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## Why are disproportionately impacted communities underrepresented in food allergy clinical trials?

### Food allergy's disproportionate impacts on Blacks and Hispanic/Latinos

Food Allergy Research & Education (FARE) states that food allergy is a potentially life-threatening disease, affecting approximately 33 million people in the US. The non-profit organization End Allergies Together (EAT) indicates that food allergy affects approximately 220 million people globally.

In a PhRMA blog post, Anita Roach, MS, FARE Vice President of Health Equity and Community Engagement, explained that “studies have revealed differences in food allergy outcomes that disproportionately impact Black and Hispanic/Latino communities, as well as households with lower incomes. Those disparities include underdiagnosis, greater risk of severe allergic reaction, subsequent hospitalization and death, and underrepresentation in food allergy clinical trials.” Further, FARE notes that “Black Americans are significantly more likely than White Americans to have food allergy and points out that finding allergy-safe foods is costly and challenging for low-income, marginalized families living in food deserts.”

### FARE's commitment to diversity

FARE is the world's largest funder of food allergy research, as well as the largest United States non-profit organization that focuses on food allergy advocacy. Its work



includes supporting patients who live with food allergies, sponsoring research and innovation, and pursuing multiple awareness and advocacy initiatives.

FARE is also “committed to reducing health inequities in food allergy, including access to research and specialized care,” according to Roach. In her blog post, she wrote that in 2021, FARE launched its Health Equity portfolio that includes the FARE Community Access Program (CAP), “a signature initiative [under] which FARE works in partnership with local and national organizations to align common goals to enable greater impact.”

### Clinical trial diversity initiatives from other organizations

Also during that time, Roach continued, the United States Food and Drug Administration (FDA) “ramped up efforts around inclu-

sion in clinical trials. In 2022, [the] FDA issued a new draft guidance to industry for developing diversity plans to encourage enrollment of more participants from underrepresented racial and ethnic populations into clinical trials.” In addition, she explained that “the United States Department of Health and Human Services (HHS) Diversity in Clinical Trials Initiative addresses barriers preventing diverse groups from participating in clinical trials and includes public education and outreach campaigns.” Further, “industry-wide efforts such as PhRMA's voluntary principles to enhance clinical trial diversity, and their grant to fund ‘Equitable Breakthroughs in Medicine Development,’ highlight the importance of community-based infrastructure to improve access to clinical trials for those in historically marginalized communities who want to participate.”

## Studying causes of underrepresentation in clinical trials

Recognizing that “minoritized racial, ethnic, and low-income populations are consistently underrepresented in food allergy research and medical research in general,” FARE conducted a study to “shed light on why this underrepresentation exists and how to address it, [thereby] ensuring that food allergy research is more inclusive.” A survey was used to “better understand what the barriers to research are, because we see low prevalence of participation in the Black community,” Adeela Abbasi, FARE’s Assistant Director of Health Equity said in an interview with *Healio*.

A multi-disciplinary team of clinicians, public health professionals, advocates, community partners and survey methodologists designed an online survey, aimed at adult patients and caregivers, to assess the barriers to and predictors of research participation among persons of lower socioeconomic status and of color.

The study authors recruited 68 adults (80% female; 84% Black; 94% non-Hispanic) with food allergy or who were caregivers of children with food allergy (68%). Participants resided in Wards 7 and 8 in Washington, DC, US, an area that is predominantly Black with lower incomes. The survey, which was approved by an investigational review board (IRB), was conducted online in April 2022.

## Six of 10 adults and children willing to participate

Findings from the survey were presented in a poster at the 2023 American College of Allergy, Asthma & Immunology Annual Scientific Meeting by FARE on behalf of the DC Community Access Program (CAP) Community Advisory Council.

Key findings showed:

- One in 10 adults and children have participated in some kind of research clinical trial
- Six out of 10 adults and children would be willing to participate in research
- Five out of 10 caregivers would allow their children to participate in research
- Seven out of 10 participants said they trust doctors who conduct medical research

The survey also asked respondents why they would want to participate in food allergy research. Their motivations included:

- to benefit people like me (59%)
- to further science (47%)
- to get paid or receive some other reward (35%)
- to improve my/my child’s health or quality of life (29%)
- to learn more about my/my child’s condition (29%) and
- to get access to a type of treatment not offered outside of a health research study (18%)

*Healio* reported the survey also determined “the most common food allergies among participants, namely: shellfish (46%), peanut (43%), tree nuts (30%), other (20%), cow’s milk (17%), sesame (10%), soy (10%), egg (9%), finned fish (9%) and wheat (9%). Generally, the survey participants reported low socioeconomic status, including 30% with an annual household income of \$12,880 or below, 10% between \$12,881 and \$21,960, and 11% between \$21,961 and \$31,040.”

Food insecurity was also an issue and may exacerbate food allergies as well, Abbasi explained to *Healio*, noting there are only three grocery stores in all of Wards 7 and 8. “Their access to healthy, safe food is very lacking in these parts of the city,” she added.

## The challenge is access—not mistrust

“They’re mostly altruistic reasons,” Abbasi observed. “People want to

do it to further science. They want to do it to make a better opportunity for the children after them. I think that speaks very positively, as well, about the potential for research in the Black community.”

Abbasi drew attention to “a big misconception that mistrust [of clinical trials or medical personnel] is the issue.” Instead, she explained, “the challenge is accessibility. There isn’t hesitancy [to participate], there is a lack of [personnel] coming into the community and educating folks and saying, ‘Hey, here’s an opportunity that’s available.’”

“Representation in outreach matters as well,” she said. “Having individuals who look like the community that they’re trying to target can be helpful. Or you could identify a person who has participated in clinical trials and use them [to provide] a testimonial or as somebody who can be a liaison between the research team and the community. Also, by conducting trials in these communities, participants would not have to travel or find childcare,” she added.

## Further recommendations for increasing participation

Roach believes that patient advocacy groups, industry sponsors, institutional review boards and scientific research teams must work together toward improving clinical trial representation of minorities. Her blog post provided multiple approaches that could be implemented before, during and after a trial. Several of her suggestions are listed here:

### *Before a trial*

- Partnering with community advisory councils that represent and engage the target audience
- Offering seats at the research table and enabling patient representatives to weigh in on study protocols and related study materials including informed consent materials

***During trial recruitment***

- Using culturally appropriate messaging to elevate the trial's visibility through social media, community websites, radio, TV, recreational centers and transportation hubs
- Inviting community leaders to take part in free, multilingual informational sessions with dedicated Q&A periods

***After a trial***

- As appropriate, making the study results available and actionable to patients as soon as possible in clear and simple language through various activations, such as engagement events

**Benefits of diversity in clinical trials**

“Clinical trials are foundational to the development of novel therapies and interventions. Thus, inclusive research is not just ‘nice to have.’ Diverse clinical trial populations can better reflect the broad patient population that will use new medicines once they are approved, improving health outcomes,” Roach wrote. “Diversity in clinical trials can provide science-based insights into the variable safety and efficacy responses people can have to therapeutic interventions.”

**Additional FARE initiatives**

FARE provides multiple initiatives designed to encourage diversity and opportunities. Three of these programs are:

***The FARE Patient Registry***

Doctors and other medical professionals who would like to connect their communities with research or research opportunities such as clinical trials can encourage patients to join The FARE Patient Registry,” explained Abassi. The private and secure database is designed to allow people with food allergies help advance research by sharing their experiences.

***The FARE Neighborhoods Initiative™***

The delivery of health education resources and interventions in the community setting is a promising strategy for managing food allergies in underserved populations. The FARE Neighborhoods Initiative™ (FNI) supports those facing food allergies in historically marginalized communities, where access to medication, allergists and safe food can be difficult due to cost and availability. To date, there are FARE Neighborhoods in Atlanta, GA; Central Arkansas, Chicago, IL; Hampton Roads, VA; Newark, NJ and Washington, DC. In each Neighborhood, FARE collaborates with schools, community organizations, health-care providers and places of worship. The work is guided by volunteer advisory councils of local parents, patients, health professionals and community stakeholders. In addition, community health workers are in place in all FARE Neighborhoods.

***The FARE Diversity Scholars Program***

As part of its Health Equity Initiative, FARE has partnered with National Medical Fellowships (NMF) to offer the FARE Diversity Scholars Program. The program provides mentorship and financial support to graduate-level students of color interested in food allergy research and community engagement. The program supports FARE's commitment to help build a pipeline of racially and culturally diverse physicians and researchers interested in investigating, evaluating and addressing the socioeconomic factors that impact healthcare access for under-resourced patients with food allergies.

The Diversity Scholars Program offers a \$10,000 annual stipend to rising second, third and fourth-year graduate students working toward an MD, PhD, or MPH, with an option to renew for one year. Over 10 months, the scholars will commit to a minimum

of 200 hours, working with the FARE Clinical Network (FCN), or other medical and academic institutions, on substantive research/data analysis projects related to food allergy prevention, management or understanding barriers to accessing food allergy care and safe foods.

**References**

Content for this article was based on, excerpted and quoted from:

- Roach A, Abbasi A, Daniel A, Barton N, Hooker Q, Curry K, Malloy M, Herbert L. Addressing the research participation gap in food allergy. Poster 193. 2023 American College of Allergy, Asthma & Immunology (ACAAI) Annual Scientific Meeting, Anaheim, CA, US. <https://epostersonline.com/acaaai2023/poster/p193>.
- Roach, A. Food allergy highlights opportunities for inclusive, representative research studies. PhRMA Blog. March 22, 2023. <https://phrma.org/en/Blog/Food-Allergy-Highlights-Opportunities-for-Inclusive-Representative-Research-Studies>.
- Barriers prevent Black patients with food allergy from participating in clinical research. Healio. December 14, 2023. <https://www.healio.com/news/allergy-asthma/20231214/barriers-prevent-black-patients-with-food-allergy-from-participating-in-clinical-research>.
- End Allergies Together. <https://endallergiestogether.com>.
- FARE announces \$3 million research competition and passage of FASTER Act. Inhalation. 15(3) 30-32. (2021). <https://www.inhalationmag.com/article/back-page-fare-announces-3-million-global-research-competition-and-passage-of-faster-act-in-us>.