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Cancer Clinical Trials: The Role of Healthcare Providers in Addressing Inequitable Racial/Ethnic Minority Representation in Biomedical Research

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CANCER CLINICAL TRIALS: THE ROLE OF HEALTHCARE PROVIDERS IN ADDRESSING INEQUITABLE RACIAL/ETHNIC MINORITY REPRESENTATION IN BIOMEDICAL RESEARCH

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INTRODUCTION

Fear of unintentionally expressing offensive and/or discriminatory ideas often causes hesitancy to address both the existence of race and ethnicity and its impact. In science, a driving force behind researchers' fear is the historical reality and contemporary potential for research findings to manipulate categories of race/ethnicity to justify discrimination, or, alternatively, to use them as evidence to identify a superior race. To compensate for this history of racialized and racist science, contemporary scientists deny race as a biological concept and prefer to see it solely as a socio-political construct isolated entirely from the realm of science. However, in areas of science such as biomedical research and medicine, the capacity to understand patients holistically– with respect to all aspects of their identity, race included– is necessary to address health disparities. In order to effectively diagnose and treat patients, holistic medicine emphasizes the uniqueness of each patient. It is an attitudinal approach to health care that not only focuses on the biological dimensions of health and illness, but also incorporates the societal, ethical, and spiritual aspects that contribute to its outcomes (Gordon, 1982, June).

"This paper aims to support the explicit incorporation and importance of race/ethnicity in biomedical research through exploring the causes of the underrepresentation of racial/ ethnic minorities in cancer research trials."

Reducing health disparities thus requires attending to patients' race and ethnicity, despite medical researchers' deeply problematic history of doing so.

This paper aims to support the explicit incorporation and importance of race/ethnicity in biomedical research through exploring the causes of the underrepresentation of racial/ethnic minorities in cancer research trials. Cancer research trials are specifically used in this paper as a microcosm for biomedical research because of the high percentage of research funding it receives relative to other medical research endeavors. The mechanisms of and appropriate treatments for cancer have yet to be comprehensively understood; thus it is a well-funded research endeavor by the government, industry, and philanthropies (Trasta, 2018). The extraordinary funding for cancer research is due, in part, to the desire to gain a more comprehensive understanding of the disease which is the second leading cause of death in Americans, following closely behind heart disease (National Cancer Institute, n.d.). In 2017, the US National Institutes of Health (NIH), allocated to cancer research 6.3 billion dollars of the 33.1 billion dollar budget established for medical research. The 19% of government medical research funding

is designated specifically for the various types of cancer research (e.g., breast cancer, cervical cancer, ovarian cancer). For this reason, the trends observed in oncological research/clinical trials can be asserted to align with other areas of medical research. Additionally, aside from funding, many causes of cancer have been irrefutably linked to environmental and social factors (Stanford Medicine Health Care, n.d.), thus making oncological research trials the optimal candidate for examination in the context of racial/ethnic minorities.

Due to the complex and flexible definition of race and ethnicity, defining its use in this paper is vital. The contemporary understanding of ethnicity, and race in biology and medicine, has evolved as a result of advancements in the scientific field and innovations in technology, such as the completion of the Human Genome Project (HGP). HGP and similar initiatives throughout history have continuously attempted to clarify and define the idea of race. As of 2003, the HGP had successfully debunked claims of race-specific genes in humans, instead explaining that an individual's genome contains the information that determines ancestral lineage (Hood & Rowen, 2013, September 13). Eventually, due to the inability to trace any biological evidence of race and ethnicity, its legitimacy as a variable in genetics research has often been criticized. Yudell et al. (2016) claim that "Phasing out racial terminology in biological sciences would send an important message to scientists and the public alike: Historical racial categories that are treated as natural and infused with notions of superiority and inferiority have no place in biology." They mention that racial categories that have historically been used to classify humans as superior or inferior have no place in biology. However, they acknowledge the importance of considering race as a socio-political category to study racism and its implications in biology: individuals practicing science, medicine, and healthcare do not exist in a vacuum without racial prejudice or systemic racism. This systemic racism, which has caused structural inequities and discrimination, has also inevitably produced health disparities in socially and culturally defined racial/ethnic minority groups (Chou, 2017). Hence in this paper, race/ethnicity is heavily intertwined with systemic racism; racial/ethnic identity is a key determinant of socioeconomic factors that dictate an individual's lifestyle. These identities are "self-reported race/ethnic" categories. Thus, the central focus of this paper will be on non-genetic factors relating to race.

Regarding the "self-reported race/ethnic" categories identified and used throughout this paper, it is crucial to first address the limitations of available terminology for describing race in most medical research. Juan F. Perea's The Black/White Binary Paradigm of Race explores this theme in great depth; Perea summarizes the Black/White Binary Paradigm as the "tendency to truncate history for the sake of telling a linear story of progress" (1997). In the biological and biomedical context, the Black/White Binary Paradigm refers to the inclination of statistics, literature, and research to divide the sample population into two neat categories for the sake of ease and efficiency. To accommodate the rapid diversification of the US healthcare system, these two categories have extended into four: White, Asian, Black, and Hispanic. However, this straightforward method of classification is remiss in acknowledging the expansive spectrum of race and ethnicities that exist between the four listed, as well as the substantial percentage of the population that comprises interracial individuals. In this regard, this paper is limited to primarily analyzing the four racial/ethnic minorities most often included in literature: White, Asian, Black, and Hispanic. Further, this paper cannot account for the consideration of interracial populations or racial/ethnic populations aside from the four listed.

CURRENT TRENDS IN CANCER RESEARCH TRIALS CONCERNING THE REPRESENTATION OF RACIAL/ETHNIC MINORITIES

In the United States, minority/ethnic groups are severely underrepresented in cancer clinical trials. According to Habr & Ferdinand (2021), relative to their US cancer incidence and expected

clinical trial participation, Black and Hispanic demographics were drastically underrepresented in clinical trials supporting the Food and Drug Administration (FDA) approval of cancer therapeutics from 2008 through 2018. Specifically, only 22% and 44% of the Black and Hispanic participants necessary to adequately represent the US cancer incidence actually participated in cancer clinical trials over the course of the decade. The insufficient research being performed to comprehensively assess and understand the nature of illness in these ethnic/racial minority communities has left cancer research vulnerable to promoting health disparities. Despite efforts currently in place to accurately represent and recruit cancer clinical research trial participants, this area of healthcare clearly continues to fall short in addressing mentioned disparities. For example, through the Revitalization Act of 1993, the National Institute of Health aimed to reform the manner in which clinical trials were conducted by mandating trial guidelines inclusive of women and minority groups. Ultimately, however, the outcome of this notion was minimal and made no substantial movements toward adequate representation of racial/ethnic minorities in clinical

Figure 1

Representation in Food and Drug Administration (FDA) approvals for cancer therapeutics 2008-2018

Race/Ethnic Categories reported	Representation in Cancer Research Trials	Comparison with the actual cancer incidence proportion in the US
White	76.3%	98% of expected
Asian	18.3%	438% of expected
Black	3.1%	22% of expected
Hispanic	6.12%	44% of expected

(Habr & Ferdinand, 2021)

As established by decades of cancer research, specific types of cancer (i.e., breast, lung, prostate, and colorectal cancers, and several hematologic malignancies) have continued to impact afflicted populations of racial/ethnic minorities to greater degrees when compared to their White counterparts (Habr & Ferdinand, 2021). Namely, according to incidence data collected through 2018 by the American Cancer Society, Asian and Pacific Islander (API) populations were found to share the highest incidence of liver and stomach cancer rates, while Black populations represented the greatest incidence of new prostate cancers (Siegel et al., 2022, January 12). Not only in rates of incidence have these trends amongst racial/ethnic minorities been identified; minority demographics have been found to be at more advanced stages upon presentation consistently, and share worse prognoses in affected patients (Habr & Ferdinand, 2021). For cancer-related deaths, multiple studies have stated that Black populations are at considerably higher risk. (Tong et al., 2022; Hadidi et al., 2020).

Precision medicine and unique tumor profiles have received accelerated focus as the ideal treatment method for cancer patients as a result of scientific advancements. This makes it imperative that the alarming representation gaps in race/ethnicity must be addressed in cancer research (McKay et al., 2021). Precision medicine treatments rely heavily on understanding and including factors that are unique to every individual (e.g., type of cancer, immune system, lifestyle) (AACR, 2022). If this is

genuinely the future of medicine– catering to the individuality of patients– a holistic approach in assessing patients' conditions must be accounted for to achieve quality healthcare provision for all. Firstly, however, it is essential to acknowledge that incorporating the effects of race/ethnicity is highly complex. According to McKay et al., racism, genetic and biological determinants, differences in diet, physical activity, psychosocial factors, socioeconomic factors, and healthcare access are factors that are likely to affect each other that make incorporating race/ethnicity difficult (2021).

FACTORS THAT CONTRIBUTE TO THE MISREPRESENTATION IN CANCER RESEARCH

The gross misrepresentation of the actual incidence of cancers amongst mutually exclusive categories of race/ethnicity in cancer clinical trials has made it extremely difficult to understand the nature of illness in these communities comprehensively. There is (usually) a two-pronged approach to mitigate the underrepresentation issues in cancer research: patient-centric and provider-centric.

Patient-centric approaches involve addressing inequitable access to quality healthcare and the hesitancy of people of color to participate in oncological clinical trial research. It is well established that racial and ethnic minorities and other medically underserved populations receive significantly lower quality care compared to White individuals; this inequity is driven by the lack of universal health insurance. According to the 2020 census, a comparable 19.5 percent of the Black and 17 percent of the Hispanic populations in the U.S. were found to live below the federal poverty level as opposed to 8.2 percent of White populations; a greater population of racial/ethnic minority individuals are of low socioeconomic status (Shrider et al., 2021, September 14). As stated by the American Association for Cancer Research, this prevalence in low socioeconomic status amongst racial/ethnic minorities directly coincides with a lack of access to quality healthcare. In this regard, without access to medical professionals with their best interest in mind or access to referring clinicians who would remotely consider them as candidates for these trials, racial/ethnic minorities will also lack access to cancer research clinical trials– a further factor exacerbating their underrepresentation.

Beyond inequitable access to healthcare, the traumatic history surrounding racial/ethnic minorities in biomedical research has cultivated a culture of hesitancy regarding medicine and trial participation. Due to research abuses such as the U.S. Public Health Service Syphilis Study at Tuskegee and the more recent case in which the Havasupai Tribe were manipulated for scientific research, racial/ethnic minorities have generally been averse to entrusting their health and well-being to clinical trial researchers (Garrison, 2013). Ultimately, however, racial/ethnic minority hesitancy is not solely to blame for the underrepresentation of POC in cancer clinical trials.

Whereas most often, the underrepresentation of racial/ethnic minorities in clinical trials is immediately attributed to inadequate access to healthcare or the fear of participating in medical research, one integral aspect of the oncology clinical trial participant screening process is gravely overlooked: researcher and clinician bias. In order to include a sample of patients in a clinical trial that is even moderately reflective of actual incidence amongst mutually exclusive categories of race/ethnicity, those responsible for patient screening and selection must not act on or possess any prejudice towards Black, Indigenous, and People of Color (BIPOC). However, according to a 2019 study conducted by Niranjan et al., racial prejudice is rampant in every step of the oncology clinical trial participant screening process; between cancer center leadership, principal investigators, research staff, and referring clinicians, the study found all four levels of clinical research to possess bias that would heavily restrict the involvement of racial/ethnic minorities in oncology clinical trials. Specifically, several of those interviewed expressed the common sentiment that constraints (e.g., limited physician time) made it burdensome to analyze the complex nuances of clinical research. For this reason, they perceived the demands of clinical medicine as a barrier to offering cancer clinical trials to racial and ethnic minorities (Niranjan et al., 2019).

In the article, one member of the research staff describes her own experience with BIPOC patient recruitment:

> *I don't know if it's more them or me because I'm uncomfortable. One of my own personal biases if I'm going to do the study and I know I have to enroll minorities, have I really had a conversation with myself? Am I really going to work–am I really willing to do the work to be able to make–to have a buy-in and to really connect with somebody and to really have a trust factor so that people understand?*

Capturing the predominant methodology/attitude of the research community, this quote underscores how researchers view the accommodation of BIPOC as an inconvenience rather than a necessity. The modern approach by the research community aims to streamline patient recruitment at the cost of sample integrity and racial/ethnic accuracy. Later in the same article, a referring clinician explains:

> *To get them to understand that requires a lot of groundwork, you know, and a lot of education, and you know, when you're pushed to see 20 patients in a day, and when the, the metric that is used to measure your performance is how much patients you put through the hospital, and that's the overriding pressure on you, clinical trials will fall by the wayside, and I would imagine that trust is more difficult to build in certain.*

Although the clinician explicitly acknowledges the complexities of inadequate medical/health education amongst BIPOC, this quote and others reveal a deeply concerning outlook on the process of educating racial/ethnic minorities that is resonant with the entire biomedical/clinical research community. For many researchers and clinicians, the process of carefully educating racial/ethnic minorities about the oncological clinical trial process is excessively laborious and minimally consequential. During the cost-benefit analysis of including BIPOC candidates for oncology clinical trials participation, those involved in the research process generally practice the ideology that "It's just too hard to try to talk them into a clinical trial, so let's just do standard therapy" (Niranjan et al., 2019).

As this approach to racial/ethnic minority involvement in oncology research persists, the specific mechanisms of participant selection criteria are called into question. Research has made it abundantly clear that the screening for participants in cancer clinical trials continues to remain unchanged, despite evidence explicitly illustrating the inadequate representation of BIPOC. As evidenced by Hao et al. in 2014, modern oncological research trials utilize an automated approach, clustering clinical trials with similar eligibility features. In order to generate selection criteria for new cancer clinical trials, researchers look to trials previously performed within similar constraints, then directly base the patient screening for their new research off of screening for old research. In this way, oncological clinical research trials have developed a cyclic nature of BIPOC exclusion; if previous clinical trials contain no effectual guidelines for adequate racial/ethnic representation, then neither will subsequent new trials. Once again, leaving the cancer clinical trial selection process unchanged produces insufficient research to comprehensively assess and understand the nature of illness for BIPOC, abandoning racial/ethnic minorities in the quest for a cure.

In considering the various contributors to the misrepresentation of racial/ethnic minority communities in cancer clinical trials, we have highlighted the rampant biases on the more individual levels (e.g., principal investigators, research staff, and referring clinicians). It is crucial, however, that we also step back and acknowledge the systemic nature of this issue. Although it is important to understand the impact of the biases we see in quotes taken from research staff and referring clinicians, the nonchalance and disinterest observed in their attitudes toward racial/ethnic minority inclusion and education echoes the profit-driven culture that surrounds them. Specifically, when working for and funded by leaders of the cancer-research industry, these clinicians and researchers are expected

to conduct trials and generate data in massive quantities, for minimum cost, at efficient rates. For this reason, the additional effort that may be required to incorporate or educate racial/ethnic minorities is felt to be extraneous – especially without any substantial framework to guide principal investigators, research staff, and referring clinicians towards BIPOC inclusion. In this regard, the responsibility to incorporate more racial/ethnic minorities into clinical trial recruitment lies on the shoulders of the companies themselves. This shift towards inclusivity that we need to see in clinical research cannot be achieved through the valiant, individual efforts of research staff and referring clinicians– this is an effort that must be made by those in charge of cancer research institutions and those who shape NIH policy. "Data-gathering efforts and research are focused on understanding the facts and circumstances that the relevant paradigm teaches us are important" (Perea, 1997). If the lens enforced by those who lead cancer research prioritizes the quantity of data to the quality of its output and impact, all data-gathering efforts and research will be geared toward a fast-production data algorithm that excludes BIPOC.

DISCUSSION AND RECOMMENDATIONS

Through oncological clinical trials, the misrepresentation of racial/ethnic minorities is starkly apparent. These racial disparities, however, translate across all areas of biomedical research. The biased approaches to the inclusivity of BIPOC, as demonstrated by cancer center leadership, principal investigators, research staff, and referring clinicians represent methodologies upheld by most of the biomedical research community. In fact, to circumvent the use of race in biomedical research, many researchers and clinicians will choose to use ancestry instead; for much of the scientific community, ancestry is greatly preferred and highlighted when race/ethnicity is involved. Ancestry is indeed a more well-defined concept than race, as the latter is socially ascribed. Ancestry is also especially helpful when identifying the genetic differences contributing to susceptibility to specific diseases. However, as much as medicine and science strive to remain neutral and fact-based, they do not exist in political and social vacuums; they are vulnerable to biases and prejudice of the community if there is no active action to address them. Biomedical researchers must acknowledge and address the role of race in their clinical trials, then actively work to guarantee that their samples are reflective of actual incidence amongst mutually exclusive categories of race/ethnicity. If these researchers fail to address these challenges or to incorporate racial/ethnic minorities in their research– if they are not actively anti-racist– then they become a part of a larger, systemic healthcare industry structure that perpetuate disparities.

As a benchmark for introducing racial/ethnic minority inclusivity to American clinical trials, we look to Trial Forge's INCLUDE Ethnicity Framework, which is enforced by the UK's National Institute for Health Research (NIHR). INCLUDE is an initiative that aims to improve trial delivery for underserved communities; INCLUDE operates with the understanding that trial teams (i.e., those responsible for organization/recruitment) have the obligation to do everything possible to make their trial relevant to the people for whom the results are intended to apply (often patients) and those expected to apply them (often healthcare professionals) (Treweek, 2022, May 25).

The INCLUDE framework details an elaborate process to achieve adequate racial/ethnic minority representation– a process in line with Principle 13 of the Declaration of Helsinki, which dictates that groups underrepresented in medical research should be provided appropriate access to participation in research (World Medical Association, 2022, September 6). Founded in 2017, INCLUDE is a relatively recent initiative by the UK NIHR to "steer development of guidance and initiatives to increase the inclusion of under-served groups in research"; INCLUDE is a nationally enforced, systematic approach to addressing the racial disparities in [biomedical/clinical] research. (Treweek, 2022, May 25)
The whole-hearted commitment to change

demonstrated by the INCLUDE framework clearly demonstrates to us that this shift towards adequate representation is achievable. Although transitioning to a similar framework may seem comparatively time and resource-consuming in the short-term, the shift will be beneficial in the long run. As the authors of INCLUDE explain, "Time and money invested in trials recruiting diverse populations are likely to deliver more relevant research, with a consequent reduction in research waste and misallocated healthcare resources in the longer term." With dedication from leaders of the cancer research industry to this systematic approach and the long-term investment from policymakers, the American healthcare and biomedical research industry can effectively integrate racial/ethnic minorities into biomedical research, producing relevant and inclusive data to protect all communities.

CONCLUSION

Despite immense evidence that explicitly demonstrates the racial disparities and inadequate BIPOC representation in biomedical research, this research continues to misrepresent racial/ethnic minorities. Following thorough examination of the various patient-centric and provider-centric approaches to these racial disparities, we recommend the implementation of a structured framework to minimize the implications of implicit bias and prejudice in all levels of clinical research. This transition towards inclusivity and representation is a responsibility that must be undertaken by leaders of cancer research institutions and the NIH.

As two members of the future medical community, and as two members of the minority communities being under and misrepresented in our future profession, we implore the biomedical research community to establish minimum criteria that the demographic of clinical research samples be representative of actual incidence reflected in research. This framework will require an active effort on all levels of research (e.g., research center leadership, principal investigators, research staff, and referring clinicians) to address this persisting problem, and must provide clinical researchers with guidelines to minimize the implications of implicit bias and prejudice. We acknowledge the considerable challenge that incorporating race/ethnicity presents to biomedical researchers as it is a complex issue for which rectification likely necessitates alterations throughout experimental/candidate screening design. However, valuable data and information from the output of research are lost by neglecting to factor in race/ethnicity. This critical loss hinders our ability to fully understand diseases and slows the movement toward optimized precision medicine. In following the footsteps of inclusivity initiatives like INCLUDE, the US healthcare system could bridge the gap left behind by decades of minority-exclusive research.

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Jilian Maxine Jalipa Frianela is an undergraduate student from the Philippines, currently pursuing a major in Biomedical Sciences with a minor in Philosophy at St. John's University. Having grown up in Manila and being exposed to a diverse range of social issues, Jilian has developed a strong passion for exploring the intersection of medical sciences and social justice. Alongside her pre-medical studies, she actively participates in various extracurricular and co-curricular activities focused