COVID-19 disparities: An urgent call for race reporting and representation in clinical research

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ARTICLE INFO

Keywords:
COVID-19
Racial/ethnic disparities
Clinical research

ABSTRACT

Background: Racial/ethnic disparities in disease burden have gained the spotlight in the United States with the spread of SARS-CoV-2 and surge of COVID-19 cases. The problem of underrepresentation in clinical research persists today. In light of the considerable COVID-19 disparities observed, this study sought to assess the race reporting and representation among COVID-19 therapeutic studies published to date.

Methods: All published COVID-19 treatment-related clinical research studies with study participants in the United States were identified. For each study, the date published, treatment investigated, study design, race/ethnicity of participants, sample size and study site were recorded. For each study site, the race/ethnicity demographics of confirmed COVID-19 positive cases were identified utilizing online publicly available department of public health data.

Results: Six studies (n = 3, observational; n = 3, randomized clinical trial) have been published to date with participants in the United States. A subset (n = 4) reported race/ethnicity data in the publication. Black patients were underrepresented in all studies relative to the affected population in the cities in which the studies took place.

Conclusions: Given that racial/ethnic disparities in COVID-19 disease burden and outcomes have emerged in the United States, it is essential that all investigators uniformly report race/ethnicity data as well as attempt, in earnest, to obtain representativeness among study participants in order to ensure that we do not develop a further widening of the treatment gap during this pandemic.

1. Introduction

Racial/ethnic disparities in disease burden have gained the spotlight in the United States with the spread of SARS-CoV-2 and surge of COVID-19 cases \cite{1}. In New York City, we observed that racial/ethnic minorities, especially African Americans, face a substantially higher mortality rate due to COVID-19 compared to other racial/ethnic groups \cite{2}. In San Francisco, rates of infection and death are overrepresented among Hispanic populations \cite{3}. These health disparities are driven by multiple social determinants of health including health care access and socioeconomic status \cite{4}.

Inclusive therapeutic clinical research is an important mechanism for addressing disparities in health outcomes. In the United States, racial/ethnic minorities remain underrepresented in clinical research with Black and Hispanic patients comprising approximately three and six percent of clinical trial participants, respectively \cite{5}. While the 1993 National Institute of Health Revitalization Act attempted to improve diversity in research by mandating the inclusion of racial/ethnic minorities in publicly funded clinical trials \cite{6}, the problem of underrepresentation persists today. In light of the considerable COVID-19 disparities observed, this study sought to assess the race reporting and representation among COVID-19 therapeutic studies published to date.

2. Methods

All published COVID-19 treatment-related clinical research studies up to July 10, 2020 were identified through a PubMed search using MeSH terms “COVID-19” and “treatment”, filtered for English language and human participants. Studies that included participants in the United States and reported on a treatment for COVID-19 were included in the analysis. For each evaluable study, the date published, treatment investigated, study design, race/ethnicity of participants, sample size

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https://doi.org/10.1016/j.conctc.2020.100630
Received 27 June 2020; Received in revised form 16 July 2020; Accepted 26 July 2020
Available online 30 July 2020
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and study site were recorded. For each study site, the race/ethnicity demographics of confirmed COVID-19 positive cases were identified utilizing online publicly available department of public health data. Investigators contacted all first authors of published studies to attempt to obtain de-identified race/ethnicity frequency data when not reported. All procedures in this study received Institutional Review Board approval.

3. Results

As shown in Table 1, six studies (n = 3, observational; n = 3, randomized clinical trial) have been published to date with participants in the United States. A subset (n = 4) reported race/ethnicity data in the publication. Investigators were able to obtain race/ethnicity data from one additional study by contacting authors directly. Fig. 1 depicts the demographics of the affected population by study site. In the New York City-based study, 11% of the study population were Non-Hispanic Black (Black) and 51% were Hispanic. According to the New York Department of Public Health, 30.5% of New York City’s cases were Black and 32.7% were Hispanic [7], therefore Black patients were underrepresented in this study and Hispanic patients were overrepresented. In the study based out of Boston, Black and Hispanic patients were underrepresented relative to the affected population in the city (Black: 23% (study) vs 38% (city burden); Hispanic: 17% (study) vs 26% (city burden)) [8]. Similarly, Black and Hispanic patients in the Minneapolis-based study were also underrepresented compared to the affected population in the city (Black: 5% (study) vs 33% (city burden); Hispanic: 5% (study) vs 28% (city burden)) [9]. Two of the six studies were conducted across multiple sites in the US and globally so data describing city-level burden was unable to be obtained. In Biegal et al. Hispanic patients comprised 23.4% of the study, while 20.6% were Black and 12.6% were Asian. In Goldman et al. Black patients were 10.5% and Asian patients were 10.0% of clinical trial participants. The study did not report the proportion of Hispanic patients.

| Study Study Design Location Sample size Race-reported Race-distribution |
|---------------------------------|-----------------|----------|-------------------|
| Compassionate Use of Remdesivir for Patients with Severe Covid-19 [13] | Retrospective | United States Japan Italy Austria France Germany Netherlands Spain Canada | 53 | No | NH White (44.4%) NH Black (23.3%) Asian (2.2%) Hispanic (16.6%) Other (2.2%) Unknown/Did not disclose (11.1%) |
| Risk of QT Interval Prolongation Associated With Use of Hydroxychloroquine With or Without Concomitant Azithromycin Among Hospitalized Patients Testing Positive for Coronavirus Disease 2019 [14] | Retrospective | Boston, MA, United States | 90 | No | NH White (9.1%) NH Black (11.0%) Hispanic (50.8%) Other (5.9%) Missing (23.2%) |
| Observational Study of Hydroxychloroquine in Hospitalized Patients with Covid-19 [15] | Retrospective | New York City, NY, United States | 1376 | Yes | NH White (59.2%) NH Black (4.6%) Asian (22.2%) Hispanic (5.3%) Native American or Alaska Native (0.5%) Middle Eastern (2.7%) South Asian (4.3%) Other (1.4%) |
| A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19 [16] | Randomized clinical trial | Minneapolis, MN, United States Montreal, Quebec, Canada | 821 | Yes | NH White (53.2%) NH Black (4.6%) Asian (12.6%) Native Hawaiian or Other Pacific Islander (0.3%) Black or AA (20.6%) White (53.2%) Multi-racial (0.3%) Hispanic (23.4%) Unknown (12.4%) Hispanic or Latino (23.4%) Black (10.5%) Asian (10.0%) Other (8.5%) |
| Remdesivir for the Treatment of Covid-19 — Preliminary Report [17] | Randomized clinical trial | United States (45 sites) Denmark (8) United Kingdom (5) Greece (4) Germany (3) Korea (2) Mexico (2) Spain (2) Japan (1) Singapore (1) | 1059 | Yes | American Indian or Alaska Native (0.7%) Asian (12.6%) Native Hawaiian or Other Pacific Islander (0.3%) Black or AA (20.6%) White (53.2%) Multi-racial (0.3%) Unknown (12.4%) Black or AA (20.6%) White (53.2%) Multi-racial (0.3%) Unknown (12.4%) Hispanic or Latino (23.4%) Black (10.5%) Asian (10.0%) Other (8.5%) |
| Remdesivir for 5 or 10 Days in Patients with Severe Covid-19 [18] | Randomized clinical trial | United States Italy Spain Germany Hong Kong Singapore South Korea Taiwan | 397 | Yes | White (71.0%) Black (10.5%) Asian (10.0%) Other (8.5%) |

* Confirmed by contacting investigators.
4. Discussion

We observed that, to date, race/ethnicity is not uniformly collected or reported in clinical research studies related to COVID-19 treatments. Among racial/ethnic data we were able to assess, Black patients were consistently underrepresented relative to their disease burden. Given that three of the six studies are retrospective observational research, these data may also suggest that there are disparities in utilization patterns of novel COVID-19 treatments based on race/ethnicity. However, future research will need to examine this further. According to the Center for Disease Control, 33.5% of COVID-19 cases in the U.S. were Hispanic and 20.1% were Black [10], despite comprising 18.5% and 13.4% of the population respectively [11]. Given that racial/ethnic disparities in COVID-19 disease burden and outcomes have emerged in the United States, it is essential that all investigators uniformly report race/ethnicity data as well as attempt, in earnest, to obtain representativeness among study participants in order to ensure that we do not develop a further widening of the treatment gap during this pandemic. As of today, there are 221 COVID-19 clinical trials recruiting in the United States [12], it is critical that they aim to achieve representation among participants.

Author contributions

Drafting of the manuscript: Borno, Zhang, Gomez.
Critical revision of manuscript: Borno, Zhang, Gomez.
Statistical analysis: N/A.
Obtained funding: N/A.

Declaration of competing interest

None.

Acknowledgements

Borno receives funding from the Prostate Cancer Foundation and Lazarex Cancer Foundation. We would like to acknowledge Drs. Mercuro, Yen, Grien, Brainard, Chokkalingam, and Boulware for their input.

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Fig. 1. City burden of COVID-19 cases and clinical trial participant demographics.
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