Gender, Race, & Socioeconomic Status: The Role of Intersectionality in Clinical Research

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Ramneek Kaur

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

Advisor

Caitlin D. Wylie, Department of Engineering and Society

Introduction:

The inclusion of women in clinical research has remained low over the past 10 years, with women comprising less than half of participants in clinical oncology trials (Bierer et al., 2022). This statistic gets worse as you take into account the different social identities associated with women, such as race, ethnicity, and socioeconomic status, with only 8-11% of patients from Black or Hispanic backgrounds represented in these same trials. This has severe implications for the diagnosis and treatment of diseases, especially ones with a higher prevalence across a specific social identity, with an incomprehension of disease risk factors.

The underlying impacts associated with the current state of clinical research representation highlight the importance of determining and analyzing the factors contributing to these disparities. These factors include internal barriers, through the trial criteria used to exclude potential patients, and the external barriers patients face when deciding whether to partake in a trial. To better understand the underlying reasons behind the lack of proper representation in clinical trials, it is important to look at the role different social identities play in women's interactions with the clinical research process. Social identities are how people are categorized into different groups, both by themselves and by the outside world.

This paper will analyze how the social identities of gender, race/ethnicity, and socioeconomic status intersect and impact women's interactions with the clinical research process, contributing to the inadequate representation of women. The analysis will be performed using the sociotechnical application of intersectionality, a term coined by Kimberlé Crenshaw, as a framework to understand how different social identities impact an individual's experience in systems of privilege and oppression (Bowleg, 2012). Crenshaw describes intersectionality as a "...lens through which you can see where power comes and collides, where it interlocks and

intersects" (Columbia Law School, 2017), highlighting that the multiple identities an individual has all contribute to systemic biases perpetuated on them, not just one of their identities. Through this, we will determine how the different social identities of women, imposed by themselves and by medical professionals, impact their interactions and underrepresentation within clinical research.

Gender Identity:

Adequate gender representation in clinical research is crucial to ensure that sex-based differences in disease manifestation and progression are accounted for. However, the representation of women in research is still a big concern today, despite progress made in the last two decades with research funding incentives rooted in inclusion. These issues are highlighted in a peer-reviewed study by Norris et al. (2020), discovering that a lack of research on cardiovascular disease (CVD) in women has led to reproductive concerns not being accounted for in CVD risk tests, despite their prevalence in the disease. This is just one example showing the importance of understanding the underrepresentation of women in clinical research based on gender identity.

Exclusion Criteria

To understand the role gender plays in the underrepresentation of women, three studies on clinical trials on CVD and Type 2 diabetes were analyzed to assess exclusion criteria specific to gender[1] (Heiat et al., 2022; Phelan et al., 2016; Stanton et al., 2024). These peer-reviewed studies were chosen based on the prevalence of these diseases amongst women and whether they

[1] In this analysis, we will focus on cisgender women. However, this does not negate the fact that the experience of women who are non-biological females in clinical research is unique and should also be researched to fully understand the impacts of gender identity on the shaping of the clinical research process. The focus is on cisgender women because this paper seeks to understand more about how reproductive health is (or is not) represented and accounted for in clinical research for women.

included requirements for clinical trial participants. The exclusion criteria discovered in these trials include pregnancy, contraception usage, and childbearing potential. A recent study by Stanton et al. (2024) on CVD research highlighted the issues with the exclusion criteria described above, finding that they have the potential to exclude more women from stroke clinical trials. In addition to this CVD trial study, another study on heart failure found that one exclusion criterion was based on left ventricular ejection fraction (LVEF) and that the majority of trial participants were often younger and male (Heiat et al., 2022). Looking deeper into the potential relationship between LVEF and gender identity, it was found that LVEF was typically higher in women (Chung et al., 2006), leading to the conclusion that LVEF exclusion criteria could be an additional reason why Heiat et al. (2002) found that women were underrepresented in their research. This implies that exclusion criteria typically assumed to impact all genders equally should be evaluated further to determine if they disproportionately exclude certain groups from participating.

The exclusion criteria on contraception usage and the childbearing potential of women also stood out as relevant factors during the clinical trial study review. In a study on Type 2 diabetes, Phelan et al. (2016) found that 59% of these clinical studies had exclusion criteria of women with child-bearing potential, and 33.4% of the studies required the use of at least one contraceptive. This criterion has severe impacts on the quality of treatment for diabetes, as women aged 25-44 have a death rate triple that of non-diabetic women (Phelan, 2016). After looking deeper into these studies, it was found that the exclusion criteria of child-bearing potential did not account for the female patient's personal choices in having children or not. This shows the possibility of eligible research participants being excluded based on criteria not aligned with their life plans, with the assumption of motherhood for all potential female patients

in a clinical trial. Additionally, many forms of contraception can have adverse risks and symptoms, such as birth control pills, which can impact a woman's decision on whether to utilize one or more forms of contraception. This personal choice thus limits the patient's ability to participate in a clinical trial. Overall, these exclusion criteria highlight the tendency of the clinical research process to impose assumptions associated with the gender identity of patients, regardless of their true relevance in a patient's life.

Personal Deterrents

Another barrier that contributes to the underrepresentation of women in clinical research is the personal deterrents associated with the social identity of gender. One study by Reza et al. (2022) discovered that some of these deterrents to women were a lack of time, poor health, and travel burdens. Out of these, the one most relevant to the social identity of women is the lack of time. Women, on average, have 13% less free time compared to men of their respective ages. This difference varies based on the woman's age and period of life, with mothers' free time limited by spending approximately 2.3 times the time on housework and childcare than men (Gender Equity Policy Institute [GEPI], 2024). This disparity in free time between men and women increases when looking at working mothers. Having less free time results in a lower ability to participate in clinical trials due to the lengthy process, in addition to the time it takes to travel to a research facility. Time spent attending these appointments reduces the free time women have for stress relief and relaxation, in addition to the time they need for the necessary tasks in their livelihood.

Another critical deterrent observed with women in a clinical trial study by Hawke et al. (2024) is the fear of losing autonomy over their healthcare choices. This is especially prevalent with gender identity due to the high politicization of women's health, specifically concerning

reproductive healthcare. These fears may relate to the potential disruption of current medication for reproductive health, such as birth control, requirements of contraception usage in trials overlooking the personal choices of the patient, and the lack of privacy for personal health choices. These concerns, in addition to the difficulty in anonymizing patients in clinical trials, could be a strong contributor to deterring women from participating in research.

The role of exclusion criteria and personal deterrents associated with women's gender identity are big factors in the underrepresentation of women in clinical research. This lack of representation, which then contributes to decreased understanding of disease progression in women, leads to a continued loop of fear, preventing women from participating in clinical research. Addressing these issues, such as modifying exclusion criteria that impact women more than men and finding ways to allow women a sense of autonomy and a limited time commitment in the clinical setting, can help ensure women are adequately involved in clinical research.

Racial/Ethnic Identity:

Many diseases vary strongly in how they progress and their impacts on a patient based on their racial and/or ethnic background; however, proper representation of these identities is still severely lacking. One study by Clarke et al. (2022) reviewed the origins of breast cancer (BCa) cell lines from major suppliers and determined that the number of cell lines derived from patients in the United States were 70-80% of European descent, despite Black women being 40% more likely to die from the disease. Lack of diversity in BCa cell lines results in a decreased understanding of the disease form that is most prevalent for Black women, even though this form is more aggressive. This study provides one example of the underrepresentation of women of color (WOC) and shows the need to understand how the role of racial/ethnic identity intertwined

with gender identity results in this healthcare disparity through the lens of the intersectionality framework.

Exclusion Criteria

The specific exclusion criteria associated with racial/ethnic identity were extracted from the same clinical trial studies used for gender identity, in addition to one study on Alzheimer's Disease (AD) (Franzen et al., 2021), chosen due to providing relevant exclusion criteria from the trials. The common criteria in these studies include contraception usage, comorbidities, elevated blood pressures, psychiatric disorders, and strict language requirements. At an initial review, these requirements do not appear to impact racial/ethnic groups differently, aside from language competency; however, when looking deeper into the statistics on these criteria, the differences become much more apparent. The criteria factors further analyzed through the intersectionality framework are contraception usage and language barriers.

Contraception usage, as discussed previously, is an exclusion criterion that strongly impacts women by not accounting for their autonomy in decision-making. When the identity of race and ethnicity come into play, disparities in contraception use are exacerbated, with one study by Dehlendorf et al. (2015) highlighting that minority women are typically less likely to use contraception. One of the potential reasons for this is the prevalence of distrust in the use of contraception when looking at the history of eugenics in the United States. Throughout the 1900s, women of Native American, Black, and Latinx backgrounds underwent sterilization abuse, with many women being sterilized involuntarily and sometimes without knowledge (Nuriddin et al., 2020). These coercive behaviors are still prevalent with a now-repealed Tennessee state law from 2017, incentivising sterilization for inmates to receive a sentence reduction in return (Equal Justice Initiative, 2017). The requirement of contraception use for

participation in clinical trials not only dismisses the personal choice specific to the gender identity of women but also the fears of exploitation and distrust prevalent based on the racial/ethnic identity of a female patient.

Language requirement exclusion criteria also play a big role in excluding patients based on their ethnic identity, especially Hispanic women. Franzen et al. (2021) found that 34.7% of clinical trials on AD require fluency in the test language, "local" language, or English, which, in the case of a US-based clinical study, would all be English fluency requirements. This criterion primarily excludes ethnic minorities despite the increased prevalence of AD amongst these communities (Anderson et al., 2004). The purpose of this requirement is to ensure the potential patient has a proper understanding of what the clinical trial involves so that they may provide their fully informed consent to volunteering. However, having a limited number of languages that a patient must be fluent in reduces the ability for different ethnic groups to participate. The issue of this requirement could be mitigated by having more providers or translators who are fluent in the patients' primary languages to ensure the data collected from the trial is representative of the whole population.

Personal Deterrents

Women of underrepresented racial and ethnic groups face external barriers associated with their racial/ethnic identity in addition to the barriers associated with gender identity, such as time and travel burdens. A study by Markan et al. (2025) analyzed the psychosocial factors impacting different racial groups' willingness to participate in clinical trials, finding that factors like religious beliefs and mistrust in the medical community deter these groups from volunteering in trials.

The role of religious beliefs and mistrust in medicine is often intertwined when it comes to a patient's willingness to participate in a clinical trial. Surveys analyzed by Jaber (2024) found that Black patients were 19% more likely to agree with statements like "God determines wellness, not research". A peer-reviewed study by Daverio-Zanetti et al. (2015) found that the religious beliefs of Latina women played a role in their interactions with clinical trials, as those more religious felt that their community would be less supportive of these trials. Both of these studies highlight how the role of religion in WOC's lives is a crucial part of their decision-making process, with clinical research based on their beliefs related to their predetermined destiny and the societal pressures that a patient may face.

Mistrust in medicine relates to the US history of perpetuating abuses on people of color, specifically in the medical field through forced sterilizations and the use of Black people's bodies for medical research, both enslaved and not (Nuriddin et al., 2020). In addition to past injustices, to this day, minority patients are not presented with adequate care, with maternal morbidity rates of Black women being approximately 2.6 times the rate of White women in 2021 (Hoyert, 2023). The continued perpetuation of systemic biases makes it difficult for minority women to trust that clinical trials will benefit them, especially because clinical trials put patients in a very vulnerable state. There is also the fear of using patients for monetary gain that is especially present within the Black community, as a result of Henrietta Lacks's story, a Black woman whose cells were taken without her informed consent and resulted in the start of a multi-billion-dollar industry (Lee et al., 2019). The effectiveness of a clinical trial is highly dependent on the relationship between the patient and the healthcare provider, and fears of abuse and exploitation of WOC can make it difficult for patients to believe the trial is for their benefit.

While the exclusion criteria and personal barriers that impact women based on their racial and ethnic identity presented in this paper are not by any means an exhaustive list, they strongly highlight how racial/ethnic identity plays a role in the lack of adequate representation for women in research. The intersection between the gender and racial/ethnic identity of a patient increases both the internal and external barriers faced by a potential participant in a clinical trial. Finding solutions that address the inequitable exclusion criteria by providing more support and resources for patients to meet the requirements and working to build trust between minority communities and healthcare providers is crucial for progress towards an equitable healthcare system.

Socioeconomic Identity:

Lower socioeconomic status patients typically are found to have worsened disease progression, in comparison to those from higher incomes and educational levels. One example of this is in a study by Astrike-Davis et al. (2022), where they discovered that disease progression was intensified amongst African American patients with rheumatoid arthritis who came from a lower socioeconomic background. In addition, it has been shown that patients of a lower socioeconomic background are often excluded from clinical research as a result of exclusion criteria unknowingly impacting these groups disproportionately (Moloney & Shiely, 2022). These groups are also often not accounted for when taking down the personal information of a clinical trial participant, leading to a lack of knowledge on how disease progression and treatment occur based on the socioeconomic status of the patient. Altogether, these studies highlight the necessity of ensuring adequate representation in clinical research based on the socioeconomic identity of a patient to help overcome healthcare disparities. To understand how

socioeconomic status intertwines with the gender identity of women, exclusion criteria and personal deterrents will be analyzed using the intersectionality framework.

Exclusion Criteria

The clinical trials evaluated for socioeconomic status include the previous three studies on trials discussed in gender and race, as well as one peer-reviewed study on clinical trials for depression (Buckman et al., 2022). These studies were chosen due to the prevalence of these diseases in women and the exclusion criteria provided. Across these trials, the most relevant exclusion criteria that stood out were contraception usage and comorbidities. Contraception use has been a key exclusion criterion impacting the different social identities associated with women, however, the relationship between socioeconomic status and contraception differs from the other identities based on the financial barriers to multiple uses of contraception. In the United States, access and quality of health care providers vary based on the economic background of a patient, in addition to their insurance provider, if a patient has health insurance. Contraception methods still typically have a requirement of interacting with a healthcare provider in some type of capacity, however, many women of lower socioeconomic statuses face limitations in accessing healthcare due to the cost associated with treatment and insurance coverage. One study by Kavanaugh et al. (2022) discovered that women from lower economic backgrounds are less likely to utilize their preferred method of contraception due to cost concerns. Women from a lower socioeconomic background are also more likely to utilize government-aided health insurance programs, however, the access and coverage of contraception through programs such as Medicaid are highly subject to the patient's home state (Chory & Bond, 2024). With the high politicization of women's health and dependency on state governments for insurance, patients using state programs are more susceptible to changes in their prescription coverage, which could

limit more women from having access to contraceptives. Overall, the criteria of contraception impact women based on their socioeconomic status, as not all women have equal access to contraceptives due to financial constraints and the unreliability of federal programs based on the location where a patient resides.

Another exclusion criterion that can unknowingly exclude women from lower socioeconomic backgrounds is the presence of comorbidities a patient may have. A study by Buckman et al. (2022) analyzed clinical trials focused on studying depression and found that prominent exclusion criteria in these trials dealt with patients who had additional personality or psychotic disorders. These criteria are also found in clinical trials facing other diseases, like cancer trials, and have been found to correlate with patients from lower socioeconomic statuses (Sharrocks et al., 2014). One possible reason why comorbidities are typically associated with low socioeconomic status is due to the disparities in healthcare access. Patients may not be able to afford to have regular checkups or have coverage that gives them adequate access to treatments, which could lead to a higher risk of developing illnesses that end up not being treated. As these illnesses progress, the risk of worsening health conditions and developing other diseases could increase (Ye et al., 2023). However, from the studies analyzed, it does not appear that clinical researchers take into account the impact of this exclusion criterion on the underrepresentation of people with low socioeconomic status in clinical research.

Personal Deterrents

The personal deterrents faced by women of lower socioeconomic status are predominantly associated with the financial burden of participating in clinical trials, with the most significant deterrents being cost and time. Women in the United States make less money than men and are more likely to be classified under the federal poverty line (Sun, 2023). This can

make it difficult to handle the costs associated with clinical trials, including travel arrangements and lost wages from getting out of work to participate in the research. In addition to the financial aspect of clinical research, the time involved with traveling and performing the actions necessary for the trial can result in time conflicts with the other regular daily activities women face (Bó, 2022). As discussed earlier with gender identity, women have significantly less free time than men due to the brunt of household responsibilities and childcare falling upon women to take care of (GEPI, 2024). This free time is even further decreased for women with low socioeconomic status, as the expenses of time-saving resources such as outsourced childcare and household cleaning are more difficult to attain with fewer financial resources. As a result, even if a clinical trial did not require as much financial cost to take part in the research, the time involved makes it even more difficult to participate based on the socioeconomic background of the patient. This highlights how the socioeconomic identity combined with the gender identity results in increased barriers, preventing adequate representation of these women from lower socioeconomic backgrounds in clinical research.

Conclusion:

The different social identities of women play a crucial role in the patient's ability and willingness to participate in a clinical trial. Adequate representation in clinical trials is necessary to ensure that the healthcare system is equitable and that researchers can determine how one's identity impacts the progression and impact a disease has on that patient. Overall, across the social identities of gender, race/ethnicity, and socioeconomic status, there are many similar exclusion criteria and personal deterrents shared across these groups, although the impact and intensity through which they emerge in the patient's life differ. As the different social identities

intertwined, as analyzed using the intersectionality framework (Bowleg, 2012), the impact of these barriers increased.

Through the analysis, it was found that much of the lack of accessibility to clinical trials for women was based on time constraints, requirements of contraception usage, and a lack of trust in the healthcare system. As we look forward to creating a clinical research process that is representative of all groups, we need to determine how we can make patients more comfortable with the process and whether there are ways we can circumvent certain exclusion criteria that disproportionately affect different social groups. By asking these questions and implementing the proper changes within the clinical research system, we will be able to move forward one step at a time to make the healthcare system equitable for all.

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