

## AAAAI Work Group Report: Trends in Oral Food Challenge Practices Among Allergists in the United States



Justin Greiwe, MD<sup>a,b</sup>, John Oppenheimer, MD<sup>c</sup>, J. Andrew Bird, MD<sup>d</sup>, David M. Fleischer, MD<sup>e</sup>,  
Jacqueline A. Pongracic, MD<sup>f</sup>, and Matthew Greenhawt, MD, MBA, MSc<sup>e</sup>; for the AAAAI Adverse Reactions to Foods  
Committee *Cincinnati, Ohio; Summit, NJ; Dallas, Tex; Aurora, Colo; and Chicago, Ill*

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**The oral food challenge (OFC) is the criterion standard for diagnosing food allergy, but prior studies indicate many allergists may not be using OFCs for various reasons. To better understand current OFC trends, practices, and barriers, the American Academy of Allergy Asthma and Immunology (AAAAI)**

**Adverse Reactions to Foods Committee subcommittee updated a 19-item survey (previously administered in 2009) and sent it to AAAAI and American College of Allergy, Asthma, and Immunology (ACAAI) membership. There were a total of 546 respondents who represented approximately a 10% response**

<sup>a</sup>Bernstein Allergy Group, Inc., Cincinnati, Ohio

<sup>b</sup>Division of Immunology/Allergy Section, Department of Internal Medicine, the University of Cincinnati College of Medicine, Cincinnati, Ohio

<sup>c</sup>Department of Internal Medicine, UMDNJ-Rutgers and Pulmonary and Allergy Associates, Summit, NJ

<sup>d</sup>Division of Allergy & Immunology, Department of Pediatrics, University of Texas Southwestern Medical Center, Dallas, Tex

<sup>e</sup>Section of Allergy and Immunology, Children's Hospital Colorado, Department of Pediatrics, University of Colorado School of Medicine, Aurora, Colo

<sup>f</sup>Division of Allergy and Immunology, The Ann and Robert H. Lurie Children's Hospital of Chicago, Northwestern University Feinberg School of Medicine, Chicago, Ill

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Corresponding author: Justin Greiwe, MD, Bernstein Allergy Group, 8444 Winton Road, Cincinnati, OH 45231. E-mail: [jcgreiwe@gmail.com](mailto:jcgreiwe@gmail.com). 2213-2198

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*Abbreviations used*

AAAAI- American Academy of Allergy Asthma and Immunology  
ACAAI- American College of Allergy, Asthma, and Immunology  
ACGME- Accreditation Council for Graduate Medical Education  
ARFC- Adverse Reactions to Foods Committee  
CI- Confidence interval  
CPT- Current Procedures and Terminology code  
E and M- Evaluation and Management  
ED- Emergency department  
NIAID- National Institute of Allergy and Infectious Diseases  
OFC- Oral food challenge  
PDT- Practices, Diagnostics, and Therapeutics committee

rate. Among the 546 respondents, compared with 2009, significantly more providers offer OFCs (95% vs 84.5%), offer >10 OFCs per month (17% vs 5.6%), obtain informed consent (82.2% vs 53.6%), and performed OFCs in fellowship (71% vs 45%) (all  $P < .001$ ). Fellowship OFC training was limited, with 56% performing <10 OFCs in fellowship and 29% performing none. Although 94% see patients <12 months of age, 35.5% do not offer OFCs for early peanut introduction. Although 79% dedicate a supervising medical provider (MD, NP, PA) and 86% have a written OFC protocol, only 60% had a standardized reaction treatment protocol and 56% prepared emergency medications before OFC. Compared with 2009, there was significant worsening of perceived barriers to performing OFCs, including time (65.6% vs 55%), space (55.3% vs 27.1%), staffing (59.6% vs 44.3%), experience (16.9% vs 11.5%), and hospital proximity (10.9% vs 7.9%), though reimbursement as a barrier improved (45.9% vs 53.7%) (all  $P < .01$ ). Compared with 2009, although more providers offer OFCs, multiple perceived barriers to performing OFCs have worsened. Hesitancy to challenge infants and emergency preparedness issues are emerging potential concerns. © 2020 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2020;8:3348-55)

**Key words:** Oral food challenge; IgE-mediated food allergy; Safety; Double-blinded food challenge; Epinephrine

The food allergy diagnostic criterion standard is an oral food challenge (OFC). However, there are limited prior data regarding allergist trends regarding the use of this procedure. A previous study published by Pongracic et al<sup>1</sup> surveyed the American Academy of Allergy Asthma and Immunology (AAAAI) membership regarding OFC practices in 2009. They found that 85.5% of responding allergists reported performing OFCs but only 5.6% performed >10 OFCs per month. The majority (70%) performed only 1 to 5 OFCs per month. Time, inadequate reimbursement, and concern regarding the risk of an adverse event were cited as the top 3 perceived barriers. Surprisingly, 45% of respondents in the 2009 survey reported having never personally performed OFCs during fellowship training, and only 54% reported obtaining written informed consent before conducting the OFC. This workgroup report further demonstrated that many allergists expressed reservations about performing this service in their office or were limiting its use for various reasons, including perception of risk, time burden, reimbursement concerns, and personnel constraints. OFCs are a critical procedure to identify patients with IgE-

mediated (and selected non-IgE-mediated) food allergy when the history and testing may not clearly confirm the diagnosis. OFCs are especially important for confirming lack of clinical reactivity in the setting of sensitization with a low pretest probability for a reaction, assessing panels of tests obtained indiscriminately where there may be unnecessary dietary elimination, or assessing for development of natural allergen tolerance.<sup>2-7</sup> Unnecessary or prolonged avoidance may potentially lead to increased patient and parental anxiety, reduced quality of life, increased social stigma, and could possibly contribute to nutritional deficiencies.<sup>8-11</sup> Therefore, it is important that physicians correctly identify true food allergies and clarify when avoidance is or is not medically necessary.<sup>12,13</sup> OFCs in this situation are essential and can be conducted safely and successfully, decreasing unnecessary food avoidance.<sup>6</sup>

There are data that demonstrate that OFCs improve the quality of life of food-allergic patients and caregivers, even if patients do not tolerate ingestion.<sup>14-16</sup> Food allergies affect approximately 8% of US children<sup>17</sup> and are associated with an annual direct and indirect total US health care cost of approximately \$24 billion.<sup>18</sup> There are strong economic arguments in favor of increasing access to an OFC, which may help reduce these health and economic burdens by optimizing the diagnosis. One study noted that in a large academic referral center population, delaying challenges could lead to millions of dollars in additional costs to patients for every month the procedure is deferred or delayed.<sup>19</sup>

OFCs are considered safe if performed by trained specialists in appropriately selected patients. Akuete et al<sup>20</sup> determined that OFCs may be much safer than previously perceived. In one of the largest data sets to date, they analyzed a total of 6377 OFCs from 2008 to 2013 across multiple centers, with 86% of patients successfully being challenged with no reaction, only 2% requiring epinephrine, and 98% of OFCs were completed without triggering anaphylaxis.<sup>20</sup> Although this patient population was somewhat biased in selection given that this was not a prospective study but rather the comparison of retrospective results of OFCs performed for clinical purposes without common criteria for how/when/why OFC was offered, these results are in stark contrast to several previous studies that reported epinephrine use during OFCs ranging from 6% to 33% (though again, the populations and OFC circumstances are heterogeneous, and are not directly comparable).<sup>2,21-27</sup> In addition to a low rate of anaphylaxis in the Akuete et al data, there is evidence supporting that late-phase and biphasic reactions after OFCs are also rare, ranging from 1.5% to 4% in previously published studies.<sup>28,29</sup> Notably, there is only 1 known OFC related fatality in the United States to date since the description of the modern OFC procedure was published in 1976, and 1 known fatality outside the United States as part of an oral immunotherapy entry challenge.<sup>30,31</sup>

A number of recent developments have increased the importance of performing OFCs in routine practice, including the establishment of multiple new food allergy centers across the United States, the implementation of an early introduction policy that involves OFCs for high-risk children, and the advances in peanut allergy immunotherapy for which establishing eliciting/tolerating doses is integral. Accordingly, the AAAAI Adverse Reactions to Foods Committee (ARFC) updated the 2009 survey for re-administration, given concerns noted in the original survey, as well as recent advances regarding food allergy care in the past 9 years.<sup>32,33</sup> Herein we report the results and trends about OFC practices as reported by the AAAAI and American College of Allergy, Asthma, and Immunology (ACAAI) membership.

## METHODS

During the ARFC meeting at the 2016 AAAAI annual meeting, a subcommittee was formed to examine the current trends regarding OFCs. A formal proposal was drafted and submitted and approved by the Practices, Diagnostics, and Therapeutics committee (PDT). AAAAI staff worked in conjunction with the OFC subcommittee to update and refine the 2009 question set, which was then submitted back to the PDT for final approval of all text by PDT and the AAAAI Board of Directors. The survey was also approved for distribution to ACAAI membership by the ACAAI Scientific Committee. Using membership accounts, an anonymous online 20-item questionnaire was sent to a random sample of AAAAI members (1319) and the entire ACAAI membership (4095) using the Survey Monkey platform. All recipients received an email with a survey link and participation was voluntary. The investigators were not involved in the distribution process.

Questions in the survey were divided into sections that covered various topics including demographic and background information, OFC practices, potential barriers to performing OFCs, and OFCs in infants. The content of the survey was based on a previous food allergy survey administered in 2009 and published by Pongracic et al, which was augmented by the clinical experiences of the participating investigators, through a process of iterative discussion to achieve unanimous consensus on changes/additions. It was further updated to reflect recent advances in food allergy and knowledge gaps that were not addressed in the previous survey, such as OFCs in very young children. Respondents completed the survey online, which was estimated to take approximately 15 to 20 minutes to complete. The survey was distributed in the winter of 2017 to AAAAI members and in the winter of 2018 to ACAAI members.

Respondent data were automatically tabulated by the Survey Monkey program and downloaded to an MS excel spreadsheet (Redmond, WA), for cleaning, and then uploaded to Stata, Version 13 (College Station, TX) for analysis. The items underwent frequency analysis to provide general descriptive trends. The data were also analyzed for inferential statistics using the Fisher exact test and logistic/linear regression, with predictive probabilities computed using analysis of marginal means with the Stata margins command. This study was approved by the University of Cincinnati IRB and is exempt from ongoing IRB review.

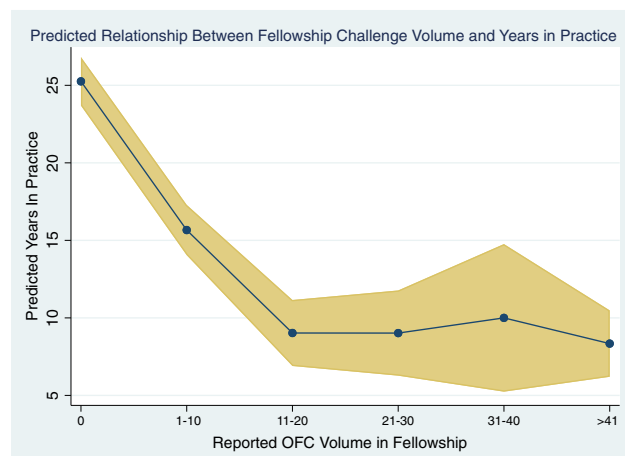
## RESULTS

There were a total of 546 respondents who represented an approximately 10% response rate from among the potential pool of allergists contacted between the AAAAI and ACAAI members. Respondents had a mean of 15 years in clinical practice after fellowship (standard deviation, 11.8), and 95% (516 of 543) noted that they currently offer OFCs in their practice. Table I details the number of reported challenges per month and number of reported OFCs performed in fellowship. There was a significant relationship between years in practice and number of OFCs performed in fellowship (adjusted  $R^2$  0.33,  $P < .001$ , coef.  $-3.34$ , 95% confidence interval [CI]:  $-3.8$  to  $-2.8$ , Figure 1). Most respondents (92%, 476 of 515) affirmatively indicated that there is a need to perform OFCs in clinical practice. When asked about total numbers of OFCs performed, the majority of respondents reported performing more OFCs in a few months than they did in their entire fellowship, with approximately 29% (155 of 535) recounting they performed no OFCs in fellowship (vs 65% [435 of 619] reporting no fellowship OFCs in 2009,  $P < .001$ ) (Table I). There was a small but significant

**TABLE I.** Reported number of oral food challenges performed during fellowship and in practice

OFC performed in fellowship (per fellowship duration), total number		Percent reporting (535 answered)
0		28.97% (155)
1-10		26.92% (144)
11-20		15.70% (84)
21-30		9.72% (52)
31-40		3.93% (21)
41 or more		14.77% (79)
OFC performed in practice (per month), total number		Percent reporting (513 answered)
0		5.46% (28)
1-5		58.09% (298)
6-10		19.30% (99)
11-15		7.21% (37)
16-20		9.94% (51)

OFC, Oral food challenge.



**FIGURE 1.** Relationship between reported fellowship OFC volume (in categories) and the number of years in practice since leaving fellowship. A statistically significant inverse relationship ( $R^2$  0.33,  $P < .001$ ) is noted in that more recent fellowship graduates report a higher number of OFCs performed during training. OFC, Oral food challenge.

association between numbers of OFCs performed in fellowship and number performed in practice (odds ratio: 1.23, 95% CI: 1-1.5,  $P = .04$ ). At least half of all respondents reported that they were performing 1 to 5 OFCs per month. All respondents surveyed offer open (nonblinded) challenges and occasionally supplement open challenges with other types of OFCs, including 26% (114 of 439) offering single-blind OFC, 9% (37 of 432) offering double-blind OFC, and 13% (55 of 437) offering double-blind, placebo-controlled OFC (multiple responses were permitted). Before performing the OFC, 82% (398 of 484) reported obtaining written informed consent from patients/parents, and of those obtaining consent, only 22% (86 of 392) did not use consent language that discussed the possibility of a fatal outcome.

Table II details the reported workflow distribution among supervising and support staff for OFC-related tasks. This

**TABLE II.** Effort and personnel involved in OFCs

	Pre-OFC examination	Administers OFC food	Monitors OFC progress
Allergist	94% (424 of 449)	49% (194 of 393)	85% (366 of 432)
Nurse	55% (217 of 394)	73% (300 of 412)	78% (322 of 413)
Nurse practitioner	30% (102 of 338)	15% (50 of 336)	27% (92 of 339)
Medical assistant	27% (97 of 362)	42% (162 of 389)	49% (188 of 386)
Physician assistant	21% (70 of 339)	10% (32 of 333)	19% (64 of 334)

OFC, Oral food challenge.

The columns represent the scenario and the rows the type of staff involved in the scenario. The question was asked as a close-ended matrix where a specific yes/no choice relative to the staff involvement had to be made.

highlights that most practices offering OFCs involve multiple types of office staff in the procedure. However, only 69% (308 of 448) reported having a specifically dedicated nurse and 79% (353 of 449) a dedicated medical provider (MD, NP, PA, etc.) supervising OFCs. OFCs were reported to be performed to a wide variety of foods. Preparation of the food to be used for OFCs varied and was dependent on the allergen administered. The vast majority of foods, in particular baked egg (90%, 408 of 452), baked milk (91%, 409 of 450), nonbaked egg (83%, 374 of 452), and nonbaked cow's milk (73%, 331 of 455), were reported to be prepared or supplied by the parent/patient as opposed to the allergist or staff. Alternatively, for other items, many respondents reported that their office provided selected items for use in OFCs, such as peanut butter (40%, 182 of 459).

Given the potential safety issues with conducting OFCs, questions in this iteration of the survey placed emphasis on understanding how practices plan and supervise the procedure, as well as respond to adverse events occurring as a result of OFCs. Before starting an OFC in the office, 100% of responding allergists reported that they assess the patient for adequate asthma control and the presence of concomitant medications that might interfere with the procedure or treatment of a reaction (eg, antihistamines, beta-blockers, etc), and 84% (378 of 449) reported assessing for eczema control. The majority of allergists obtain skin prick testing (92%, 409 of 446) or serum-specific IgE tests (88%, 396 of 448) before the OFC and report following a clearly specified written protocol for dosing administration and observation (86%, 385 of 446).

Similarly, 99% (450 of 453) of physicians report directly examining the patient when there is concern of a reaction occurring after a dose, with ancillary staff also performing examinations at varying degrees of frequency. Treatment, when necessary, was administered directly by the supervising physician (84%, 369 of 441) or nurse (81%, 321 of 398). [Table III](#) describes the duration of time for both pre-OFC task preparation and post-OFC observation both after a routine asymptomatic OFC and in the event of medication administration.

For severe reactions requiring a single dose of epinephrine, observation time was split among physicians, with 48% (216 of 452) reporting observing such patients in the office for 1 to 2 hours, 31% (138 of 452) for 3-4 hours, and 17% (78 of 452) reporting that they send the patient to the closest emergency department (ED) instead of observing the patient in the office. Most physicians (75%, 336 of 451) reported sending patients to the closest ED if they experience a severe reaction requiring multiple doses of epinephrine.

Subjective complaints occurring during OFCs without obvious objective findings were reported to be handled by extending the dosing interval to allow for more waiting time before the next dose

(21%, 98 of 459), repeating the dose (12%, 54 of 459), proceeding along as per planned protocol (5%, 24 of 459), and stopping the challenge (3%, 13 of 459). A majority of respondents (59%, 269 of 459) reported not having any prespecified standardized approach to managing subjective symptom development and treated this on an individual case-by-case basis. A similar percentage (60%, 268 of 447) reported having a standardized protocol for stopping the challenge (for objective symptoms) and treating any reaction should it occur, whereas 56% (252 of 448) had emergency medicine premeasured and ready in the challenge space before starting the OFC. Importantly, in response to a direct question regarding allergist willingness to offer OFCs, as this survey took place after the report of the first known fatality in the United States related to an OFC, 25% (111 of 450) of respondents reported that they are less willing to provide OFCs in their offices due to this fatality, though willingness was inversely proportional to the number of OFCs provided per month ([Figure 2](#)).

To follow up the 2009 survey responses that noted multiple perceived barriers to performing OFCs, including lack of time, lack of staff, and lack of office space, these questions were repeated in this survey iteration. [Figure 3](#) compares responses from 2009 to the same question asked in the current survey, noting multiple statistically significant differences between time periods. Although barriers and issues such as perception of inadequate reimbursement and the lack of need to perform OFCs have decreased, barriers such as lack of time, staff, space, and experience have increased. With regard to reimbursement and implementation of new Current Procedural Terminology (CPT) coding specific to OFC since 2009, this iteration of the survey asked how physicians code for OFCs, with 46% (220 of 476) reporting that they submit both Evaluation and Management (E and M) and ingestion challenge procedure codes (95076 for the first 120 minutes, 95076 and 95079 if challenge goes beyond 151 minutes). Over half (51%, 244 of 476) used the ingestion challenge procedure code only, and 2.5% (12 of 476) used only an E and M code. This reflects a change from 2009 where 59% submitted both an E and M and ingestion challenge procedure code, 29% an ingestion challenge procedure code only, and 7% only an E and M code. No questions were asked regarding the actual level of reimbursement received or amount charged, on average, per OFC.

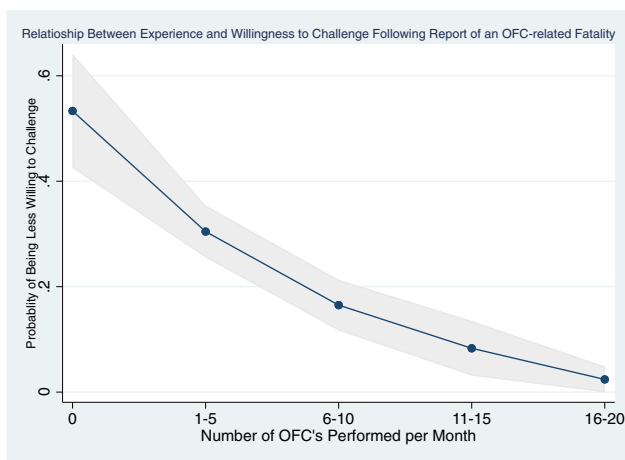
Finally, respondents were queried about performing OFCs in infants and issues related to early peanut introduction, which are evolving practices since 2009 ([Table IV](#)). Although 94% (455 of 486) of allergists reported currently managing children under the age of 12 months in their practices, a minority of participants (37%, 158 of 431) reported an increase in referrals for skin testing and/or in-office introduction of peanut for high-risk infants (as defined in the National Institute of Allergy and Infectious Diseases



**TABLE III.** Comparison of time-related events before and during OFCs

Preparation time for OFC-related tasks	1-10 min	11-20 min	21-30 min	>30 min		
Food prep	68%	18.5%	3.5%	4%		
Emergency med prep	80%	5%	1.5%	0.6%		
Patient consent	86%	7%	2%	0.8%		
Post-challenge instructions	60%	32%	6%	1.5%		
Observation time	<1 h	1-2 h	3-4 h	5-6 h	>6 h	ED
Total duration of feeding time	7.7%	59.4%	29.1%	3.1%	0.7%	
After last dose	26.9%	70%	2.4%	0.4%	0.2%	0%
After mild reaction treated with antihistamines	17.9%	75.5%	6%	0.2%	0.2%	0.2%
After moderate reaction treated with multiple (non-epinephrine) medications	7.2%	72.6%	17.3%	1.1%	0.2%	1.5%
After severe reaction requiring single epinephrine dose	1.3%	47.8%	30.5%	2.2%	0.9%	17.3%
After severe reaction requiring multiple epinephrine doses	0%	8%	13.1%	3.8%	0.7%	74.5%

ED, Emergency department; OFC, oral food challenge.



**FIGURE 2.** Relationship between experience and willingness to challenge following report of an OFC-related fatality. The survey found that 25% of responding allergists are less willing to provide OFCs in their office after the recent food challenge fatality. Their willingness was inversely proportional to the number of OFCs provided per month. OFC, Oral food challenge.

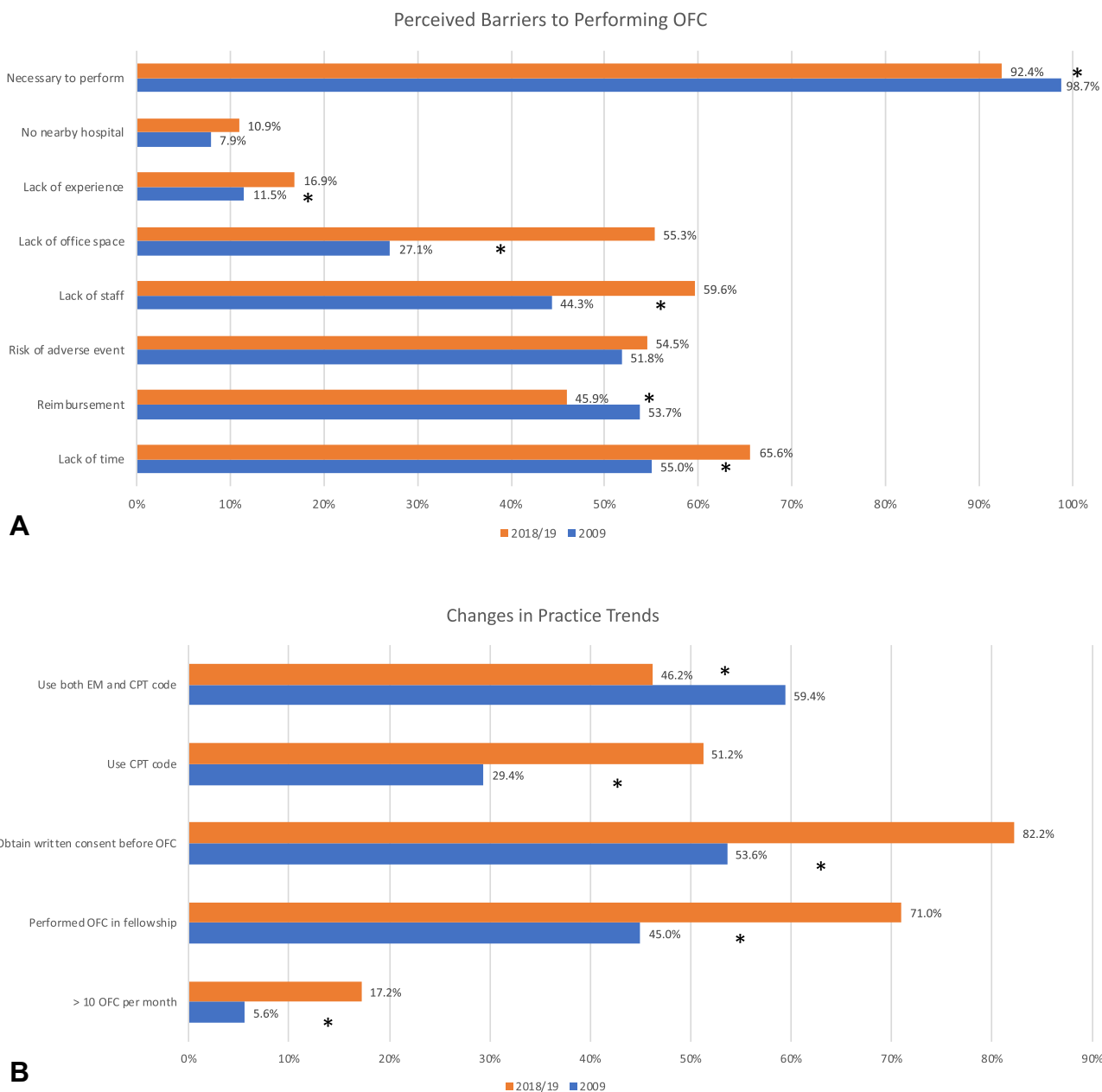
[NIAID] addendum guidelines), though slightly more than half noted an increase in referrals for all infants (including high-risk infants) who have already undergone serologic IgE testing to either peanut, egg, or both by an outside nonallergy provider. The vast majority of respondents (79%, 340 of 429) reported encouraging caregivers of infants between the ages of 4 to 11 months to incorporate peanut into their diets, though just half of respondents followed recommendations for skin testing high-risk infants 4 to 11 months of age. Only 38% (162 of 431) performed an in-office feeding for high-risk infants, whereas 36% (153 of 431) of respondents do not offer in-office feeding for high-risk infants, 15.8% (68 of 431) respondents offer challenge to all infants, and 11.1% (48 of 431) do not offer these due to lack of applicability to their practice or lack of opportunity.

## DISCUSSION

The OFC is a critical diagnostic procedure used to evaluate the presence of both IgE- and non-IgE-mediated food allergy and remains the criterion diagnostic standard for food allergy. In the

hands of an experienced and trained provider, this is a safe and reliable procedure. The OFC remains necessary given the inherent limitations of misclassification from blood or skin tests that have been used as surrogates for the OFC, in particular when these are applied at a population level.<sup>34-36</sup> Little was known about provider trends in performing OFCs until 2009, when the initial iteration of this survey noted that OFCs were viewed as labor- and resource-intensive procedures that provided inadequate reimbursement for the time and effort spent, reflected by 82.6% of providers performing <5 challenges per month. Since the publication of the initial workgroup report, multiple advances in the field have occurred that have increased the practice of OFCs, including the advent of food allergy immunotherapy (either as a clinical practice or as a clinical trial), the recent NIAID early peanut introduction guidelines, an increase in the number of dedicated food allergy centers across the United States, greater awareness of the limited predictive value of serologic or skin testing, and new CPT codes to help improve reimbursement.<sup>37</sup> These are well reflected in the statistically significant uptick of respondents who are performing at least 5 OFCs per month compared with 2009.

Although this current survey indicates positive shifts in access and willingness, other trends have become more problematic. There is still a relative potential lack of access—although the number of providers offering OFCs has increased, most practices offer approximately 1 challenge per week, which may not be sufficient to meet the community needs. This survey deliberately did not assess the characteristics of the patient being offered the OFC (eg, a potential estimation of likelihood of reactivity based on testing and/or clinical history). There was a significant shift in the number of respondents reporting that experience was a barrier to performing OFCs, and this may be reflective of current trends in fellowship. Despite reported increases in opportunity to perform OFCs in fellowship, 56% (299 of 535) of respondents reported performing 10 or fewer OFCs during their entire fellowship, and 29% (155 of 535) reported having no experience at all. With the institution of Accreditation Council for Graduate Medical Education (ACGME) requirements, more recent fellowship graduates are required to participate in a minimum of 5 OFCs. Such minimal requirements for supervising OFCs should reduce future concerns regarding a complete lack of experience as a barrier. Given the importance of the OFC procedure, it is the opinion of the authors that competency in performing OFCs at all ages, especially in infants, should be a priority in evaluating allergy training programs by the ACGME.<sup>38</sup>



**FIGURE 3.** Reported barriers to performing an OFC. Comparison of reported barriers between survey waves from 2009 (A) and 2018/19 (B). Asterisks denote  $P < .05$  for the trend. *CPT*, Current Procedures and Terminology code; *EM*, Evaluation and Management; *OFC*, oral food challenge.

Trends that have worsened significantly since 2009 include issues surrounding time, office staff, and office space as reported barriers. Similarly, the data captured in this survey are concerning for adherence to new early peanut introduction guidelines and access to such care (despite nearly all respondents reporting seeing infants <12 months of age in their practice). Although this survey was not specifically designed to capture the full range of barriers and facilitators to this practice, the NIAID policy is heavily nested in both opportunity for access to this care and willingness of providers to perform the service.

It is encouraging that compared with allergists sampled in 2009, fewer report reimbursement issues as a barrier to

performing OFCs, which may reflect the implementation of new CPT codes in 2013. Reimbursement for OFCs can now be billed under codes 95076 (first 120 minutes, including pre/post-OFC evaluation) and 95079 (each additional 60 minutes). Greater than 50% of the allotted time must be used (61 minutes for 95076 and 31 minutes for each unit of 95075). The total time of the OFC begins with the pre-challenge evaluation, and not just when the first increment of food is consumed, and then stops when the patient is discharged from the clinic or the challenge is terminated due to a reaction.<sup>39</sup> We noted an approximate doubling in the number of providers who report use of the new ingestion codes. We did not query about the actual dollar

**TABLE IV.** Practice trends in infants targeted for early peanut introduction

Trend	For all infants	NIAID high-risk infants only	For no infants	No opportunity
Encourage early peanut introduction	79.2%	10.9%	5.1%	1.4%
Note increase in referrals for early peanut screening	36.6%	20.9%	39.9%	0.7%
Note increase in PCP tested early peanut referrals	42.7%	10.2%	43.4%	1.4%
Routinely testing for peanut before early peanut introduction	18.3%	50.6%	26.2%	3.2%
Routinely testing for egg before early peanut introduction	14.2%	32.2%	48.7%	3.5%
Performing OFC for early peanut introduction	15.8%	37.6%	35.5%	9.5%

NIAID, National Institute of Allergy and Infectious Diseases; OFC, oral food challenge; PCP, primary care provider.

amount being reimbursed per challenge, nor did we query the degree to which these new codes were linked to the reported increase in OFC utilization.

This survey has several limitations. Foremost the sampling frame is different. Unlike the 2009 survey, which was sent exclusively to the general AAAAI membership (physicians and allied health persons both), this survey was administered to a random sample of members of the AAAAI as well as the general membership of the ACAAI. Overall, the estimated response rate for the “field” was approximately 10%, which puts these data at potential risk for sampling bias and limited generalizability. There is also potential for responder bias in that only those with an interest in food allergy or performing OFCs may be more inclined to respond to open surveys of this nature. There are distinct restrictions on how both the AAAAI and ACAAI conduct member surveys and the availability of nonresponder demographic data to gauge propensity of response. However, this largely follows a similar procedure and has similar response rates to both the 2009 survey and other published membership surveys. Higher response rate is an inherent systematic issue for nonincentivized membership surveys, and as such, the data could have significant limitations regarding generalizability, though these are unavoidable. Although these data are not shown, there were few differences in comparing AAAAI and ACAAI responses. We were limited in the number and scope of questions asked, because the planned aim was to update the prior survey accessing trends over time and to focus specifically on areas of emerging potential gaps or perceived needs. In particular, there are additional questions not asked that would be more relevant for a separate survey investigating OFC trends in infants, which we plan to address in a future dedicated survey pertaining to this topic. In addition, no assessment was completed to assess the willingness of parents/caregivers to have their child undergo OFCs according to published guidelines, which may affect the number of challenges performed. Lastly, although we think this is a minute risk and does not affect the results, we cannot entirely rule out the possibility that someone took the survey twice, or that members of the same practice may be represented. This is a risk with de-identified survey collection, and in theory we cannot rule out with 100% certainty that any cases eluded software restrictions that limit more than 1 participant from the same IP address.

In conclusion, although improvements in performing OFCs have been made over the 10 years since the initial workgroup report, there continue to be many barriers to performing OFCs. These barriers include training and experience, time and effort to conduct the procedure, and staffing. It is concerning that obtaining written consent before an OFC is not universal, especially with the recent fatality. A recent AAAAI workgroup

report on OFCs recommends that all patients undergoing an OFC have documented verbal or signed written consent that should better protect both the allergist and the patient. It is reassuring that reimbursement is decreasing as a cited barrier to performing OFCs. There is also emerging concern for hesitancy in challenging infants. Demand for OFCs in infants and toddlers will likely continue to increase, and existing guidelines and emerging therapies are predicated on both access and willingness to perform OFCs in this age group. This may require targeted surveys of barriers and facilitators specific to this age-related hesitancy, with the results supported by education to enhance provider comfort and willingness to offer OFCs to this population. There are signs that previously identified barriers are improving, with an increase in the number of allergists performing OFCs and improved access to OFC training in fellowship. Targeted efforts are recommended to promote expanding OFC fellowship training opportunities to increase comfort and experience among allergists performing higher-risk challenges. Continued follow-up tracking OFC educational trends in allergy training programs is required to make sure that this core competency skill is being taught more frequently. The ARFC plans to update these data in the next 5 to 10 years and will more than likely pursue dedicated surveys related to hesitancy for infant OFCs in the interim to address this potential issue as a practice gap.

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### REFERENCES

- Pongratic JA, Bock SA, Sicherer SH. Oral food challenge practices among allergists in the United States. *J Allergy Clin Immunol* 2012;129:564-6.
- Fleischer DM, Bock SA, Spears GC, Wilson CG, Miyazawa NK, Gleason MC, et al. Oral food challenges in children with a diagnosis of food allergy. *J Pediatr* 2011;158:578-83.
- de Leon MP, Drew AC, Glaspole IN, Suphioglu C, O’Hehir RE, Rolland JM. IgE cross-reactivity between the major peanut allergen Ara h 2 and tree nut allergens. *Mol Immunol* 2007;44:463-71.
- Sicherer SH. Clinical implications of cross-reactive food allergens. *J Allergy Clin Immunol* 2001;108:881-90.
- Ewan PW. Clinical study of peanut and nut allergy in 62 consecutive patients: new features and associations. *BMJ* 1996;312:1074-8.
- Couch C, Franxman T, Greenhawt M. Characteristics of tree nut challenges in tree nut allergic and tree nut sensitized individuals. *Ann Allergy Asthma Immunol* 2017;118:591-6.

7. Maloney JM, Rudengren M, Ahlstedt S, Bock SA, Sampson HA. The use of serum-specific IgE measurements for the diagnosis of peanut, tree nut, and seed allergy. *J Allergy Clin Immunol* 2008;122:145-51.
8. Alvares M, Kao L, Mittal V, Wu A, Clark A, Bird JA. Misdiagnosed food allergy resulting in severe malnutrition in an infant. *Pediatrics* 2013;132:e229-32.
9. Christie L, Hine RJ, Parker JG, Burks W. Food allergies in children affect nutrient intake and growth. *J Am Diet Assoc* 2002;102:1648-51.
10. Hobbs CB, Skinner AC, Burks AW, Vickery BP. Food allergies affect growth in children. *J Allergy Clin Immunol Pract* 2015;3:133-4.
11. Brough HA, Turner PJ, Wright T, Fox AT, Taylor SL, Warner JO, Lack G. Dietary management of peanut and tree nut allergy: what exactly should patients avoid? *Clin Exp Allergy* 2015;45:859-71.
12. Sicherer SH, Noone SA, Munoz-Furlong A. The impact of childhood food allergy on quality of life. *Ann Allergy Asthma Immunol* 2001;87:461-4.
13. Robbins KA, Wood RA, Keet CA. Milk allergy is associated with decreased growth in US children. *J Allergy Clin Immunol* 2014;134:1466-8.
14. van der Velde JL, Flokstra-de Blok BM, de Groot H, Oude-Elberink JN, Kerkhof M, Duiverman EJ, et al. Food allergy-related quality of life after double-blind, placebo-controlled food challenges in adults, adolescents, and children. *J Allergy Clin Immunol* 2012;130:1136-1143.e2.
15. DunnGalvin A, Cullinane C, Daly DA, Flokstra-de Blok BM, Dubois AE, Hourihane JO. Longitudinal validity and responsiveness of the Food Allergy Quality of Life Questionnaire Parent Form in children 0-12 years following positive and negative food challenges. *Clin Exp Allergy* 2010;40:476-85.
16. Soller L, Hourihane J, DunnGalvin A. The impact of oral food challenge tests on food allergy health-related quality of life. *Allergy* 2014;69:1255-7.
17. Dyer AA, Gupta R. Epidemiology of childhood food allergy. *Pediatr Ann* 2013;42:91-5.
18. Gupta R, Holdford D, Bilaver L, Dyer A, Holl JL, Meltzer D. The economic impact of childhood food allergy in the United States. *JAMA Pediatr* 2013;167:1026-31.
19. Couch C, Franxman T, Greenhawt M. The economic effect and outcome of delaying oral food challenge. *Ann Allergy Asthma Immunol* 2016;116:420-4.
20. Akuete K, Guffey D, Israels RB, Broyles JM, Higgins LJ, Green TD, et al. Multicenter prevalence of anaphylaxis in clinic-based oral food challenges. *Ann Allergy Asthma Immunol* 2017;119:339-348.e1.
21. Noone S, Ross J, Sampson HA, Wang J. Epinephrine use in positive oral food challenges performed as a screening test for food allergy therapy trials. *J Allergy Clin Immunol Pract* 2015;3:424-8.
22. Lieberman JA, Cox AL, Vitale M, Sampson HA. Outcomes of office-based, open food challenges in the management of food allergy. *J Allergy Clin Immunol* 2011;128:1120-2.
23. Perry TT, Matsui EC, Conover-Walker MK, Wood RA. Risk of oral food challenges. *J Allergy Clin Immunol* 2004;114:1164-8.
24. Ram G, Cianferoni A, Spergel JM. Food allergy to uncommonly challenged foods is rare based on oral food challenge. *J Allergy Clin Immunol Pract* 2016;4:156-157.e5.
25. Cianferoni A, Garrett JP, Naimi DR, Khullar K, Spergel JM. Predictive values for food challenge-induced severe reactions: development of a simple food challenge score. *Isr Med Assoc J* 2012;14:24-8.
26. DunnGalvin A, Segal LM, Clarke A, Alizadehfar R, Hourihane JO. Validation of the Cork-Southampton food challenge outcome calculator in a Canadian sample. *J Allergy Clin Immunol* 2013;131:230-2.
27. DunnGalvin A, Daly D, Cullinane C, Stenke E, Keeton D, Erlewyn-Lajeunesse M, et al. Highly accurate prediction of food challenge outcome using routinely available clinical data. *J Allergy Clin Immunol* 2011;127:633-639.e1-639.e3.
28. Järvinen KM, Amalanayagam S, Shreffler WG, Noone S, Sicherer SH, Sampson HA, et al. Epinephrine treatment is infrequent and biphasic reactions are rare in food-induced reactions during oral food challenges in children. *J Allergy Clin Immunol* 2009;124:1267-72.
29. Lee J, Garrett JP, Brown-Whitehorn T, Spergel JM. Biphasic reactions in children undergoing oral food challenges. *Allergy Asthma Proc* 2013;34:220-6.
30. Clopton J. Alabama Boy's Death Worries Food Allergy Parents. *WebMD Health News*; 2017. Available from: <https://www.webmd.com/allergies/news/20170807/alabama-boys-death-worries-food-allergy-parents>. Accessed May 20, 2018.
31. Pouessel G, Beaudouin E, Tanno LK, Drouet M, Deschildre A, Labreuche J, et al. Allergy Vigilance Network®. Food-related anaphylaxis fatalities: analysis of the Allergy Vigilance Network® database. *Allergy* 2019;74:1193-6.
32. Du Toit G, Roberts G, Sayre PH, Plaut M, Bahnson HT, Mitchell H, et al. Identifying infants at high risk of peanut allergy: the Learning Early About Peanut Allergy (LEAP) screening study. *J Allergy Clin Immunol* 2013;131:135-43.
33. Du Toit G, Roberts G, Sayre PH, Bahnson HT, Radulovic S, Santos AF, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. *N Engl J Med* 2015;372:803-13.
34. Perry TT, Matsui EC, Kay Conover-Walker M, Wood RA. The relationship of allergen-specific IgE levels and oral food challenge outcome. *J Allergy Clin Immunol* 2004;114:144-9.
35. Moneret-Vautrin DA, Kanny G, Frémont S. Laboratory tests for diagnosis of food allergy: advantages, disadvantages and future perspectives. *Eur Ann Allergy Clin Immunol* 2003;35:113-9.
36. Celik-Bilgili S, Mehl A, Verstege A, Staden U, Nocon M, Beyer K, et al. The predictive value of specific immunoglobulin E levels in serum for the outcome of oral food challenges. *Clin Exp Allergy* 2005;35:268-73.
37. Togias A, Cooper SF, Acebal ML, Assa'ad A, Baker JR Jr, Beck LA, et al. Addendum guidelines for the prevention of peanut allergy in the United States: report of the National Institute of Allergy and Infectious Diseases—sponsored expert panel. *World Allergy Organ J* 2017;10:1.
38. Knibb RC, Ibrahim NF, Stiefel G, Petley R, Cummings AJ, King RM, et al. The psychological impact of diagnostic food challenges to confirm the resolution of peanut or tree nut allergy. *Clin Exp Allergy* 2012;42:451-9.
39. MacGinnitie AJ, Young MC. The role of food challenges in clinical practice. *J Allergy Clin Immunol Pract* 2018;6:353-60.