AWARD NUMBER: W81XWH-21-1-0051

TITLE: Addressing Post-Intensive Care Syndrome Among Survivors of COVID (APICS-COVID)

PRINCIPAL INVESTIGATOR: James C. Jackson, PsyD

CONTRACTING ORGANIZATION: Vanderbuilt University, Nashville, TN

REPORT DATE: February 2022

TYPE OF REPORT: Annual

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

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
January 2022	Annual	15Jan2021-14Jan2022

4. TITLE AND SUBTITLE

Addressing Post-Intensive Care Syndrome Among Survivors of COVID (APICS-COVID)

5a. CONTRACT NUMBER
W81XWH-21-1-0051

5b. GRANT NUMBER
PR202630P1

6. AUTHOR(S)
James C. Jackson

E-Mail: james.c.jackson@vumc.org

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

VANDERBILT UNIVERSITY MEDICAL CENTER
VUMC
1161 21ST AVE S STE D3300 MCN
NASHVILLE TN 37232-0011

8. PERFORMING ORGANIZATION REPORT NUMBER

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

U.S. Army Medical Research and Development 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

APICS-COVID seeks to address a key clinical and operational knowledge gap by defining patterns of unmet needs, resource utilization, readmissions, and long-term functional outcomes among ICU survivors in the age of COVID-19, allowing direct knowledge of COVID-19 patterns as well as comparison with the APICS-01 cohort, which has nearly completed enrollment with identical methodology, to allow comparisons. In the first year of award, APICS-COVID initiated enrollment and data collection ahead of schedule. The study team has started following patients through 6 months of follow-up. For the next study period we will continue patient enrollment and data collection.

15. SUBJECT TERMS

Acute Lung Injury, Recovery after Clinical Illness, Cohort Study

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRDC
Unclassified	Unclassified	Unclassified	Unclassified	12	19b. TELEPHONE NUMBER *(include area code)*

TABLE OF CONTENTS

1. INTRODUCTION:

The overall proposed approach is to generate an observational cohort and use pseudo-randomization (inverse probability of treatment weighting) to interrogate the relationship between unmet needs and hospital readmissions. This will occur in a multicenter cohort of patients with respiratory failure due to COVID-19 (as well as COVID-19 "bystanders," patients who have acute respiratory failure during the pandemic not due to the SARS-CoV-2 virus) that we anticipate will usefully reflect the experience of service members and veterans.

2. KEYWORDS:

Acute Lung Injury, Long-term Outcomes, Intensive Care, Recovery from Illness/Injury

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Major Task 1: Prepare Study for Data Collection and Execution. Major Task 1 has been completed ahead of schedule. All subtasks have been completed ahead of schedule.

Major Task 2: Patient Enrollment and Data Collection. We initiated enrollment ahead of schedule and as of January 15, 2022 we have enrolled 139 of 200 (70%) patients across all sites. All the investigator meetings are happening on-time and consistently. The study team continues to follow patients through 6-month follow ups. All subtasks are being completed on time or ahead of schedule.

Major Task 3: Data Analysis and Dissemination. The work under this task will begin in year 3, once enrollment and follow-up are completed.

What was accomplished under these goals?

Major Activities: Primary activities in this study period were preparing study for data collection and execution. As indicated above, these goals were achieved ahead of schedule. Formal findings will be reported after enrollment is completed.

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

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?

For the next study period, we will continue patient enrollment and data collection.

4. **IMPACT:**

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

Nothing to Report

What was the impact on other disciplines?

Nothing to Report

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

We are completing our milestones and enrollment ahead of schedule. We do not anticipate problems at this stage.

Changes that had a significant impact on expenditures

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

Significant changes in use or care of vertebrate animals

No animal use research will be performed to complete the Statement of Work

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to Report

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

Nothing to Report

Other publications, conference papers and presentations.

Nothing to Report

- **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?

VUMC Personnel:
Name: James C. Jackson
Contribution to Project: No change

Name: Carla Sevin
Contribution to Project: No change

Name: Margaret Hays
Contribution to Project: No change

BIDMC Personnel:
Name: Somath Bose
Contribution to Project: No change

Name: Valerie Banner-Goodspeed
Contribution to Project: No change

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

For Dr. Jackson, the following funding is now providing effort:
UTR002243-05, "Vanderbilt Institute for Clinical and Translational Research (VICTR)" (NCATS, 10% effort)
RAG061161-02, "Cognitive and Physical Exercise to Improve Outcomes after Surgery in the Elderly (COPEiOS)" (NIA, 10% effort)
W81XWH-20-PRMRP-IIRA-COV:, Addressing Post Intensive Care Syndrome in Survivors of Lung Injury with COVID-19" (DOD, 20% effort)
RAG058639-03, "BRAIN-ICU-2 Study: Bringing to Light the Risk Factors and Incidence of Neuropsychological Dysfunction (Dementia) in ICU Survivors, 2nd Study" (NIA, 26% effort)
RAG065249-02 "Early Cognitive Training and Rehabilitation to Prevent Cognitive Decline in Older Hospitalized Adults with Delirium" (NIA, 13% effort).

For Dr. Sevin, the following funding is now providing effort:
W81XWH-20-PRMRP-IIRA-COV:, Addressing Post Intensive Care Syndrome in Survivors of Lung Injury with COVID-19" (DOD, 10% effort)

For Dr. Bose, the following funding is now providing effort:
W81XWH-20-PRMRP-IIRA-COV:, Addressing Post Intensive Care Syndrome in Survivors of Lung Injury with COVID-19" (DOD, 7% effort)

What other organizations were involved as partners?

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: A collaborative award is present and an annual report for the collaborative report is being submitted.

QUAD CHARTS: Included in the Appendix.

9. APPENDICES: Quad Chart & Award Chart

W81XWH-18-1-0813: Addressing Post-Intensive Care Syndrome Among Survivors of COVID

PI: JAMES C. JACKSON, PSYD, VANDERBILT UNIVERSITY MEDICAL CENTER **Budget:** $760,307

Topic Area: COVID-19 **Mechanism:** CDMRP

Research Area(s): 1102, 1001 **Award Status:** 1/15/2021 - 1/14/2024

Study Goals:

This study seeks to address this clinical and operational knowledge gap for ARDS survivors by defining patterns of unmet needs, resource utilization, readmissions, and long-term functional outcomes among ICU survivors particularly those with COVID-19. We will employ a prospective, multi-center, observational study of outcomes and healthcare utilization among ARDS survivors which are directly relevant to a military population.

Specific Aims:

Aim 1: Assess the relationship between unmet needs after discharge and 3-month death or readmission, adjusting for the propensity to have unmet needs, among COVID-19 patients and COVID-19 bystanders. Secondarily compare post-discharge outcomes among acute respiratory failure survivors during the COVID-19 pandemic to those of patients in the APICS-01 cohort.

- **Hypothesis**: Unmet needs in the first 1-4 weeks after hospital discharge are associated with readmission or death after hospital discharge at 3 months, even after adjusting for the likelihood of having unmet needs, and we hypothesize that survivors of respiratory failure during COVID-19 pandemic will differ from those enrolled in the APICS-01 cohort.

Key Accomplishments and Outcomes:

Study launched ahead of schedule. Enrollment (N=139/200) ahead of schedule.

Publications: none to date
Patents: none to date
Funding Obtained:

Addressing Post Intensive Care Syndrome among Survivors of COVID (APICS-COVID)

W81XWH2110051
PR202630P1

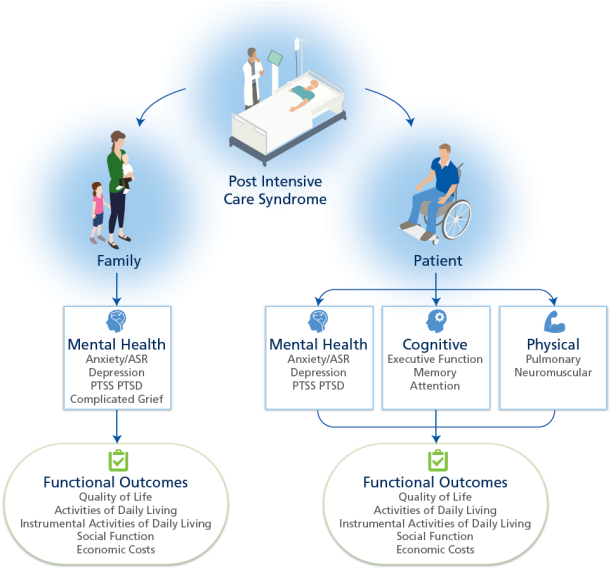
PI: James C. Jackson, PsyD **Org:** Vanderbilt University Medical Center **Award Amount:** $760,307

Study/Product Aim(s)

Aim 1: Assess the relationship between unmet needs after discharge and 3-month death or readmission, adjusting for the propensity to have unmet needs, among COVID-19 patients and COVID-19 bystanders.
Secondarily compare post-discharge outcomes among acute respiratory failure survivors during the COVID-19 pandemic to those of patients in the APICS-01 cohort.

Approach

The overall proposed approach is to generate an observational cohort and use pseudo-randomization (inverse probability of treatment weighting) to interrogate the relationship between unmet needs and hospital readmissions. This will occur in a multicenter cohort of patients with respiratory failure due to COVID-19 that we anticipate will usefully reflect the experience of service members and veterans.



Timeline and Cost

Activities	CY	21	22	23
Obtain IRB and HRPO Approval				
Site Education and Training				
Patient Enrollment and Data Collection				
Data Analysis and Dissemination				
Estimated Budget ($K)	**$760**	**$251**	**$270**	**$239**

Updated: 15 January 2022

Goals/Milestones

CY21 Goal – Study Initiation
☑ Submit study for IRB and HRPO approval
☑ Standardize training and site education

CY22 Goals – Patient Enrollment and Data Collection
☑ Enroll patients
☑ Perform 6 month follow up visits

CY23 Goal – Data Analysis and Dissemination
☐ Perform primary and secondary data analysis
☐ Submit final report to the military
☐ Submit primary manuscript to peer-reviewed journal

Budget Expenditure to Date
Projected Expenditure: $760,307
Actual Expenditure: $214,482