Racial and Ethnic Disparities in Research and Clinical Trials

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KEYWORDS

• Skin of color • Ethnic skin • Health disparities • Diversity • Dermatology • Research • Health equity • Clinical trials

KEY POINTS

- Racial and ethnic minorities are underrepresented in clinical trials across medical specialties including dermatology.
- Racial and ethnic minorities, particularly Blacks, have a documented history of mistreatment and human experimentation without consent.
- Multiple well-recognized physicians credited with significant medical advancements have a history of unethical medical practices against Blacks and other marginalized minority groups.
- There is inadequate reporting and representation of racially and ethnically diverse participants in dermatologic clinical trials.
- Lack of education, mistrust, and language barriers are concerns that should be addressed in order to recruit and retain racial and ethnic minorities as participants in research studies including clinical trials.

INTRODUCTION

Racial and ethnic minorities are underrepresented in medical research and clinical trials at numbers significantly lower than their overall population in the United States. Racial and ethnic minorities are defined as individuals identifying as Black, Hispanic/Latinx, Asian, American Indian, Alaska Native, and Pacific Islander.[1] In 2011, it was found that only 5% and 1% of participants in all clinical trials across medical specialties were Black and Hispanic, respectively.[2] Across various US clinical trials registered in ClinicalTrials.gov, there has been underrepresentation of racial/ethnic minorities.[3] For example, Black, Hispanic/Latinx, American Indian or Alaska Native, and mixed race individuals have been found to be underrepresented in stem cell clinical trials.[4] Another study of cardiometabolic drugs (2008–2017) revealed that women and minorities, primarily Black individuals, were underrepresented in cardiac trials.[5] Vaccine clinical trials have also highlighted a near absence of Black, Indigenous and People of Color (BIPOC) communities.[6] Dermatology clinical trials unfortunately have also exhibited this trend, with studies revealing a lack of diversity in trials associated with conditions such as alopecia areata, atopic dermatitis, and acne.[7,8]

Possible contributing factors underpinning underrepresentation of racial ethnic minorities in clinical trails across specialities were discussed in a study conducted by Niranjan and colleagues.[9] They assessed bias and stereotyping when recruiting minorities for oncology clinical trials and found that clinical professionals viewed recruitment efforts for minority participants to be

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challenging. They did not view potential minority recruits as ideal candidates, noting concerns for protocol compliance. Providers were found to withhold opportunities from potential minority study participants. Furthermore, they had misperceptions that potential minority participants had low knowledge of cancer clinical trials and used language barriers as another excuse to not enroll minorities. They also thought that certain minority patients were perceived as having distinct temperaments, making these discussions more difficult.

In addition to underrepresentation in clinical trials, there is overall underreporting of data on race and ethnicity. A systematic review was conducted to assess the representation of minorities in clinical trials that found that minorities were underrepresented in the trials, and that they were also underreported in the trials.[10] Of the clinical trials analyzed, 70.4% had no report on the race/ethnicity of study participants. NIH funded trials were found to be more consistent in reporting demographic characteristics likely due to NIH-specific policies that have been in place for several decades. In 1993, the National Institutes of Health passed its Revitalization Act requiring that all clinical trials receiving NIH funding include women and minority representation. Geller and colleagues[11] conducted a study assessing compliance with these guidelines and found that a large percentage of studies were noncompliant. Of 69 studies, 18% did not offer a breakdown of study participants by racial and ethnic group and 87% provided no analysis by race/ethnicity. Additionally, 87% of these studies did not report on any of their outcomes by sex and women were largely underrepresented. These findings are a sobering reflection of current clinical trial representation, which shows a lack of consistent compliance to these policies.

As the US continues to diversify, it is necessary that participants in clinical research be reflective of the general population. In 2011, Blacks and Hispanics made up 12% and 16% of the general US population, respectively.[2]

Historical Treatment of Racial and Ethnic Minorities in Medical Research

It has been documented that a contributor to challenges in the recruitment of minority populations into clinical trials and research studies stems from a deeply engrained history of mistrust of the health-care system.[12] Much of this mistrust is rooted in historical injustices and experimentation without consent against these marginalized populations. Several examples of this experimentation will be discussed in greater detail in this section.

Dr J. Marion Sims

The history of Dr J. Marion Sims, called the "Father of Gynecology," may be one of the oldest documented examples of human experimentation without consent and abuse of medical practices. Dr Sims, a renowned surgeon in the 1800s, was credited with the development of treatments for vesicovaginal fistula and antiseptic technique.[13] He built his practice in Montgomery, Alabama, by treating and conducting research on enslaved women without anesthesia. He operated under the widely held racist belief that Blacks did not feel pain. In situations where enslaved women were unable to reproduce due to gynecologic issues, they were brought to Dr Sims and became his property until treatment was complete. According to Dr Sims, there was never a time when he could not operate and because of this freedom, he considered it the most memorable time of his life.[14] Of note, many of the early vesicovaginal fistula surgeries were unsuccessful. One enslaved woman underwent 30 surgeries by Dr Sims before he became more skilled at the procedure.[14] After this time, he transitioned to operating on White women under anesthesia.

The Tuskegee Syphilis study

The Tuskegee Syphilis study is another historic example of unethical medical practice involving the Black community.[15] This study is one of many that have contributed to Black individuals' feeling distrust of the US health-care system. In 1932, the US Public Health Service began an experiment in Mason County, Alabama, assessing the natural course of untreated syphilis in Black men.[15] The study consisted of 400 Black men with syphilis and 200 uninfected Black men serving as controls. Penicillin became available in the 1950s for treatment of syphilis but study participants were not offered therapy. Treatment was deliberately withheld from study participants to gain scientific clarity on the natural course of syphilis at the expense of the increased morbidity and mortality of these men. Notably, the men participated in the study under the impression that they would be receiving treatment of "bad blood." They were given medications such as mercurial ointment and inadequate doses of neoarsphenamine, both ineffective treatments for syphilis. The original plan was to continue the study for 6 months but the study continued for years until 1972 when it was paused by the Department of Health, Education, and Welfare. By this time, likely more than 100 participants had died of causes directly related to advanced syphilis.[15] A system charged with doing no harm and saving lives deliberately withheld life-saving treatment from these

men, leading to the death of many. This history is a significant reason the Black community remains weary of the motives of the health-care system.

Henrietta Lacks

The history of Henrietta Lacks reflects another example of research involving a minority individual without consent. Mrs. Lacks was a 31-year-old Black woman who presented to Johns Hopkins Hospital's Gynecology Clinic in Baltimore, MD, with complaints of spotting in between periods in 1951.[16] Physical examination revealed a lesion on her cervix that was subsequently biopsied. Biopsy specimens were sent to the pathology laboratory as well as Dr George Gey's tissue culture laboratory. Mrs. Lacks had provided consent for surgery but did not provide consent for her tissue samples to be shared and distributed in any manner.

Mrs. Lacks was diagnosed with epidermoid carcinoma, a very aggressive adenocarcinoma of the cervix. She underwent radiation treatment that was unsuccessful in slowing the spread of the disease and she ultimately died a few months after her initial presentation.

After the tissue samples were shared with Dr Gey's laboratory, her cells were cultured and then mass-produced and distributed to other colleagues. They were used for research on the polio and other vaccines. They were ultimately named HeLa cells in commemoration of her first and last name.[17] However, it took many years for Henrietta Lacks to actually be credited for the use of her cells and the scientific contribution, which came from them. Today, descendants of Henrietta Lacks have been vocal about the widespread use of her cells in laboratories around the world despite the original lack of informed consent. The use of Henrietta Lacks tissue and cells has had significant influence on medical research bioethics.

Dr Albert Kligman

Dr Albert Kligman was a dermatologist credited with the discovery of tretinoin in the 1960s while working as a medical researcher in dermatology at the University of Pennsylvania.[18] Dr Kligman's research and testing of tretinoin as well as various chemicals occurred on incarcerated individuals at the Holmesburg prison without consent. Of note, two-thirds of the experiment participants were Black. In 1960, he also conducted an experiment to study dioxin, which was applied to the foreheads and backs of the incarcerated men.[18] In some instances, he chose to apply 486 times the recommended dosage, leaving these men with various chronic dermatologic issues. Years later, Dr Kligman was quoted as saying things were "simpler" before informed consent was required. He said, "No one asked me what I was doing. It was a wonderful time."[18] Since this time, several former inmates have come forward with complaints of long-term effects from the experimentation. In 1990, the city of Philadelphia, Holmesburg prison, and the University of Pennsylvania were all sued by a former inmate who believes he developed leukemia because of experiments in the prison. The suit was settled outside of court without any admission of guilt from the university.[19]

Summary

The examples of mistreatment and injustice against marginalized groups serve to foster a deep sense of mistrust of the health-care system among individuals from those communities. In various studies looking at the perceptions of Blacks of clinical research, lack of trust was a consistent theme.[12] Not only do these groups tend to lack trust for the health-care system as a whole, the overall research process and the researchers themselves are often deemed untrustworthy.

In addition to this mistrust, additional common barriers to the participation of Blacks in clinical research include issues with communication, lack of awareness of research opportunities, logistics associated with the research, and type of study.[20] Studies have found that Blacks are willing to agree to participate in studies with low perceived risk, such as surveys or providing urine or blood samples.[21,22] They are less likely to agree to more perceived high-risk studies involving medications or injections. Logistical issues pertaining to the time commitment for participation, transportation, and childcare services have also been cited as a few additional barriers inhibiting the participation of Blacks in clinical trials.[23]

Racial and Ethnic Diversity in Dermatologic Research and Clinical Trials

Disparities in dermatologic clinical trials

Clinical trials allow for the approval of new drugs and therapies as well as provide important information on the safety and efficacy of novel treatments. Dermatology, similar to many other fields in medicine, currently lacks adequate representation of racial and ethnic minorities in clinical trials. There have been few studies conducted to evaluate this issue (**Table 1**). One study examined racial and ethnic diversity as well as reporting of minority groups in all randomized clinical trials (RCTs) related to alopecia areata, atopic dermatitis, acne, psoriasis, vitiligo, lichen planus, and seborrheic dermatitis conducted from 2010 to

Table 1
Racial and ethnic diversity data for dermatologic clinical trials

	Author, Year	White, % (N)	Black/African American, % (N)	Hispanic, % (N)	Asian, % (N)	American Indian or Alaskan Native, % (N)	Native Hawaiian/ Pacific Islander, % (N)	Mixed Race, % (N)	Other/ Unspecified, % (N)
Combined data for SOC studies[7,28]	Charrow et al,[7] 2017	72% (8016/11140)	13% (1446/11140)	14.7% (1639/11140)	3.3% (370/11140)	-	-	-	-
	Ferguson et al,[28] 2021[a]	72.9%	8.4%	5.3%	5.2%	0.13%	0.17%	-	7.8%
Clinical trials for dermatological drugs[25]	Ding et al, 2021	80.4% (28065/34890)	9.8% (3242/33240)	18.9% (2614/13860)	5.5% (1535/27696)	-	-	-	-
Acne[31]	Montgomery et al,[31] 2021	-	10.3% (34/330)	4.8% (16/330)	54.7% (181/330)	-	-	21.8% (72/330)	8.2% (27/330)
Acne- Pediatrics[34]	Ding et al, 2021	71.9% (20695/28771)	17.6% (5066/28771)	30.4% (6384/28771)	5.9% (1698/28771)	0.5% (136/28771)	0.3% (89/28771)	-	-
Atopic dermatitis[8,27,31]	Price et al,[8] 2020	54% (5301/9808)	8.9% (871/9808)	3.7% (365/9808)	16.2% (1585/9808)	0.2% (17/9808)	0.2% (20/9808)		20.5% (2014/9808)
	Montgomery et al,[31] 2021	-	17.1% (62/361)	2.2% (8/361)	63%(228/361)	-	-	11.3% (41/361)	6.1% (22/361)
	Hirano et al,[27] 2012	62.1% (13679/22202)	18% (3954/22202)	2% (441/22202)	6.9% (1523/22202)	0.02% (4/22202)	0.3% (57/22202)	0.05% (12/22202)	6.8% (1506/22202)
Dyschromia[31]	Montgomery et al,[31] 2021	-	8.2% (41/498)	9.6% (48/498)	64.1% (319/498)	-	-	11.1% (55/498)	7.0% (35/498)
Hidradenitis Suppurativa[33]	Price et al,[33] 2021	68% (669/984)	14% (138/984)	1.5% (15/984)	2.9% (29/984)	0.3% (3/984)	0.1% (1/984)	-	14.6% (144/984)
Psoriatic Arthritis and Biologic Treatments[24]	Shwe et al,[24] 2021	80.60% (6082/7500)	0.40% (30/7500)	6.19% 467/7500	3.56% (269/7500)	0.61% (46/7500)	0.08% (6/7500)	0.45% (34/7500)	8.11% (612/7500)

[a] N values were not provided for this study.

2015.[7] It found that merely 11.3% of international studies and 59.8% of US studies reported the racial/ethnic demographic characteristics of participants. Of the 59.8% of US studies with recorded race/ethnicity, 74.4% of these participants were White. Findings such as this highlight the lack of diversity in dermatologic clinical trials and the underreporting of demographic data.

A recent cross-sectional study sought to assess the representation of minorities in clinical trials using biologic agents for the treatment of psoriatic arthritis from 2020 to 2021. Only half of the studies reported race and ethnicity, 44% reported only race, and 6% reported only ethnicity.[24] Most participants were White (80.6%). The percentages of Black, Asian, American Indian, and Native Hawaiian/Pacific Islander participants were 0.40%, 3.56%, 0.61%, and 0.08%, respectively. Similar findings were seen in a study on clinical trials for drugs for dermatologic diseases. A total of 36 novel drugs approved by the Food and Drug Administration between 1995 and 2019 were assessed. White participants were overrepresented at 80.4%, with Black and Asian participants comprising 9.8% and 5.5%, respectively.[25]

Price and colleagues recently looked at disparities in clinical trials for atopic dermatitis. A total of 33 randomized clinical trials worldwide were included with 82% of the trials including information on the race and/or ethnicity of study participants.[8] Of these trials, 81% included race exclusively and 19% included both. More than 50% of participants across all studies were White (54%), whereas Asians and those who were Black and of African descent comprised 16.2% and 8.9% of participants, respectively. Despite the health disparities of Blacks with atopic dermatitis including Black children being 6 times more likely to develop severe atopic dermatitis than their White counterparts, there continue to be insufficient numbers of Blacks in atopic dermatitis clinical trials.[26] An earlier study similarly assessed reporting of diversity of clinical trials in atopic dermatitis (2000–2009) in the United States and found reporting rates of race and ethnicity to be 59.5% and that White participants were overrepresented across all included studies.[27] During the 9 years of the study, there continued to be no significant improvement in diversity numbers.

A systematic review identified all randomized clinical trials between 2005 and 2020 related to acne/acneiform eruptions, lichen planus, vitiligo, psoriasis, eczema, seborrheic dermatitis, vitiligo, atopic dermatitis, and alopecia areata.[28] A total of 287 US-based studies and 1217 non-US studies were included and trends in reporting and diversity of participants were recorded. During the 15-year period, there was an increase in the reporting of race/ethnicity. The percentage of Black participants decreased from 8.8% to 8.4%, American Indian participants increased from 0.11% to 0.13%, Pacific Islander decreased from 0.24% to 0.17% and Hispanic also decreased from 5.5% to 5.3%. Of note, Asian representation increased from 1.8% to 5.2%.

Chen and colleagues recently compared levels of racial/ethnic representation between dermatologic clinical trials conducted between 2010 to 2015 and 2015 to 2020. They found that in comparison to the period from 2010 to 2015, clinical trials from 2015 to 2020 had an increased rate of racial/ethnic reporting. However, the proportion of studies containing a percentage of racial/ethnic minorities representative of the US population remained unchanged at 38.1%. Additionally, psoriasis trials in particular were shown to be the least diverse.[29]

Research on conditions disproportionately affecting skin of color

The 3 most common dermatologic chief complaints for individuals with SOC are acne, dyschromia, and atopic dermatitis.[30] A study evaluated the quantity of peer-reviewed research on these conditions in SOC and found that only 1.6% of the studies were specific to SOC.[31] Of those studies, the majority of them were conducted in Asian populations with 54.7% representation in acne studies, 63% in atopic dermatitis, and 64.1% in dyschromias. The research included in this article was not exclusive to clinical trials and included all research conducted in SOC. Research studies focused on skin of color (SOC) are lacking in darker skin types, particularly Fitzpatrick skin type IV through VI.[31]

There are also limited trials on conditions that disproportionately affect SOC populations such as keloids, central centrifugal cicatricial alopecia, and hidradenitis suppurative. Hidradenitis suppurativa (HS), a debilitating, chronic disease with increased prevalence among Blacks has also been found to lack diversity in its trials.[32] One of few studies assessing the distribution of race/ethnicity in HS RCTs found that among the most recent trials from 2000 to 2019, 68% of participants were White and 14% were Black or African American.[33] Only 2.9%, 0.3%, and 0.1% were Asian, American Indian/Alaska native, and Native Hawaiian or Pacific Islander, respectively.

Pediatric dermatology

Interestingly, disparities in pediatric clinical trials in dermatology do not seem to mirror those of adult trials. Acne vulgaris is considered the most

common skin disease and is highly prevalent among women and children.[34] Randomized clinical trials between 2006 and 2018 on pediatric acne treatment were assessed for the level of reporting and representation of race/ethnicity. The frequency of reporting of race/ethnicity was found to be relatively low. Race and ethnicity was reported in 61.3% and 46.8% of all RCTs, respectively.[34] White participants predominated, however, the proportions of various races were more representative of the general population. Black, Asian, and Hispanic/Latinx participants comprised 17.6%, 5.9%, and 30.4% of clinical trials, respectively.

Call to Action

Addressing the issue of insufficient racial/ethnic diversity and reporting in research and clinical trials will require a multiprong approach. For SOC communities, robust community engagement and relationship building are tools that have been found to be helpful in increasing participation in clinical trials.[6] A study looking at the recruitment and retention of Blacks in clinical trials found the most commonly used strategies included distribution of fliers at various community-based locations such as outpatient clinics and recreational centers, advertising in local newspapers that the population of interest was likely to read, speaking to patients at their regular clinic visits, field-based community outreach, and "snowballing" in which participants would tell friends and family about studies that were of interest to them. Notably, the most effective strategy was found to be the field-based approach in which researchers looking to recruit would go into the community and explain the study to potential participants. Newspaper advertisements and snowballing were the next most effective means of recruitment.[35]

Working with community-based and religious-based organizations, such as churches, is another grassroots strategy for increasing participation in research initiatives, particularly in the Black community.[36] Additional recommendations for increasing clinical trial diversity center largely around the education of minority communities on clinical trials. A significant barrier to low participation is lack of education on the purpose and implications of such research studies.[37] Community information sessions should be held and widely accessible to those interested in learning more. Additionally, language differences can also be a considerable barrier to participation. Bilingual and culturally diverse medical and research staff are incredibly helpful to address this issue and to help foster trust between potential participants and researchers.

Cultural competence also plays an important role in improving diversity in research.

This includes providing services that are respectful and considerate of the health beliefs, practices, cultural, and linguistic needs of diverse populations.[38] The lack of cultural competence among researchers and health-care providers has been indicated as a considerable barrier to the participation of minorities in research and contributes to feelings of mistrust.[39] When researchers exhibit cultural competency and respect for the cultural practice of their target population, they are more equipped to develop strategies for effective recruitment. Having a research team member of a similar identity can aid in community engagement efforts.[35]

Race concordant interactions are also helpful to establish rapport with minority individuals.[2] Coakley and colleagues suggests that increased representation of minority physicians is an important factor in increasing the number of minority patients open to participating in clinical trials. Additionally, Gorbatenko-Roth and colleagues[40]. conducted a cross-sectional study assessing Black patients' perceptions of their dermatologic care and found that, overall, patient–dermatologist racial concordance was preferred. This kind of rapport and trust, which has been shown to improve clinical care and health-care outcomes, can also help with increased study recruitment.

Beyond recruitment, it also critical to establish strategies for the retention of study participants. Intensive follow-up and communication have been found to improve participation as well as retention.[41] The importance of maintaining the same interviewers or research field staff has also been emphasized as a simple, yet impactful, means of encouraging participants to remain in research studies.

Stronks and colleagues made a compelling argument for diversity efforts that included more than just a blanket declaration to work to increase the inclusion of minorities in clinical trials. They proposed a more comprehensive and methodological strategy that includes designing entirely new RCTs that test specific treatments that have already been studied in trials comprising more homogenous groups.[42] Another proposed option is to increase the allotment of participants in ongoing clinical trials, thus creating an opportunity to increase the representation of minorities within these studies.

SUMMARY

Diverse and equitable representation in clinical research is essential for the development of safe

and efficacious therapies for all patients. Oh and colleagues[43] discusses the importance of diversity in clinical trials citing that adequate representation of various racial/ethnic groups grants us the opportunity to study the impact of ancestral influences, social factors, and environmental exposures on health outcomes. Knowing that disease patterns and clinical responses to treatment can vary significantly by racial and ethnic background, it is prudent that research studies include diverse populations.[43]

Diverse representation of minority groups in clinical trials is necessary so that the results can be made generalizable to various demographic groups including minority populations.[44] Expanding the representation of these populations in medical research including clinical trials continues to be an important and significant challenge.

Recent data support the persistence of inadequate representation of racial/ethnic minority groups within dermatology. This limitation can contribute to health disparities and result in further widening of the gap in health outcomes between SOC individuals and their White counterparts. Policies such as those created by NIH-funded trials requiring adequate representation of minorities are necessary to increase adherence to reporting and diversifying pools of participants. There have been important strides and policies created to improve the current underrepresentation of racial and ethnic minorities in research but significant work remains. Dermatology as a specialty must recognize these gaps and work toward making participation in dermatologic research including clinical trials more representative of our continually diversifying nation.

CONFLICTS OF INTEREST

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