ICPE Abstract

Title: How COVID-19 Randomized Controlled Trials Reported on Demographic and Clinical Characteristics

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Background: Mortality in COVID-19 patients varies by sex, age, race/ethnicity, and concomitant comorbid conditions. Because of this variation, treatments to prevent or treat COVID-19 are likely to have heterogeneous effects, making external validity in randomized controlled trials (RCTs) especially important. To assess the external validity of RCT findings to target populations of interest, it is necessary to characterize trial populations and the reporting of specific patient-level characteristics.

Objectives: To assess the reporting of key patient-level demographic and clinical characteristics among COVID-19 related RCTs.

Methods: We queried English-language articles from PubMed, Web of Science, clinicaltrials.gov, and the CDC library of gray literature databases using keywords of ‘coronavirus’, ‘covid’, ‘clinical trial’ and ‘randomized controlled trial’ from January to October 2020. We restricted to studies with “trial” in their title and reviewed abstracts to confirm they were RCTs with final results. Lastly, we abstracted the demographic and clinical characteristics reported in Table 1 of the final publication.

Results: From the initial 42,586 manuscripts, we excluded 41,946 articles without ‘trial’ in their titles. After a preliminary abstract review, 583 more articles were excluded because the “RCTs” described were not truly randomized or reported no results. Our final eligible manuscripts consisted of 61 RCTs described in 57 articles. The trials were largely conducted in China (20), Iran (9), and the U.S. (8). Most (50) studied potential treatments, while fewer studied vaccines (8) and prophylaxis strategies (3). Study populations ranged from 10 to 5040 participants (median=89). All 61 reported on age (median of 55.8 with IQR (44.5, 59.8)), 59 on sex, 48 on the prevalence of at least one comorbidity, 22 on use of oxygen therapy, and 14 on race. The two comorbidities whose prevalence was most frequently described were hypertension (38) and diabetes (42), but few studies reported comorbid asthma (14) or COPD (11). Pregnant women were explicitly excluded from 46 of the trials. No trials reported on income, urban vs rural residence, or other indicators of socioeconomic status.

Conclusions: Reporting on age, sex, and comorbidity distributions may assist in characterizing populations enrolled in RCTs. Unfortunately, limited reporting on race and other markers of SES may make it difficult to draw conclusions in the most impacted populations without making unlikely assumptions about homogeneous treatment effects. These findings highlight the need for more robust reporting on the clinical and demographic profiles of COVID-19-related RCT populations.