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To cite this article: Kelly Robertson, Kimberly Reimold, Ann M. Moormann, Raquel Binder, Kristen A. Matteson & Heidi K. Leftwich (2023) Investigating demographic differences in patients' decisions to consent to COVID-19 research, The Journal of Maternal-Fetal & Neonatal Medicine, 36:1, 2148097, DOI: [10.1080/14767058.2022.2148097](https://doi.org/10.1080/14767058.2022.2148097)

To link to this article: <https://doi.org/10.1080/14767058.2022.2148097>



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Published online: 04 Jan 2023.



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Investigating demographic differences in patients' decisions to consent to COVID-19 research

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ABSTRACT

Objective: COVID-19 disease severely impacted pregnant persons, resulting in a significant increase in poor maternal health outcomes, with a disproportionate impact on minority populations and individuals with low socioeconomic status. We sought to determine demographic differences between birthing parents with SARS-CoV-2 infections who consented to research study participation versus those who declined. By analyzing demographic differences, we are able to ensure the generalizability of study outcomes and to aid in future prospective research design, with the ultimate goal of recognizing and ameliorating research disparities.

Methods: We conducted a secondary analysis to investigate demographic differences in patients who consented to versus declined study participation, in an effort to confirm the external validity of the study results and ensure minority populations most affected by SARS-CoV-2 infection were accurately represented. An IRB waiver was obtained to conduct retrospective chart review for demographic data collection of all patients approached for the COVID-19 Analysis on Perinatal Specimens Related to ExpoSure (CARES) research study. Pregnant patients with SARS-CoV-2 infection were identified at a single hospital center and approached either in person or via phone, with a translator if primary language listed as non-English. Demographic variables including race, ethnicity, primary language, and insurance type were obtained from the electronic medical record and analyzed via Chi-square to determine significant differences between individuals who consented to participation and those who declined participation.

Results: One hundred and fifty-eight pregnant patients with SARS-CoV-2 infection were approached for CARES study participation. Eighty-nine patients consented to study participation, while 69 declined study participation. A retrospective chart review was conducted on all 158 patients. Patients who identified as Black race or non-White race were more likely to decline participation (23.2%, $p = .031$, 68.1%, $p = .026$), compared to patients who identified as White (31.9%) (Table 1). Patients with public insurance were also more likely to decline study participation (72.5%, $p = .049$) compared to those with private insurance (27.5%). There was no significant difference between primary language spoken or ethnicity in patients who participated or declined. There was no difference in study participation between patients who identified as Asian race or Other race, compared to patients who identified as White race.

Conclusions: We found significant differences in race and insurance type between pregnant patients with SARS-CoV-2 infection who consented versus declined research study participation. Our study showed that patients who identify as Black race or have public insurance are less likely to consent to research study participation. However, when demographics of consented patients are compared to county, state, and national demographics of female patients age 18–49 with confirmed SARS-CoV-2 infection obtained from a dataset collected by the Center for Disease Control and Prevention (CDC), there was no significant difference between race representation of patients who consented to study participation. This suggests that though the external validity of the CARES study is confirmed, more efforts need to be made to address racial and socioeconomic disparities in research participation.

ARTICLE HISTORY

Received 2 August 2022
Revised 19 October 2022
Accepted 7 November 2022

KEYWORDS

COVID-19; research participation; consent; socioeconomic demographics; maternal health

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Introduction

Since the emergence of SARS-CoV-2 and the disease it causes, COVID-19, a rapidly growing body of research has sought to answer questions regarding its viral transmission, clinical effects, and treatment. This knowledge largely depends on patients' willingness to consent to research participation. Unfortunately, the consent process itself may introduce bias into study outcomes. One important goal of clinical research studies is to influence clinical practice and promote standards and equity of care. If there are significant differences in demographics between individuals who consent to participate in research and those who decline, then the study outcomes may not be generalizable to the affected population. Therefore, to ensure generalizability of the study and to provide a framework for reviewing minority representation in research, we obtained approval for demographic retrospective chart review on all patients approached for the study, regardless of participation.

Studies show that racial/ethnic minority populations and individuals with low socioeconomic status have been disproportionately impacted by COVID-19 [1,2]. Minority populations including Hispanic/Latinx, Black, American Indian/Alaska Native, and Native Hawaiian/other Pacific Islander have experienced an increased incidence of COVID-19 disease compared to population data [1]. Black individuals have a higher mortality rate from COVID-19, irrespective of clinical and social indices adjustments [2]. A systematic review found that Black and Hispanic populations experienced disproportionately higher rates of SARS-CoV-2 infection, hospitalization, and COVID-19-related mortality compared with non-Hispanic White populations [3]. Therefore, it is imperative to ensure that minority populations, particularly Black and Hispanic populations, are represented in COVID-19 research studies.

Due to mistrust as a result of systemic racism in the medical field, minority populations may be hesitant to participate in research studies [4,5]. One study found that while most participants expressed attitudes toward research that were generally favorable, key domains of trust/mistrust were identified. These domains were associated with demographic variables and can be used to understand differences in demographics regarding study participation, as well as provide a framework for tailored intervention to increase broader research participation [4].

In the field of perinatal health specifically, there are significant racial and ethnic inequities in terms of health outcomes. Center for Disease Control and Prevention (CDC) data collected from 2020 show that

maternal mortality rates continue to rise in the USA, and that the maternal mortality rate for non-Hispanic Black birthing parents (55.3 per 100,000) was 2.9 times the rate for non-Hispanic white birthing parents (19.1 per 100,000) [6]. Therefore, it is vital that racial and ethnic minorities who are disproportionately impacted in terms of both maternal mortality and SARS-CoV-2 infections are appropriately represented in research.

In this study, we aim to assess minority representation in the CARES study to ensure that the study outcomes are applicable to the communities that are most impacted by this disease and have been historically underrepresented in research.

Materials and methods

Patient recruitment

Between April 2020 and August 2021, 158 pregnant patients with SARS-CoV-2 infection were identified at UMass Memorial Health Center and approached to participate in our prospective COVID-19 Analysis on Perinatal Specimens Related to ExpoSure (CARES) Study in accordance with our approved IRB protocol (#H00020140), approved 4/7/2020. Patients were identified in multiple ways: through daily medical record review in EPIC/UMass CCTS Data Core and through direct patient care at UMass Memorial labor and delivery, maternal ICU, or other negative pressure inpatient hospital room. Inclusion criteria were adult pregnant patients with suspected or confirmed SARS-CoV-2 at 24 weeks gestational age or greater that plan to deliver at UMass Memorial Hospital. Patients under age 18, with HIV infection, with Hepatitis B or C infection, or who are prisoners were excluded from the study. The patients were contacted either in person or via phone and a translator was used if English was not listed as primary language. Approached patients were given a study ID number, and demographic and perinatal outcomes were collected from medical record review. An IRB exemption was approved for collection of certain demographic variables (included in this manuscript) from all approached patients, including those who declined study participation. This information was stored in a password protected REDCap database. Race, ethnicity, and primary language were extracted directly from the EMR. Insurance type was defined as the insurance recorded in the EMR while the patient was giving birth, or most recent primary insurance coverage in the EMR and recorded as public or private based on insurance type.

We conducted a secondary analysis of demographic data from the CARES study, which was designed to

Table 1. Demographics of patients who consented to versus declined participation in the CARES study.

Patient demographics	Study participants, N = 89	Patients who declined to participate (n = 69)	Significance
Race			
Black	12 (13.5%)	16 (23.2%)	<i>p</i> = .031
White	44 (49.4%)	22 (31.9%)	<i>p</i> = .026
Other	29 (32.6%)	29 (42.0%)	<i>p</i> = .059
Asian	4 (4.5%)	2 (2.9%)	<i>p</i> = 1
Hispanic or Latino			<i>p</i> = .423
Yes	37 (41.6%)	33 (47.8%)	
No	52 (58.4%)	36 (52.2%)	
Primary language			
English	61 (68.5%)	39 (56.5%)	<i>p</i> = .148
Spanish	19 (21.3%)	22 (31.9%)	<i>p</i> = .111
Portuguese	4 (4.5%)	4 (5.8%)	<i>p</i> = .541
Other	5 (5.6%)	4 (5.8%)	<i>p</i> = .933
Insurance type			<i>p</i> = .049
Public	51 (57.3%)	50 (72.5%)	
Private	38 (42.7%)	19 (27.5%)	

Race was compared to White race and language was compared to English. White race was compared to non-White race. English language was compared to non-English language. Significant comparisons are bolded. There is a significant difference when comparing Black and White race between groups ($p = .031$) and when comparing White and non-White race between groups ($p = .026$). Individuals with Black race or non-White race were less likely to consent to participation. There is also a significant difference between insurance type between the two groups ($p = .049$). Individuals with public insurance were less likely to consent to participation.

determine the impact of SARS-CoV-2 on birthing parents. Race, ethnicity, primary language, and insurance type were compared between individuals who were enrolled and those who declined to participate. These data were also compared to demographic data collected by the CDC on patients with confirmed SARS-CoV-2 infection at the hospital county, state, and national level.

County, state, and national data

County, state, and national data on demographics of patients with confirmed COVID-19 infection was obtained from the CDC, COVID-19 Response public data set: COVID-19 Case Surveillance Public Use Data with Geography (version date 4 March 2022). For national data, the filters female, age 18–49, and current status of laboratory-confirmed cases were applied. For state data, the addition of resident state of Massachusetts was used. For county data, resident county of Worcester was also selected. Race (Black, White, Asian) and ethnicity (Hispanic, Non-Hispanic) were obtained. These data were used for comparison of study data to determine whether regional differences in race and ethnicity were reflected in study participation.

Statistical analysis

Chi-square and ANOVA were used to evaluate differences in study and geographic populations. For race, comparisons were made between all race variables, as well as separated into Black and White, Other and

White, Asian and White, and White and non-White. For primary language, comparisons were made between all language variables, as well as separated into Spanish and English, Portuguese and English, Other and English, and non-English and English.

Results

Study participation

A total of 158 pregnant patients with SARS-CoV-2 infection were approached for study participation. Eighty-nine patients consented to be enrolled in the CARES study, while 69 declined. The demographics between patients who were enrolled and those who declined to participate were obtained (Table 1). Patients who identified as Black or non-White were significantly more likely to decline participation (23.2%, $p = .031$, 68.1%, $p = .026$), compared to patients who identified as White (31.9%). Patients with public insurance were also more likely to decline study participation (72.5%, $p = .049$) compared to patients with private insurance (27.5%). There was no significant difference between primary language or ethnicity in study participation. There was no significant difference in study participation of patients self-identified as Asian or Other race compared to White race.

County, state, and national comparison

In order to better estimate whether our consented study population was similar to the demographics of those impacted in our area with SARS-CoV-2 infection,

Table 2. Comparison of demographics between patients who consented to the CARES study compared with CDC data of patients with confirmed SARS-CoV-2 infection who are female and between the ages of 18 and 49.

Patient demographics				
	Study participants	County cases	State cases	National cases
<i>Race</i>				
Black	12 (20%)	3345 (11.1%)	36,075 (14.8%)	1,683,927 (18.5%)
White	44 (73.3%)	25,037 (83.4%)	189,156 (77.7%)	6,925,044 (76.0%)
Asian	4 (6.7%)	1632 (5.4%)	18,272 (7.5%)	501,028 (5.5%)
<i>Hispanic or Latino</i>				
Yes	37 (41.6%)	4073 (13.3%)	27,795 (12.4%)	1,645,709 (18.6%)
No	52 (58.4%)	26,514 (86.7%)	195,567 (87.6%)	7,208,791 (81.4%)

County refers to Worcester, MA. State refers to Massachusetts. Nation refers to the United States of America. There is a significant difference when comparing Black and White race only between study and county groups ($p = .025$). Patients with Black race represented a larger population in our study than in county cases. There is no significant difference when comparing Black and White race between our study data and state or national data. Our study had a significantly higher representation of Hispanic patients compared to county, state, and national data.

we then compared demographics by county, state, and national distributions obtained from the CDC COVID-19 Case Surveillance Public Use Data with Geography (Table 2). We included patients with laboratory confirmed SARS-CoV-2 testing who were female and between the ages of 18–49 to remain consistent with our study inclusion criteria. There was a significant difference when comparing Black and White race only between our study and county groups ($p = .025$). Patients with Black race represented a larger population in our study (20%) than in county cases (11.1%). There was no significant difference when comparing Black and White race between our study data and state or national data. However, our study had a higher representation of Hispanic patients. There were no significant differences in race when compared to state or national data.

Discussion

A persistent conundrum when interpreting research study outcomes is that minority populations are over-represented by disease impact and underrepresented in disease research. The goal of this analysis from the CARES study was to become aware of demographic differences between individuals who consented and declined study participation. It is also important to ensure that populations that have been disproportionately impacted by COVID-19, namely Black race and Hispanic ethnicity, are represented in this study of pregnancy and birth outcomes. Given that clinical guidelines are based on scientific research, it is imperative that study results be generalizable to all patients affected by a disease and not just populations more likely to consent to research.

We found that patients with Black race, non-White race, and public insurance were less likely to consent to research participation. When compared to state and

national averages, there was no significant difference between race in our consented patients and there was an increased representation of Hispanic ethnicity. These similarities support the external validity of the CARES study regarding racial and ethnic minority populations. The increase in representation of non-White race in the population who did not consent to CARES study participation could indicate that racial minorities are more affected by SARS-CoV-2 than is being captured by the CDC database. Another reason for the increased racial and ethnic representation in our study group could be that the recruitment center was located in a safety-net hospital, providing care for all patients regardless of payment or insurance. Increased representation of Hispanic race could be attributed to study design, as all of our study patients had both race and ethnicity recorded, where the CDC dataset did not.

Our findings highlight the importance of ensuring that study populations are comparable to populations affected by the topic of study. They also outline groups less likely to participate in research. There have been a few studies characterizing research hesitancy in minority populations [4] and research disparities in field-specific research [7,8] but further investigation into the representation of patients with public insurance, minority race, and low socioeconomic status in research, as well as reasons underlying this difference, is necessary. While the scientific and medical community are becoming more aware of disparities in healthcare and research [1–3,7–9] we should strive to ensure that minority populations are represented in research and continue to work with these communities to increase research engagement.

Strengths and limitations

Strengths of this study include the ability to obtain information on race, language, and ethnicity for all

patients. Our study group had equal or increasing racial and ethnic diversity when compared to regional controls. Our study was limited by differences in categorization of race and ethnicity. Many individuals in our study who identified as Other race were of Central and South American descent, highlighting a need for more descriptive race terms. Nondescript and non-inclusive racial terminology also made comparison between our data and CDC data difficult, as Other race was excluded from county, state, and national CDC data comparison due to vague language defining race and many patients with ethnicity or race but not both reported. This problem has been previously identified [10] but remains a persistent barrier. Relying on EMR recorded race, language, and ethnicity data introduces variability as the data recording process may not be standardized. Additionally, the CDC data used for comparison could not be restricted to include only pregnant individuals, introducing the possibility of selection bias.

Conclusions

We found that there was a significant difference in race and insurance type between patients who consented to versus declined study participation. Patients identified as Black, non-White, and those with public health insurance were less likely to consent to study participation. Additionally, these populations have been more significantly impacted by SARS-CoV-2 infection. The comparison between our study population and geographically matched populations highlights this impact. Though our consented patients matched geographical racial representation, the consented study population was significantly less diverse than patients who declined. There is a clear need for researchers to analyze their study populations to ensure that the racial and ethnic diversity matches the demographics of populations affected by the disease. It is imperative to be critical of racial and ethnic diversity in studies, particularly, those that can influence clinical guidelines. Furthermore, this study provides a framework for reviewing demographic differences in research participation and highlights populations less likely to consent to research participation. Future work includes investigating reasons for research hesitancy and identifying strategies to improve research disparities.

Disclosure statement

The authors report no conflict of interest.

Funding

Research reported in this manuscript was supported by the Worcester Foundation Grant and the University of Massachusetts COVID-19 Pandemic Research Fund.

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