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 2017;5:335-44)**

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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

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Abbreviations used
BCH- Boston Children's Hospital
OFC- Oral food challenge
SCAMP- Standardized Clinical Assessment and Management Plan
sIgE- Specfic 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