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AWARD NUMBER: W81XWH-16-2-0055

TITLE: Evaluation of the Effectiveness of the Burn Navigator in Improving Resuscitation Outcomes

PRINCIPAL INVESTIGATOR: Jose Salinas, PhD

RECIPIENT: American Burn Association

REPORT DATE: OCT 2019

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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Jose Salinas, PhD

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American Burn Association, Chicago, IL
USAISR, Fort Sam Houston

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Approved for public release; distribution is unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The goal of this study is to validate the Burn Navigator as an effective decision support tool in acute burn resuscitation by demonstrating that total intravenous fluids infused during resuscitation is an adequate amount to prevent complication associated with dehydration/under-perfusion while avoiding the consequences of giving too much intravenous fluid in the acute phase after burn injury.

15. SUBJECT TERMS

Burn resuscitation, decision-support

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(Include area code)*

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TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

The goal of this study is to validate the Burn Navigator as an effective decision support tool in acute burn resuscitation by demonstrating that total intravenous fluids infused during resuscitation is an adequate amount to prevent complication associated with dehydration/under-perfusion while avoiding the consequences of giving too much intravenous fluid in the acute phase after burn injury.

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

Burn resuscitation, decision-support

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

Objective 1: Describe Burn Navigator resuscitations and build a comprehensive database of Burn Navigator data Objective 2: Assess resuscitation outcomes from the Burn Navigator and compare burn center differences in resuscitation outcomes. Objective 3: Harmonize the comprehensive Burn Navigator database with other ABA studies in order to obtain a common dataset to evaluate the efficacy of the Burn Navigator. Task 1: Prepare regulatory documents and research protocol – core protocol approved by IRB on 31AUG2017 Task 2: Build comprehensive Burn Navigator database (e.g. retrospective and prospective data collection) Task 3: Analyze Burn Navigator database to assess association between resuscitation volumes and outcomes of interest

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.

Core protocol was approved 31AUG2017.

1. All 5 sites have enrolled subjects throughout this past year.

2. Participating site---UTMB: All UTMB Burn Research was placed on suspension by the site's Provost as of 04 Dec 2018 (not related to Burn Navigator study) and site PI (Dr. Kramer) sent HRPO (Katelyn Gibbs) notification of this suspension on 08 Jan 2019, along with completion of requested documentation. Site received local IRB closure letter on 17 July 2019. UTMB's access to their BN data in REDCap was blocked. As of 18 Sept 2018, UTMB's PI did update lead site regarding completion of audit and how they are resubmitting Burn Navigator protocol to the UTMB IRB for re-approval for this reporting period. Once local IRB approval received, lead site will submit to HRPO.

3. Bi-monthly (every other month) scheduled site research coordinators, ABA, DCC, and Lead site teleconferences started on 06 JUN 18. We have had a total of 5 teleconferences (19DEC18, 06FEB19, 05JUN19, 07AUG19, and 02OCT19 this past year of reporting. Ongoing discussions/training on the use of the Burn Navigator Data Tool continue during these teleconferences.

4. As of 02OCT19, the following are enrollment numbers and data completion per site:

Site	Retrospective Enrolled	Prospective Enrolled	Unidentified Enrolled
USAISR	50	39	0
Arizona Burn Center	16	25	0
UTMB_Galveston	8	8	0
UTSW_Parkland	0	11	0
Washington_Harborview	35	60	0
Total Enrolled Per Section	**109**	**143**	**0**

Total Enrolled	**252**

REDCap and data management: Total w/complete data:230

Site	# of Subject Completed Data entered in RedCap	# of Subject Data Incomplete/Queries Pending
USAISR	89	2
Arizona Burn Center	31	10
UTMB_Galveston	11	5
UTSW_Parkland	9	2
Washington_Harborview	90	12

Target required for clinical significance: 300 (150 retrospective, 150 prospective) between 5 sites

Target approved for clinical significance: 300 (between 5 sites)

5. Reporting amendments submitted to MRMC IRB for this last year:

Amendment #6 – For USAISR Site-specific protocol for Version 6.0, dated 10 October 2018 for addition of 2 new coordinators and removal of 2 study team members. Approval received 13 November 2018.

Amendment #6 – Core Protocol for Version 5, dated 30 September 2019 for addition of new PI for UTSW and revising enrollment numbers to 300 total (to include prospective and retrospective) from 5 centers. Some sites may enroll more than 100 due to some sites not able to enroll enough as expected. Still pending IRBO and HRPO approval. This amendment was sent to USAMRMC IRB on 08 October 2019.

Amendment #7 – For USAISR Site-specific protocol for Version 7.0, dated 12 June 2019 for personnel changes and minor administrative updates. Approval received 29 August 2019.

Amendment #8 – For USAISR Site-specific protocol for Version 8.0, dated 12 September 2019 for minor administrative updates and personnel changes. This amendment was sent to USAMRMC IRB on 12 September 2019 and still pending approval at this time.

6. Our 3rd Investigator's meeting was held at the Annual ABA conference in April 2019 in Las Vegas, NV.

7. USAISR research team is planning a site visit for re-training on Core Protocol and Burn Navigator data extraction for staff due to new PI and personnel on October 28, 2019 with UTSW.

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.

To have at least 98% complete data in REDCap for all enrolled subjects, including adding a goal of 285 subjects enrolled (overall). We also plan to continue bi-monthly teleconferences with all participating sites, ABA, and DCC.

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

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

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

Nothing to report.

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

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

Nothing to report.

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

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

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

Nothing to report.

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

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

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

Nothing to report.

5. **CHANGES/PROBLEMS:** The Project Director/Principal Investigator (PD/PI) is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer 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.

A No Cost Extension and a new Statement of Work (with minimal changes) was approved and effective for another year of Period of Performance on 01 Sept 2019-29 Sept 2020.

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.

IRB delays continued to be addressed at higher levels in order to prevent in the future.

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.

Nothing to report.

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

Nothing to report.

Significant changes in use or care of vertebrate animals.

Not applicable.

Significant changes in use of biohazards and/or select agents

Not applicable.

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. In addition to a description of the technologies or techniques, describe how they will be 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. State whether an application is provisional or non-provisional and indicate the application number. 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;*
  - *biospecimen 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).*

Name: *Jose Salinas*
Project Role: *Principal Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0002-6368-6375*
Nearest person month worked: *No change*

Contribution to Project: *Responsible for overall conduct of study, study design, data analysis, and preparation of manuscripts*

Name: *Julie Rizzo*
Project Role: *Associate Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0002-4066-7331*
Nearest person month worked: *No Change*
Contribution to Project: *Serve as a resource to the PI, study design, data analysis, and preparation of manuscripts*

Name: *Maria Serio-Melvin*
Project Role: *Associate Investigator*
Researcher Identifier (e.g. ORCID ID): *0000-0001-9084-1222*
Nearest person month worked: *No Change*
Contribution to Project: *Serve as a resource to the PI, study design, data analysis, and preparation of manuscripts*

Name: *Elsa Coates*
Project Role: *Clinical Research Coordinator*
Researcher Identifier (e.g. ORCID ID): *N/A*
Nearest person month worked: *No change*
Contribution to Project: *Responsible for daily efficient functioning of study, assist in the preparation of progress reports, and maintaining all regulatory documents*

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 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.