AWARD NUMBER: W81XWH-12-1-0550

TITLE: Early ICU Standardized Rehabilitation Therapy for the Critically Injured Burn Patient

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REPORT DATE: October 2017

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2017	Annual	20Sep2016 - 19Sep2017

4. TITLE AND SUBTITLE
Early ICU Standardized Rehabilitation Therapy for the Critically Injured Burn Patient

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0550

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)

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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

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

This project was originally funded in order to conduct a multicenter, randomized controlled trial to determine whether early ICU rehabilitation, for Burn Intensive Care Unit (BICU) patients, would decrease hospital length of stay. The original protocol specified fifty subjects to be randomized at each of three sites for a total of 150 subjects. After twenty-three study subjects had been enrolled and the outpatient phase of testing was instituted, new data from a similar study was published in a medical ICU population that caused great discussion across the investigators. The results of that study in combination with the patient care delivery pattern within the original design of this study caused a shift in focus of this study. The original study was deemed phase I and closed. The second phase proposed to examine medical records within a large national hospital database to identify optimal care delivery patters. Minimizing the duration of immobilization of patients and developing strategies to lessen its impact are the goals of the second phase.

15. SUBJECT TERMS

Burn Injury, Critical Care, Intensive Care, Standardized Rehabilitation Therapy

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	15	19b. TELEPHONE NUMBER *(include area code)*

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1. INTRODUCTION:

This project was originally funded in order to conduct a multicenter, randomized controlled trial to determine whether early ICU rehabilitation, for Burn Intensive Care Unit (BICU) patients, would decrease hospital length of stay. The original protocol specified fifty subjects to be randomized at each of three sites for a total of 150 subjects. Study start-up was initiated in Year 1 and all sites began to enroll patients. Twenty-three study subjects had been enrolled. Out-patient visits during post-enrollment, post-hospital discharge phase of the study were also initiated and the outpatient phase of testing was instituted. This study however did receive great discussion across the investigators due to a recently completed similar study that was administered within a medical ICU population. The results of that study in combination with the patient care delivery pattern of within the original design of this study caused a shift in focus of this study. The original study was deemed phase I and closed. The second phase proposed to examine medical records within a large national hospital database to identify optimal care delivery patterns. Minimizing the duration of immobilization of patients and developing strategies to lessen its impact are the goals of the second phase.

2. KEYWORDS:

Burn Injury, Critical Care, Intensive Care, Standardized Rehabilitation Therapy

3. ACCOMPLISHMENTS:

What were the major goals of the project?

- Award transferred to the University of Kentucky- completed May 2016
- All IRB and HRPO obligations were met- completed November 2016
- All subcontract sites had working relationship with the University of Kentucky- completed May 2017
- Data refinement and analysis of Phase I- 75% completed
- Research protocol for Phase II prepared and refined- completed June 2017
- Evaluate retrospective data and report findings- 75% completed

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.

A clinical study was undertaken and initiated. Burn Patients were enrolled until the point the investigators halted the study for worry about efficacy given the new reports available from other studies since the initiation of the Burn Patient Rehabilitation study

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

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?

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.

Nothing to Report.

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.

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.

Nothing to Report.

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.

No items to report that impacted expenditures.

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.

Nothing to Report.

Significant changes in use of biohazards and/or select agents

Nothing to Report.

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.*

There is a clinical study patient database held currently at Wake Forest School of Medicine.

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: Peter Morris, M.D.

Project Role: PI

Nearest person month worked: 1

Contribution to Project: Dr. Morris has led the project, created and refined the protocol, and initiated discussion among the team to facilitate the progression of the project.

Funding Support: NIH, FDA

Name: Bradley Freeman, M.D.

Project Role: Site-I

Nearest person month worked: 1

Contribution to Project: Dr. Freeman assists in the protocol creation and refinement process for phase II of the award and is involved in discussions with the database contacts regarding the necessary variables to extract.

Name: Bruce Cairns, M.D.

Project Role: Site-I

Nearest person month worked: 1

Contribution to Project: Dr. Cairns has managed the data from Phase I of this trial for his site.

Name: Michael Berry, Ph.D.

Project Role: Site-I

Nearest person month worked: 1

Contribution to Project: Dr. Berry has managed the data from Phase I of this trial at his site.

Name: James Holmes, M.D.

Project Role: Site-I

Nearest person month worked: 1

Contribution to Project: Dr. Holmes has managed the data from Phase I of this trial at his site.

Name: Douglas Case, Ph.D.

Project Role: Site-I

Nearest person month worked: 1

Contribution to project: Dr. Case has provided data management guidance and additional information for statistical analysis regarding Phase I of the project.

Name: Evan Cassity, M.S.

Project Role: Project Manager

Nearest person month worked: 3

Contribution to Project: Mr. Cassity has been responsible for organizing all meetings, managing financial and administrative tasks, communicating with sites, and ensuring all necessary HRPO and IRB tasks are completed.

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?

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.*

Washington University in St. Louis
St. Louis, Missouri
Collaboration

University of North Carolina- Chapel Hill
Chapel Hill, North Carolina
Collaboration

Wake Forest University
Winston-Salem, North Carolina
Collaboration

Wake Forest University Health Sciences
Winston-Salem, North Caroline
Collaboration

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

9. APPENDICES: N/A