

Correspondence and Reply

Increasing diversity in peanut oral immunotherapy research and accessibility



To the Editor:

The Palforzia peanut oral immunotherapy (PN-OIT) product was recently approved by the US Food and Drug Administration as the first treatment for peanut allergy based primarily on its compelling clinical trial efficacy data. Although Palforzia stands to provide a tremendous benefit to patients, it is important to acknowledge and work to resolve the knowledge gaps that remain with PN-OIT, in particular regarding specific patient groups. One such group is patients seen in nonacademic community-based allergy clinics. The recent article by Afinogenova et al¹ reports on 783 patients in a private community-based center with a focus on adverse events during PN-OIT. They found that as high as 19% of this population experienced a systemic reaction during PN-OIT and 11% required epinephrine to treat an allergic reaction. Despite this, there were no hospitalizations or mortalities and 89% of patients successfully completed the treatment protocol. A review of patient characteristics showed increased odds of a systemic reaction with increasing age and peanut-specific IgE.

In their conclusion, the authors suggest risk stratification for patient-specific treatment protocols, a goal that we share. Although age, sex, and atopic history are considered, it is noteworthy that patient race, ethnicity, or socioeconomic status is not described. In 2015, Dyer et al² characterized peanut allergy prevalence and diagnosis trends among 3218 children with food allergy. Peanut allergy was reported most often in white children (47.7%) and children from households with an annual income of \$50,000 to \$99,999 (41.7%). Similarly, a large database study of 1070 children, two-thirds with a peanut reaction, by Leickly et al³ found that children with peanut allergy were predominantly white (78%) and male (63%) and had private health insurance (80%). There is a paucity of real-world data on all patients with peanut allergy given socioeconomic and racial disparities in diagnosing peanut allergies.

A quick literature review (Table I) of 5 recent PN-OIT studies and clinical trials (2017-2019) with 231 participants, 64.1% males, reveals the lack of diversity in research. The article by Chinthrajah et al⁴ did not report patient race but did state that 11 patients (9.2%) were Hispanic/Latino and 109 (90.8%) were not Hispanic/Latino. In the 4 other studies, 111 patients (83.8%) were white.

Given the lack of diversity in peanut allergy diagnosis and PN-OIT research, we must ensure research is more generalizable and increase access to PN-OIT. Despite Food and Drug Administration approval, allowing insurance coverage of Palforzia, health disparities make access difficult for all patients. The initial appointment lasts 2 to 4 hours, and in the first 6 months of treatment, patients have 11 one-hour-long allergist visits. For a pediatric patient with 2 working parents, these restrictions alone make treatment almost impossible. To reach all peanut allergy patients, we could consider transportation vouchers or expanding allergy clinics to underserved areas. Future research could increase focus on ethnic and racial groups not well-represented in studies, analyze in-home treatment efficacy, and investigate avenues to safely decrease the number of doses and visits required to reach the maintenance phase. Does the initial visit need to last 2 to 4 hours or can you go directly into the slow build-up? Allergists must help reduce health disparities and ensure PN-OIT research and administration is equitable to all with peanut allergies.

Hunter G. Smith, MPH
Edwin H. Kim, MD, MS

University of North Carolina School of Medicine, Chapel Hill, NC.

Conflicts of interest: H. G. Smith reports no financial disclosures or conflicts of interest.

E. H. Kim reports clinical medical advisory board membership with DBV Technologies; consultancy with Aimmune Therapeutics, DBV Technologies, Duke Clinical Research Institute, ALK-Abelló, AllerGenis, Kenota Health, Ukko Inc, Vibrant America, and Belhaven Biopharma; and receives grant support to his institution from the National Institute of Allergy and Infectious Diseases, National Center for Complementary and Integrative Health, Food Allergy Research & Education, and the Wallace Research Foundation.

Received for publication December 19, 2020; accepted for publication February 4, 2021.

Corresponding author: Hunter G. Smith, MPH, 108 Parchment Ct., Cary, NC 27518.

E-mail: Hunter_smith@med.unc.edu.

REFERENCES

1. Afinogenova Y, Rubin TN, Patel SD, Powell R, Gilo J, Denno M, et al. Community private practice clinical experience with peanut oral immunotherapy. *J Allergy Clin Immunol Pract* 2020;8:2727-35.
2. Dyer AA, Rivkina V, Perumal D, Smeltzer BM, Smith BM, Gupta RS. Epidemiology of childhood peanut allergy. *Allergy Asthma Proc* 2015;36:58-64.
3. Leickly FE, Kloepper KM, Slaven JE, Vitalpur G. Peanut allergy: an epidemiologic analysis of a large database. *J Pediatr* 2018;192:223-8.e1.
4. Chinthrajah RS, Purington N, Andorf S, Long A, O'Laughlin K, Lyu S. Sustained outcomes in oral immunotherapy for peanut allergy (POISED study): a large, randomized, double-blind, placebo-controlled, phase 2 study. *Lancet Lond Engl* 2019;394:1437-49.
5. Bird JA, Spergel JM, Jones SM, Rachid R, Assa'ad AH, Wang J, et al. Efficacy and safety of AR101 in oral immunotherapy for peanut allergy: results of ARC001, a randomized, double-blind, placebo-controlled phase 2 clinical trial. *J Allergy Clin Immunol Pract* 2018;6:476-85.e3.

TABLE I. Study patient demographics

Author	Participants (n)	Male	Female	White	Black	Biracial/multiracial	American Indian/Alaska			
							Native	Asian	Other	
Chinthrajah et al ⁴	120	81	39	—	—	—	—	—	—	—
Bird et al ⁵	55	36	19	46	0	0	1	2	6	
Kim ⁶	10	7	3	9	0	1	0	0	0	
Kim ⁷	16	6	10	12	1	3	0	0	0	
Shreffler ⁸	30	18	12	26	0	2	0	2	0	

6. Kim E. Oral immunotherapy for peanut allergy (PMIT). 2018. Available from: <https://clinicaltrials.gov/ct2/show/NCT00597675>.
7. Kim E. Oral immunotherapy for peanut allergy-peanut oral immunotherapy (PnOIT3). 2018. Available from: <https://clinicaltrials.gov/ct2/show/NCT00815035>.
8. Shreffler WG. Oral peanut immunotherapy. 2018. Available from: <https://clinicaltrials.gov/ct2/show/NCT01324401>.

<https://doi.org/10.1016/j.jaip.2021.02.010>

Reply to “Increasing diversity in peanut oral immunotherapy research and accessibility”



To The Editor:

We appreciate the correspondence by Smith and Kim.¹ We share their concern for health disparities and the need for greater equity in our field, especially as it pertains to the availability and utilization of peanut oral immunotherapy (PN-OIT). Health inequities exist in every facet of medical care, and the field of allergy and immunology is by no means an exception.

We estimate that less than 5% of the patient population we treated was black or Hispanic. We hope that with broader access to health care, these numbers will become more representative of the peanut-allergic population.

At this time, we would be hesitant to adjust our own PN-OIT protocols, which are based on well-established body of literature.²⁻⁶ However, we agree that further research into avenues suggested that would make PN-OIT more broadly accessible is essential. If new protocols could be developed that allow for greater access to PN-OIT while ensuring a similar

level of safety, we would eagerly adapt them into our clinical practice.

Gary Soffer, MD^a

Yuliya Afinogenova, MD^b

Jeffrey M. Factor, MD^c

^aYale Medicine, Department of Pediatrics, New Haven, Conn

^bYale Medicine, Department of Rheumatology, Allergy and Immunology, New Haven, Conn

^cNew England Food Allergy Treatment Center, Connecticut Children's Medical Center, West Hartford, Conn.

Conflicts of interest: The authors declare that they have no relevant conflicts of interest. Received for publication February 2, 2021; accepted for publication February 4, 2021.

Corresponding author: Yuliya Afinogenova, MD, Yale University, PO BOX 208013, New Haven, CT 06520. E-mail: yuliya.afinogenova@yale.edu.

REFERENCES

1. Smith H, Kim EH. Increasing diversity in peanut oral immunotherapy research and accessibility. *J Allergy Clin Immunol Pract* 2021;9:2132-3.
2. PALISADE Group of Clinical Investigators Vickery BP, Vereda A, Casale TB, Beyer K, du Toit G, et al. AR101 Oral immunotherapy for peanut allergy. *N Engl J Med* 2018;379:1991-2001.
3. Nachshon L, Goldberg MR, Katz Y, Levy MB, Elizur A. Long-term outcome of peanut oral immunotherapy—real-life experience. *Pediatr Allergy Immunol* 2018;29:519-26.
4. Vickery BP, Berglund JP, Burk CM, Fine JP, Kim EH, Kim JI, et al. Early oral immunotherapy in peanut-allergic preschool children is safe and highly effective. *J Allergy Clin Immunol* 2017;139:173-81.e8.
5. Wasserman RL, Factor JM, Baker JW, Mansfield LE, Katz Y, Hague AR, et al. Oral immunotherapy for peanut allergy: multipractice experience with epinephrine-treated reactions. *J Allergy Clin Immunol Pract* 2014;2:91-6.
6. Wasserman RL, Hague AR, Pence DM, Sugarman RW, Silvers SK, Rolen JG, et al. Real-world experience with peanut oral immunotherapy: lessons learned from 270 patients. *J Allergy Clin Immunol Pract* 2019;7:418-26.e4.

<https://doi.org/10.1016/j.jaip.2021.02.011>