(A) Baseline characteristics of SARS-CoV-2 positive participants. (B) Heatmap comparing FLU-PRO response in each participant. (C) Principal component analysis followed by k-means clustering identified three groups of participants. (D) Crude and adjusted association of identified cluster with hospitalization.

Conclusion. Our findings have identified three distinct groups with early-symptom phenotypes. With further validation of the clusters' significance, this tool could be used to improve COVID-19 prognosis in a precision medicine framework and may assist in patient triaging and clinical decision-making.

Disclaimer.

Draft Disclaimer

Views expressed are those of the author(s) and do not reflect the official policy/position of USU; DHA; Henry M. Jackson Foundation; BAMC; MAMC; TAMC; WRNMMC; US Army Medical Department; US Army Office of the Surgeon General; Department of the Army, Air Force, or Navy; DOD; or the USG. Investigators followed human subjects protection 45CFR46 policies.

No COI to declare.

Disclosures. **David A. Lindholm, MD**, American Board of Internal Medicine (Individual(s) Involved: Self): Member of Auxiliary R&D Infectious Disease Item-Writer Task Force. No financial support received. No exam questions will be disclosed ., Other Financial or Material Support **Ryan C. Maves, MD**, **EMD Serono** (Advisor or Review Panel member)**Heron Therapeutics** (Advisor or Review Panel member) **Simon Pollett, MBBS**, **Astra Zeneca** (Other Financial or Material Support, HJF, in support of USU IDCRP, funded under a CRADA to augment the conduct of an unrelated Phase III COVID-19 vaccine trial sponsored by AstraZeneca as part of USG response (unrelated work))

459. COVID-19 Hospitalization and 30-Day Readmission: A Cohort Study of U.S. Hospitals

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Background. Evidence on outcomes after COVID-19 hospitalization is limited. This study aimed to characterize 30-day readmission beyond the initial COVID-19 hospitalization.

Methods. This descriptive retrospective cohort study included adult patients admitted between 07/01/2020 and 01/31/2021 with a discharge diagnosis of COVID-19 (ICD-10-CM: U07.1), using a large hospital inpatient chargemaster with a linked open claims dataset. The first COVID-19 hospitalization was considered index hospitalization; baseline was defined as first 2 days of index hospitalization; readmission was assessed within 30 days of discharge from index hospitalization. We describe the demographics, treatments and outcomes of the index hospitalization and readmission.

Results. For index hospitalization, we identified 111,624 COVID-19 patients from 327 hospitals across US. Mean age was 63 and 54% were male. Over the study period, use of remdesivir (RDV) increased from 11% to 50% while use of steroids (66% -73%) and anticoagulants (32% - 35%) remained relatively stable (Figure 1). Overall, 21% required ICU or CCU admission, 13% died, and median length of stay (LOS) was 7 days (range 4 -11 days). Among 61,182 (55%) with ≥ 30-day follow-up post discharge, all-cause 30-day readmission was 16% and remained stable (15% - 17%) over the study period; median days to readmission was 6 days (range 1-30). All-cause readmission (13 % vs 17%) was lower in patients treated with RDV during index hospitalization over time (Figure 2), particularly in those requiring high flow oxygen (17% vs 18%), low flow oxygen (13% vs 16%) or no oxygen (12% vs 17%), but not in ECMO or invasive ventilation (33% vs 29%). Compared to non-readmitted, readmitted patients were older (60 vs 65), had more comorbidities such as COPD (24% vs 37%) (see Table 1) and LOS (6 vs 7 days) in index hospitalization. Overall, the most frequent diagnoses of readmission were COVID-19 (63%), other viral pneumonia (36%), and acute respiratory failure with hypoxia (34%).

Figure 1. Use of anticoagulants, remdesivir and steroids over time during index hospitalization

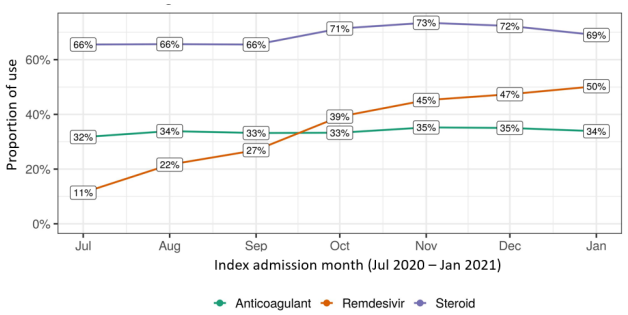

Figure 2. Monthly 30-day all-cause readmission by RDV treatment during index hospitalization

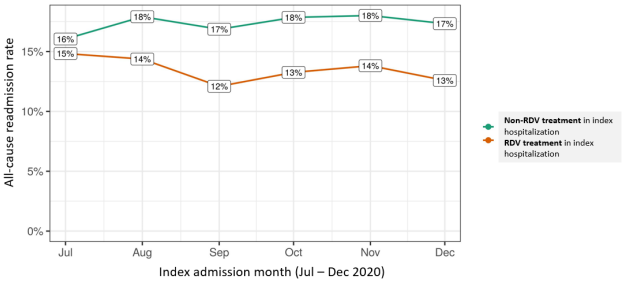

Table 1. Baseline characteristics and comorbidities of non-readmitted and readmitted patients

		Non-readmitted patients N=51,434		Readmitted patients N=9,748	
		N	%	N	%
Mean age (SD)			60 (15.5)		65 (14.8)
Baseline severity (index hospitalization)	ECMO/invasive mechanical ventilation	723	1%	308	3%
	High-flow oxygen of non-invasive mechanical ventilation	4,254	8%	887	9%
	Low-flow oxygen or oxygen supply	11.,076	22%	1,938	20%
Key comorbidities	COPD Without Asthma	12,316	24%	3,577	37%
	Aids/HIV	555	1%	159	2%
	Asthma	12,555	24%	2,759	28%
	Cerebrovascular disease	14,400	28%	4,065	42%
	Diabetes	27,931	54%	6,312	65%
	Congestive heart failure	14,315	28%	4,320	44%
	Hypertension	40,546	79%	8,704	89%
	Obesity	26,605	52%	5,298	54%
	Renal disease	2,839	6%	1,375	14%

Conclusion. In a large, geographically diverse cohort of hospitalized COVID-19 patients, 16% required readmission, especially in those with greater age and comorbidities. Over the study period, all-cause readmission remained stable and was lower in RDV treated patients.

Disclosures. **Essy Mozaffari, PharmD, MPH, MBA**, **Gilead Sciences** (Employee, Shareholder) **Shuting Liang, MPH**, **Gilead Sciences** (Employee) **Henry Morgan Stewart, PhD**, **IQVIA** (Employee) **Mark Thrun, MD**, **Gilead Sciences** (Employee, Shareholder) **Paul Hodgkins, PhD, MSc**, **Gilead Sciences** (Employee, Shareholder) **Richard Haubrich, MD**, **Gilead Sciences** (Employee, Shareholder)

460. Disproportionalities in COVID-19 Clinical Drug Trials in the United States: A Systematic Literature Review

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Session: P-21. COVID-19 Research

Background. To combat higher rates of COVID-19 infection, hospitalization, and death among minorities, it is crucial to identify safe, efficacious, and generalizable treatments. Therefore, the purpose of this systematic literature review was to assess the demographic characteristics of COVID-19 clinical trial participants.

Methods. A literature search was performed according to the PRISMA checklist using PubMed from December 1, 2019 to November 24, 2020 with the following search terms: 2019-nCoV, COVID-19, SARS-CoV-2, clinical trial, randomized controlled trial, observational study, and veterinary. To capture additional results, keyword searches were performed using various versions and plural endings with the title/abstract field tag. Randomized controlled trials evaluating a pharmacologic treatment for COVID-19 patients from one or more U.S site written in the English language were eligible for inclusion. Descriptive statistics were calculated to characterize age, gender, race, and ethnicity of patients enrolled in the included COVID-19 clinical trials, as well as for comparison with national COVID-19 data.

Results. A total of 4472 records were identified, of which 16 were included. Most were placebo-controlled (69%) and included hospitalized patients with COVID-19 (69%). Demographic data were reported for each study arm in 81% of studies. Median number of participants was higher in studies of nonhospitalized patients (n=452 [range 20-1062] vs n=243 [range 152-2795]). Nine (56%) studies reported mean or median ages of 50 years or older amongst all study arms. Males comprised more than half of the study cohort in 50% of studies. Race and ethnicity were reported separately in five (31%) studies, reported in combination in four (25%), while six (38%) reported only race or ethnicity. White or Caucasian patients made up most participants across all arms in 75% of studies. Based on national COVID-19 data, hospitalizations were similar between White persons and African American persons, but higher than other race or ethnic groups, and evenly distributed among males and females.

Conclusion. Lack of heterogeneously reporting demographic characteristics of COVID-19 clinical trial participants limits the ability to assess the generalizability of pharmacologic treatments for COVID-19.

Disclosures. **All Authors**: No reported disclosures