

The Role of Food Challenges in Clinical Practice



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1. To identify indications for performing oral food challenges.
2. To safely perform food challenges in their allergy practice.
3. To identify patient factors that may influence the safety of food challenges in adult patients.

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Food challenges are the criterion standard for establishing the presence or absence of food allergy. However, they remain underused because of their resource-intensive nature, inadequate reimbursement, and concern for the risk of anaphylaxis. Here, we review indications for performing food challenges, including scenarios of uncertain diagnosis, quality-of-life effects following food challenges, and the impact on office practice including coding and reimbursement issues. Demand for food challenges is likely to increase and allergists should be capable of providing

this service to their patients when indicated. © 2017 American Academy of Allergy, Asthma & Immunology (*J Allergy Clin Immunol Pract* 2018;6:353-60)

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INTRODUCTION

The ongoing food allergy epidemic and recent research on early infant diets resulting in new infant dietary guidelines¹ have placed the allergist at the forefront for guidance on diagnosis, prevention, and treatment. The oral food challenge is uniquely performed by the allergist, and with these prominent issues, there is increased attention on this procedure. This review will examine the utility and applications of the oral food challenge in clinical practice, including impacts on quality of life and the allergist's office practice. Key points are summarized in Table I.

Skin prick tests and serum specific IgE levels are imperfect predictors of true food allergy. Food challenges are therefore considered the criterion standard to establish or refute the presence of food allergies.² However, they are also time and resource intensive and carry the risk of anaphylaxis. Therefore, selecting those patients who are most likely to benefit from challenge is of great importance. Identification of appropriate patients is based not only on results of testing and risk-benefit

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*Abbreviations used**EoE- Eosinophilic esophagitis**FPIES- Food protein–induced enterocolitis syndrome**HRQOL- Health-related quality of life*

analysis but also on consideration of patient and family preferences. For example, an 18-year-old individual with a single food allergy may benefit from challenge even with a low predicted chance of passing, whereas an infant with multiple nut sensitizations might forgo challenge to a single nut with a high predicted passing rate, because the family would continue avoidance of all nuts regardless of challenge outcome.

INDICATIONS FOR FOOD CHALLENGES IN CLINICAL PRACTICE

Indications for food challenge can be broadly divided into establishing the diagnosis of food allergy in equivocal cases and documenting resolution of food allergy.

Establishing the diagnosis of food allergy

With a clear reaction history supported by strongly positive testing, the diagnosis of food allergy is established without the need for food challenge. In the following common scenarios below, where the history and/or test results are equivocal, a food challenge is necessary for definitive diagnosis.

Sensitization in the absence of a clear history of clinical reaction.

It is not unusual for allergists to encounter patients referred by another provider, with positive food allergy test results in whom testing may not have been indicated, who had either never eaten the food, or who had been consuming it regularly.^{2,3} Examples would include testing performed before food introduction (eg, infants at high risk for peanut allergy), screening patients with atopic dermatitis or eosinophilic esophagitis (EoE), and testing patients with symptoms not typical of food allergy, such as chronic abdominal pain or chronic urticaria.

In general, patients who are consuming a food regularly in their diet without reactions should be encouraged to continue consumption. Exceptions are patients with severe atopic dermatitis exacerbated by specific foods, or EoE, in which case a trial of elimination may be appropriate.^{4,5} There are multiple reports indicating that in children with eczema managed with elimination diets, subsequent reexposures to the eliminated food trigger immediate-type reactions including anaphylaxis.^{6,7} There are also similar case reports of milk anaphylaxis developing after milk elimination diets prescribed for the management of EoE.^{8,9} Therefore, such patients should be challenged under observation if they have persistently positive testing.

In patients with skin wheal diameters and serum specific IgE values indicating high likelihood of reaction but no history of exposure, it is typically not necessary to challenge; rather patients are instructed to avoid that food. However, if testing is not definitive, food challenge should be offered to establish or refute the diagnosis. This determination is complicated by the fact that no studies address the predictive values of testing in this population.

Clinical history of reactions without sensitization. Conversely, allergists also see patients with history of allergic reactions to food with negative allergy testing to the food. In these cases, it is important to first establish that the observed symptoms

are consistent with an IgE-mediated mechanism. If they are, it should be recognized that testing is not 100% sensitive or specific.¹⁰ We would recommend performing both skin prick and serum specific IgE testing in these cases to minimize the risk of false-negative testing. It may also be helpful to perform prick-to-prick testing with the actual food that caused the reaction if testing with standardized extracts is negative. Examples of positive testing to the actual food but negative test result to the commercially prepared extract include pollen fruit syndrome¹¹ and parasite-contaminated fish.¹² However, even with negative blood and skin testing results, some patients can have reactions consistent with IgE-mediated allergy (eg, hives within minutes of consumption of the food) and in these cases, food challenge is indicated.

Introduction of highly allergenic foods in sensitized infants.

The landmark Learning Early about Peanut Allergy (LEAP) trial established that early introduction of peanut in high-risk infants dramatically decreased the ultimate rate of peanut allergy.^{13,14} Studies of early egg introduction have shown conflicting results,¹⁵⁻¹⁸ but the paradigm that early introduction of allergenic foods protects against allergy seems valid. Consensus guidelines on peanut introduction recommend testing for infants with moderate to severe eczema and/or a history of egg allergy, and conducting food challenges to peanut for those with skin prick test wheals of 3 to 7 mm.¹ In addition, in our experience, many parents of infants with a strong family history of peanut allergy are hesitant to introduce this food without previous testing. LEAP and consensus guidelines suggest modified challenges for those with low positive testing and, as discussed below, there may be a role for supervised feeding in these situations. Bird et al¹⁹ have recently provided guidelines for conducting peanut challenges in infants.

Other indications. Food challenges are often required before and after research interventions for food allergy such as immunotherapy to establish efficacy of the therapy. These are typically high-risk challenges because all patients are expected to have reactions and many participants are highly allergic. Currently these high-risk challenges are not performed in routine clinical practice. As new treatments for food allergy receive Food and Drug Administration approval, the use of challenges in clinical practice will likely increase. This may be particularly true for therapies such as epicutaneous immunotherapy, which do not involve regular ingestion of the allergenic food.

Finally, evidence from food immunotherapy trials and other sources indicates that many patients with food allergies do not have a reaction until they are exposed to substantial amounts of allergen.^{20,21} Thus, it has been proposed that some patients might benefit from low-dose challenges to decrease anxiety and allow ingestion of, for example, foods with precautionary labeling. However, what constitutes a low-dose challenge is not defined. There is also evidence that the typical 15- to 30-minute interval between doses during challenges may be too short and overestimate the tolerated dose.²² In addition, reaction thresholds and severity can be variable in the same individual over time, making conclusions based on a single low-dose challenge problematic.

Documenting resolution of food allergy

Up to 80% of children with egg, milk, soy, and wheat allergy will outgrow their allergy and a lower but significant proportion of peanut, tree nut, and seafood allergies are outgrown. Typically, allergists repeat some combination of skin prick and serum

TABLE I. Key points: What we know

Food challenges are the criterion standard for food allergy diagnosis or resolution of food allergy.
Skin prick and serum specific IgE tests have positive and negative predictive values, but do not replace the conclusive outcomes of food challenges.
Multiple published protocols for performing food challenges are available; there is no optimal protocol. The choice of protocol may be dependent on the level of risk, and physician and patient preference.
High-risk foods, a history of anaphylaxis, and asthma all increase the risk of severe reactions during food challenge.
Food challenges can be safely conducted in physician's office, but require trained personnel and equipment along with readiness to treat anaphylaxis and the availability of transport to nearby emergency facility.
Food challenges can improve the quality of life of food-allergic patients even when the challenge is positive (reacted with symptoms).

specific IgE tests over time, often every 1 to 2 years depending on allergen, reaction history, age, and previous test results.²³ Component testing, available for peanut and several tree nuts, can be helpful in identifying patients whose positive testing is more related to cross-reactivity with pollens than true food allergy.²⁴⁻²⁶ The use of component testing to differentiate these patients from those at risk for anaphylaxis is likely to increase the utility of food challenges. Food challenges can be performed when the benefits of potentially passing a challenge outweigh the risk of reactions, which can be severe. The first food challenge series was reported in 1976,²⁷ and until recently no fatalities had been recorded. However, a recent report of a child who died during a food challenge emphasizes the small but present risk of severe reactions.²⁸ A recent multicenter review of food challenges conducted over a 6-year period showed no fatal reactions in more than 6000 challenges with an overall rate of anaphylaxis of 2%.²⁹

Tolerance of baked egg and milk. Studies indicate that about two-third of milk- and egg-allergic individuals are tolerant of extensively heated milk and egg protein in baked products, and consumption of these baked egg and milk products expedites resolution of egg and milk allergy.³⁰ Therefore, all milk- and egg-allergic patients who are not already eating baked milk and egg should be screened for eligibility for undergoing food challenges to baked milk and egg; skin test wheal diameters, specific IgE levels, including ovomucoid specific IgE for baked egg and casein for baked milk, provide some guidance, but are not definitive.^{30,31} The decision to order food challenges to baked forms of these foods is based on these tests and clinical assessment.³²

When conducting baked egg and milk challenges, it is important that the challenge food be sufficiently cooked to allow the allergen to be denatured. We recommend baking at 350°F for at least 30 minutes and the food should be checked before the challenge to make sure it is well cooked all the way through.³⁰

Other indications

Some patients or families, particularly those with strongly positive testing, but no history of exposure, may request challenges to establish how severe the reaction would be. We would generally recommend against challenging such patients if there is not a reasonable chance that they would pass the challenge. Many of these patients are good candidates for research interventions.

Some families may also request challenge or supervised feeding for siblings or other relatives even in the face of negative testing. Although the food may be safely introduced at home in this situation, conducting a challenge or supervised feeding may be the only way that the family is comfortable adding the food to the diet and continuing regular consumption.

ELIGIBILITY CRITERIA FOR PERFORMING CHALLENGES SAFELY

Crucial issues are which patients can be safely challenged, and what is an acceptable pass rate for undergoing a challenge. Testing can provide an approximation of the chance of passing, but recommendations must be individualized on the basis of both patient and practice/institutional factors. Note that a history of anaphylaxis to the food and/or the presence of asthma leads to an increased risk of severe reaction.³² Wood³³ has advocated for an approach where the allergist gives an idea of how likely a patient is to pass and allows the patient/family to choose whether to proceed.

Various factors including severity of previous reactions, presence or absence of other food allergies, fear of possible need for epinephrine, and patient/family preference will all affect how eager patients and families are to pursue challenges. Other considerations include the patient's ability to communicate early signs of a reaction, which may be lacking in infants and younger children, along with patients with developmental delay and language deficits.

It must be recognized, however, that physician practices can differ widely in their comfort with challenges, particularly those with a high risk of reaction. For instance, in our institution we can triage higher risk challenges to an infusion center with direct supervision by an MD or NP with attending physician backup immediately available. Although rarely used, a pediatric code team can be summoned and patients needing aggressive therapy can be moved directly to the emergency department or even the intensive care unit. On the other hand, in one of our (MCY) private practices and in satellite clinics, only lower risk challenges are conducted because of lesser available resources and the need to transfer patients via ambulance for higher levels of care for severe reactions. The success rate of challenges reported in the literature ranges from 60% to 85%, with lower rates generally reported in academic centers.^{32,34-38} A recent large multicenter study showed an overall reaction rate of 14%, with 2% of patients experiencing anaphylaxis.²⁹

It has also been established that a history of asthma and severe reactions is predictive of the need for epinephrine administration and these factors should be considered when deciding to proceed with challenge.^{32,34,38} It should be stressed that even patients with a history of mild reactions or without exposure have a risk of anaphylaxis while undergoing challenge.³⁹

FOOD CHALLENGE METHODOLOGY

This area will be reviewed in detail in an upcoming work group report of the AAAAI Adverse Reactions to Foods Committee that will update the previous 2009 AAAAI work group report on food challenges⁴⁰; this review will highlight only key points.

Before challenge, risks and benefits should be reviewed with the patient or parents, the procedure reviewed, and any questions answered. We strongly recommend having the patient or parents sign an informed consent form. Patients need to be off oral and

TABLE II. Special issues: What we do not know

1. What are the criteria for determining the most appropriate procedure for the individual patient: formal hospital food challenge, office challenge, or supervised feeding?
2. Under what circumstances can a food be safely (re)introduced at home?
3. When are single- or double-blind challenges appropriate in the setting of routine office practice?
4. What are the parameters for stopping or continuing a challenge in a patient with subjective but not objective symptoms?
5. Does a positive (reacted with symptoms) food challenge with anaphylaxis affect subsequent quality of life and patient adherence?
6. What role will food challenges have in the administration and monitoring of new therapies for food allergy, eg, epicutaneous immunotherapy?

intranasal antihistamines for an appropriate time to prevent masking early symptoms of a reaction; ocular antihistamines may be continued.⁴¹ In addition, asthma, if present, should be well controlled with no recent use of short-acting β -agonist; however, asthma controller medicines, including inhaled corticosteroid/long-acting β -agonist combinations, should be continued.

In typical food challenge protocols, patients ingest the food in question, with an initial dose 0.1% to 1% of the total dose, with increasing doses every 15 minutes, with careful observation for reactions and monitoring of vital signs.⁴⁰ Multiple 2- to 7-step protocols have been proposed without clear guidance as to the optimum starting dose or progression. In general, more doses and a lower starting dose are advisable for patients at a higher risk of failing or at risk for severe reactions. Increments are generally given at 15- to 30-minute intervals although some data suggest that many reactions are delayed.²² However, an interval of 120 or even 60 minutes between increments may be unrealistic in most settings. Patients are typically observed 30 to 60 minutes after a passed challenge, although longer intervals may be appropriate in cases of a history of delayed reactions, inclement weather, or those who live far from an emergency room.

A common dilemma in deciding when to stop the food challenge occurs with patients who report subjective symptoms only (eg, oral or skin pruritus) without objective symptoms, often associated with anxiety that can be triggered by challenge.^{41,42} Our preference is to try and continue until objective symptoms occur, but it may be helpful to postpone further doses to allow time for other symptoms to occur or subjective symptoms to resolve. Significant abdominal pain, particularly if it leads to clear change in demeanor, may be an indication for stopping in the absence of objective symptoms.

SPECIAL ISSUES

Although food challenges are clearly indicated in certain circumstances, there are also situations in which the role of standard food challenges is not clear (Table II).

Challenge versus supervised feeding

There are instances where the risk of reaction is low and it is appropriate to allow the patient to simply eat the food in a monitored setting. Examples are patients who had until recently consumed the food in their diet, those with negative skin and blood testing results with no or unclear reaction history, or introduction of highly allergenic foods in infants with a strong family history. In these cases, simple ingestion of a serving of the food in the office may suffice. Although there is currently no

International Classification of Diseases, Tenth Revision code for such a procedure, an evaluation and management code for an office visit can be billed.

Home challenges

In certain circumstances, introduction of a food at home can be considered. For example, a patient already tolerating baked and stove-top-cooked egg at home with negative or very low skin and blood testing could gradually introduce egg itself at home. This could be done in one sitting, similar to a clinic food challenge, or over several days or weeks.

Blinded challenges

Although double-blind placebo-controlled food challenges represent the criterion standard for research studies, they are rarely used in clinical care and can be difficult to implement. However, there are patients with significant anxiety regarding food ingestion who might benefit from at least single-blinded challenge. Reaction rates to placebo during blinded challenges range from 2.8% to 12.9%.^{43,44}

In a typical research study, patients undergo blinded challenges to both the challenge food and placebo on different days, with blinding of patient, family, and administering personnel. This is typically accomplished through the use of a vehicle such as pudding into which the challenge food is mixed. It can be difficult to make the challenge truly blinded, because many patients can detect the smell of a food or will develop mild oral symptoms with active but not placebo doses.

Another option is inclusion of 1 or more challenge doses within a single-day challenge often at the start and sometime within the first few doses (eg, placebo, first dose, placebo, second dose, placebo, subsequent doses). This might be most helpful in patients who failed an open challenge with solely subjective symptoms.

Food challenges for non-IgE-mediated reactions

Food protein-induced enterocolitis syndrome (FPIES) is characterized by profuse vomiting often accompanied by an ill appearance and diarrhea 1 to 4 hours after food ingestion.⁴⁵ Most but not all infants outgrow FPIES by age 3 years, although significant variation is seen by both country and food.^{45,46} In addition, cases of FPIES are increasingly recognized in adults, particularly to seafood.⁴⁷ Because of the delayed nature of the reaction, challenges in patients with a history of FPIES are difficult. Because of the risk of fluid loss and hypovolemia with severe reactions, FPIES food challenges should be performed with an intravenous line in place, for administration of fluids along with steroids and ondansetron in case of reaction.⁴⁵ In addition, patients should be observed for a prolonged period given the delayed nature of these reactions.⁴⁵

Food challenges for other non-IgE-mediated reactions including allergic colitis and atopic dermatitis can often be accomplished at home, but supervised feeding or challenge may be indicated when reintroducing a high-risk food after a period of restriction particularly for those with positive testing, as in atopic dermatitis and EoE.^{6,7,48}

Considerations for food challenges in adults

The clinical indications for food challenges in adults are most commonly for diagnosis of food allergy; food challenges are less commonly performed in adults to demonstrate resolution because most adult-onset food allergies do not resolve.⁴⁹

Common adult-onset food allergies are to fruits and vegetables, related to oral allergy syndrome/fruit pollen syndrome caused by pollen sensitization.⁴⁹ This diagnosis is made clinically with the patient's characteristic symptoms localized to the oropharynx and the pathognomonic tolerance of the fruit or vegetable in cooked or processed forms; food challenges are typically unnecessary for this diagnosis unless the symptoms are atypical, for example, systemic.^{11,50} Adult-onset food allergies to peanut, tree nuts, sesame seed, seafood, mammalian meat/alpha-gal,⁵¹ as well as more unusual foods, for example, sea urchin roe,⁵² may require diagnosis with food challenges. Other disorders more common in adults related to possible food allergy etiology are EoE and allergic enteropathies, occupational asthma, and other occupational diseases in food industry workers; food challenges may be needed for more effective management.⁵³ Specific food-associated exercise-induced anaphylaxis and postprandial anaphylaxis may also require food challenges for clarification of diagnosis.⁵⁴

The performance of food challenges in adults follows the same protocols as in children. However, there are several considerations specific for adults that require special attention. Adults are often on medications that can impact food challenges. Beta blockers attenuate the effectiveness of epinephrine and need to be discontinued at least 24 to 48 hours before food challenges.⁴⁰ Angiotensin-converting enzyme inhibitors have the theoretical potential of enhancing reactions or inducing kinin-associated angioedema, and should be stopped 24 to 48 hours before challenge.⁴⁰ Aspirin and nonsteroidal anti-inflammatory drugs and alcohol consumption are reported cofactors that enhance food allergic reactions; they should also be discontinued at least 24 to 48 hours before the time of food challenge.^{55,56} Tricyclic antidepressants and benzodiazepines can inhibit histamine release and should be discontinued 3 days to 3 weeks before challenge depending on the drug.⁵⁷ Adults often have comorbidities that increase the risk of more severe reactions on challenge, such as severe asthma, chronic obstructive pulmonary disease, myocardial and cardiovascular disorders. Before ordering a food challenge in the adult patient, a comprehensive medical history is required along with a thorough discussion with the patient, to aid in the risk-benefit analysis of undergoing the food challenge.

Signs and symptoms of reactions

Several series of food challenges indicate that cutaneous reactions are most common but a significant fraction of reactions involves the gastrointestinal system along with the upper and lower respiratory tracts.^{32,58} Significant cardiovascular reactions are rare although mild tachycardia may be observed. As discussed above, it is usually best to not consider a challenge positive without objective signs but a pause in dosing with subjective symptoms may be indicated.

Mild reactions (skin or upper respiratory tract only) can be treated with either observation or antihistamines. Although there is limited data, we support the use of nonsedating antihistamines such as cetirizine, in place of diphenhydramine.⁵⁹ These seem to be equally effective and somnolence from diphenhydramine can interfere with patient assessment. Patients with more systemic reactions should be treated with injectable epinephrine. We believe that attempts to avoid epinephrine administration (eg, by using albuterol for lower respiratory tract symptoms) are likely to be ineffective and send the wrong message to patients. In addition, use of epinephrine in a controlled setting represents a

“teachable moment” for patients and parents. Patients with reactions should be observed a minimum of 1 and ideally 2 hours and at least that long for reactions requiring epinephrine given the risk of biphasic reactions.⁶⁰

POSTCHALLENGE CARE

In 1 study, 13% of patients who passed food challenges (negative challenge) experienced allergic reactions to eating the food on the following day; the authors hypothesize that undergoing a 7-step up-dosing challenge protocol may have a desensitizing effect in some patients.⁶¹ For definitive diagnosis of a negative challenge, the patient needs to tolerate a full dose on the following day. We recommend that patients who pass their challenge ingest a similar portion of food at home for the next 2 to 3 days following the challenge, and then include it in their diet on a regular basis.

As some reports indicate, continued consumption is protective against resensitization; it is recommended that patients consume at least 1 portion of the food weekly.^{62,63} However, data from a number of series indicate that many patients do not regularly incorporate the previously implicated food in their diet after passing a challenge.⁶⁴⁻⁶⁷ We recommend discussing with patients the potential risk of food allergy relapse from inadequate food consumption to encourage the inclusion of that food in their diet.

Patients with clear reactions are considered to have a positive food challenge and should continue to avoid the food and have self-injectable epinephrine available. Having a positive food challenge does not seem to affect the natural history of food allergy,⁶⁸ and many patients with an initial positive food challenge can subsequently have a negative challenge to the same food at a later date.

Occasionally patients will have a delayed reaction after completion of the challenge, often after leaving the office. In this case, antihistamines or epinephrine should be administered as appropriate and in the case of a severe reaction, the patient be transported via ambulance to the nearest emergency department.

Some patients, particularly young children, are able to consume only a portion of the challenge dose. Our practice is that if at least half the challenge dose is consumed, to discharge the patient with instructions to consume that amount in their diet for the next 2 to 3 days, and then gradually increase. If successful, they are considered to have passed the challenge. It may also be appropriate to have some of these children return to complete the challenge another day under supervision depending on history of reactions and family and physician comfort.

We recommend that all patients be given a handout summarizing postchallenge care along with verbal instructions. This should address what to do if a reaction develops later in the day including close monitoring and immediate availability of epinephrine autoinjector, whether the patients can return to work/school or other activities that day, and the treatment to administer and procedures to follow in case of a delayed or biphasic reaction. For those with a positive food challenge, continued avoidance of the food should be advised, whereas for negative challenges, recommendations about ongoing consumption should be included.

EFFECTS OF FOOD CHALLENGES ON QUALITY OF LIFE

Multiple studies have demonstrated that patient and parent/caregiver health-related quality of life (HRQOL) improves after a

negative food challenge.⁶⁹⁻⁷⁴ Surprisingly, HRQOL also improves after a positive food challenge^{70-72,74} albeit not in all studies.^{69,73} The explanation for this is not clear, but anecdotally patients are often relieved that even consumption of sizeable amounts of the implicated food only leads to mild or moderate symptoms, which can be reassuring regarding the likely impact of accidental exposure or cross-contamination. In addition, a definitive diagnosis provided by food challenge reduces uncertainty, which is associated with stress and poorer quality of life.⁶⁹ To date, studies have not addressed the effect of positive challenge with anaphylactic reaction on HRQOL; this might be anticipated to have a detrimental effect. Likewise, it would be of interest to examine quality-of-life changes in those with negative challenge to the only food they were allergic to, compared with those with negative challenges who remain allergic to other foods.

PHYSICIAN ATTITUDES AND PRACTICE-RELATED ISSUES

In a survey administered by the AAAAI Adverse Reactions to Foods Committee, allergists were surveyed on their use of food challenges in their practice.⁷⁵ The top 3 barriers to performing office food challenges were time, inadequate reimbursement (77%), and risk of adverse reactions.⁷⁵ Despite these barriers, 98.7% of respondents indicated the need to conduct food challenges in their practice.⁷⁵ The authors emphasized the need to overcome these barriers with improved education, advocacy, and reimbursement, to increase the use of this important and necessary procedure in allergist practices.

Reimbursement for food challenges can be billed under codes 95076 (first 120 minutes) and 95079 (each additional 60 minutes). These codes were adopted effective January 1, 2013, and represent significant improvements in reimbursement over the previous codes (3.45 relative value units [RVUs] for 95076 and 2.41 for 95079 vs 1.85 units for the previous code 95075). Greater than 50% of the allotted time must be used (61 minutes for 95076 and 31 for each unit of 95075) and timing begins when the first increment of food is consumed and stops when the patient is discharged from the clinic or the challenge is stopped because of a reaction. In case of reaction, an evaluation and management code can be charged on the basis of care provided (in addition to the challenge code, if appropriate). Although direct physician contact is not required to bill for a food challenge, the supervising physician must be immediately present for questions and to manage reactions.

Although clear guidance on documentation is not available, it is recommended that specific times of arrival, administration of each food increment, and discharge be noted. In addition, a physician attestation should be part of the final documentation.

Regarding cost-effectiveness, a recent economic analysis indicated that delays in performing food challenges resulted in substantially increased medical costs,⁷⁶ although this area remains understudied.

CONCLUSIONS

Food challenges remain the criterion standard for the diagnosis of IgE-mediated food allergy. Although a clear reaction history supported by diagnostic testing can rule-in food allergy, the low specificity of these tests is often insufficient to rule out food allergy.

The oral food challenge is a well-established procedure uniquely provided by allergists, and the need is likely to increase in the near future for several reasons: The current food allergy epidemic has resulted in increased use of food specific IgE screening panels for individuals without a history of immediate-type reactions, resulting in overdiagnoses due to poor specificity of these tests. The new Addendum Guidelines for Prevention of Peanut Allergy will increase peanut challenges and supervised feeding for peanut-sensitized infants with eczema and/or egg allergy. Many patients outgrow food allergies, particularly for milk and egg, but also other common and uncommon allergens. New therapies for food allergy may also increase the demand for food challenges.

The increasing need for food challenges must be balanced against high-resource utilization including nursing supervision and prolonged occupation of clinic space, along with concerns with inadequate support to treat potential anaphylaxis, which although uncommon, does occur.

Although understudied, cost analyses indicate substantial savings from ruling out food allergy and HRQOL appears to improve regardless of challenge outcome. With these considerations, it is clear that food challenges are presently underused. Allergists need to use food challenges as part of their standard practice, but innovation and thoughtful planning will be necessary to fully optimize the use of this procedure.

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