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Original Article

Implementation of a Standardized Clinical Assessment and Management Plan (SCAMP) for Food Challenges

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What is already known about this topic? Oral food challenges remain the gold standard for determining if a patient is truly allergic, but skin prick and specific IgE testing have limited predictive power for which patients are likely to pass.

What does this article add to our knowledge? An iterative process can increase the number of challenges performed without increasing reaction rates or need for epinephrine. Testing along with provider judgment can identify challenges at high risk of requiring epinephrine.

How does this study impact current management guidelines? Consideration can be given to triaging oral food challenges to high- and low-risk categories, with low-risk challenges using fewer increments and less intensive support.

BACKGROUND: Oral food challenges (OFCs) are routinely used to confirm ongoing food allergy. Serum-specific IgE (sIgE) and skin prick testing (SPT) are imperfect predictors of which patients will pass OFCs.

OBJECTIVE: The objective of this study was to describe the design and implementation of a Standardized Clinical Assessment and Management Plan (SCAMP) to study and iteratively improve sIgE and SPT thresholds to determine when and where to conduct OFCs for patients.

METHODS: Allergists consulted recommended sIgE and SPT thresholds when ordering challenges although diversions were permitted. Criteria were iteratively improved after periodic analyses of challenge outcome and diversions.

RESULTS: Over 3 years, allergists ordered 2368 food challenges for 1580 patients with histories of IgE-mediated reactions to food: 1386 in an outpatient clinic and 945 in a higher resource infusion center. Reactions to challenge were observed in 13% of

clinic and 23% of infusion center challenges. Six patients challenged in clinic required treatment with epinephrine compared with 22 in the infusion center. The need for epinephrine was more common in patients with asthma—5% of asthmatic patients required epinephrine compared with 1% of non-asthmatic patients ($P < .01$). Recommended sIgE and SPT thresholds were incrementally changed and, using the control chart methodology, a significant decrease was noted in the proportion of challenges ordered in the higher resource location. **CONCLUSIONS:** By setting and continually refining sIgE and SPT recommendations using the SCAMP method, allergists can better determine the risk of severe reaction and triage patients to the appropriate setting for an OFC. © 2016 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2016;■:■-■)

Key words: Food allergy; Food challenges; Quality improvement; Allergy testing

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The prevalence of pediatric food allergy has steadily increased in recent years^{1,2} and with it the need to accurately identify those patients who stand to benefit from oral food challenges (OFCs). Given a high probability that standard testing may yield false-positive results,³⁻⁵ OFCs remain the gold standard for diagnosing clinically relevant food allergy.

Determining when to order a food challenge for a patient can be difficult. OFCs are resource intensive, and although indicators such as age, past reaction history, and allergy testing results are used to gauge the potential for the development of a reaction during a food challenge and its relative severity, the predictive value of such measures varies.⁶⁻¹⁰ Although studies have shown that food challenges performed in an appropriately medically equipped setting are safe,^{7,10-12} the anxiety generated when a child reacts during an OFC can be stressful to both patient and family. However, a passed challenge may eliminate the fears

*Abbreviations used**BCH*-Boston Children's Hospital*OFC*-Oral food challenge*SCAMP*-Standardized Clinical Assessment and Management Plan*sIgE*-Specific IgE*SPT*-Skin prick test

surrounding a child's food allergy and render restrictive and potentially nutritionally deficient diets unnecessary.

Studies have employed a variety of factors to predict OFC outcome with mixed success. Allergen-specific IgE (sIgE) levels and skin prick test (SPT) wheal sizes are commonly used to approximate the potential value of conducting an OFC. However, although both elevated sIgE levels and larger SPT wheal sizes tend to correlate with failed challenges,^{3,5,8,12-14} such measures are less useful in identifying those patients who are likely to pass a challenge.^{5,15} These individuals typically exhibit sensitization that falls below established sIgE and SPT cutoff points.³⁻⁵ Further, criteria identified as indicating high or low probability of passing an OFC may vary among studies.¹⁵ This variability is likely multifactorial. Skin testing protocols differ among centers and the criteria stated in one study may not apply in another location if the extracts and testing devices vary.¹⁶⁻¹⁸ Likewise, although most studies use the Phadia ImmunoCAP technology, there are alternative techniques for determination of serum-specific IgE and results are not identical.^{19,20} Finally, characteristics of the population studied—including age, percentage of patients with immediate reactions, and percentage of patients with only a history of positive testing—potentially affect the predictive value of standard allergy tests. Some data indicate that functional testing such as the basophil activation test can increase predictive value, but this test is not yet widely available.²¹

These considerations suggest that allergists would benefit from a system whereby sIgE and SPT thresholds could be tailored to their specific patient population. To this end, we have designed and implemented a Standardized Clinical Assessment and Management Plan (SCAMP) for a food challenge. SCAMPs are innovative quality improvement devices that comprise iterative, data-driven care pathways for patient populations with a specific diagnosis. Data are collected on the medical decision making for and the treatment and outcomes of the identified population. These data are analyzed and the results are then used by the involved clinicians to improve upon the care pathway.²²

Over a 2-year period, we implemented a SCAMP in the Allergy Program at Boston Children's Hospital (BCH) to test and iteratively improve recommended sIgE and SPT thresholds used to determine when and where to challenge patients with potential food allergy. We used these thresholds to triage patients effectively into 1 of 2 locations for their challenges: an infusion center equipped for high intensity care and our outpatient allergy clinic. We also documented introduction of foods at home for select patients.

MATERIALS AND METHODS

The SCAMPs program is a quality improvement initiative that assists in developing and implementing SCAMPs in an effort to improve patient outcomes, reduce practice variation, and eliminate unnecessary resource utilization.²² SCAMPs are designed to

complement currently available research methods and to allow for more data-driven decision making by health care providers. They consist of clinical care pathways for diverse patient populations with specific diagnoses or disorders and are continuously revised and refined using findings from iterative analyses of data collected throughout the episode of care. Because these data are strictly used to inform, improve, and streamline the health care delivery process (ie, they are quality improvement activities), SCAMPs are exempt from human subject regulations, as determined by the BCH Institutional Review Board.

The food challenge SCAMP was developed in collaboration with doctors, nurses, and other care providers in the BCH Allergy Program. Initial care pathways and recommendations were established after a literature review and were informed by the experiences of providers in the program. A central tenant of the SCAMP methodology is that initial planning should be limited, with focus placed on iterative improvement. SCAMP care pathways are created with the expectation that allergists will divert from the recommended treatment plan when they feel it is clinically indicated. These diversions are captured along with clinical outcomes and other patient data elements that figure into treatment decisions. Collected data are analyzed every 1 to 2 years after a sufficient number of patients have had OFCs ordered by their providers and undergone challenges. The periodic analyses are used to evaluate whether clinicians are frequently diverting from a certain recommendation and to examine their reasons for choosing a nonrecommended course of action. Analyses are also used to ensure that the quality of care has not been compromised as a result of the SCAMP's implementation.

SCAMPs undergo a redesign after each analysis. Changes may be made to the SCAMP's care pathways, data collection tools, and operational protocols based on the latest analysis findings (Figure 1). In the food challenge SCAMP, the redesign was primarily used to make adjustments to the proposed sIgE and SPT thresholds that help allergists triage patients to the most appropriate setting for food challenges. The format of the data collection tools was also adjusted to better suit the workflow of clinicians participating in the SCAMP. Once all revisions have been finalized, the SCAMP begins a new iteration. Clinicians refer to the updated pathways when making clinical decisions and data collection resumes until it is time for another analysis. This is the process that distinguishes SCAMPs from other strategies meant to monitor and improve clinical practice (eg, clinical practice guidelines). The continuous cycle—analysis, redesign, data collection, analysis—allows SCAMPs to be adapted to diverse clinical settings and patient populations.

Study population

The study population included 1580 patients evaluated by the Allergy Program at BCH between January 2012 and May 2015. Patients were enrolled when a food challenge was ordered based on the review of the patient's clinical history, sIgE, and skin testing. Asthma diagnosis was made clinically by the ordering allergist. Initial SCAMP recommendations regarding where and when to hold a challenge were proposed based on local experience and published literature; however, clinicians had the option to divert when ordering a challenge. Open food challenges were subsequently performed in either the outpatient allergy clinic or the hospital's infusion center. Some patients were also advised to incorporate the food into their diet at home.

Patients were included in the study if they had a history of reactions to food allergens likely to be IgE-mediated—indicated

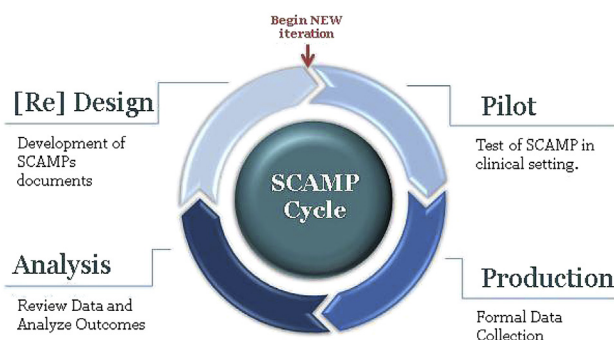


FIGURE 1. The Standardized Clinical Assessment and Management Plan (SCAMP) cycle.

either by the presentation of consistent symptoms (eg., hives, wheezing, vomiting, hypotension) less than 2 hours after ingestion or by positive sIgE and/or positive SPT—or both. Patients were excluded if they had exclusively gastrointestinal symptoms and negative testing (suggesting allergic proctocolitis or food protein-induced enterocolitis syndrome),²³ had exclusively oral symptoms to a fruit or vegetable (suggesting oral allergy syndrome), or had reactions limited to food-dependent exercise-induced anaphylaxis.

Skin prick testing and serum-specific IgE

SPT and sIgE testing were generally obtained within 1 year before ordering the challenge. Skin testing was done using standard techniques in our allergy clinic. Either a multitest device or a single test device (both from Lincoln Diagnostics, Decatur, Ill) was used depending on the number of allergens tested. Histamine and normal saline were used as positive and negative controls, respectively. For some foods, skin testing was not available. sIgE was performed using the Phadia ImmunoCAP system (Thermo Scientific, Cambridge, MA).

Oral food challenges

A total of 1009 open oral food challenges were included in the study. Single food allergens included egg, baked egg, milk, baked milk, peanut, soy, wheat, sesame seed, and sunflower seed. All other food allergens were classified into the following 7 categories: tree nuts, fish, shellfish, fruits and/or vegetables, meats, grains, and other foods.

Patients were advised to discontinue antihistamines 2 weeks before the challenge date, with the exception of diphenhydramine, which could be administered up to 72 hours prior. Challenges were not performed if patients had urticaria, severe atopic dermatitis, wheezing or other signs of respiratory distress, or evidence of acute infection such as vomiting or diarrhea on arrival.

The challenge protocol depended on whether the challenge was held in an outpatient clinic setting or in the infusion center. In the clinic, nurses administered 3 doses of the food in progressively larger quantities for a total of 6–8 g of food protein. In the infusion center, between 3 and 6 doses were administered for up to 11.6 g of food protein. Dosing in both settings was adjusted depending on the age of the patient and the type of food allergen being challenged. There was a 15- to 30-minute interval between doses, and patients were observed for a minimum of 30 minutes in the clinic, and 60 minutes in the infusion center, after the last dose to ensure that the patient did not develop a reaction. Challenges were halted at the first sign of clinical reactivity, and the supervising allergist evaluated the patient to determine the appropriate treatment. Challenges were considered

successful if the patient consumed all or most administered doses without developing a reaction and/or without worsening subjective symptoms.

We attempted to capture data on food challenges performed at home. Unfortunately, data were only obtained on a subset of these home challenges limiting the amount of information available on home introduction.

Classification of reactions

The nurse administering the challenge documented all reactions. Symptoms were grouped according to the organ system into the following 6 categories—cutaneous, upper respiratory, lower respiratory, gastrointestinal, and cardiovascular. Cutaneous reactions consisted of hives, urticaria, angioedema, rash, pruritus, and/or worsening atopic dermatitis. Upper respiratory reactions included rhinorrhea, sneezing, and/or congestion. Lower respiratory symptoms were wheezing, coughing, and stridor. Gastrointestinal symptoms consisted of abdominal pain, vomiting, and/or diarrhea. Cardiovascular symptoms included hypotension and/or lethargy.

To help differentiate the severity of the reactions, we classified the reactions according to the World Allergy Organization Subcutaneous Immunotherapy Systemic Reaction Grading System.²⁴ Symptoms that indicated either cutaneous or upper respiratory system involvement comprised grade 1 reactions. Lower respiratory symptoms, gastrointestinal symptoms, or symptoms that indicated the involvement of more than 1 organ system were classified as grade 2 reactions. Grade 3 reactions comprised symptoms that were indicative of significant lower respiratory system involvement (ie, symptoms that did not dissipate with the administration of an inhaled bronchodilator) and of significant upper respiratory involvement (eg, laryngeal, uvula, or tongue edema with or without stridor). Signs of respiratory failure or symptoms indicative of cardiovascular collapse were considered grade 4 reactions. There were no grade 4 or 5 (fatal) reactions in this study.

Statistical methods

Patient demographic and clinical characteristics are reported as counts and percentages for categorical variables and, as means (along with standard deviation) and median (along with minimum and maximum values) for continuous variables, respectively. The proportion of patients planned to be challenged in the infusion center over time were used to generate a control chart (*p*-chart). Any results from food challenges at home were excluded from all analysis. Food challenge results were categorized into passed, failed, and did not complete. To evaluate the usage of epinephrine, results for failed challenges were further stratified into used epinephrine/did not use epinephrine, respectively. Based on the sample size, a χ^2 or Fisher's exact test was used to evaluate the association between categorical variables. All analyses were performed using SAS 9.4 (SAS Institute, Cary, NC).

RESULTS

Characteristics of challenges ordered and performed

Allergists ordered 2366 food challenges for 1580 patients (Table 1). A total of 1435 (61%) orders were for males and the median age was 7.1 years at the time of the order (range, 0.8–21.1 years). A total of 1388 (59%) challenges were ordered to take place in the outpatient clinic and 945 (40%) of challenges were ordered to occur in the higher resource infusion center. In 33 cases (1%), patients were directed to introduce the food allergen gradually into their home diet. The proportion of

TABLE I. Patient and challenge characteristics for the challenges ordered

Characteristic	Overall	Ordered in infusion center	Ordered in clinic	Ordered at home
Total	2366	945	1388	33
Age at first visit (y)				
N	2366	945	1388	33
Mean (standard deviation)	8.0 (4.4)	8.6 (4.3)	7.7 (4.3)	4.8 (3.7)
Median (min, max)	7.1 (0.8, 21.1)	7.9 (1.0, 21.1)	6.8 (0.9, 20.9)	3.2 (0.8, 13.3)
Gender, n (%)				
Female	931	360 (39)	558 (60)	13 (1)
Male	1435	585 (41)	830 (58)	20 (1)
Allergen challenged, n (%)				
Baked egg	569	54 (21)	195 (76)	6 (2)
Baked milk	421	35 (22)	120 (76)	2 (1)
Egg	270	89 (33)	168 (62)	13 (5)
Fish	255	34 (57)	25 (42)	1 (2)
Fruits/vegetables	157	32 (43)	40 (54)	2 (3)
Grains	129	11 (50)	11 (50)	
Meats	104	23 (61)	15 (39)	
Milk	90	45 (35)	82 (64)	2 (2)
Other	78	14 (42)	19 (58)	
Peanut	74	191 (45)	225 (53)	5 (1)
Sesame seed	60	59 (66)	30 (33)	1 (1)
Shell fish	47	23 (29)	55 (71)	
Soy	38	60 (58)	44 (42)	
Sunflower seed	33	6 (32)	12 (63)	1 (5)
Tree nut	22	237 (42)	332 (58)	
Wheat	19	32 (68)	15 (32)	

challenges ordered in the infusion center decreased modestly but significantly after September 2014 (Figure 2). The majority of orders were for tree nut (24%), peanut (18%), baked egg (11%), egg (11%), and baked milk (7%) challenges. A full list of the allergens for which challenges were ordered is shown in Table I.

It took time for allergists to become accustomed to the SCAMP's implementation in the department, and some allergists misunderstood the recommendations when the project was first launched. For this reason, adherence to the SCAMP-recommended location cannot be reported for the first iteration. Recommendations were more clearly delineated in iterations 2 and 3. Overall, providers followed SCAMP recommendations in 71% of cases, a rate that did not change between the second and third iterations.

By the end of the follow-up period, patients had presented for 579 of the 1388 (42%) challenges ordered in the outpatient clinic and for 415 of the 945 (44%) challenges ordered in the infusion center. Follow-up data were available for 15 of the 33 challenges ordered at home. Among patients who completed their challenge, the median time between the date the challenge was ordered and the date the patient presented for the challenge was 111 days. Figure 3 depicts the flow of patients through the SCAMP from the point at which patients were enrolled to the completion of an OFC.

Challenge outcomes

Challenge failure rates stratified by challenge location are presented in Figure 4. Because follow-up information was unavailable for many of the food introductions at home, these

challenges were excluded from the analysis of challenge outcomes. Overall, 1009 challenges were performed with a failure rate of 17%. Failure rates were significantly higher in the infusion center than the clinic (21% and 13%, respectively, $P < .01$). Reaction data for failed challenges are presented in Table II. Rates of reaction were similar to those seen before implementation of the SCAMP (data not shown). Approximately half (51%) of all reactions involved more than 1 organ system and cutaneous symptoms were the most common (65%). Reactions were significantly more likely to be multisystemic in the infusion center than in the clinic (60% vs 41%, $P = .02$). Specifically, there were significantly more reactions involving cutaneous ($P < .01$), lower respiratory ($P < .01$), and gastrointestinal systems ($P = .03$) in the infusion center than in the clinic. Most reactions were classified as grade 1 (40%) or grade 2 (58%) in terms of severity. Only 3 reactions surpassed grade 2—all were grade 3 and occurred in the infusion center. No significant difference was noted in the severity of reactions in the infusion center and the clinic. Gender, age, and asthma severity were not associated with failed challenge outcome (Table III, Figure 5).

Epinephrine was used to treat reactions in 28 (3%) of the 994 challenges, with higher rates in the infusion center than the clinic setting (5% vs 1%, $P < .01$, Figure 4). This is similar to rates seen in the analysis of baseline food challenges before implementation of the SCAMP (data not shown). Asthma was a significant predictor of reactions requiring epinephrine. Patients with asthma were more likely to have a severe reaction requiring epinephrine compared with those without asthma (5% vs 1%, $P < .01$). Overall, patients with asthma accounted for 37% of

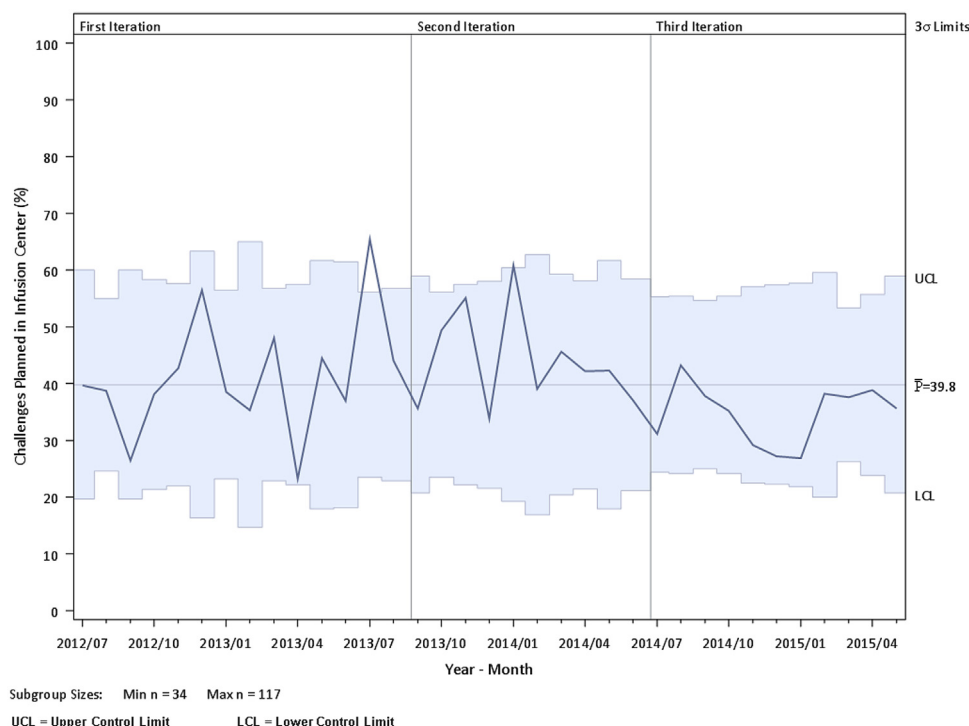


FIGURE 2. Planned use of the infusion center for challenges ordered over time (years/quarter).

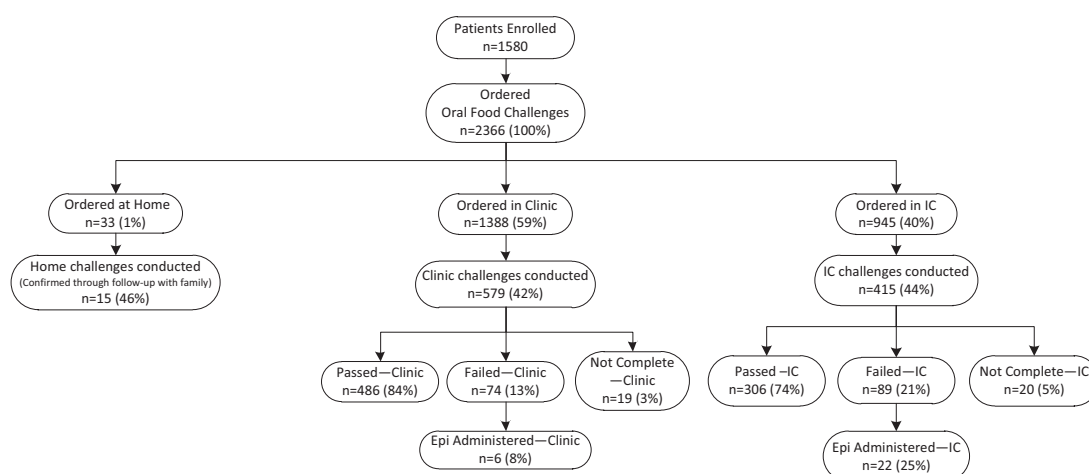


FIGURE 3. Flow of patients through Standardized Clinical Assessment and Management Plan (SCAMP) from enrollment to challenge completion. IC, Infusion center.

total challenges but comprised 73% of challenges requiring epinephrine treatment—including 2 of 3 grade 3 reactions (Table III, Figure 5). Most patients with asthma requiring epinephrine (13 of 19, 68%) were classified as having intermittent asthma and therefore were not on daily controller therapy. Furthermore, wheezing and other lower respiratory symptoms were noted in just 6 of the 19 (32%) patients with asthma who required epinephrine.

For peanut allergy, the SCAMP also offered recommended thresholds for component testing. Of the 212 peanut challenges that were carried out, only 40 (19%) had Ara h2 component

testing performed. The majority (63%) had sIgE levels to Ara h2 that were less than 0.10 kU/L—92% of these patients passed their OFC. Only 15 patients had sIgE levels to Ara h2 that exceeded 0.10 kU/L—12 passed and 3 failed their OFC.

Iterative changes in challenge criteria

The sIgE and SPT criteria—used to guide clinicians who were determining the appropriately resourced setting for an OFC—were modified after each SCAMP analysis and implemented at the start of the next iteration. Table IV and Table E1 (available in this article's Online Repository at www.jaci-inpractice.org)

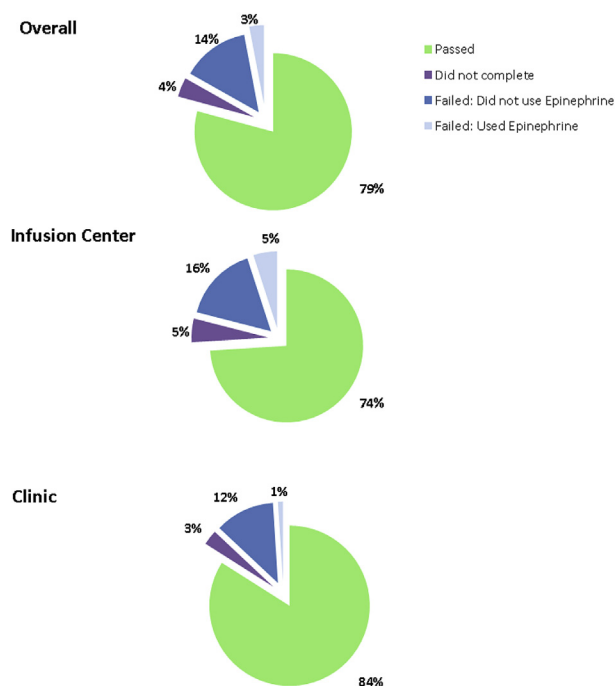


FIGURE 4. Food challenge results by the location of a challenge.

TABLE II. Reactions in the clinic and infusion center

	Total, n (%) [*]	Clinic, n (%)	Infusion center, n (%)	P value
Total patients with reaction	163	74	89	<.01
Reactions with >1 organ system involvement, n (%)	83 (51)	30 (41)	53 (60)	.02
Organ system involvement, n (%)				
Cutaneous	106 (65)	39 (53)	67 (75)	<.01
Upper respiratory	29 (18)	9 (12)	20 (22)	.09
Lower respiratory	19 (12)	2 (3)	17 (19)	<.01
Gastrointestinal	60 (37)	34 (46)	26 (29)	.03
Cardiovascular	0 (0)			
Other	67 (41)	29 (39)	38 (43)	.65
Reaction severity, n (%)				.29
Grade 1	65 (40)	32 (43)	33 (37)	
Grade 2	95 (58)	42 (57)	53 (60)	
Grade 3	3 (2)		3 (3)	
Grade 4	0 (0)	0 (0)	0 (0)	
Grade 5	0 (0)	0 (0)	0 (0)	

*Note. Food challenges at home were excluded.

depict the specific testing criteria used for food allergens in each iteration. As shown in Table E2 (available in this article's Online Repository at www.jaci-inpractice.org), the majority of OFCs were held in the clinic in all iterations (iteration 1: 58%, iteration 2: 53%, iteration 3: 59%), and failed challenges occurred most frequently in the infusion center (iteration 1: 55% of all failed challenges, iteration 2: 56%, iteration 3: 51%). Epinephrine use

TABLE III. Assessment of risk factors for failed challenges and failed challenges with epinephrine

Risk factors	Total number of challenges n	Failed challenges		Failed challenges treated with epinephrine	
		n (%)	P value	n (%)	P value
Overall	994	163 (16)		28 (3)	
Age			.87		.44
≤ 3 y	77	14 (18)		3 (4)	
4-11 y	736	119 (16)		18 (2)	
≥ 12 y	181	30 (17)		7 (4)	
Gender			.34		.24
Male	595	92 (15)		20 (3)	
Female	399	71 (18)		8 (2)	
Asthma [*]			.21		<.01
Yes	366	67 (18)		19 (5)	
No	592	90 (15)		7 (1)	

Note. Food challenges at home were excluded.

^{*}Did not include patients with missing/unknown asthma status.

also remained highest in the infusion center in all iterations—13% of failed infusion center challenges required epinephrine in iteration 1, 18% in iteration 2, and 11% in iteration 3.

Diversions from SCAMP recommendations

Diversions in the first iteration cannot be reported because allergists learned how to report accurately whether they had followed SCAMP recommendations in an adjustment period after the project's initiation. However, in the second and third iteration of the SCAMP, 116 (29%) challenges were ordered in a location other than the one advised by the SCAMP's testing criteria. Outcomes for challenges that followed SCAMP recommendations and challenges that did not follow SCAMP recommendations are compared in Figure 6. Of the patients who had sIgE and SPT values that fell within the recommended thresholds for a clinic challenge, 14% failed their challenge in the clinic and 13% failed their challenge in the infusion center; this difference was not statistically significant. Of the patients who had sIgE and SPT values that fell within recommended thresholds for an infusion center challenge, 23% failed their challenge in the infusion center and 26% failed their challenge in the clinic; this difference also was not statistically significant. Of the patients with sIgE and SPT values that exceeded recommended cutoffs for an OFC in the infusion center, 38% failed their challenge. Similarly, 8 patients had sIgE and SPT values that fell below the recommended cutoff for a challenge in the clinic (and therefore would have been recommended for a home challenge) yet still experienced symptoms during their OFC. The most common reasons cited for not adhering to the SCAMP's proposed challenge location were provider preference, parent preference, and history and/or severity of the previous reaction. Other reasons for diversion can be found in Table E3 (available in this article's Online Repository at www.jaci-inpractice.org).

DISCUSSION

OFCs remain the gold standard to diagnose or rule out food allergy.²⁵ Allergists rely heavily on results of SPT and sIgE when deciding which patients should undergo OFC. Although negative testing has high specificity and thresholds have been established in specific populations to help identify patients who are

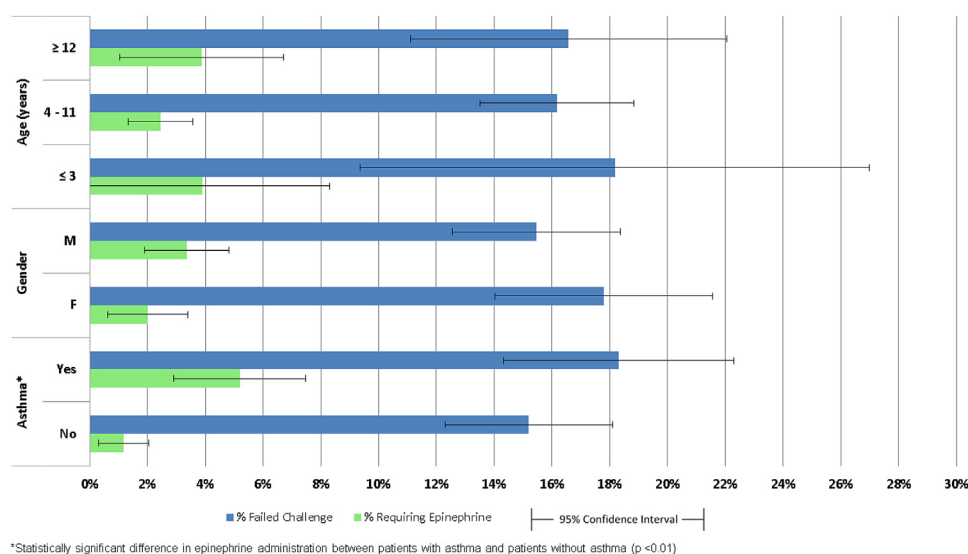


FIGURE 5. Assessment of risk factors for failed challenges and failed challenges with epinephrine.

unlikely to tolerate an allergen, a large proportion of patients have intermediate values resulting in substantial uncertainty about whether these patients are truly allergic.^{3-5,8-10,12-15}

We report here on the development of a SCAMP to establish, test, and modify the sIgE and SPT thresholds that allergists refer to when determining the appropriate timing and location of OFCs. The SCAMP encourages allergists to reference other factors such as reaction history and asthma status when ordering OFCs and to divert from SCAMP recommendations when clinically indicated. This method was used to triage patients safely to either a low- or high-intensity care setting (clinic and infusion center, respectively) for their food challenges. The challenges in the low-intensity setting utilized fewer doses of food allergen, and thus were likely less costly.

Of the 1009 OFCs conducted in our study, 17% resulted in a failed challenge, a failure rate similar to that seen in some recent studies,^{9,26,27} but lower than in others.^{5,28} Cutaneous symptoms were most common—seen in 65% of all reactions. Nearly all failed challenges (98%) were grade 1 or 2 in terms of reaction severity. Only 3 challenges were grade 3 and all took place in the higher resource infusion center setting.

Our study employed a relatively novel 2-tiered system whereby challenges deemed high risk took place in the hospital's infusion center—a setting better equipped for high-intensity care in the event of a severe reaction. Conversely, challenges that were considered lower risk took place in the outpatient allergy clinic. We found that higher risk challenges were effectively triaged to the higher risk setting, evidenced by the fact that failure rate was significantly higher in the infusion center than in the clinic (21% vs 13%). Likewise, rate of epinephrine administration during challenges was significantly higher in the infusion center setting than in the outpatient clinic (5% vs 1%). This was expected, as patients challenged in the infusion center were more likely to have higher test results, a cautionary medical history, or both.

The SCAMP was analyzed 3 times in the course of this study and, after each analysis, the results were used to justify slight modifications to the care pathways and recommendations. The testing criteria that determined when it was appropriate to order

an OFC and recommended an adequately equipped challenge setting were liberalized so that patients with higher sIgE and SPT results could qualify for challenges to specific allergens or have their challenge moved to a lower risk, lower cost setting. One might expect that raising these thresholds would prompt an increase in the rate of failed challenges or epinephrine use. However, we saw only a slight fluctuation in failure rate and epinephrine usage between the SCAMP's 3 iterations demonstrating that even patients with elevated sIgE and SPT results may safely rule out food allergies with an OFC. Analysis of data before implementation of the SCAMP process and guidelines showed similar rates of failure and need for epinephrine (data not shown). It is notable that neither implementation of the SCAMP nor successive iterations of challenge criteria led to significant changes in rates of reaction or need for epinephrine. Although this might be seen as a failure of the SCAMP methodology, it can also be seen as a success in that more patients were challenged and many challenges were moved to a lower intensity setting without an increase in adverse events. Of note, patients challenged in clinic required significantly less time (3 food increments in clinic vs 3-6 in the infusion center) and nursing resources (1 nurse typically did 3 simultaneous challenges in clinic vs 1 or 2 in the infusion center). We will continue to modify SCAMP criteria over time and to monitor results; for example, we now include history of asthma in determining where challenges are conducted.

Permitting clinicians to divert from established recommendations is key to the SCAMP method and enhanced our ability to triage failed challenges and severe reactions to the infusion center. Although incremental improvements have been made over the course of the SCAMP to the sIgE and SPT thresholds that are used to recommend challenges, the predictive capability of these values is still relatively poor. Our data therefore support the findings of other studies and demonstrate that in a population with low to intermediate positive sIgE and SPT testing, these results are not clear indicators of whether a patient will pass or fail a challenge. Instead, they are most useful when interpreted in the context of a patient's clinical history.

TABLE IV. Iteration 3 criteria for recommended challenge location

Best clinical judgment (consider for home)		Home	Clinic	Infusion center	Best clinical judgment (consider for CAT/CR)	Not recommended
Egg		sIgE $\leq$ 0.35 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.35 and $\leq$ 2 kU/L SPT $>$ 5 and $\leq$ 7 mm	sIgE $>$ 2 and $\leq$ 6 kU/L SPT $>$ 7 and $\leq$ 8 mm	sIgE $>$ 6 and $\leq$ 10 kU/L SPT $>$ 8 and $\leq$ 10 mm	sIgE $>$ 10 kU/L SPT $>$ 10 mm
Baked egg		EW sIgE $\leq$ 1 kU/L OVM sIgE $\leq$ 1 kU/L SPT $\leq$ 10 mm	EW sIgE $>$ 1 and $\leq$ 10 kU/L OVM sIgE $>$ 1 and $\leq$ 10 kU/L SPT $>$ 10 and $\leq$ 25 mm	EW sIgE $>$ 10 and $\leq$ 20 kU/L OVM sIgE $>$ 10 and $\leq$ 15 kU/L SPT $>$ 25 and $\leq$ 35 mm	EW sIgE $>$ 20 and $\leq$ 40 kU/L OVM sIgE $>$ 15 and $\leq$ 35 kU/L SPT $>$ 35 mm	EW sIgE $>$ 40 kU/L OVM sIgE $>$ 35 kU/L
Milk		sIgE $\leq$ 0.5 kU/L SPT neg (0)	sIgE $>$ 0.5 and $\leq$ 2 kU/L SPT $>$ 0 and $\leq$ 8 mm	sIgE $>$ 2 and $\leq$ 5 kU/L SPT $>$ 8 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 12 mm	sIgE $\geq$ 15 kU/L SPT $>$ 12 mm
Baked milk		sIgE $\leq$ 1 kU/L SPT $\leq$ 10 mm	sIgE $>$ 1 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 kU/L and $\leq$ 20 kU/L SPT $>$ 15 mm and $\leq$ 20 mm	sIgE $>$ 20 and $\leq$ 40 kU/L SPT $>$ 20 and $\leq$ 35 mm	sIgE $>$ 40 kU/L SPT $>$ 35 mm
Peanut	sIgE $\leq$ 0.35 kU/L SPT neg (0) Ara h2 $\leq$ 0.35 kU/L		sIgE $>$ 0.35 and $\leq$ 0.7 kU/L SPT $>$ 0 and $\leq$ 5 mm Ara h2 $\leq$ 0.35 kU/L	sIgE $>$ 0.7 and $\leq$ 1 kU/L SPT $>$ 5 and $\leq$ 8 mm Ara h2 $>$ 0.35 and $\leq$ 1 kU/L	sIgE $>$ 1 and $\leq$ 15 kU/L SPT $\geq$ 8 and $\leq$ 10 mm Ara h2 $>$ 1 and $\leq$ 2 kU/L	sIgE $\geq$ 15 kU/L SPT $\geq$ 10 mm Ara h2 $\geq$ 2 kU/L
Tree nut	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 0.5 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 0.5 and $\leq$ 3 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 3 and $\leq$ 18 kU/L SPT $>$ 6 and $\leq$ 8 mm	sIgE $\geq$ 18 kU/L SPT $\geq$ 8 mm
Fish	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 0.9 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 0.9 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $\leq$ 10 kU/L SPT $>$ 5 and $\leq$ 20 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 20 mm
Shell fish	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 1 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 1 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $\leq$ 20 kU/L SPT $>$ 5 and $\leq$ 40 mm	sIgE $\geq$ 20 kU/L SPT $\geq$ 40 mm
Soy	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 2 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 5 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 65 kU/L SPT $>$ 10 and $\leq$ 20 mm	sIgE $\geq$ 65 kU/L SPT $\geq$ 20 mm
Wheat	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 2 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 10 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 10 and $\leq$ 80 kU/L SPT $>$ 10 and $\leq$ 20 mm	sIgE $\geq$ 80 kU/L SPT $\geq$ 20 mm
Sesame seed	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 1 kU/L SPT $>$ 0 and $\leq$ 3 mm	sIgE $>$ 1 and $\leq$ 7 kU/L SPT $>$ 3 and $\leq$ 6 mm	sIgE $>$ 7 and $\leq$ 10 kU/L SPT $>$ 6 and $\leq$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Sunflower seed	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 5 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 5 and $\leq$ 7 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 7 and $\leq$ 10 kU/L SPT $>$ 6 and $\leq$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Fruits/vegetables	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 5 kU/L SPT $>$ 0 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $\leq$ 30 kU/L SPT $>$ 15 and $\leq$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Meats	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 5 kU/L SPT $>$ 0 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $\leq$ 30 kU/L SPT $>$ 15 and $\leq$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Grains	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 5 kU/L SPT $>$ 0 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $\leq$ 30 kU/L SPT $>$ 15 and $\leq$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Other foods	sIgE $\leq$ 0.35 kU/L SPT neg (0) mm		sIgE $>$ 0.35 and $\leq$ 1 kU/L SPT $>$ 0 and $\leq$ 3 mm	sIgE $>$ 1 and $\leq$ 5 kU/L SPT $>$ 3 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 kU/L SPT $>$ 15 mm

EW, Egg white; OVM, ovomucoid; sIgE, specific IgE; SPT, skin prick test.

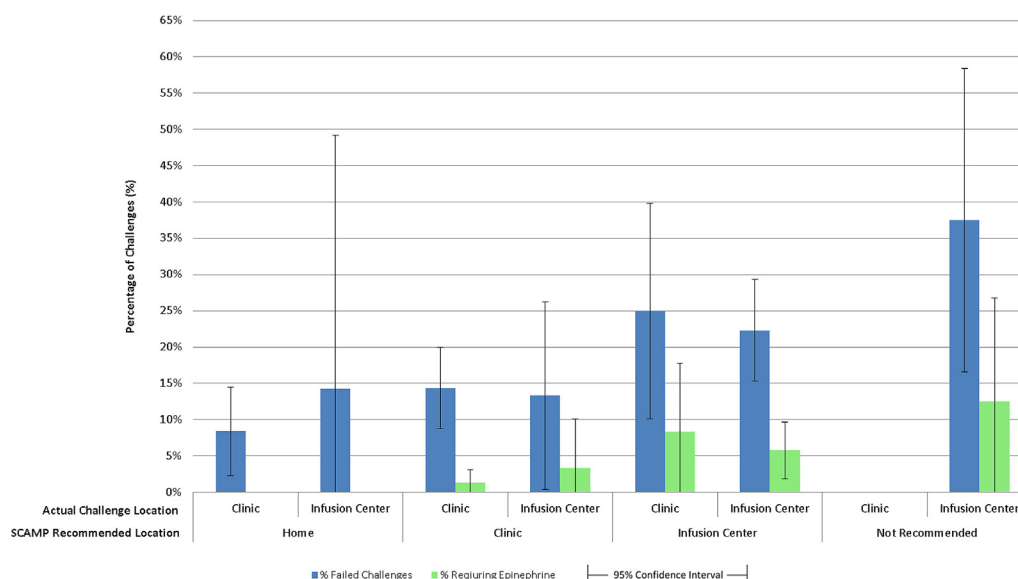


FIGURE 6. Rate of failed challenges by the Standardized Clinical Assessment and Management Plan (SCAMP)-recommended location and actual challenge location.

Other studies have had similar success in incorporating factors from the patient's medical history into the prediction of OFC outcomes. For instance, DunnGalvin et al⁹ retrospectively applied a prognostic model that used patient sex, age, and history of reaction, in addition to sIgE, total IgE minus sIgE, and SPT, to predict food challenge outcome. They found that their model was able to predict OFC results with 92% accuracy as compared with 81% when sIgE levels and SPT wheal size were used alone. Cianferoni et al²⁸ took their study a step further, using multilogistic regression in a retrospective chart review to identify factors that were independently associated with anaphylaxis during OFCs. They discovered that the age and history of the previous noncutaneous reaction, in addition to the patient's SPT wheal size, were predictive of multisystem reactions during food challenges.

In our study, asthma was a significant predictor of reactions requiring epinephrine administration. Reactions in patients with asthma necessitated the use of epinephrine in 5% of challenges compared with 1% of challenges in patients without asthma. However, no relationship was found between the severity of the patient's asthma (intermittent vs persistent asthma) and the need for epinephrine during an OFC. This observation could indicate that ongoing inflammation in the lungs predisposes individuals with asthma to respiratory reactions; alternatively, the presence of asthma might simply be a marker of more significant systemic allergic diathesis. Interestingly, the majority of our patients with anaphylaxis in the setting of preexisting asthma did not experience wheezing or other respiratory symptoms as part of their reaction.

There are several limitations to this study. First, we only gathered data on patients for whom a food challenge was ordered. No information was gathered for patients who were recommended or elected to continue avoidance of a food. We are therefore unable to compare these patients with the subjects in our present study. A second limitation is the lack of data for patients who were instructed (and agreed) to introduce a

suspected food allergen at home. The SCAMP provides recommendations for such home introduction for patients with sufficiently low sIgE levels and SPT wheal sizes. Our current methods to capture data on the outcome of these "home challenges" are insufficient, and we have been able to document only 33 home challenges since the launch of the SCAMP. Consequently, our profile of patients on the SCAMP with the lowest sIgE and SPT results is incomplete.

Determining if and when a patient should undergo an OFC remains an imprecise process. This study introduces an iterative system that can provide decision support to allergists based on sIgE and SPT results while also leaving room for the allergist to incorporate patient-specific knowledge into their assessment. Over time, the SCAMP protocol has allowed our institution to liberalize criteria for open challenges and increase the number of children who complete food challenges successfully. Employing the SCAMP protocol could provide a unique opportunity for allergists to customize challenge criteria for their specific patient populations.

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TABLE E1. Iteration 1 and 2 criteria for recommended challenge location

	Home	Clinic	Infusion center	Best clinical judgment (consider for infusion center)	Not recommended
Iteration 1 criteria					
Egg	sIgE $\leq$ 0.35 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.35 and $\leq$ 0.6 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.6 and $\leq$ 2 kU/L SPT $>$ 5 and $<$ 6 mm	sIgE $>$ 2 and $<$ 6 kU/L SPT $\geq$ 6 and $<$ 7 mm	sIgE $\geq$ 6 kU/L SPT $\geq$ 7 mm
Baked egg	OVM sIgE $\leq$ 1 kU/L SPT $\leq$ 7 mm	OVM sIgE $>$ 1 and $\leq$ 4 kU/L SPT $>$ 7 and $\leq$ 35 mm			OVM sIgE $>$ 4 kU/L SPT $>$ 35 mm
Milk	sIgE $\leq$ 0.35 kU/L SPT neg (0 mm)	sIgE $>$ 0.35 and $\leq$ 0.8 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 0.8 and $\leq$ 2 kU/L SPT $>$ 5 and $\leq$ 7 mm	sIgE $>$ 2 and $<$ 15 kU/L SPT $>$ 7 and $<$ 9 mm	sIgE $\geq$ 15 kU/L SPT $\geq$ 9 mm
Baked milk	sIgE $\leq$ 1 kU/L SPT $\leq$ 7 mm	sIgE $>$ 1 and $\leq$ 15 kU/L SPT $>$ 7 and $\leq$ 13 mm			sIgE $>$ 15 kU/L SPT $>$ 13 mm
Peanut		sIgE $\leq$ 0.35 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.35 and $\leq$ 0.7 kU/L SPT $>$ 5 and $\leq$ 7 mm	sIgE $>$ 0.7 and $<$ 15 kU/L SPT $>$ 7 and $<$ 9 mm	sIgE $\geq$ 15 kU/L SPT $\geq$ 9 mm
Tree nut		sIgE $\leq$ 0.5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.5 and $\leq$ 3 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 3 and $<$ 18 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 18 kU/L SPT $\geq$ 8 mm
Fish		sIgE $\leq$ 0.9 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.9 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $<$ 10 kU/L SPT $>$ 5 and $<$ 20 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 20 mm
Shell fish		sIgE $\leq$ 1 kU/L SPT $\leq$ 5 mm	sIgE $>$ 1 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $<$ 20 kU/L SPT $>$ 5 and $<$ 40 mm	sIgE $\geq$ 20 kU/L SPT $\geq$ 40 mm
Soy		sIgE $\leq$ 2 kU/L SPT $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 5 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 5 and $<$ 65 kU/L SPT $>$ 10 and $<$ 20 mm	sIgE $\geq$ 65 kU/L SPT $\geq$ 20 mm
Wheat		sIgE $\leq$ 2 kU/L SPT $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 10 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 10 and $<$ 80 kU/L SPT $>$ 10 and $<$ 20 mm	sIgE $\geq$ 80 kU/L SPT $\geq$ 20 mm
Sesame Seed		sIgE $\leq$ 1 kU/L SPT $\leq$ 3 mm	sIgE $>$ 1 and $\leq$ 7 kU/L SPT $>$ 3 and $\leq$ 6 mm	sIgE $>$ 7 and $<$ 10 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Sunflower seed		sIgE $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $\leq$ 7 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 7 and $<$ 10 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Fruits/vegetables		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm			sIgE $>$ 5 kU/L SPT $>$ 10 mm
Meats		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm			sIgE $>$ 5 kU/L SPT $>$ 10 mm
Grains		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm			sIgE $>$ 5 kU/L SPT $>$ 10 mm
Other foods		sIgE $\leq$ 1 kU/L SPT $\leq$ 3 mm			sIgE $>$ 1 kU/L SPT $>$ 3 mm
Iteration 2 criteria					
Egg	sIgE $\leq$ 0.35 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.35 and $\leq$ 0.6 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.6 and $\leq$ 2 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 2 and $<$ 6 kU/L SPT $>$ 6 and $<$ 7 mm	sIgE $\geq$ 6 kU/L SPT $\geq$ 7 mm

(continued)

TABLE E1. (Continued)

	Home	Clinic	Infusion center	Best clinical judgment (consider for infusion center)	Not recommended
Baked egg	EW sIgE $\leq$ 0.6 kU/L OVM sIgE $\leq$ 0.35 kU/L SPT $\leq$ 4 mm	EW sIgE $>$ 0.6 and $\leq$ 6 kU/L OVM sIgE $>$ 0.35 and $\leq$ 0.7 kU/L SPT $>$ 4 and $\leq$ 11 mm		EW sIgE $>$ 6 and $<$ 9.7 kU/L OVM sIgE $>$ 0.7 and $<$ 3.4 kU/L SPT $>$ 11 and $<$ 25 mm	EW sIgE $\geq$ 9.7 kU/L OVM sIgE $\geq$ 3.4 kU/L SPT $\geq$ 25 mm
Milk	sIgE $\leq$ 0.35 kU/L SPT neg (0 mm)	sIgE $>$ 0.35 and $\leq$ 0.8 kU/L SPT $>$ 0 and $\leq$ 5 mm	sIgE $>$ 0.8 and $\leq$ 2 kU/L SPT $>$ 5 and $\leq$ 7 mm	sIgE $>$ 2 and $<$ 15 kU/L SPT $>$ 7 and $<$ 9 mm	sIgE $\geq$ 15 kU/L SPT $\geq$ 9 mm
Baked milk	sIgE $\leq$ 1 kU/L SPT $\leq$ 7 mm	sIgE $>$ 1 and $\leq$ 15 kU/L SPT $>$ 7 and $\leq$ 13 mm		sIgE $>$ 15 kU/L SPT $>$ 13 mm	
Peanut		sIgE $\leq$ 0.35 kU/L SPT $\leq$ 5 mm Ara h2 $\leq$ 0.35 kU/L	sIgE $>$ 0.35 and $\leq$ 0.7 kU/L SPT $\leq$ 5 mm Ara h2 $\leq$ 0.35 kU/L	sIgE $>$ 0.7 and $<$ 15 kU/L SPT $>$ 5 and $<$ 15 mm Ara h2 $>$ 0.35 and $<$ 1 kU/L	sIgE $\geq$ 15 kU/L SPT $\geq$ 15 mm Ara h2 $\geq$ 1 kU/L
Tree nut		sIgE $\leq$ 0.5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.5 and $\leq$ 3 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 3 and $<$ 18 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 18 kU/L SPT $\geq$ 8 mm
Fish		sIgE $\leq$ 0.9 kU/L SPT $\leq$ 5 mm	sIgE $>$ 0.9 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $<$ 10 kU/L SPT $>$ 5 and $<$ 20 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 20 mm
Shell fish		sIgE $\leq$ 1 kU/L SPT $\leq$ 5 mm	sIgE $>$ 1 and $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $<$ 20 kU/L SPT $>$ 5 and $<$ 40 mm	sIgE $\geq$ 20 kU/L SPT $\geq$ 40 mm
Soy		sIgE $\leq$ 2 kU/L SPT $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 5 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 5 and $<$ 65 kU/L SPT $>$ 10 and $<$ 20 mm	sIgE $\geq$ 65 kU/L SPT $\geq$ 20 mm
Wheat		sIgE $\leq$ 2 kU/L SPT $\leq$ 5 mm	sIgE $>$ 2 and $\leq$ 10 kU/L SPT $>$ 5 and $\leq$ 10 mm	sIgE $>$ 10 and $<$ 80 kU/L SPT $>$ 10 and $<$ 20 mm	sIgE $\geq$ 80 kU/L SPT $\geq$ 20 mm
Sesame seed		sIgE $\leq$ 1 kU/L SPT $\leq$ 3 mm	sIgE $>$ 1 and $\leq$ 7 kU/L SPT $>$ 3 and $\leq$ 6 mm	sIgE $>$ 7 and $<$ 10 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Sunflower seed		sIgE $\leq$ 5 kU/L SPT $\leq$ 5 mm	sIgE $>$ 5 and $\leq$ 7 kU/L SPT $>$ 5 and $\leq$ 6 mm	sIgE $>$ 7 and $<$ 10 kU/L SPT $>$ 6 and $<$ 8 mm	sIgE $\geq$ 10 kU/L SPT $\geq$ 8 mm
Fruits/vegetables		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $<$ 30 kU/L SPT $>$ 15 and $<$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Meats		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $<$ 30 kU/L SPT $>$ 15 and $<$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Grains		sIgE $\leq$ 5 kU/L SPT $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 and $<$ 30 kU/L SPT $>$ 15 and $<$ 25 mm	sIgE $\geq$ 30 kU/L SPT $\geq$ 25 mm
Other foods		sIgE $\leq$ 1 kU/L SPT $\leq$ 3 mm	sIgE $>$ 1 and $\leq$ 5 kU/L SPT $>$ 3 and $\leq$ 10 mm	sIgE $>$ 5 and $\leq$ 15 kU/L SPT $>$ 10 and $\leq$ 15 mm	sIgE $>$ 15 kU/L SPT $>$ 15 mm

EW, Egg white; OVM, ovomucoid; sIgE, specific IgE; SPT, skin prick test.

TABLE E2. New criteria (number of challenges in each location, reaction rate)

	Iteration 1	Iteration 2	Iteration 3
Number of challenges, n (%)			
Total number of challenges	527	242	240
Home challenges	5 (1)		10 (4)
Clinic challenges	308 (58)	129 (53)	142 (59)
Infusion center challenges	214 (41)	113 (47)	88 (37)
Total number of failed challenges	80	39	45
Number of failed challenges, n (%)			
Failed challenges at home			1 (2)
Failed challenges in clinic	36 (45)	17 (44)	21 (47)
Failed challenges in infusion center	44 (55)	22 (56)	23 (51)
Overall epinephrine needed*	11 (14)	9 (23)	8 (18)
Epinephrine needed in each challenge location (n/total number of failed challenges per location, %)			
Epinephrine at home			
Epinephrine in clinic	1 (1)	2 (5)	3 (7)
Epinephrine in infusion center	10 (13)	7 (18)	5 (11)

*Iteration 1 epinephrine usage was collected retrospectively. Usages of epinephrine for all patients challenged in iterations 2 and 3 were collected at the time of the challenge.

TABLE E3. Reasons for diverting from the SCAMP-recommended challenge location

Reasons for diversion from SCAMP recommendations*	n (%)
Provider preference	34 (18)
Parent preference	31 (16)
History/severity of reaction	29 (15)
SPT low/negative	14 (7)
Low sIgE	13 (7)
Previously tolerated food	9 (5)
Never eaten	9 (5)
No history of reaction	7 (4)
sIgE close to cutoff	6 (3)
Low risk	6 (3)
High total IgE	5 (3)
Age	4 (2)
Multiple food allergies	4 (2)
Testing inconclusive/unavailable	3 (2)
Tolerates allergen in baked food	2 (1)
Comorbidities affect care	2 (1)
Questionable exposure	1
SPT high	1
Reason not recorded	11 (6)

SCAMP, Standardized Clinical Assessment and Management Plan; sIgE, specific IgE; SPT, skin prick test.

*Reasons for diversion reported for iterations 2 and 3 only.