INCLUSION OF MINORITY COMMUNITIES IN COVID-19 ANTIVIRAL DRUG TRIALS FROM 2020-2023

By

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List of Abbreviations

AIAN	American Indian and Alaska Native
AIDS	Acquired Immunodeficiency Syndrome
CBPR	Community-Based Participatory Research
CDER	Center for Drug Evaluation and Research
CRO	Contract Research Organization
DHHS	Department of Health and Human Services
EUA	Emergency Use Authorization
FCT	Fundamental Cause Theory
FDA	Food and Drug Administration
HIV	Human Immunodeficiency Virus
IND	Investigational New Drug
IRB	Institutional Review Board
MERS	Middle East Respiratory Syndrome
NDA	New Drug Application
NHPI	Native Hawaiian or Pacific Islander
NIAID	National Institute of Allergy and Infectious Disease
NIH	National Institutes of Health
NLM	National Library of Medicine
NRA	National Research Act
SARS-CoV2	Severe acute respiratory syndrome coronavirus 2
SDOH	Social Determinants of Health
SES	Socioeconomic Status

Introduction

COVID-19 has affected everyone in the United States, but its effects on communities of color have been more substantial than other groups. Black, Latino, and Indigenous American communities are infected, hospitalized, and die at higher rates than their proportion of the population (Okonkwo et. al, 2021).

Examining social determinants of health shows why some populations were more deeply harmed by COVID-19 than others. Race and ethnicity have been analyzed in regard to COVID-19 deaths, but the data needs to be analyzed by income, disability status, and neighborhood, for instance, to more effectively show which communities are hurt more. The risk of getting infected varies based on the conditions of people's lives and their capacity to seek medical care. Factors such as where one lives and works affect their ability to get help and their ability to stay home when unwell (Phuong et. al, 2022). Being able to social distance is a privilege. People of color are at much higher rates of being essential workers, so that increases the likelihood of exposure. The government was willing to sacrifice people's lives for the economy, and those people were predominantly Black and Brown (Sylvia, 2020).

Because census categories are overlaid into biomedical research, there are laws regarding diversity in clinical trials in terms of race, ethnicity, and gender. Both the Food and Drug Administration and the National Institutes of Health have laws and regulations about the inclusion of minorities and women in clinical trials. In the 1980s, there was critique of the one-size-fits-all approach to biomedical knowledge-making. From both a social perspective and a biomedical perspective, a one-size-fits all methodology is unrealistic because results are not generalizable to the overall population. The "one-size" that was primarily studied was middle-age white men (Epstein, 2007). Groups such as women, racial and ethnic minorities, children,

and the elderly were not accounted for. However, the National Research Act of 1974 brought along new changes and marked the transition to the era of protectionism. The main pillars of the National Research Act are that it established informed consent and it formalized institutional review boards (Stark, 2012). While an implication of the National Research Act is that it limits who can be studied in medical research to avoid exploitation, we are now in an era deemed as the inclusion-and-difference paradigm that puts emphasis on diversity, but perhaps not using the best means (Epstein, 2007).

The 1998 Demographic Rule requires that effectiveness data and safety data be presented by gender, age, and race. Race is a political category, though and should not be aligned with biomedicine (Epstein, 2007). Epstein terms this phenomenon as categorical alignment; it naturalizes identity categories and treats them as essential figures of the body. The NIH Revitalization Act of 1993 requires that clinical research done by the NIH must include both enough women and minorities to determine if the factor affects them differently (Freedman et. al, 1995). These laws seem like a foil to the one-size-fits all approach, however, diversity in clinical trials via political categories does not address the root of what causes health disparities.

Background

Without medical research and without human volunteers, treatments would likely never be discovered or improved. Clinical trials are necessary in developing new drugs and treatments for people; it is an important step of the experimental process in creating new therapies. When these types of studies happen, there is a regulated, routine process that is generally followed. Usually, drugs and vaccines cannot be marketed in the United States until they have been approved and reviewed by the Food and Drug Administration (FDA) (Van Norman, 2016). The process of drug development, from initial discovery to final market approval, takes 10 years on

average. The main division of the FDA that is responsible for approving drugs is the Center for Drug Evaluation and Research (CDER). The purpose of the CDER is to ensure that drugs are safe, effective, and beneficial to the public (Ciociola et, al., 2014). The investigational new drug application (IND) must provide information on "the chemistry, manufacturing, pharmacology, and toxicology of the drug (p. 621)" and describe the human tests that will be conducted. After the product has gone through laboratory and animal studies, researchers can submit an investigational new drug application to the FDA, and once that is approved human clinical trials may begin (Thaul, 2015).

There are four phases of a clinical trial. Phase I is designed to test what a safe dosage of the drug is and if there are significant side effects in a healthy population. Healthy volunteers are required for Phase I and no control group is needed. Phase II requires a new set of subjects. People with the condition that the drug is designed to treat are necessary for Phase II, which tests the actual efficacy of the drug. There are also usually two groups in Phase II of clinical trials; one group receives the experimental drug, and one group receives a placebo. Phase III is the randomized portion of the clinical trial and tests the effectiveness of the drug while continually monitoring for side effects. Since it is testing the effectiveness of the drug, it also requires people with the condition that the therapy is meant to treat rather than healthy volunteers. Phase IV is observational, so there is no control group. This phase happens when the drug is on the market to gain extra information about its risks and benefits (Weiss & Koepsell pg. 284). Once the drug investigations are completed, the company may then submit a new drug application (NDA) that includes the data from the clinical trials demonstrating its safety and effectiveness. After that the drug will either be found as approvable or not approvable by the FDA. Approved drugs still usually include post market commitments to help keep the public safe (Ciociola et, al., 2014).

However, in the case of emergencies, some rules and processes are changed. For instance, during the AIDS epidemic, activists fought for patients to receive experimental treatments that were not fully approved (Epstein, 1998). The emergency use authorization (EUA) process is different than the full approval of products because in some emergency situations, people cannot wait for all the evidence needed for full FDA approval. Instead, the FDA uses availably known evidence about the potential options and weighs the potential public benefits of administering it against the known potential risks of using unproven products. The EUA program was formalized under the *Project BioShield Act* in 2004, and it allows the FDA Commissioner to authorize unapproved drugs and other medical products during a public health emergency (Patel, 2023). The first EUA was for a vaccine to protect people at risk of anthrax mail attacks. There have also been EUAs for the treatment of "H1N1 swine flu, MERS, Ebola virus, Zika virus, and organophosphorus nerve agents" as they were all public health emergencies (Knowlson et. al, 2022 p. 2). However, none of the prior EUA issuances compare to that of the COVID-19 pandemic in terms of quantity. There were more EUAs for COVID-19 than any other public health crisis. This is because of the higher incidence of COVID-19 infection globally (Knowlson, et. al, 2022). EUA provides more timely access to drugs, diagnostic tests, or other critical medical products that may help during the emergency when there are no adequate, approved, and available options. The EUA process is much swifter than the traditional drug approval process and involves only a few steps. First, there must be the determination and declaration of an emergency. Then the request for an EUA is reviewed by the FDA, and it is either issued or denied. The final step of the EUA process is once the public health emergency has concluded, the EUA is terminated (Patel, 2023).

This thesis examines minority representation in clinical antiviral drug trials during the COVID-19 pandemic for drugs that had emergency use authorization. The health status of minorities was more greatly impacted by the pandemic because of sociopolitical inequalities rather than their biology. It explores why they were not well represented, and it explains why better categorization in biomedical research is necessary opposed to sociopolitical categories like race. Using a hereditary trait such as race reinforces biological difference between people. The American Medical Association (2020) has indicated that "racial essentialism exacerbates health disparities and results in detrimental health outcomes for marginalized and minoritized communities (p.1)." In fact, basing biological differences on any social construction that separates people makes them inherently and essentially different. While there is nothing intrinsically wrong with people having variations in their genetic makeup, it is deceptive and misleading to claim that those differences are based on levels of melanin.

Literature Review

Abadie (2010) studies and reports on individuals who participate in clinical trials or medical research studies as paid participants. These individuals volunteer to be part of scientific studies to test the safety and efficacy of new drugs, medical treatments, or procedures. They are compensated for their participation, and their involvement helps researchers gather data and assess the effects and potential risks of the interventions being studied. Abadie (2010) discusses the coercive nature of this process because the financial incentive is predatory to low-income vulnerable populations. They are deemed as "professional guinea pigs," and this can be a source of income for some individuals who choose to participate in these trials regularly. Phase I generally offers a large stipend to volunteers because of the risks associated with it. The stipends intensify the already existing economic and social inequalities. Fisher (2020) also writes at

length about the overrepresentation of Black and Brown participants in early phases of clinical trials because of the financial incentive. Fisher argues that people without health insurance are more likely to participate in research to access care, and that the clinical trials industry, therefore, exploits the poor and does not serve their interests. The paid volunteer is the prime example of a person who lives without security or predictability in their life because they are uninsured and dependent on irregular employment (Alenichev & Nguyen, 2019). Oftentimes clinical research trials are marketed as a way to acquire "free" doctors' visits, diagnostic tests, and medications. According to Fisher, 90% of volunteers said that money was a main motivator for participating in trials, meaning even the minimal payment approved by IRBs draws volunteers who need it (Fisher, 2020). To get involved in clinical trials, participants must be recruited; usually that recruitment is done via contract research organizations.

Stark (2018) discusses the genesis of contract research organizations. Contract research organizations (CROs) are the primary means for which pharmaceutical companies acquire human subjects. Institutions carrying out clinical trials outsource the job of recruitment to CROs. Human subject research mostly happened in prisons prior to the National Research Act of 1974, but after its enactment, it was necessary for researchers to find a new population of subjects to study because prisoners were deemed a vulnerable group.

Procurement contracts "allowed a public agency to purchase use of healthy humans for experiments from private organizations" (p. 820). Stark's (2018) work documents how the exchange of money for human subjects was formalized via procurement contracts, which is a process that has lasted into modern times. The key to the NIH's success in human-subject recruitment was "procuring" healthy people from total institutions (Stark, 2018).

Procurement contracts led to contract research organization (CROs), and they are now the key form of recruitment for drug research and development of new therapeutics. “CROs allow drug developers to pay other medical firms to recruit ‘human subjects’ into studies and to collect the raw data that developers needed to get regulatory approval for new products—and thereby get broad access to medical markets” (p. 845). In the 1950s people wanted to participate in clinical trials because volunteers felt as though their experiences were valuable to the community. Though they may have experienced pain and suffering, they felt rewarded; while today the intentionality behind involving oneself in a clinical trial has more to do with access to medical care and compensation (Stark, 2018; Fisher, 2009).

There is a disproportionate relationship between risk and benefit in many clinical trials, as well. The human guinea pigs needed in the development of new drugs usually do not benefit from the creation of said drug because they are uninsured and once the drug or therapeutic is on the market, they will no longer have access to it (Fisher, 2009). Nelson (2011) talks about the kidnapping of Black people in the middle of the night by “night riders” during the 19th century and the scientific discoveries with Henrietta Lacks’ cells as examples of times when Black bodies were used for scientific development and discovery, but the benefits that they yielded were not for their partaking or enjoyment. The impressive scientific results were beneficial to those in the larger population, but those sacrifices were nonconsensual and there was a mismatch between who bore the risks and who reaped the benefits.

Fisher (2009) also highlights the difference in demographics according to which phase of the clinical trial is being conducted. Phase II, also known as efficacy studies, attracts more middle-class white women. However, Phase I, also known as first-in-human trials, attracts mostly low-income minority men. Phase I is much riskier than Phase II and its purpose is to test

the safety of the drug. Phase I tests how much of an IND can be given to healthy volunteers without inflicting too much harm. Coleman (2021) says that there is no realistic possibility that study participants will directly benefit from the study interventions in Phase I. The indirect benefits could include feelings of fulfilment and/or health screenings. The middle-class white women participate because they want better healthcare for their ailment than what they receive while low-income people of color enroll in studies for money. Her findings suggest that there is an overlay between income and race as well as the motivation to participate in a clinical study. Fisher (2009) makes keen observations about motive, race, and social status. These are all very important factors to consider when considering how to conduct biomedical research. George et. al (2014) reported the biggest facilitator that attracted minority communities across four racial/ethnic groups to participate in clinical research were benefits such as mild monetary incentive, free lunch, or free health examination.

For most first-in-human clinical trial volunteers, the biggest motivating factor that inclines them to participate in the research is financial gain (Abadie, 2010; Fisher, 2009). The incentivization causes them not to consider the risks associated with the trials much, so the question of why minority groups tend to be more distrusting of researchers and clinical trials has an apparent answer. There has been and still exists a system that extracts resources from vulnerable populations for capital gain. Participation in those studies may reinforce some Black people's impression that pharmaceutical research is extractive, rather than beneficial to them, and is better avoided (Fisher, 2009). This leads to the issue of underrepresentation of minorities in clinical trials in subsequent phases.

Researchers conducted a study that focused on improving palliative care outcomes for Latinos with advanced cancer. Palliative care focuses on easing the symptoms of a disease. This

research highlights some barriers to access that prevent minority communities from palliative care. Particularly in cancer research, representation is crucial because cancer therapies have become more individualized and tailored to unique genetic mutations. By not including the markers that are more prevalent in minority communities, they are excluded which makes it more challenging to find new therapies for them (Fischer et. al, 2017). Cancer research, specifically, differs from other clinical trials because patient-subjects usually must pay to be part of it, even if that payment happens through an insurance company. Thus, people without health insurance do not participate in cancer research unless they are very affluent (Fisher, 2009). The researchers identified the four barriers to recruitment for Latinos in a cancer clinical trial as mistrust; language and communication barriers; lack of access to academic cancer center; and inability to participate due to transportation, childcare, or work responsibilities (Fischer et. al, 2017). Language can be a barrier even for Latinos who speak English fluently because of the medical jargon that is unfamiliar. Access to the cancer center is also a barrier primarily for those who live in rural areas, which relates to the last barrier of other responsibilities withholding them from participation. Espinoza-Gutarra et al. (2022) also found the main barriers of recruitment to be “lack of awareness, fear of side effects, being uninsured, being low socioeconomic status, transportation barriers, lack of access to academic or specialized cancer centers, language and communication barriers, and mistrust” (Espinoza-Gutarra et al.,2022, p. 381). While inclusion and accessibility are evidently quite important, the ways in which groups are included and historical wrongdoings lead to feelings of hesitancy and apprehension.

In her book, "Native American DNA: Tribal Belonging and the False Promise of Genetic Science" TallBear (2013) examines the intersection of genetics, identity, and tribal belonging among Native American communities. She argues that genetic science has been misused and

misinterpreted in relation to Native American identities and tribal affiliations. To say that someone's Native American identity can be determined by genetic tests is misguided. She says that that oversimplifies the complexities of Native American identity, culture, and kinship systems. More of the mistrust narrative is conveyed when TallBear talks about the commodification of Native DNA and the potential for genetic science to reinforce colonial narratives and power imbalances. And this suspicion exists for good reason because there is historical evidence of times when blood quantum policies were used to quantify Native American ancestry. There are too many historical instances of research being *done to* Indigenous peoples, rather than for, with, or by Indigenous peoples (Tsosie et. al, 2021). Indigenous people experience a cycle of victim-blaming and coercion in genomic research. Another community in the US that has had research done to them rather than for or with them is the Black community.

Gorelick et al. (1998) found when interviewing three groups from a clinical trial: patients who remained in the study, patients who withdrew from the study, and patients who refused to participate in the study that the main reason among African American communities for refusing or withdrawing from a clinical trial was because of concern of being used as a human guinea pig. They also found that the most prevalent reason among the people who participated in the study was to help find a cure for stroke, so the sentiment of altruism exists, but it is not the generally the main motivator. George et al (2014) has also cited lack of access to information about clinical trials as a barrier to participation and a lack of representation in studies. For instance, Walker et al. (2022) reported that Black women with metastatic breast cancer were willing to participate in studies, but they were unaware of them, so evidently never enrolled.

From these examples, it is evident that there is both a mistrust of medical researchers among minority communities and an issue of accessibility. Barriers to access can range from

language barriers to knowledge that trials are happening, or physical ability to get to the site, for example. There needs to be greater access to increase representation. Inaccessibility is rooted in social systems that disproportionately affect communities of color, so to address the issue there must be political action taken to make trials more accessible. The case studies of different minority groups are to show that along racial lines there is inequality and that underlying remaining constant is not the race but rather SES and access. Abadie's (2010) point of participants' involvement in studies being a bit coercive is fueled by the idea that there is apprehension from the outset. The over and under representation of minorities is a cyclical process. Because overrepresentation is a form of exploitation, fewer people want to participate in clinical trials thus leading to an underrepresentation of minorities.

There are reasons for mistrust on behalf of minority populations. Besides the ongoing overrepresentation of economically disadvantaged people of color without insurance and/or stable jobs in research studies, there is also a sordid history in the United States of researchers using minority bodies as property. One of the more infamous unethical research experiments is the Tuskegee Syphilis Study. This study lasted for 40 years, and it was analyzing the long-term effects of untreated syphilis. The population of the study was restricted to Black men in Alabama, and even when penicillin was found to be an effective cure for syphilis, the study continued (Reverby, 2011). This study is what led to many of the codification of ethics that are in place today such as the National Research Act and the Belmont Report (Algahtani et.al, 2018). However, there are several other instances of experimental injustices on Black bodies that predate the Tuskegee Syphilis Study. Washington (2006) describes how Dr. J Marion Sims would attempt to reposition the skull bones of Black infants. Sims also refused to give anesthesia to Black patients during surgery, but he would always give anesthesia to white patients for the

same surgery. She also describes involuntary radiation experiments that were performed primarily on the Black community towards the end of World War II. The purpose was to calibrate plutonium's physiological devastation to help develop the atomic bomb. The list of medical experimentation that makes people, especially Black people, wary can go on indefinitely, but the purpose of these few examples is to show that these types of happenings were occurring long before Tuskegee. Washington (2006) says, "The harm done to African Americans in such scenarios goes far beyond the injuries to the subject themselves. As African Americans came to learn of the experiments that Sims and his contemporaries conducted, these experiments fed an aversion to the health system (p. 73.)"

It is of the utmost importance to understand the history of unethical research because it contextualizes the regulation of research today and why protecting laws and codes is crucial, and they may also help frame an understanding of why members of society feel as strongly about these protections as they do.

Laws and regulations for protection of human subjects

The National Research Act of 1974 established institutional review boards (IRBs) and informed consent. The initial purpose of IRBs was to protect the rights of human subjects in clinical trials; they are group reviews of studies prior to their being conducted (Stark, 2012). Essentially, informed consent lets participants of a study become fully aware of the research that they are going to engage in and the potential consequences of that participation. It also involves informing participants of alternative treatments that may be better for them. Subjects must be made aware of who to contact with questions about the research. (Weiss & Koepsell, 2014). However, Fisher (2009) says regulations are falsely celebrated as the salve to coercive and deceptive medical research. Adriana Petryana (2009) says that harm is still produced even with

the oversight of ethics review committees and informed consent forms. She says that experimental subject's well-being is buried beneath "paper ethics." Heimer and Petty (2010) also say that IRBs protect institutions from lawsuits more than human subjects from harm. Stark (2012) makes a similar argument in saying that the guidelines are in place to protect the site of the research rather than the participants. Glickman et. al (2009) say that the regulations governing human research are becoming more complex which only makes compliance, documentation, and training more challenging for the researchers, but it is not heightening the quality of the research practices.

Laws and regulations for diversity in clinical trials

One of those laws that makes medical research more complex is the National Institutes of Health (NIH) Revitalization Act of 1993. It establishes many new regulations, but one key feature of it is that it mandates women and members of minority groups be included as research subjects in NIH-funded studies. This forces research organizations to consider diversity in recruitment from the conception of a study; it is no longer allowed to be an afterthought. Applicants for NIH funding are required to include their diversity goals in their application and if approved they must also report the demographics of sex/gender, race, and ethnicity of who was actually recruited. (Epstein, 2008). Epstein (2008) argues that there are both advantages and disadvantages to this law. On one hand, it emphasizes the importance of engaging with the group and taking their perspectives seriously, which seems to be the intended purpose of the law. However, it can also have the effect of treating racial or ethnic groups merely as categories on a form. Not only that, but an unintended consequence of this is that it potentially leads to the belief in biological distinctions between races.

Alternatives to current legislation

Community based participatory research has shown to be a more promising salve to minority distrust, though. Michener et. al (2020) reported that community-based organizations had greater success in implementing public health initiatives. Partnerships that engage with the community build trust.

The other issue was lack of accessibility. Greater accessibility will surely increase minority representation in clinical trials, but the onus cannot and should not be placed on minority communities. Public policies related to resource allocation, social welfare programs, education, and healthcare systems can have a substantial impact on the social conditions that affect people's health. Oh et. al (2015) describe approaches to make research studies more accessible that include having childcare available for those who have children, having travel support available for those who live in rural areas, and providing food during study visits to name a few.

Some critics may argue, if race is simply a social construct and there are no biological differences between people of different races, racial diversity in clinical trials should be unimportant. However, the social determinants of health are the factors that shape health beyond genes and lifestyle choices (Phuong et. al, 2022). The social determinants of health are the economic and social factors that play a significant role in shaping the health status of individuals and communities. These factors include things like income, education, employment, housing, social support networks, and access to healthcare services. The distribution of these social determinants is influenced by public policies, which is why factors like race and class matter, especially in the US when thinking of health outcomes.

Okonkwo, et. al (2021) compare the COVID-19 pandemic with Hurricane Katrina. They said both are catastrophic events that people often think will affect everyone equally, but in both instances (the pandemic and the hurricane) it was clear that minority communities suffered more greatly. Lower income communities suffered more in the natural disaster because of a lack of resources to rebuild, but also lack of resources made the pandemic more challenging for low-income communities in comparison to communities with high access to resources.

Narayanasamy et. al (2022) conducted a study analyzing the demographics of who participated in hydroxychloroquine and/or azithromycin studies for hospitalized patients. The researchers found a high rate of nonparticipation from Black people, which emphasizes the concern that clinical trials for therapeutics may not target key populations with high mortality rates. Chastain et. al, (2020) also talk about how it is alarming that long-standing racial health disparities have been extended to COVID-19 clinical trials when racial and ethnic minority groups have so much to gain from this research, including the opportunity to receive lifesaving treatment.

My research is primarily uncovering if COVID-19 drug trials for the drugs molnupiravir, remdesivir, and Nirmatrelvir-ritonavir were more representative in terms of demographics than traditional clinical trials and what follows is an exploration of how to better attain diversity in clinical trials.

Methodology

The first step of my methodology was to conduct a critical literature review to establish a foundation for the research. My initial searches focused on clinical exploitation and using human bodies as property in experimental research. As the search progressed, I learned about both the underrepresentation and overrepresentation of minorities in clinical trials; this made me question the representation in COVID-19 clinical drug trials, mainly because the virus had a greater

impact on minority communities. Using the risk-benefit analysis framework, I deemed it paramount that they be represented in the efficacy phases of COVID-19 antiviral drug trials. My preliminary research revealed the reasons behind the underrepresentation of minorities, particularly in Phases II and III of clinical trials. Thematically, I researched topics on minority representation in clinical trials and the COVID-19 pandemic, laws and regulations guiding human research and their histories, and exploitative research and recruitment methods.

I used some free-text searches in the Jean and Alexander Heard Vanderbilt University library using key terms such as: "clinical trials," "diversity and representation," and "recruitment and retention." I used keywords such as COVID-19, regulations, emergency use authorization, and minorities when searching the databases. I used the databases PubMed and ProQuest Social Sciences Premium Collection predominantly. I also searched the scholarly journals *Social Studies of Science* and *Science, Technology, & Human Values.* These resources led me to references that I use throughout this work. I also read the references sections for additional articles. The literature review provided valuable insights and formed the basis for my further research.

My research question aimed to analyze the racial demographics of clinical antiviral drug trials for emergency use during the COVID-19 pandemic. I wanted to know if COVID-19 antiviral trials were more representative than nonemergency trials.

My research design was qualitative descriptive analysis. I gathered demographic data from twenty-five COVID-19 antiviral drug clinical trials from February 2020 – May 2022. However, I ultimately analyzed seventeen studies because eight were not applicable to my research. I collected data from the online database ClinicalTrials.gov. ClinicalTrials.gov is a website and online database of clinical research studies and information about their results

maintained by the National Library of Medicine (NLM). ClinicalTrials.gov has a user-friendly interface, and studies are not required to be published to be in this database, so it is more expansive.

I based my inclusion and exclusion criteria on the condition or disease studied, the intervention/treatment, and the availability of results. The condition or disease being studied needed to be COVID-19. I also included variations of how to write COVID-19 that included: Covid19, COVID 19, covid19; Coronavirus disease 2019; COVID-19 infection; SARS-CoV2 Infection; COVID-19 Virus Infection. I used those variations to ensure comprehensive coverage. The intervention/ treatment of interest needed to be one of the following: nitralmervir-ritonavir, molnupiravir, or remdesivir. Paxlovid, Lagevrio, and Veklury are all brand names of the respective drugs. I restricted my search to only studies with results, as the goal was to analyze the data. The date range was from 2020 until June 28, 2023, which is when I stopped collecting data. I did not put any restrictions on the funder type or geographical location.

I focused on remdesivir, nirmatrelvir-ritonavir, and molnupiravir in my research because they are the three major small molecule antivirals that received EUA for the COVID-19 pandemic. Remdesivir (Veklury) works by preventing more viral RNA from being produced. Remdesivir is administered intravenously and was authorized for emergency use in May 2020. At that time, it was only for hospitalized patients that were at least 12 years old and had severe COVID-19. In October 2020, the FDA approved Remdesivir for patients 12 and older, and an EUA was put in place for those younger than twelve. By January 2022, Remdesivir was approved for non-hospitalized patients with mild-to-moderate COVID-19.

The drug Paxlovid is a combination of nirmatrelvir and ritonavir. Nirmatrelvir is the primary protease inhibitor of SARS-CoV-2, and ritonavir is a supplement that boosts the

nirmatrelvir and helps it work better to fight the virus. In December 2021, Paxlovid was authorized, thus making it the first authorized oral antiviral treatment for COVID-19. Patients must be at high risk of developing severe COVID-19, have a positive test, have mild-to-moderate COVID-19, and be at least 12 years old to take Paxlovid. Little post-authorization data was available on Paxlovid at the time of this writing as studies were in progress.

Molnupiravir (Lagevrio) is also an oral antiviral treatment for COVID-19. Molnupiravir works by introducing errors into the genetic material of the virus, thus preventing it from replicating properly. It was authorized for emergency use in December 2021 for adults that tested positive for COVID-19 (Yoo et al., 2022).

My analysis focused on the racial demographic information presented in each table. I compared the percentage of specific racial groups in the studies with their proportion in the overall population of the United States to determine how representative the samples were. I then examined my findings through theoretical frameworks, specifically Link and Phelan's (1995) fundamental cause theory and Epstein's (2007) politics of difference inclusion-and-difference paradigm.

The conceptualization of race may differ outside the United States, and many clinical trials occur in settings beyond the US. Recruitment strategies were only consistently reported in some studies. ClinicalTrials.gov was used as a data source, but it may not provide a comprehensive list of clinical trials. However, ClinicalTrials.gov is closer to being comprehensive than any other clinical trial database.

By addressing these limitations and employing a systematic methodology, this study aimed to provide valuable insights into the racial demographics of clinical antiviral drug trials during the COVID-19 pandemic, explicitly focusing on minority representation.

Results

I analyzed seventeen studies for antiviral COVID-19 drugs, including nirmatrelvir-ritonavir, molnupiravir, and remdesivir. The date ranges of the studies were from February 2020 – May 2022. I excluded eight studies from the analysis because in six of them, the drug of interest was the standard of care, and two were observational rather than interventional studies. Two clinical trials in my analysis are for the drug nirmatrelvir-ritonavir, five are for molnupiravir, and the other ten are for remdesivir. Sponsors of the studies included Ridgeback Biotherapeutics, Pfizer, National Institute for Allergy and Infectious Diseases, Merck Sharp & Dohme LLC, Hoffman-La Roche, and Gilead Sciences. Below I provide the racial demographics for each of the studies.

Paxlovid

There were two completed studies with results for nirmatrelvir/ritonavir (Paxlovid). These studies were sponsored by Pfizer, and they were both Phase II/III. Trial NCT04960202 was a global study that lasted from July 2021- April 2022; the total number of participants analyzed was 2246. American Indian or Alaska Native accounted for 8.5% of the total, Asians made up 14% of the study, there were no Native Hawaiian or Other Pacific Islanders, Black or African Americans were 4.9% of trial participants, Whites made up 71.6% of the study, there were 3 people categorized as more than one race (0.1%), and 20 people selected Unknown or did not report (0.9%).

Trial NCT05047601 was a global study that was conducted from September 2021 – April 2022. Trial NCT05047601 analyzed 2736 participants and of those 5.8% were American Indian or Alaska Native, 1.2% were Asian, none were Native Hawaiian or Other Pacific Islander, 14.9%

were Black or African American, 77.8% were White, 0.1% (3 people) were more than one race, 4 people either did not report race or classified as unknown.

	Paxlovid	
	Phase II/ Phase III	
	NCT05047601	*NCT04960202*
American Indian or Alaska Native	5.8%	8.5%
Asian	1.2%	14.0%
Native Hawaiian or Other Pacific Islander	0%	0%
Black or African American	14.9%	4.9%
White	77.8%	71.6%
More than one race	0.1%	0.1%
Unknown or Not Reported	0.1%	0.9%

Table 1 Source: ClinicalTrials.gov

Lagevrio

There were five studies with results for molnupiravir (NCT04575597, NCT04575584, NCT04392219, NCT04405570, NCT04405739). Four of them were completed, and one was terminated for business reasons (NCT04575584). One was based in the United Kingdom (NCT04392219), two were based in the US (NCT04405570 and NCT04405739), and two were global (NCT04575584 and NCT04575597). Three of the studies were sponsored by Ridgeback Biotherapeutics, LP (NCT04392219, NCT04405570, and NCT04405739) and the other two were sponsored by Merck Sharp & Dohme LLC (NCT04575597 and NCT04575584).

Trial NCT04392219 took place from April 2020 to August 2020. This study was sponsored by Ridgeback Biotherapeutics and was a Phase I trial conducted in the United Kingdom. The racial groups present in this trial were Black or African American, White, and more than one race. Whites accounted for over 90% of the trial and there were four Black or African American participants as well as four participants of more than one race.

Based in the United States, trial NCT04405570 took place from June 2020 until February 2021. There were 202 total participants. Of them, eleven were Black or African American, five were classified as Other, four people identified as multiple races, six were Asian, and the remaining 176 were White. It was a Phase II study sponsored by Ridgeback Biotherapeutics.

Trial NCT04405739 was conducted from June 2020 - February 2022. This study was based in the United States, and there were 71 participants enrolled. It was a Phase II study conducted by Ridgeback Biotherapeutics. The demographic breakdown is as follows: three of the 71 participants were Asian, fifteen people were Black, 34 were White, 2 people reported their race as unknown/ not reported, 15 study participants identified as 'Other', 2 people were more than one race, and none were American Indian or Alaska Native or Native Hawaiian or Other Pacific Islander.

Trial NCT04575597 was conducted from October 2020 – May 2022, and it was a Phase II/ Phase III study. Trial NCT04575597 had a total of 1735 participants. Of those, 6.6% were American Indian or Alaska Native, 2.9% were Asian, none were Native Hawaiian or Other Pacific Islander, 5.6% were Black or African American, 59.3% were White, 25.5% were more than one race, and one person did not report or was classified as unknown.

Trial NCT04575584 was in progress from October 2020 to August 2021. It was sponsored by Merck Sharp & Dohme LLC and terminated for business reasons. It was a Phase

II/Phase III study, meaning those two phases of the study were combined. This study had 304 total participants. Six of them were American Indian or Alaska Native, twenty-three were Asian, one was Native Hawaiian or Other Pacific Islander, eighteen were Black or African American, 227 were White, twenty-seven people identified as more than one race, and two were unknown or not reported.

	Lagevrio				
	Phase I	Phase II		Phase II/ Phase III	
	NCT04392219	*NCT04405739*	*NCT04405570*	*NCT04575597*	*NCT04575584*
American Indian or Alaska Native	0%	0%	0%	6.6%	2%
Asian	0%	4.2%	3%	2.9%	7.6%
Native Hawaiian or Other Pacific Islander	0%	0%	NA	0%	0.3%
Black or African American	3.1%	21.1%	5.4%	5.6%	5.9%
White	93.8%	47.9%	87.1%	59.3%	74.7%
More than one race	3.1%	2.8%	2%	25.5%	8.9%
Unknown or Not Reported	0%	2.8%	NA	0.1%	0.7%
Other	NA	21.1%	2.5%	NA	NA

Table 2 Source: ClinicalTrials.gov

Veklury

Searching for remdesivir in the database with the proper parameters yielded 18 search results for studies. However, in six of these studies, remdesivir was the standard of care rather than the experimental drug, so I am excluding those (NCT04391309, NCT04546581, NCT04583956, NCT04988035, NCT04583969, NCT04593940). There were also two

observational studies (NCT04582266 and NCT05502081) that I am excluding since they were not interventional. Three of the studies were terminated but still had study results, so I am including those.

Trial NCT04292899 was a Phase III global study sponsored by Gilead Sciences. It happened from March 2020 – June 2020. It had a total of 4838 participants. The demographic breakdown is as follows: 2567 were White (53.1%), 804 were Black (16.6%), 693 were labeled as 'Other' (14.3%), 446 were Asian (9.2%), for 240 participants the collection of race information was not permitted (5%), 47 were American Indian or Alaska Native (1%), and 41 were Native Hawaiian or Pacific Islander (0.8%).

Trial NCT04292730 was a global study sponsored by Gilead Sciences. It was a Phase III study, and it was conducted from March 2020 – June 2020. It had 1087 participants. Out of 1087 participants, 588 were White (54%), 206 were Black (19%), 163 were Asian (15%), 6 were American Indian or Alaska Native (0.6%), and 4 were Native Hawaiian or Pacific Islander (0.4%). Eighty-two people were classified as 'Other' (7.5%), and race information was not permitted to be collected from 38 participants (3.5%).

Trial NCT04409262 was a global Phase III clinical trial sponsored by Hoffmann-La Roche. It lasted from June 2020 – March 2021. There were 649 participants, and two-thirds of study participants were White (67.2%). About 14% of trial participants reported race as unknown or did not report. Slightly over a tenth of the participants were Black or African American (11.1%). Eight people were American Indian or Alaska Native (1.2%), 22 people were Asian (3.4%), 10 were Native Hawaiian or Other Pacific Islander (1.5%), and 11 were more than one race (1.7%).

Trial NCT04539262 lasted from September 2020 – March 2021. It was sponsored by Gilead Sciences, and this study was Phase I/II, meaning Phases I and II were combined. This study was based in the United States. Out of the 154 participants, 126 were White, 16 were Black, 3 were identified as Other, 2 were Asian, 2 were American Indian or Alaska Native, and for five of the participants the collection of race information was not permitted.

Trial NCT04501952 was conducted from September 2020 – May 2021. It was sponsored by Gilead Sciences, and it was a Phase III study. This trial was primarily based in the United States and Europe. According to the sponsor, "The study was terminated due to study enrollment feasibility and changing needs of non-hospitalized participants. This decision is not based on efficacy or safety concerns." There were 562 participants. American Indian or Alaska Natives made up 6.4% of the study participants, Asians accounted for 2.3%, Black people were 7.5%, one person was Native Hawaiian or Pacific Islander (0.2%), 80.4% of the participants were White, five people (0.9%) identified as other, and the collection of race information was not permitted for 2.3% of the participants.

Trial NCT04745351 was a global study sponsored by Gilead Sciences. It was conducted from March 2021 – May 2022. The study was terminated due to study enrollment feasibility. According to the sponsor, "This decision is not based on efficacy or safety concerns." This was a Phase III clinical trial. Of the 243 participants, 65.4% were White, 25.1% were Black, one person was American Indian or Alaska Native (0.4%), one person was Native Hawaiian or Pacific Islander (0.4%), six people were Asian (2.5%), eleven people were classified as 'Other' (4.5%), and four people's race was unknown or not reported (1.6%).

Trial NCT04280705 was sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). It was a Phase III global study. It was an adaptive COVID-19 treatment trial.

There were four wings of this study. It was from February 2020 – May 2020, and it had 1062 participants. American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and people classified as more than one race each made up less than one percent of trial participants. White people comprised 53.3% of the study, Black people comprised 21.3% of the study, Asian people comprised 12.7% of the study, and unknown or not reported race accounted for 11.4% of the study.

Trial NCT04401579 was a global study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). It was run from May 2020 – July 2020. It was a Phase III study and there were 1033 participants. It was also an adaptive COVID-19 treatment trial. The racial demographics are as follows: 1% were American Indian or Alaska Native, 9.8% were Asian, 1.1% were Native Hawaiian or Other Pacific Islander, 15.1% were Black or African American, 48% were White, none were more than one race, and 25.1% reported race to be unknown or did not report.

Trial NCT04492475 was a global study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). It was conducted from August 2020 – December 2020, and was also an adaptive COVID-19 treatment trial. This was a Phase III clinical trial. There were 969 participants, and the demographics are as follows: 60% were White, 16.5% were Black, 8.6% were Asian. American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and more than one race each accounted for less than one percent of the trial participants. Twelve percent of the participants' race was unknown or not reported.

Trial NCT04640168 was based primarily in the United States and Asia. It was sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), and it was a Phase III clinical trial. It was from December 2020 – June 2021, and it was also an adaptive COVID-19

treatment trial. There were 1010 participants enrolled. Slightly less than 2% were American Indian or Alaska Native, almost 7% were Asian, 5 people were Native Hawaiian or Other Pacific Islander (0.5%), slightly less than a fifth of participants were Black or African American (18.6%), almost three-fifths of study participants were White (58.2%), there were 5 people considered more than one race (0.5%), and 13.5% did not report race or it was unknown.

	Veklury									
	Phase I/ Phase II	Phase III								
	NCT04 539262	*NCT04 409 262*	*NCT04 745 351*	*NCT04 501 952*	*NCT04 292 899*	*NCT04 292 730*	*NCT04 640 168*	*NCT04 401 579*	*NCT04 280 705*	*NCT04 492 475*
American Indian or Alaska Native	1.3%	1.2%	0.4%	6.4%	1%	0.5%	1.8%	1%	0.7%	1.1%
Asian	1.3%	3.4%	2.5%	2.3%	9.2%	15%	6.9%	9.8%	12.7%	8.6%
Black or African American	10.4%	11.1%	25.1%	7.5%	16.6%	19%	18.6%	15.1%	21.3%	16.5%
Native Hawaiian or Other Pacific Islander	NA	1.5%	0.4%	0.2%	0.8%	0.3%	0.5%	1.1%	0.4%	0.9%
White	81.8%	67.2%	65.4%	80.4%	53.1%	54%	58.2%	48%	53.3%	60.3%
More than one race	NA	1.7%	NA	NA	NA	NA	0.5%	0%	0.3%	0.5%
Not Permitted	3.2%	NA	NA	2.3%	5%	3.5%	NA	NA	NA	NA
Other	2%	NA	4.5%	0.9%	14.3%	7.5%	NA	NA	NA	NA
Unknown or Not Reported	NA	13.9%	1.6%	NA	NA	NA	13.5%	25.1%	11.4%	12.1%

Table 3 Source: ClinicalTrials.gov

Discussion

Of the 17 studies, 8 combined phases of the clinical trial process, which was highly expected. I thought more of them would have been combined because of the pandemic's emergency status and the work to develop drugs swiftly. All of the studies that combined phases were sponsored by private companies. Over half of the studies I analyzed were Phase III studies, which is the phase that tests effectiveness and monitors for side effects. That is understandable because the primary mission was to find a treatment for COVID-19. There were only two Phase I studies; however, that could be because molnupiravir, nirmatrelvir, and remdesivir have all been used in humans before. Molnupiravir has been used for kidney problems before, and nirmatrelvir-ritonavir has also been used for other diseases.

Though trial NCT04392219 was a Phase I trial, it was overwhelmingly white. This goes against the arguments in *The Professional Guinea Pig* and *Medical Research for Hire*, but the studies in those books were based in the United States, and trial NCT04392219 was based in the United Kingdom. It actually had the lowest proportion of Black participants compared to any of the other studies in my analysis.

The four adaptive COVID-19 treatment trials were sponsored by the NIH and were more representative of Black or African American groups. Those studies had larger sample sizes and were multisite, global studies, which probably helped them to be more representative. Even when white people were at their lowest representation, it was still 47%, almost half.

Asian is a broad category which fuels the argument that it needs to be representative. In the studies I analyzed, the study with the most significant proportion of Asians was 15%. In 10 of the 17, Native Hawaiian or other Pacific Islanders were underrepresented. In 11 of the 17 studies, American Indian or Alaska Native people were well represented in relation to their

overall proportion of US demographics, but as Chastain, et al. (2020) point out, their ratios in the clinical trials should correlate to the toll of the pandemic on their health, not their existence in the United States alone.

The category ‘other’ for race was really interesting because I did not expect a high proportion of people to deem themselves as ‘other.’ It was not applicable in ten of the seventeen studies, so that leaves seven, but of those seven, nearly half had ‘other’ as greater than 5%, and in two studies, the proportion of people classified as ‘other’ was greater than 10%. I hypothesize that this may have happened because these studies were global, and people outside the US may not identify their race in the same terms as Americans. Identity politics are much more potent in the United States than in other states of the world.

Four of the studies also had a category for ‘not permitted.’ Race must be reported for NIH studies, so it is interesting that that category exists. However, the ones where it was not allowed were in trials sponsored by Gilead Sciences.

In a combined Phase II/Phase III study sponsored by Merck Sharp & Dohme LLC with the focus drug being molnupiravir, people who identified as more than one race accounted for a quarter of the trial demographics, which stood out as an outlier to me. Again, however, this was a global multisite study, and other places’ conception of race differs from that of Americans. A 2022 Phase III study was conducted by the National Institute of Allergy and Infectious Diseases on the drug remdesivir in which one-quarter of the participants reported their race as unknown. However, this trial happened in the US along with the UK, Spain, Singapore, Mexico, South Korea, Japan, and Denmark. The United States has a very distinctive history with race that may not be as notable in some other countries. Both of these demographic subsets are generally

smaller, at least in the American context, so for them to account for 25% of trial participants stood out.

A study from Turner et al. (2020) reported that for the past twenty years, most studies on ClinicalTrials.gov do not report race/ethnicity enrollment data, and the underrepresentation of minorities has had insubstantial improvement over time. Based on the results of my study, those improvements are still happening and are still modest.

Chastain et al. (2020) argue that the clinical trials for COVID-19 drug treatments need not be proportional to US demographics but instead proportional to the COVID-19 death rates. They analyzed two of the same studies as me and concluded that Black, Latinx, and Native Americans were all underrepresented. In their analysis, they note that the location of the study is of importance because those minority populations were overrepresented in the communities where the studies took place, but their makeup of the clinical trial was comparable to that of the overall US. One limitation of my study is that I did not look at the demographics of each city or county where the clinical trials in my dataset took place. This would help me determine better what would be proportionate for certain races.

There is a barrage of potential reasons why there is a lack of diversity in COVID-19 clinical drug trials, and based on the dataset alone, I cannot make any inferences as to why. However, based on other researchers and similar studies, I can gather several reasons that explain a lack of diversity in clinical trials.

Surprisingly, the trials were not sufficiently diverse. Although, the emergency pandemic status, the media outreach for recruitment efforts, and the disproportionate effects of COVID-19 on minorities would lead one to believe otherwise. Some could interpret the pandemic status as an invitation to help solve the problem by enrolling in clinical trials that help scientists figure out

how to cure COVID-19. This would lead me to believe that people of all backgrounds would sign up. The media outreach for enrollment was also massive. The recruitment process of clinical research is typically outsourced to contract research organizations, but with the COVID-19 pandemic there were recruitment efforts from several different sources to get people involved in studies. Since COVID-19 rates were higher among minority communities, one would expect their enrollment in drug trials to be higher.

However, I was also not surprised by these findings because of historic distrust from minority communities in medical research, vaccine hesitancy, other studies with similar findings, lack of access to clinical trials, and another interpretation of the emergency status could be not to get involved. Minority communities, particularly in the United States, have a dark and abysmal history with medical research and their bodies being used as property. That collective memory does not disappear in a public health emergency. In fact, it could be more of a reason not to get involved because during the height of the pandemic, top officials' guidance was to simply stay at home. Also, I believe that sentiments about the COVID-19 vaccines can be used as a proxy for how people felt about the antiviral clinical drug trials. According to Hildreth & Alcendor (2021), vaccine hesitancy among non-Hispanic whites was drawn along geographical lines more, with people living in rural areas being more hesitant than those in urban areas and along political party identification lines as well with Republicans being less likely to receive a COVID-19 vaccine. Among African American and Hispanic/Latino communities, hesitation was present due to distrust of the medical system and conspiracy theories. They also had less access to COVID-19 testing. Lastly, many other studies also found the COVID-19 antiviral drug trials to not be representative which corroborates my findings (Millet et al. 2020; Narayanasamy et al. 2022;

Turner et al. 2022; Chastain et al. 2020; Alegria et al. 2021) which makes it unsurprising that the 17 studies I analyzed were mostly not representative.

However, it is neither a fair, nor valid argument to say that minorities do not participate in clinical research and have worst health outcomes without exploring why, which I will do using the fundamental cause theory from Link and Phelan (1995).

When analyzing the results of the COVID-19 pandemic (or any public health crisis) the important factor to focus on is basic social conditions (Link & Phelan, 1995). Without addressing the fundamental cause, which is SES, new issues continually arise. People with more resources are better able to insulate and protect themselves from disease. Comparing the results of the COVID-19 pandemic with epidemics like AIDS and tuberculosis the results are similar in that there was a more rapid spread of infection in low-income areas.

The disparate outcomes of the COVID-19 pandemic are the fault of the government for not addressing fundamental causes of health risks and ensuring that groups with less access and less resources were able to get what they needed. Individualized advice such as staying at home, wearing masks, washing hands, and social distancing were the proximal solutions to the mechanism yet, millions of people still died because there has not been an address of the fundamental cause. Link and Phelan predicted that the consequence would be that "lives and money are wasted, and the American public will lose confidence in the ability to implement changes that really improve health." (p.89). They were correct.

Though I argue race is an undesirable characteristic to identify people by in biomedical research, it can be considered a fundamental cause of inequality and disease (Link and Phelan, 1995). They argue that racism is the fundamental cause of racial differences in SES. Since SES is

the fundamental cause of health disparities, racial inequalities in health endure (Link & Phelan, 2015).

The results of this study show that the COVID-19 antiviral clinical drug trials were not representative of groups greatest effected by the virus, but it is crucial that clinical trials be representative, and I lay out what steps need to be taken to conduct research better.

Conclusion

A one-size-fits-all approach to biomedical knowledge is inefficient (Epstein, 2007). He argues that what currently happens in biomedical research is the inclusion-and-difference paradigm. Including members of diverse groups as research subjects is highly promoted, and then the measurement of outcome differences is done across medical subgroups. That is evident in some of the rhetoric surrounding COVID-19 and its harsher effects on communities of color. Epstein urges readers to delve deeper to understand that there is an underlying cause for health disparities across racial lines. He says that using census categories to group people in biomedical research needs to be revised, and other factors are more important.

With my study, in particular, I analyzed the racial demographics of COVID-19 antiviral drug clinical trials because that is the available data. Race is a category that gives meaning to inequality, so it is still important to analyze, but there are better options. Social practices and structures, for instance, are better determinants of health (Epstein, 2007). We should not limit how we think about health, illness, and risk to race categories. Some examples of categories that are more important than race include “childhood residence, current residence, occupation, diet, exercise, age, wealth, income, and regularity of medical care (Epstein, 2007, p. 288).” With the example of COVID-19, subgroups such as age, SES, and underlying health conditions would be better suited. Some of those issues are along racial lines; however, limiting it to race without

considering other social determinants of health makes it seem more biological. When researchers essentialize certain traits and assert biological differences, it leads to a slippery slope reminiscent of eugenics.

Epstein also reminds us that representation is not a cure-all. He says that no methodology can guarantee external validity for all of humanity, so definitely not for a specific subgroup either. He reminds us that there are limits to technology and what policy can change. I think for this reason, studies like *Race and ethnicity do not impact eligibility for remdesivir: A single-center experience* must exist (Pischel et al., 2021). They examined if there were differences in eligibility for treatment with remdesivir based on clinical trial criteria for racial and ethnic minorities compared to non-Hispanic Whites. They found no difference in eligibility for remdesivir based on race or ethnicity alone.

Political categories being transposed onto medical research makes clinical trials more representative, but it does not get to the root of health disparities. Just including different groups of people in research is not enough unless some of the basic assumptions that traditional research relies on are also challenged. Race, class, and gender are social constructions that cause different expressions of illness. COVID-19 is a respiratory disease, so health officials advised people to wear masks. At the height of the pandemic, not everyone had access to masks, specifically poor people. Other factors besides race determined if someone could not get to the store to purchase masks or did not have an ample supply of masks. Public health officials also advised people to social distance and stay at least six feet away from others. That is not something that is inherently more challenging for Black and Brown people, but it is more difficult for people who live in multigenerational homes, for people who do not have the luxury of being able to stay at home, or for people who live in densely populated areas, etc. Another advice from health

officials was to stay at home. Again, that is not a racial issue, but people who are essential workers and are required to go out into the public cannot stay at home, and in the United States, many of these inequalities are along racial lines. However, biomedical research should not analyze health disparities along sociopolitical lines. Someone's access to resources is more critical in determining health status than their race or any other categorical grouping.
The people greatest affected by COVID-19 need representation in the clinical trials, and it is not because they are biologically different, but because they do have different life circumstances that are affecting their health; therefore, they need to be studied.

While COVID-19 garnered significant attention about its devastating effects on minority communities, it is crucial to recognize that similar disparities exist in many other health crises. I focus on two primary reasons for the lack of minority representation in clinical trials: mistrust and structural barriers that make participation inaccessible. However, equitable representation in clinical trials is possible via organizing more community-based participatory research and legislating structural changes that make research participation more accessible.

Michener et. al (2020) say that rebuilding trust in medical research after a history of misconduct requires adopting community-based participatory research. Government agencies and academic collaborators must treat communities as equal partners in research. The research must address concerns that matter to the community and actively work towards reducing inequities in testing, treatment, and access to vaccines. Community engagement and partnerships are crucial for achieving health equity, especially during pandemics. Oh et. al (2015) also argue that it is crucial to prioritize the inclusion of diverse populations in research. They say recruitment approaches should be considered as criteria for scientific merit scoring. Rather than the advancement of science and medicine conflicting with social justice for underrepresented

groups, those two initiatives can and should work hand in hand. The results of studying diverse populations include sound science and political and economic equality (Oh et. al, 2015).

More meaningful representation can be achieved by considering diversity beyond political categories and incorporating factors like income, neighborhood, and lifestyle, for example. Hacking (2001) discusses how people categorize different things. He basically says that we use language to categorize things based on what already exists. I think this argument works well in explaining why there is an overlay of race in biomedicine, but it conversely works well in explaining that new categories can be created. Since race is a category that people were already familiar with, we continued to use it even in instances where it was irrelevant such as biomedical research. However, that is not to say that people are unable to create new categories, and perhaps better categories. Collecting socioeconomic status data for participants interested in clinical trials, particularly those involving financial incentives, can mitigate the exploitative nature of first-in-human trials and a fundamental cause of health disparities, namely SES. (Link & Phelan, 1995; Epstein, 2007). Link and Phelan (1995) suggest policies that address SES, like capital-gain taxes and head-start programs, are relevant to the cause of disease and address the social issue.

Biomedical research must move beyond categorizing individuals solely based on race and address the root causes of health disparities. If we do not address the fundamental cause, there will continue to be more public health crises that disproportionately harm low SES communities. By striving for diversity, inclusivity, and equity, we can create a more just and effective healthcare system that considers the broader social determinants of health and works towards the well-being of all individuals.

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