizabeth Gimbel	Louisville SIV and IMV-01	18-JUN-2019
Year Four SEP-2019 to SEP-2020	Frank Guyette Barbara Early Peter Adams Meghan Buck Joshua Hutton	Dallas, TX LITES Networking event held during AAST conference	19-20-SEP-2019
Year Five SEP-2020 to SEP-2021	N/A	N/A	N/A
Year Six SEP-2021 to SEP-2022	N/A	N/A	N/A

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

The linking of intensive prehospital 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?

Nothing to report to date, publications forthcoming

What was the impact on technology transfer?

Nothing to report.

What was the impact on society beyond science and technology?

Nothing to report.

5. CHANGES/PROBLEMS:

Changes in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

Year One – Year Two	<ul style="list-style-type: none">▪ Centralizing data capture from individual sites that use multiple methods of data collection.<ul style="list-style-type: none">- Held individual site calls and quarterly data calls with all sites.- FAQ developed and posted on website.▪ Delays in obtaining executed contracts with all sites.
Year Three	<ul style="list-style-type: none">▪ Centralizing data capture from individual sites that use multiple methods of data collection. Held individual site calls and quarterly data calls with all sites.▪ 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.▪ Continued to work with sites to identify possible solutions to issues found in transferred data files.<ul style="list-style-type: none">- Field names are inconsistent with data dictionaries.- Missing data.- Missing LITES IDs/local identifiers not removed.- Errors identified in linking datasets.- Inconsistencies in data submission formats.- Linkage issues.
Year Four – Year Five	<ul style="list-style-type: none">▪ Centralizing data capture from individual sites that use multiple methods of data collection. Held individual site calls and quarterly data calls with all sites. Also discussed:<ul style="list-style-type: none">- Inconsistencies in data submission formats.- Linkage issues.

	<ul style="list-style-type: none"> ▪ Harmonization has taken longer than anticipated.
Year Six/ Final	<ul style="list-style-type: none"> ▪ Delays in data submissions due to COVID staffing issues. Resolved in JAN-2022 ▪ Inconsistencies in data submission formats. Resolved in JAN-2022

Changes that had a significant impact on expenditures

Year One	<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.
Year Two	<ul style="list-style-type: none"> ▪ Nothing to report
Year Three – Year Five	<ul style="list-style-type: none"> ▪ Centralizing data capture from individual sites that use multiple methods of data collection. ▪ Harmonization has taken longer 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.
Year Six/ Final	<ul style="list-style-type: none"> ▪ Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report to date, publications forthcoming

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:

• **Publications, conference papers, and presentations**

Journal publications.

Nothing to report to date, publications forthcoming

Books or other non-periodical, one-time publications.

Nothing to report.

Other publications, conference papers and presentations.

In-Progress Review (IPR) Meetings (formally Expert Panel Committee Quarterly Update)	
▪ LITES Kick-Off Meeting	28-NOV-2016

▪ First Quarterly LITES Network Meeting Open Session	27-FEB-2017
▪ Second Quarterly LITES Network Meeting Open Session	25-MAY-2017
▪ Third Quarterly LITES Expert Panel Meeting	02-AUG-2017
▪ IPR Meeting	01-NOV-2017
▪ IPR Meeting	16-MAR-2018
▪ IPR Meeting	11-DEC-2018
▪ IPR Meeting	06-AUG-2019
▪ IPR Meeting	31-JAN-2020
▪ IPR Meeting	01-DEC-2020
▪ IPR Meeting	17-DEC-2021
▪ IPR Meeting	13-DEC-2022
<ul style="list-style-type: none"> ▪ Prehospital shock index and early clinical outcomes (interim dataset only) <ul style="list-style-type: none"> - 2020 MHSRS Meeting – Virtual - 2020 AAST Meeting – Virtual 	
<ul style="list-style-type: none"> ▪ Prehospital time following traumatic injury is independently associated with the need for in-hospital transfusion and early mortality for specific injury types (interim dataset only) <ul style="list-style-type: none"> - Abstract posted on MHSRS website in AUG-2021 – conference held virtually 	
<ul style="list-style-type: none"> ▪ Prehospital time following traumatic injury is independently associated with the need for in-hospital transfusion and early mortality for specific injury types (complete dataset) <ul style="list-style-type: none"> - Abstract presented at NAEMSP in JAN-2022 - Abstract presented at MHSRS on 13-SEP-2022 	
<ul style="list-style-type: none"> ▪ Prehospital Trauma Patient Volume & Outcomes <ul style="list-style-type: none"> - Presented at American College of Surgeons Committee on Trauma in OCT-2022 	

- **Website(s) or other Internet site(s)**

Nothing to report.

- **Technologies or techniques**

Nothing to report.

- **Inventions, patent applications, and/or licenses**

Nothing to report.

- **Other Products**

Nothing to report.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Final Personnel Listing (duration of project – completed): 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?

Nothing to report.

What other organizations were involved as partners?

Nothing to report.

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

Final Quad Chart: see page 18 (also attached)

9. APPENDICES:

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), Sandy Snyder

Email: sandy.j.snyder.civ@health.mil

Final Personnel Listing (duration of project – completed)

Final Personnel Listing (completed)			
W81XWH-16-D-0024-0001			
Department	Personnel Name	UPitt Role	T0 % Effort
Surgery	Aggarwal, Sarika	FICA-Paying Student	0%
Surgery	Ardolino, Michelle	Financial Administrator II	100%
Emergency Medicine	Barton, David John Jr	Assistant Professor	33%
Surgery	Blandon, Stephanie	FICA-Paying Student	0%
Surgery	Buck, Meghan	Staff Administrator I	100%
Surgery	Desantes, Lisa	Central IRB Coordinator	100%
Surgery	Dubovecky, Michele	Financial Administrator II	100%
Surgery	Early, Barbara	Program Administrator	85%
Epidemiology (GSPH)	Fabio, Anthony	CO-Investigator	5%
Computing and Information	Frisch, Adam	Physician Researcher	1%
Emergency Medicine	Guyette, Francis	PI	33%
Surgery	Hayes, Hannah	Clinical Researcher II	10%
Computing and Information	He, Daqing	Physician Researcher	
Critical Care Medicine	Huang, David	CO-Investigator	2%
Surgery	Jackson, Alan	Data Manager	50%
SCI-Informatics	Ji, Yuelu	Graduate Research Assistant	33%
Epidemiology (GSPH)	Kania, Michael	Systems Developer III	40%
Epidemiology (GSPH)	Knopf, Steve	Systems Engineer IV	100%
Computing and Information	Luo, Zhimeng	Graduate Research Assistant	33%
Epidemiology (GSPH)	Luther, James	Biostatistician IV	40%
Epidemiology (GSPH)	Macey-Kalcevic, Melody	Data Manager, Research V	50%
Emergency Medicine	Martin-Gill, Christian	CO-Investigator	10%
Surgery	Mazzella, Carolyn	Financial Administrator	100%
Surgery	McKinnon, Lisa	FICA-Paying Student	0%
Surgery	Mclaughlin, Wesley	Temporary Employee	0%
Surgery	Merti, Alexandra	Health Professional I	100%
Epidemiology (GSPH)	O'Neal, Scott	Coordinator	10%
Neurosurgery	Okonkwo, David	CO-Investigator	1%
Epidemiology (GSPH)	Over, Lisa	Clinical Data Manager, Research III	50%
Surgery	Phillips, Kaitlin	FICA-Paying Student	0%
Epidemiology (GSPH)	Rosario-Rivera, Bedda	CO-Investigator	5%
Epidemiology (GSPH)	Silfies, Laurie	Systems Engineer IV	25%
Surgery	Sperry, Jason	PI	3%
Surgery	Stephenson, Joshua	Temporary Employee	0%
Epidemiology (GSPH)	Stewart, Mary	Administrative Assistant IV	50%
IRB	Thomas, Carey	Central IRB Coordinator	50%
Surgery	Vincent, Laura	Program Administrator	100%
Computing and Information	Wang, Zhendong	Systems Developer I	100%
Epidemiology (GSPH)	Wanovich, Renee	Administrative Assistant (temp)	50%
Epidemiology (GSPH)	Weller, Allison	Clinical Data Manager, Research III	5%
Epidemiology (GSPH)	Wisniewski, Stephen	PI	3%
Epidemiology (GSPH)	Zadorozny, Eva	Data Analyst	100%
Surgery	Zhu, Ying	Data Manager	50%

FINAL 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

Total Unique IDs: 77,575 Pre-hospital pts.: 39,828
 Total Records: 191,773 In-hospital pts.: 74,370

- ✓ Data collection was from 01JAN2017 to 30JUN2021
- ✓ DCC is curating and analyzing data from all three data sources (trauma hospital, and non-hospital)- working on primary analysis.
- ✓ Potentially Preventable Mortality (PPM) reviews completed: Louisville, Denver, Oregon, Arizona, Baylor- 3 sites remain.
- ✓ Abstract accepted for oral presentation at MHSRS; presented on 06 SEP 2022!
Prehospital time following traumatic injury is independently associated with the need for hospital transfusion and early mortality for specific injury type

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 13JAN-2023)

Goals/Milestones

- CY17 Goals– Network Startup and Data procurement/extraction**
- ✓ Base Hiring; TO1 IRB approval; Central IRB organization, subcontract initiation
 - ✓ Data extraction and procurement planning; Pittsburgh data capabilities
 - ✓ Final site HRPO / IRB approval; Final subcontract execution
 - ✓ Site data extraction and procurement
- CY18 Goals– Patient enrollment 10,000/5,000**
- ✓ 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 compared to Actual thru 30DEC-2022

- Actual Expenditure: \$10,842,111.60
- Scheduled Expenditure: Invoicing complete

DATA COUNT
Annual Data Submissions (by site)
01-JAN-2017 to 30-JUN-2021

SITE	SOURCE	2017	2018	2019	2020	2021	TOTAL
PITTSBURGH	TQIP	2,148	2,253	2,038	1,928	976	9,343
	Prehospital	2,148	2,251	2,035	1,894	917	9,245
	In-Hospital	2,147	2,251	2,037	1,925	973	9,333
UT HOUSTON	TQIP	3,316	3,213	3,595	4,745	2,537	17,406
	Prehospital	1,219	1,282	1,486	2,202	1,182	7,371
	In-Hospital	3,307	3,211	3,587	4,733	539	15,377
ARIZONA	TQIP	1,654	1,666	1,887	1,834	830	7,871
	Prehospital	1,452	905	986	1,000	474	4,817
	In-Hospital	1,640	1,664	1,885	1,834	830	7,853
LOUISVILLE	TQIP	2,233	2,250	2,305	2,573	1,287	10,648
	Prehospital	716	910	896	1,058	452	4,032
	In-Hospital	2,229	2,247	2,302	2,564	1,283	10,625
DENVER HEALTH	TQIP	1,347	1,465	1,400	1,530	763	6,505
	Prehospital	239	873	717	667	332	2,828
	In-Hospital	1,347	1,465	1,400	1,529	763	6,504
OREGON	TQIP	1,283	1,464	1,394	1,404	363	5,908
	Prehospital	687	841	759	731	235	3,253
	In-Hospital	1,253	1,438	1,376	1,403	363	5,833
VANDERBILT	TQIP	3,108	3,266	3,310	3,560	1,962	15,206
	Prehospital	1,312	1,083	1,263	1,309	682	5,649
	In-Hospital	2,819	3,181	3,171	3,396	1,652	14,219
BAYLOR	TQIP	921	956	1,057	1,166	588	4,688
	Prehospital	645	477	513	669	329	2,633
	In-Hospital	887	954	1,047	1,154	584	4,626
Total Unique IDs:							77,575
Prehospital patients:							39,828
In-hospital patients:							74,370
Total Records:							191,773