

REVIEW

The Impact of Underrepresentation in Cardiovascular Trials on Minorities in the United States

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Abstract:

In the United States, a great underrepresentation of minorities in cardiovascular trials was registered. This brings a lot of harm to their health because underrepresentation does not provide the possibility to develop the right knowledge to treat them in the best way possible. In addition, minorities in the United States are more likely to have a low socioeconomic status and not be able to afford health insurance and access care. Therefore, minorities have little to no access to specialty care centers used as referral bases for clinical trials making it harder and more expensive to recruit them. Economic issues, however, also impact people's choice to enroll in clinical trials, as taking time off work and away from children to be part of the trial may represent a great hindrance for someone. Minorities usually avoid participating in trials because of psychosocial factors, especially mistrust, fear of unexpected outcomes or exploitation. Racism also affects their choice, as it worsens communication between patients and providers, who are predominantly white, and even outcomes. Hence, underrepresentation leads to minorities having higher Cardiovascular Disease mortality and risk factors rates than White people. Disorders like Hypertension, Hypercholesterolemia, Obesity, and Diabetes are more prevalent among minorities especially because of their low socioeconomic status and less access to continuous care. Over the past years, the situation was tried to improve, but without any success. Despite the approval of guidelines, many researchers do not even report the patients' races, not allowing them to have a vivid portrait of the situation. Many actions can be taken to solve this issue, starting from adopting new recruitment strategies, for example the use of social media, but also making more thorough choices for referral bases,



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employing a more diverse staff, and investing more money to offer free meals, childcare, or even remuneration to patients. A rapid change is extremely necessary. Minorities are growing fast and many of them are not insured, have no access to primary care, and are more likely to die from Cardiovascular Disease.

Keywords: Cardiovascular disease, Minorities, Representation, Trials

Introduction

According to the United Kingdom National Health Service, [1] Cardiovascular Diseases (CVDs) can be defined as "any condition that affects the heart or blood vessels". The World Health Organization [2] considers CVDs as the following diseases: Coronary Heart Disease, Cerebrovascular Disease, Peripheral Arterial Disease, Rheumatic Heart Disease, Congenital Heart Disease, Deep Vein Thrombosis, and Pulmonary Embolism.

690,882 people died of heart disease in 2020, making it the leading cause of death in the United States, which is an increase of 4.8% since 2012.[3] Specifically, Coronary Heart Disease (CHD) is the cause of one in four deaths.[4] Despite the great impact that CHD and CVDs have on the whole American population, racial/ethnic minorities are underrepresented in clinical trials and research, and less likely to receive proper treatments than their White counterparts.

In 1993, to tackle this problem, the US Congress passed the Revitalization Act establishing guidelines for the participation of women and minorities in biomedical trials. After twenty-eight years, more than 40% of the American population (according to the 2019 U.S. Census[5]) is not accurately represented in trials.

This seems to be yet another discrimination minorities have to face in the American healthcare system. In fact, not only do they have less access to care than Whites, having higher rates of uninsured people, but they also have to cope with the lack of knowledge about conditions and treatments for nonwhite patients.

Health insurance is essential in the United States to receive care. According to the U.S. Census Bureau, [6] 5.4% of Non-Hispanic Whites were uninsured in 2018 compared to 9.7% of African Americans, 6.8% of Asian Americans, and 17.8% of Hispanics/Latinos.

In addition, African Americans, Asian Americans, and Hispanics/Latinos have higher CVD risk factors and mortality rates. This highlights the urgent need to address disparities and move researchers' focus from a predominantly White group to a more diverse and inclusive group of people that reflects the real American population.

This review analyzes the reason that leads to minorities' underrepresentation and the impact that it has, along with why there is an urgent need for a change.

Literature Review Methodology

The method followed in this review was adopted to answer two main questions:

- (a) are minorities underrepresented in cardiovascular trials?
- (b) are minorities more likely to be affected by CVD risk factors?

In order to answer these questions, different types of data were sought using Google Scholar. The search was limited to articles written from 2009 to 2021.

The following descriptors were used during the search: cardiovascular trials, minorities, CVD risk factors in minorities, Coronary Heart Disease, health disparities, minorities underrepresentation, health insurance, CVD racial disparities, CVD in nonwhite patients, recruitment in cardiovascular trials. In addition, federal sources were used for updated values of the U.S. population. Some of the sources employed in this review were found in the reference lists of relevant articles shown as outcomes of searches on Google Scholar.

The articles were initially selected on the basis of the following criteria:

- (a) date of publication
- (b) credentials of the source's author
- (c) number of citations
- (d) compatibility with the research question

After this initial step, the articles were carefully analyzed and relevant data was collected. It was then divided into qualitative and quantitative data. It was summarized in separate documents in which the name of the source and which question it answered were stated for each piece of data.

As question (a) are minorities underrepresented in cardiovascular trials? had an affirmative answer based on the data initially collected, the author decided to add a third main question (c) what causes underrepresentation? To answer this question the same method stated above was used.

Underrepresentation of minorities, data

In 2020, the U.S. Census Bureau published a report of the expected growth of the population within the next four decades (2020-2060). According to this projection, Non-Hispanic Whites will not constitute the majority of the American population in 2060, owing to a severe decrease in birth rate and significant increases in deaths.[7(p3)] Meanwhile, African Americans will compose 15% of the population, Asian Americans 9.1%, and Hispanics/Latinos 27.5%. The Asian American and Hispanic population is expected to double in this time frame.

These percentages are essential to understand the vast number of people, who are not properly represented in cardiovascular trials. Underrepresentation is extremely harmful to minorities' health because it leads to a lack of appropriate knowledge about risk factors, symptoms, treatments, and responses to drugs in nonwhite patients."[4,8-12]

Sardar et al.[13(p.1869)] studied the cohorts chosen for randomized controlled trials (RCTs) for atrial fibrillation (AF), heart failure (HF), and acute coronary syndrome (ACS). Firstly, it was found that less than a quarter of RCTs reported patients' race, but the number increased over time. The researchers found that 86% of patients enrolled in AF and ACS RCTs were White and 6% were Black; in HF RCTs 73% of patients were White and 19% were Black.

RCTs are very relevant because they have a great influence on clinical procedures, and the American College of Cardiology/American Heart Association guidelines for those diseases are mainly based on them. In addition, RCTs are considered the gold standard for research, because randomization allows a significant reduction of biases.[14] Despite this, Sardar et al.[13] demonstrated that RCTs are not perfect because they do not represent the American population properly. Flaws have been detected even by Hariton and Locascio,[14] who declared RCTs to be more expensive, have fewer possibilities of follow-ups, and do not have a proper representation of the population, because of lack of minority volunteers.

Zhang et al.[15(pp.54,55)] conducted a review on two hundred fifty cardiovascular trials conducted between 1997 and 2010. Almost half of them did not report the patients' races. Considering only Coronary Artery Disease trials, it was seen that Non-Hispanic Whites were highly overrepresented, as they made up 88% of the cohort when in 2013 they constituted 78% of the U.S. population. The only overrepresented minority was Asian Americans: 5% was the mean enrollment rate, but it was actually 2% of the population. African Americans were considerably underrepresented with an enrollment of 3%, although they made up 13% of the population. Hispanics were the only group that was properly represented with a 6% enrollment rate, when constituting 7% of the population.

These studies show not only the great issue of underrepresentation of minorities that, as mentioned before, leads to disparities in care, but also the predominant trend of avoiding reporting patients' races. This information would give us a more comprehensive view of the issue. As a matter of fact, Zhang et al.[15] suggested making reporting race mandatory.

Reasons for minorities' underrepresentation

Despite being aware of the harm underrepresentation causes to understudied groups, nothing impactful has been done in the last few decades. For instance, in 1993 the Revitalization Act established guidelines to include minorities and women in trials, but data of minorities' enrollment are still very low, why?

Some argue that minorities' recruitment would increase the costs and take more time because minorities have less access to specialty care institutes that are usually used as referral bases for trials.[16(p3)] In addition, another barrier for minorities is the absolute prevalence of White researchers and investigators. This has two main consequences. Firstly, researchers often do not tailor their approach to the culture and language of their patients - making it harder for people with different cultural backgrounds to fully understand the information about the program.[17(p16)] Secondly, minority patients are more likely to enroll in studies if the investigators have the same ethnicity, language, and culture as them.[16(p3)]

Psychosocial factors have a great impact and usually create additional barriers that prevent minorities from participating in trials. Mistrust is very widespread among understudied groups, usually due to lack of knowledge. Many people are also discouraged by the possibility of getting unexpected results during the trial that are in conflict with treatments the patient is already receiving and increase the medical cost. Furthermore, patients are concerned about health insurance not covering costs and finding the time to participate, especially if they work multiple jobs and have children to take care of. Some patients fear exploitation as well. This is related to the history of minorities' enrollment in abusive trials, such as the Tuskegee Syphilis Study. In addition, minorities do not want to enroll in studies

that will not help their communities, but will only treat them as "lab rats".[17(pp17,21-22)]

Racism, unfortunately, affects even biomedical research and especially African Americans' enrollment. Racism in this field can be internalized, affecting and worsening the communication between patients and providers, or interpersonal, resulting in discriminatory acts and worse outcomes for racialized patients.[17(p17)]

Economical barriers can be easily overcome: it is easy to understand that investing money in minorities' inclusion in trials would be life-changing for many people and create many more benefits that will exceed the costs. Disparities have a cost even for the healthcare system, which in 2015 amounted to 1.24 trillion US dollars.[8(p238)] In some cases, people would be more encouraged to participate if, for instance, childcare and meals were granted to enrolled patients when busy for the trial.

The impact of underrepresentation on minorities and their health

Underrepresentation in trials, low socioeconomic status (SES), less access to care, and fewer insured people are all factors that highly contribute to worsening the CVD burden for minorities. As a matter of fact, it was shown that minorities have higher CVD risk factors rates than Non-Hispanic Whites.[4(p1)] Overall, the main risk factors, regardless of patients' ethnicity, are Hypertension, Cigarette Smoking, Hypercholesterolemia, Diabetes mellitus, and Obesity.

Hypertension.

Hypertension is very common among minority groups but is usually undiagnosed or untreated. Among African Americans, 42.4% of men and 44% of women have Hypertension - 10 to 12% higher than Non-Hispanic Whites. African Americans or Non-Hispanic Blacks are more likely to have their Hypertension diagnosed and treated, but their blood pressure is not as controlled as Whites'.[11(p397)] Even Hispanics/Latinos are more likely to be affected by Hypertension than Whites, and the illness is more prevalent among Dominican men (32.6%) and Puerto Rican women (29.1%), having higher systolic (the pressure in arteries when the heart beats) and diastolic (the pressure in arteries when the heart sets between beats) blood pressure.[9(pp231,232)] Asian Americans' hypertension mean rate is 16.9%, but Filipino Americans are the subgroup with the highest percentage (23.9%), probably due to a lack of knowledge about risk factors and prevention among Filipinos.[12(pp720,722)]

Cigarette Smoking

Cigarette smoking is another relevant risk factor for CVDs mostly spread among white people (25.8%) but affects even minorities. African Americans have a slightly lower rate than whites (25.4%) but are more exposed to tobacco smoke.[11(p401)] 25.7% of Hispanic men enrolled in the Hispanic Community Health Study/Study of Latinos (HCHS/SOL) were smokers at the time of the study, a rate almost equivalent to Whites. In Hispanic/Latino women, rates are significantly lower than in men with a mean rate of 15.2%.9(pp234,235) On average, 13.2% of Asian Americans smoke with a considerable increase in Filipino Americans (17.7%).[12(p720)]

Hypercholesterolemia.

Regarding Hypercholesterolemia, limited data was found, and nothing regarding Asian Americans was come across.

High Cholesterol levels (>200mg/dL) are more frequent in African American women (36.1%) and men (32.6%) than in their White counterparts.[11(p398)] In the Jackson Heart Study, one-third of African American participants between the ages of thirty-five and eighty-four were affected by Hypercholesterolemia (>240 mg/dL), 69% of them were aware of their condition and 43% received treatments. In HCHS/SOL, 51.7% of men and 36.9% of women had Hypercholesterolemia with greater prevalence among Central American men (54.9%) and Puerto Rican women (41%).[9(p232)]

Diabetes mellitus.

Diabetes mellitus type 2 is very likely to stay undiagnosed among African Americans, as a matter of fact, 37% of Black patients affected by diabetes are not aware of their illness. 21.8% of African Americans suffer from Diabetes and they have a greater likelihood of 1.52 times among men and 2.14 times among women to develop it than their white counterparts.[11(pp397,398)] Even among Hispanics/Latinos, diabetes is more frequent than in Whites, as they have a 19% mean rate.[9(pp232,234)] Asian Americans have a lower Diabetes rate than other minorities. On average, 5.9% of Asians are affected by diabetes, but with an increase among Indian-Americans (8.2%). They usually develop this condition at a younger age and lower BMI (body mass index) than their White counterparts.[12(pp720,722)]

Obesity.

Obesity is a great health issue among minorities and creates a significant risk for many diseases. The highest Obesity rate is registered among African American women (58%) and African American men (38%). They also have the highest severe Obesity rate (12.1%): twice as much as Hispanics' and Whites'.[11(p399)] Among HCHS/SOL participants, 41% of men and 42.6% of women were obese.[9(p234)] Asian Americans had significantly lower Obesity rates than Whites and other minorities. On average, the rate was 7.6% with an increase among Filipinos (13.2%).[12(p720)]

Minorities are more likely to be obese or affected by Diabetes, this may be caused by the lesser access these groups have to a healthy diet. As a matter of fact, African Americans and Hispanics are more likely to live in low-income neighborhoods and food deserts. According to the US Department of Agriculture, a food desert is an area with both poor food access and low area income. This means that they live in areas with very few supermarkets where fruit, vegetables, and healthier food are sold. Many people living in these neighborhoods do not own automobiles and have to take public transport, making it longer to reach the store. Therefore 23.5 million people in the U.S. are discouraged from traveling far from home and opt for convenience stores and unhealthy food. Despite having less access to a healthy diet, the real risk factor for people living in a food desert is their low SES. Their income does not allow them to have health insurance and access to care, hence their mortality rates for cardiovascular diseases and myocardial infarction are high. [18]

Very often African Americans suffer from CVD risk factors, but have them undiagnosed and untreated. Unawareness and lack of treatments make African Americans the minority with the highest likelihood to die from CVDs.[8(p239)]

Hispanics/Latinos instead have a low mortality rate despite having high risk factors rates. Leigh et al.4 reported it as the "Hispanic Paradox", but Daviglus et al.[9] justified this trend by saying that Hispanic people are the youngest minority.

African Americans and Hispanics/Latinos are the minorities that have the highest rate of uninsured people (10% among African Americans and 18% among Hispanics/Latinos), this highly affects and increases the CVD burden these two ethnic groups have to endure. Figure 1 shows the result of the 2018 report made by the U.S. Census Bureau.[6]

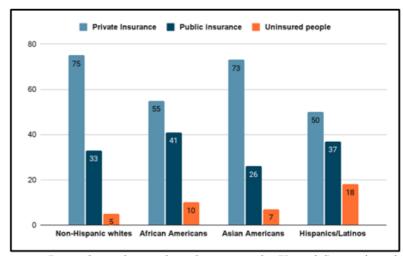


Figure 1. Insured people rate by ethnicity in the United States (2018)

Representation in cardiovascular trials will allow the development of broad knowledge of health conditions and treatments that are best for minorities. This, along with an extension of health insurance coverage to everyone and awareness campaigns to educate minorities about risk factors, will lighten the CVD burden for minorities.

Ortega et al.[19] declared that women and minorities are underrepresented even in Food and Drug Administration (FDA) trials needed to approve drugs. This means that today when prescribing a drug used to cure CVDs, physicians are not completely sure of its efficacy on minority patients.

It is extremely necessary to focus on creating ways to solve such an important issue, or, at least, reduce the really negative impact that it has on people's health conditions. Underrepresentation was shown to be present even in the most reliable studies, hence to stop this phenomenon and fill the knowledge gap created by decades of improper representation new recruitment methods need to be experimented, for instance, the use of social media which can yield positive effects, since these platforms are very common among minorities as Figure 2 shows.

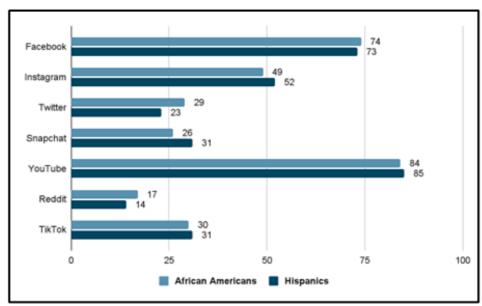


Figure 2. Use of social media among African Americans and Hispanics/Latinos.[23]

Past research papers show the great existence of health disparities in a country with a dramatic history of racism and discrimination. Underrepresentation is part of a bigger system not built to consider white and nonwhite patients at the same level. Being part of an understudied group leads to physicians and providers not knowing treatments, symptoms, and response to drugs of minorities as precisely as they do for Whites. These increase the possibility of suffering from a risk factor and not having it treated or even diagnosed.

Discussion

The data reported show the existence and great impact that disparities in healthcare have on minorities. These disparities are due to their underrepresentation in clinical trials, which prevents physicians from developing acquaintance with their symptomatology, response to treatments, and drugs. This is extremely harmful to minorities, who have a greater likelihood to be affected by risk factors for CVD and consequently contract it. However, also the higher number of uninsured people among minorities represents a relevant factor which leads to these disparities.

Underrepresentation is shown by the very high mean enrollment rate of White people, that for cardiovascular trials is around 80% (as a matter of fact, Sardar et al.[13] reported that Whites' representation amounted to the 86% in AF and ACS RCTs and to 73% in HF RCTs; Zhang et al.[15] reported that 88% of patients enrolled in the studies considered were White), a great overrepresentation since White people constitute 60.1% of the population.[5] Even in the type of trials considered the most reliable and unbiased there is a great overrepresentation of Whites.

Minorities are almost excluded because, according to researchers, it is more expensive to recruit them than White people. Recruitment is already a very expensive and long process, maybe the most challenging part of the whole research, because people, regardless of ethnicity, are scared of participating. The costs for this part of the project can increase by 600.000 to 8 million dollars with a one-to

six-month delay due to recruitment issues.[20] Minorities are more difficult to recruit because many of them do not have access to specialty institutes used as referral bases. In addition, they do not trust the system and researchers as much as White people do, especially for the discriminations minorities have had to face for centuries.

It will be easier to overcome economic barriers first, as it is only a matter of investing more money for recruitment, but it will take a lot more to eliminate mistrust and fear.

CVD risk factors are more common among minorities that have a less healthy lifestyle, do not stay as active as White people, and are more likely to be ignorant about those conditions. As they prefer to turn to hospital's emergency departments than primary care doctors, they do not receive continuous and preventive care. [21,22]

Hypertension, Diabetes mellitus, Hypercholesterolemia, and Obesity are a lot more prevalent among African Americans, Asian Americans, and Hispanics. Especially for these last two groups, usually there is a great difference between subgroups, because they come from very different parts of the world, even though they are in the same continent.

Many people have their CVD risk factors undiagnosed, because they do not go to the doctor, as it is too expensive, especially for those families who do not have health insurance. However, if their disorder is diagnosed, many do not get treatments, probably because they cannot afford it.

Health insurance is a huge problem in the United States, because many people, especially minorities, cannot afford private insurance, but at the same time earn more than what is required to have public health insurance. Without health insurance, it is impossible for a family to access treatments, medications, and care, therefore they cannot recover from illnesses, get treated, and are more likely to die from them.

The effect of risk factors would be reduced if health insurance was granted to everyone. Table 1 shows the rate of uninsured and insured people among different ethnicities according to a 2018 report published by the U.S. Census Bureau [6] Among Non-Hispanic Whites, 74.8% have private insurance, 33.2% have public insurance, and 5.4% are uninsured. Among African Americans, 55.4% have private insurance, 41.2% have public insurance, and 9.7% are uninsured. Among Asian Americans, 73.1% have private insurance, 26.1% have public insurance, and 6.8% are uninsured. Among Hispanics, 49.6% have private insurance, 36.5% have public insurance, and 17.8% are uninsured.

Applications

What can be done to implement minorities' inclusion in cardiovascular trials?

Firstly, referral bases need to be chosen after a thorough evaluation of the available infrastructure and access of the targeted population.[20] Secondly, having a more diverse staff will improve the situation for two main reasons.[19] Minorities will be encouraged to enroll in studies if researchers have the same culture as them.[16(pp3,21)] Then hardships in communication between patients and providers will be limited and fears due to lack of information about the trial will decrease.[17(p16)] Offering free meals, childcare, remunerations, and other facilitators will help those who do not enroll for economic issues and have a tight schedule.[17].

Mistrust and fear cannot be eliminated by different recruitment strategies, because they are the product of centuries of discrimination. Researchers, however, can help minority patients with transparency, easy-to-understand protocols, and consent forms, that inform patients of what they will undergo and how risky it will be.

In addition, recruitment strategies need to be rethought to also include minorities. Using social media can be a good strategy that allows to reduce costs and reach minorities more easily, because social media platforms are very common among them, as Figure 2 shows.

Figure 2 shows the percentages of social media use by minorities. The data are from the Pew Research report of April 2021 [23] and exclude Asian Americans. Facebook (74% of African Americans, 73% of Hispanics) and YouTube (84% of African Americans, 85% of Hispanics) are the most common platforms among African Americans and Hispanics. Instagram (49% of African Americans, 52% of Hispanics) and TikTok (30% of African Americans, 31% of Hispanics) are rather spread, followed by Twitter (29% of African Americans, 23% of Hispanics) and Snapchat (26% of African Americans, 31% of Hispanics). The least common social media platform is Reddit, used by 17% of African Americans and 14% of Hispanics.

However, the effectiveness of social media in recruiting participants is still debated. Topolovec-Vranic and Natarajan[24] reported that 40% of the analyzed studies considered it a valid strategy, but some others were not able to recruit many or any participants. The cost-effectiveness of this strategy is not proved, but among the studies that analyzed it in Topolovec-Vranic and Natarajan's research, six considered it less costly. It needs to be acknowledged that the use of social media as a recruitment strategy is still not prevalent, but needs to be further tested. Thus, social media may become a new tool to bridge underrepresentation in a country that is facing great changes in its demography.

Conclusions

Underrepresentation in cardiovascular trials is part of a system which seems to be built to oppress and hinder minorities as it causes extremely negative consequences for their health. As a matter of fact, underrepresentation does not allow to build the knowledge needed to grant good-quality care to minorities, hence they are not receiving treatments designed for issues that specifically affect them. In addition, minorities are the poorest part of the American population and many people live in neighborhoods where it is difficult to access primary care or cannot afford health insurance. This has created a very heavy CVD burden for them and led to a higher likelihood to suffer from CVD risk factors. It is time to take action and fix the system now because if nothing will be done, there is the risk that in less than forty years more than half of the population will not have the proper opportunities to be treated.

Limitations

The research only analyzes data about the health conditions and representation in trials of the three most numerous minorities in the United States: African Americans, Hispanics/Latinos, and Asian Americans. However, according to the U.S. Census Bureau[7], in the United States, other minorities are present: Native Hawaiians and Other Pacific Islanders (0.2% of the American population in 2019), Native Americans and Alaskan Natives (1.3% of the American population in 2019), and people identifying as part of two or more races (2.8% of the American population in 2019). Nothing was found about the three minority groups listed above. This complete lack of knowledge highlights, even more, the need for a rapid and urgent change in the inclusion of minorities in trials. In the future, it will be necessary to include these other groups, because different symptoms, responses to treatments, and drugs may be found.

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