

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: Vanderbilt University Medical Center, Nashville, TN

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TYPE OF REPORT: Annual

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

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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 completed enrollment with identical methodology, to allow comparisons. In the first year of award, APICS-COVID initiated enrollment and data collection ahead of schedule; in the second year, enrollment was completed ahead of schedule. In the coming period, the study team will complete the 6 months of patient follow-up, clean data, and report findings.						
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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 have reached our target enrollment of 200 patients ahead of schedule (note that due to a patient who withdrew after consent but before study procedures had been performed, a total of 201 patients were nominally enrolled). All the investigator meetings are happening on-time and consistently. All subtasks are being completed on time.

Major Task 3: Data Analysis and Dissemination. The dataset is closed and data cleaning/validation is complete. Analysis of the primary and secondary aims has begun with one manuscript in the process of submission and a second manuscript drafted. Dissemination of findings will continue in the coming months with 2 planned manuscript submissions. A no-cost extension is requested to allow completion of additional analyses and manuscripts.

What was accomplished under these goals?

Major Activities: As indicated above, we have reached target enrollment and all goals are being achieved. Formal findings will be reported this coming year. A 1-year no cost extension was requested to allow completion of DCC activities and completion of all analyses and manuscript reporting. The DCC activities primarily relate to ad hoc data queries and data management to support ongoing analyses related to publication and dissemination of scientific research manuscripts for the primary and secondary objectives of the APICS-COVID study.

Enrollment Report – July 2022

	Total
BIDMC	21
IMC	54
JHU	100
VA	11

VUMC	15
TOTAL	201

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

Junior researchers have taken the lead in first-authorship and are being supported by the senior team members in professional development of further researchers.

How were the results disseminated to communities of interest?

Formal manuscript submission will complete the goal of dissemination in the coming period.

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

Follow through with the formal reporting process via manuscript submission.

4. IMPACT:

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

Impact of the project is pending dissemination of our results.

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 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 from semi-annual report.

Name: Carla Sevin

Contribution to Project: No change from original submission.

Name: Margaret Hays

Contribution to Project: No change from original submission.

BIDMC Personnel:

Name: Somnath Bose

Contribution to Project: No change from original submission.

Name: Valerie Banner-Goodspeed

Contribution to Project: No change from original submission

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:
VUMC95051, INSPIRE-ICU Long Term Outcomes (Sedana Medical AB, 2% effort)
R01OHL161847, Research COVID to Enhance Recovery (RECOVER) Initiative (NHLBI, 10% effort)
There is no change in other support for Drs. Sevin or Bose.

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: The Quad Chart and the Award Chart



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

W81XWH2110051

PR202630 P1

PI: James C. Jackson, PsyD

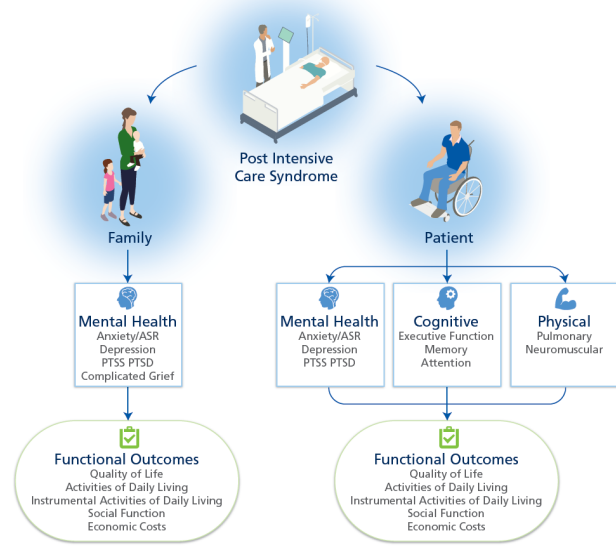
Org: Vanderbilt University Medical Center Award Amount: \$760,307

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. Secondly 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 mimic the experience of service members and veterans. The population of patients treated at this facility is representative of the military.



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	\$234	\$270	\$239

Updated: 24 January 2024

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**
- Complete all 6-month follow-up visits and close dataset
 - 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: \$504,903



W81XWH-21-1-0051: Addressing Post-Intensive Care Syndrome Among Survivors of COVID

PI: JAMES C. JACKSON, VANDERBILT UNIVERSITY MEDICAL CENTER

Budget: \$760,307

Topic Area: COVID-19

Mechanism: CDMRP

Research Area(s): 1102, 1001

Award Status: 1/15/2021 - 1/14/2025

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=201/200) ahead of schedule.

Publications: none to date

Patents: none to date

Funding Obtained: \$760,307