Broadening Diversity in Alopecia Areata Clinical Trial Participants

Amy J. McMichael[1]

Journal of Investigative Dermatology Symposium Proceedings (2020) **20,**S78–S79. doi:10.1016/j.jisp.2020.04.010

Diversity in medicine is an important topic, especially in specialties where very little diversity exists among providers. The conversation of diversity in medicine usually involves gender and ethnic diversity with a focus on direct patient care. Very little work has been done on the clinical research side of medicine and even less has been done in the dermatology clinical research space. As clinical trial research in skin diseases moves forward with new medications and treatments, one important consideration will be to reach those patients who have the diseases of interest. As the US population becomes more diverse, it will be imperative to have a plan for clinical research that includes this diverse population.

The US Census Bureau population projections are that there will be a majority–minority shift in the next 50 years. Among the population under age 18 years, whites will decrease from 53% in 2012 to 23% in 2060. Hispanics will increase from 24% to 38%, and those people of two or more races will increase in the population as well (Frey, 2012). The reality of diversity in this country is indisputable, and the known benefits of diversity in the medical workforce are as follows: improvement in patient care, increased access to care for patients with low incomes, racial and ethnic diversity, non–English-speaking patients, individuals with Medicaid, and lastly, race-concordant visits show higher patients satisfaction than race-discordant visits (Cooper and Powe, 2004).

Dermatology has fallen significantly behind in the US population with only 3% of dermatologists having African American ancestry compared with 12% of the current African American population and 4.2% of dermatologists having Hispanic descent compared with 16.3% of the current Hispanic population (Pandya et al., 2016). Therefore, it is no surprise that the demographic shift in the US population is not reflected in dermatology clinical researchers. The impact of this lack of diversity can result in an inability to generalize results and studies that may fail to detect the relevant findings in specific groups.

The National Institutes of Health enforces federal law requiring the inclusion of women and minorities in all clinical research as appropriate for scientific goals (National Institutes of Health, 2019). The Food and Drug Administration currently requires that all investigational new drug and new drug application studies should include demographic information before approval, and it is clear that African Americans, Hispanic individuals, and women are generally underrepresented in clinical and randomized controlled trials as well as within specific subspecialties. Charrow et al. (2017) assessed the representation of racial and/or ethnic minorities and women in dermatology randomized clinical trials (RCTs) between the years 2010 and 2015 (. A total of 626 RCTs were evaluated across eczema, seborrheic dermatitis, psoriasis, acne, lichen planus, vitiligo, and alopecia areata. Moreover, 52 of 626 international studies (11.3%) and 58 of 97 studies (59.8%) conducted exclusively within the US reported on the racial or ethnic demographics of study participants. Race was not always reported, but when it was reported in the US RCTs, 74.4% of study participants were white. These authors did note that eight RCTs in alopecia areata were included in their evaluation, but no underrepresented minorities (URM) were included in these trials.

In fact, the likelihood that URM patients will participate in dermatology trials is not reported commonly in the dermatology literature. Only one reference reported the likelihood of African American participation in clinical dermatology trials with a study that examined parents in pediatric dermatology clinic (Shaw et al., 2009). These authors showed that disparities existed between white and African American parents with white parents being slightly more trusting and more knowledgeable about research than African American parents. African American parents were more inclined to think that their children would be used as guinea pigs.

This begs the question of what dermatology clinical research investigators should do to increase diversity in all clinical trials, but specifically those involving alopecia areata. These specific recommendations were noted in an editorial by Charrow et al. (2017) (Desai et al., 2017). It will be important to utilize the standardized race and/or ethnicity language for study inclusion to facilitate tracking specific research data. There should be a clearly defined minimum set of demographic data collected including specific diversity data in all the studies. There should be an identification and prioritization of dermatologic knowledge and research gaps for underrepresented groups. Finally, when planning racially, culturally, and gender-inclusive studies, it is best to always include the methods to

[1]*Department of Dermatology, Wake Forest Baptist Medical Center, Winston-Salem, North Carolina, USA*

Correspondence: Amy J. McMichael, Department of Dermatology, Wake Forest Baptist Medical Center, 4618 Country Club Road, Winston-Salem, North Carolina 27104, USA E-mail: amcmicha@wakehealth.edu

disseminate results back to the stakeholders in question.

In terms of recruitment of URM patients for clinical trials, there are several practices that have been shown to increase success. Site commitment and effort important in the actual process can move the needle toward more recruitment of URM participants. To increase the further success, incentives for patients and staff workers can be offered. It has been shown that more the community connections in place, higher is the success. There is a role for sponsors as well, with more successful URM recruitment when sponsors reinforce diversity recruitment. Although it may seem simple, staff that can speak the same language as the diverse populations in the area of the research site can help as well. Finally, having a culturally competent staff is an important factor.

Although a complete review of how to increase cultural competence in the dermatology workplace is beyond the scope of this review, the RISK method has been described as an easy way to explain what is needed where the mnemonic stands for: resources, individual identity, skills, and knowledge (McKesey et al., 2017). These four factors can define and direct the clinical trialist's actions that can impact recruitment and retention of URM participants in research trials.

Clarifying what will be needed to bring diversity of clinical trials for alopecia areata includes training researchers on the diverse backgrounds of patients with alopecia areata. Including diverse students and researchers on grants and research projects, including implicit bias training, and diversifying clinical research staff can all support the diversity in alopecia areata clinical trials. Working with the National Alopecia Areata Foundation to publish clinical trial recruitment information on social media and encouraging industry partners to make diversity in studies a priority are final recommendations for increasing diversity in alopecia areata clinical trials.

ORCID

Amy J. McMichael: http://orcid.org/0000-0002-5342-2181

CONFLICT OF INTEREST

AJM has received research, speaking, and/or consulting support from a variety of companies, including Aclaris, Allergan, Bioniz, Cassiopea, Concert Pharmaceuticals, Covance, eResearch Technology Inc, Galderma, Incyte, Informa Healthcare, Johnson & Johnson, Keranetics, Merck & C Inc, Pfizer, Proctor & Gamble, Samumed, and UpToDate. There are no conflicts pertinent to this manuscript.

ACKNOWLEDGMENTS

This article is published as part of a supplement sponsored by the National Alopecia Areata Foundation.

Funding for the Summit and publication of this supplement was provided by the National Alopecia Areata Foundation. This Summit was supported (in part) by the National Institute of Arthritis and Musculoskeletal and Skin Diseases under Award Number R13AR074890. The opinions or views expressed in this professional supplement are those of the author and do not necessarily reflect the official views, opinions or recommendations of the National Institutes of Health or the National Alopecia Areata Foundation.

REFERENCES

Charrow A, Xia FD, Joyce C, Mostaghimi A. Diversity in dermatology clinical trials: a systematic review. JAMA Dermatol 2017;153:193–8.

Cooper LA, Powe NR. Disparities in patient experiences, healthcare processes, and outcomes: the role of patient–provider racial, ethnic, and language concordance. New York, NY: The Commonwealth Fund; 2004.

Desai SR, Hernandez C, McMichael AJ. Spectrum of diversity in dermatology: the need to broaden clinical trial participants in our increasingly multiethnic and multicultural society. JAMA Dermatol 2017;153:132–4.

Frey WH. Census projects new "majority minority" tipping points. https://www.brookings.edu/opinions/census-projects-new-majority-minority-tipping-points/; 2012 (accessed 1 December 2018).

McKesey J, Berger TG, Lim HW, McMichael AJ, Torres A, Pandya AG. Cultural competence for the 21st century dermatologist practicing in the United States. J Am Acad Dermatol 2017;77:1159–69.

National Institutes of Health. Guidelines for the review of inclusion on the basis of sex/gender, race, ethnicity, and age in clinical research. https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf; 2019 (accessed 1 December 2018).

Pandya AG, Alexis AF, Berger TG, Wintroub BU. Increasing racial and ethnic diversity in dermatology: A call to action. J Am Acad Dermatol 2016;74:584–7.

Shaw MG, Morrell DS, Corbie-Smith GM, Goldsmith LA. Perceptions of pediatric clinical research among African American and Caucasian parents. J Natl Med Assoc 2009;101:900–7.