AWARD NUMBER:	W81XWH-13-2-0080
TITLE:	Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP trial) - TACR
PRINCIPAL INVESTIGATOR:	Jason L. Sperry, MD, MPH
RECIPIENT:	University of Pittsburgh, Pennsylvania 15213
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TYPE OF REPORT:	Annual Report
PREPARED FOR:	U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

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Study of Tranexamic Acid During Air Medical Prehospital Transport Trial (STAAMP trial) - TACR

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5b. GRANT NUMBER
W81XWH-13-2-0080

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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

University of Pittsburgh
Pittsburgh, Pennsylvania 15213

8. PERFORMING ORGANIZATION REPORT

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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

Multi-center, prospective, randomized, blinded, controlled interventional trial focusing on patients with concern for bleeding who are transported via medical transport to definitive care.

15. SUBJECT TERMS
Prehospital; Tranexamic acid

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
U	U	U	UU	7	**19b. TELEPHONE NUMBER** *(include area code)*

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1. **INTRODUCTION:**
   - The primary hypothesis is that the prehospital infusion of tranexamic acid in patients at risk for bleeding will reduce the incidence of 30-day mortality. The secondary hypotheses include that prehospital tranexamic acid will reduce the incidence of hyperfibrinolysis, acute lung injury, multiple organ failure, nosocomial infection, mortality, early seizures, pulmonary embolism and early resuscitation needs, reduce or prevent the early coagulopathy as demonstrated by improving presenting INR and rapid thromboelastography parameters, reduce the early inflammatory response, plasmin levels, leukocyte, platelet and complement activation, and determine the optimal dosing of tranexamic acid post-injury.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).
   - Prehospital; Tranexamic acid

3. **OVERALL PROJECT SUMMARY:** Summarize the progress during appropriate reporting period (single annual or comprehensive final). This section of the report shall be in direct alignment with respect to each task outlined in the approved SOW in a summary of Current Objectives, and a summary of Results, Progress and Accomplishments with Discussion. Key methodology used during the reporting period, including a description of any changes to originally proposed methods, shall be summarized. Data supporting research conclusions, in the form of figures and/or tables, shall be embedded in the text, appended, or referenced to appended manuscripts. Actual or anticipated problems or delays and actions or plans to resolve them shall be included. Additionally, any changes in approach and reasons for these changes shall be reported. **Any change that is substantially different from the original approved SOW (e.g., new or modified tasks, objectives, experiments, etc.) requires review by the Grants Officer's Representative and final approval by USAMRAA Grants Officer through an award modification prior to initiating any changes.**

SITE	PROGRESS	PENDING
Pittsburgh Coordinating Center	- Conducted the final review of data and the dataset was locked on 17-MAR-2020! - Received IRB Annual Renewal approval on 29-APR-2020. - Received HRPO Continuing Review approval on 30-JUN-2020.	
Pittsburgh Site	- Closed to enrollment on 31-OCT-2019. - Received IRB Annual Renewal approval on 27-MAY-2020. - Received HRPO Continuing Review approval on 30-JUN-2020.	
San Antonio Site	- Received IRB Annual Renewal approval on 17-JAN-2020. - Submitted for HRPO Continuing Review on 10-MAR-2020.	Pending 2020 HRPO ackn. of CR
Arizona Site	- Received HRPO Continuing Review approval on 09-OCT-2019. - Received IRB Annual Renewal approval on 06-AUG-2020. - Submitted for HRPO Continuing Review on 25-AUG-2020.	Pending 2020 HRPO ackn. of CR
Utah Site	- Received HRPO Continuing Review approval on 13-OCT-2019. - Received IRB Annual Renewal approval on 24-JUN-2020. - Submitted for HRPO Continuing Review on 26-JUN-2020.	Pending 2020 HRPO ackn. of CR

4. **KEY RESEARCH ACCOMPLISHMENTS:** Bulleted list of key research accomplishments emanating from this research. Project milestones, such as simply completing proposed experiments, are not acceptable as key research accomplishments. Key research accomplishments are those that have

contributed to the major goals and objectives and that have potential impact on the research field.

- Final DSMB meeting was held on 09-MAR-2020.
    - The board voted to accept the final trial data and for the study team to proceed with closeout and publications.
- No Cost Extension (NCE) approval received! (modification for the 2020 extension which extends the research end date to 29-SEP-2021 is attached).

5. CONCLUSION: Summarize the importance and/or implications with respect to medical and /or military significance of the completed research including distinctive contributions, innovations, or changes in practice or behavior that has come about as a result of the project. A brief description of future plans to accomplish the goals and objectives shall also be included.

- The study concluded that for injured patients at risk of hemorrhage, prehospital tranexamic acid did not result in a significant lower rate of 30-day mortality. No differences were found for any of the prespecified ancillary outcomes. Rates of venous thromboembolism, seizures or adverse events including arterial thrombotic complications did not differ between treatment groups. Prespecified dosing regimen and post-hoc subgroup analyses demonstrates prehospital TXA is associated with significantly lower 30-day mortality.

- The administration of prehospital tranexamic acid during air medical or ground transport is safe and can be provided to patients at risk of hemorrhage in the prehospital setting and is associated with survival in specific subgroups of patients.

Future Plans:

- Secondary analysis of samples
- Developed platform to requesting a data set.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

a. List all manuscripts submitted for publication during the period covered by this report resulting from this project. Include those in the categories of lay press, peer-reviewed scientific journals, invited articles, and abstracts. Each entry shall include the author(s), article title, journal name, book title, editors(s), publisher, volume number, page number(s), date, DOI, PMID, and/or ISBN.

(1) Lay Press: ***Nothing to report***

(2) Peer-Reviewed Scientific Journals:

- The STAAMP study manuscript was formally accepted in JAMA Surgery in JUN-2020. Early release expected in OCT-2020.

(3) Invited Articles: ***Nothing to report***

(4) Abstracts:

- Abstract accepted for Oral Presentation at the 2020 MHSRS (later conducted virtually due to the pandemic) > Tranexamic Acid During Prehospital Transport In Patients At Risk of Hemorrhage Following Injury: A Randomized, Double-Blind, Phase 3, Multicenter, Placebo-Controlled, Superiority Trial

b. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.

- STAAMP was accepted to be presented at the 2020 American College of Surgeons meeting for late breaking clinical trials presentations.

7. **INVENTIONS, PATENTS AND LICENSES:** List all inventions made and patents and licenses applied for and/or issued. Each entry shall include the inventor(s), invention title, patent application number, filing date, patent number if issued, patent issued date, national, or international.
   - ***Nothing to report***

8. **REPORTABLE OUTCOMES:** Provide a list of reportable outcomes that have resulted from this research. 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. This list may include development of prototypes, computer programs and/or software (such as databases and animal models, etc.) or similar products that may be commercialized.

   - The study concluded that for injured patients at risk of hemorrhage, prehospital tranexamic acid did not result in a significant lower rate of 30-day mortality. No differences were found for any of the prespecified ancillary outcomes. Rates of venous thromboembolism, seizures or adverse events including arterial thrombotic complications did not differ between treatment groups. Prespecified dosing regimen and post-hoc subgroup analyses demonstrates prehospital TXA is associated with significantly lower 30-day mortality.

   - The administration of prehospital tranexamic acid during air medical or ground transport is safe and can be provided to patients at risk of hemorrhage in the prehospital setting and is associated with survival in specific subgroups of patients.

9. **OTHER ACHIEVEMENTS:** This list may include degrees obtained that are supported by this award, development of cell lines, tissue or serum repositories, funding applied for based on work supported by this award, and employment or research opportunities applied for and/or received based on experience/training supported by this award.
   - ***Nothing to report***

   For each section, 4 through 9, if there is no reportable outcome, state “Nothing to report.”

10. **REFERENCES:** List all references pertinent to the report using a standard journal format (i.e., format used in *Science*, *Military Medicine*, etc.).

11. **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.

NOTE:

TRAINING OR FELLOWSHIP AWARDS: For training or fellowship awards, in addition to the elements outlined above, include a brief description of opportunities for training

and professional development. Training activities may include, for example, courses or one-on-one work with a mentor. Professional development activities may include workshops, conferences, seminars, and study groups.

- ***Nothing to report***

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: