

Preliminary psychometric analyses and clinical performance of a caregiver self-efficacy scale for food allergy self-management

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ABSTRACT

Background: Food allergy health-related quality of life has been defined, but self-efficacy is poorly described.

Objective: To examine the preliminary reliability, validity, and clinical performance of a novel food allergy self-efficacy index.

Methods: An 8-item Food Allergy Self-Efficacy Questionnaire (FASEQ) was adapted for food allergy–related themes and coadministered with the Food Allergy Quality of Life Parental Burden (FAQL-PB) index to caregivers self-reporting a food allergic child (group A) and those with children followed up at a food allergy referral center clinic (group B). FASEQ split-half reliability, 2-week recall, factor analysis, and construct and discriminative validity were assessed. Multiple linear regression was used to explore predictive associations between the FAQL-PB and the FASEQ.

Results: Among 2,308 caregivers, the mean FASEQ score was 2.69 (95% CI, 2.66–2.73) and was lower (better) among group A (mean FASEQ score, 2.52; 95% CI, 2.49–2.56) vs group B (mean FASEQ score, 3.75; 95% CI, 3.66–3.84; $P < .001$). The FASEQ Cronbach α was 0.87, and the 2-week intraclass correlation coefficient (ICC) was 0.75. Total and 6 of 8 individual FASEQ domain scores were significantly lower among caregivers with children having anaphylaxis or epinephrine use vs none and peanut or tree nut allergy vs milk or egg allergy, demonstrating good discriminative validity. Total FASEQ score was associated with FAQL-PB score (ICC, 0.13; 95% CI, 0.06–0.19; $P < .001$), with 6 of 8 FASEQ individual domains significantly associated (ICC range, –0.17 to 0.3; $P < .01$ for all). Factor analysis revealed 2 domains (medical care and social functioning) with construct validity.

Conclusion: We present preliminary evidence the FASEQ is a valid tool to assess caregiver food allergy self-efficacy. Self-efficacy is a distinct but related concept that captures aspects of self-management that are an important companion to health-related quality of life.

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Introduction

Food allergy is major public health disorder that affects nearly 15 million Americans, including 8% of children in the United States, at an estimated cost of \$24.8 billion annually.^{1–3} Allergic reactions

may occur on initial food exposure, and ability to predict reaction severity is poor, with reactions ranging from mild to highly severe. Several promising food allergy treatments are under development, although currently no therapy exists beyond allergen avoidance.⁴ Research has found an adverse effect of food allergy on health-related quality of life (HRQL) for the child, teen, adult, and parent.^{5–7} Caregiver HRQL in food allergy has been well described, and food allergy–specific indexes measure the perceived difficulty of living with the burden of illness.^{5,8} Overall, research using disease-specific measures demonstrates worse HRQL associated with epinephrine use, reported anaphylaxis, multiple food allergies, multiple food allergic children in the family, lower reported family income, certain allergen types, and emergency department visits for food allergy. Research using generic HRQL measures found worse HRQL in food allergy compared with other pediatric chronic diseases, such as type 1 diabetes or rheumatoid arthritis. Negative

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associations also have been noted with epinephrine device provision and use, increased food allergy–related health services, older age, and female sex. Significant differences in how teens perceive their food allergy compared with their parents have also been found.^{6,9–33} However, HRQL measures are developed to capture the burden of living with food allergy and are not designed to assess the individual's perception of control over management or their ability to make behavioral changes to better manage the disease.^{34,35}

Self-efficacy describes an individual's perceived capabilities for learning or performing actions to manage a situation.³⁶ Thus, the perceived ability or perception of control to make changes that can influence an outcome is a key coping mechanism. Self-efficacy is a powerful influence on motivation and achievement.^{36,37} In other health care fields, self-efficacy has been associated with successful chronic disease management but has been minimally explored in food allergy.^{38–42} It is important to understand how self-efficacy influences HRQL (and vice versa); therefore, the development of a validated outcome measure for food allergic families could help better monitor life with the disease, as well as evaluate emerging food allergy therapies, both clinical and educational. The main aim of this study was to perform a preliminary psychometric validation of a measure of caregiver food allergy self-efficacy. A secondary aim was to assess how self-efficacy relates to caregiver food allergy HRQL.

Methods

This was a cross-sectional, observational study conducted within a large cohort of individuals drawn from 2 populations to provide as robust a sampling of potential segments of the food allergic community as possible. Group A consisted of caregivers who self-reported having a food allergic child and were recruited nationally for participation in an online survey during summer and fall 2012 via e-mail contact, social media feeds, and the websites of Kids with Food Allergies (now a division of the Allergy and Asthma Foundation of America) and the Food Allergy and Anaphylaxis Network (since renamed Food Allergy Research and Education), 2 large, national food allergy advocacy groups. The details of the questions asked and methods of this process have been previously described.^{10,11} Eligible participants included caregivers older than 18 years with at least one food allergic child with a physician-diagnosed food allergy. Caregivers with more than one food allergic child were asked to retake the survey based on their experience with each child independently. Analysis was restricted to cases with milk, egg, peanut, or tree nut allergy, the 4 most commonly reported allergens in the cohort.

Group B consisted of caregivers of food allergic children evaluated and managed for milk, egg, peanut, or tree nut allergy at the Division of Allergy and Clinical Immunology, University of Michigan clinics from 2009 to 2011. These individuals were identified by review of a divisional food allergy patient database and were recruited for participation in this study by mail, or by telephone between November 2011 and August 2012. These 4 allergens represented those most commonly seen in the practice. Selection process and survey data details for this cohort are described elsewhere.^{11,24}

Both cohorts (groups A and B) separately completed an online series of identical questions that contained 3 sections. Section 1 consisted of an internally developed measure of caregiver self-efficacy, named the Food Allergy Self-Efficacy Questionnaire (FASEQ). In section 2, each caregiver also completed the Food Allergy Quality of Life Parental Burden (FAQL-PB) index.¹¹ A survey section (section 3) collected information on the most severe reaction to the diagnosed allergen, reaction treatment, follow-up care, allergic and nonallergic comorbidities, emergency management training, and sociodemographic information, adapted from a divisional food allergy registry form. Information obtained from the

clinic cohort questionnaire data (group B) was additionally verified through medical record review of the patient's medical record to account for potential recall bias. National Institutes of Allergy and Infectious Diseases/Food Allergy and Anaphylaxis Network anaphylaxis criteria were applied to both the parent-reported symptoms and those detailed through medical record review.⁴³

The FAQL-PB is a 17-item, self-administered questionnaire that measures the effect of pediatric food allergy on caregivers, developed by Cohen et al,⁶ with excellent validity and reliability (intra-class correlation coefficient [ICC] = 0.93 and Cronbach α = 0.95) to assess cross-sectional HRQL. The index has not been validated for longitudinal use. Caregiver HRQL was not assessed at a uniform time from diagnosis during the formulation and validation of this scale. Each index item is 7-point Likert-style response scale, and the index is scored as a summated rating scale, with a higher FAQL-PB score indicating worse HRQL.⁶ The index was recently determined to have 2 domains and a minimal clinically important difference (MCID) (eg, the smallest difference in score that patients perceive as beneficial, and would mandate, in absence of troublesome adverse effects and effective cost, a change in the patient's management) of 0.3, although elsewhere an MCID of 0.5 has been estimated.^{11,44}

The FASEQ consists of 8 Likert-item questions designed to evaluate caregiver confidence in managing food allergy. Short yet reliable instruments have been emphasized as important for the health care professionals as a tool to be used on a regular basis in clinical practice.⁴⁵ Content was developed through the adaptation of a self-efficacy measure designed for use in asthma, with wording of certain items changed to reflect terms used for food allergy.³⁶ This content was assessed for face validity internally within the Division of Allergy and Clinical Immunology, in conjunction with team members from the University of Michigan School of Public Health's Center for Managing Chronic Disease, who have expertise in self-regulatory behavior.³⁵ The index was then briefly piloted as part of a secondary outcome measure in small, blinded randomized clinical trial of a self-regulation intervention for anaphylaxis management.³⁴ Items in the FASEQ are scored similarly to the FAQL-PB, as a summated rating scale with lower score reflective of better self-efficacy, using a 5-point scale (range, 0–4). Wording reflects comfort with the 8 items listed.

Data distribution was analyzed using descriptive statistics. Next, we performed a series of analyses to explore the reliability and validity of the FASEQ. FASEQ split-half reliability testing was performed to test for any item redundancy. Construct validity was explored through factor analysis, a data reduction method that seeks to define latent traits (eg, domains) within a data set. We used the iterative principal factor method with oblique and orthogonal rotation separately for groups A and B and together to ensure construct validity across different groups. The Bartlett test of sphericity and Kaiser-Meyer-Olkin Measure of Sampling Adequacy were performed to show adequate variable correlation for factor analysis. Scree plots were used to determine the number of relevant factors to be retained. The χ^2 , Fisher exact, or unpaired independent-samples *t* test for bivariate inferential comparisons was performed to examine discriminative or known groups validity (eg, the ability of the FASEQ to discriminate between subgroups where a difference would be expected).⁴⁶ The MCID for the FASEQ was calculated using the SE of measurement method within the individual and total populations by the following formula: SE of measurement = SD $\times$ square root [(1 – reliability)].^{47–49}

We performed multiple linear regressions between total and domain specific FAQL-PB and FASEQ scores to explore whether an association existed between HRQL and self-efficacy. We expected a significant but low to moderate association because the 2 measures purport to assess different, although related, constructs. Adjusted multiple linear regression was performed to explore the cross-

sectional predictive ability of the FASEQ and the associations between the main outcome of FASEQ score and the covariates assessed in the questionnaire, which were used as predictive variables. The variables used as predictors were prespecified, based on previously reported research from our group. Multicollinearity of independent variables was assessed using inspection of variance inflation factor and model specification through the Ramsey reset test for omitted variables. Regression predictive probabilities were calculated using the Stata margins command.

Data were analyzed with STATA SE, version 13 (StataCorp, College Station, Texas). On the basis of a level of significance of .05, the study had 80% power to detect a 0.5 difference in score between groups with 64 patients per arm. The University of Michigan Medical School Institutional Review Board approved this study.

Results

A total of 2,308 caregivers were included in this study. The demographics of the sample are given in Table 1, and the mean FASEQ scores by item are shown in Figure 1. The mean FASEQ score for the population was 2.69 (95% CI, 2.66–2.73) on a 0- to 4-point scale.

The FASEQ index has good content validity and is able to discriminate self-efficacy based on several different caregiver attributes in the expected direction. In the total population, the mean total and 6 of 8 individual item scores reported by caregivers were significantly lower in children who had experienced anaphylaxis than those who had not. Similarly, the mean total and 6 of 8 individual item scores were significantly lower for those reporting children with past epinephrine use, peanut or tree nut allergy vs milk or egg allergy, and for those reporting more than 3 food allergies vs 1 or 2 food allergies (Fig 2).

FASEQ Psychometric Properties

The FASEQ index had a Cronbach α of 0.87 ($n = 2,308$) and a 2-week test retest ICC of 0.75 ($n = 37$), indicating good reliability. Split-half reliability testing noted no redundancy of the 8 items. Factor analysis of the items revealed a 2-domain structure (factor 1 loading 5 items, factor 2 loading 3 items), capturing confidence in daily medical care and social functioning related to food allergy. The same latent pattern held for groups A and B. The amount of variance explained in SE by the 2 domains was 65.1% by the daily medical care domain and 34.9% by the social functioning domain. Using the SE of measurement method, a MCID of 0.3 was calculated for the FASEQ (Table 2).

FASEQ Performance

Analysis of differences using independent t tests showed that for the 2 individual FASEQ domains identified mean scores were

significantly lower in children who had experienced anaphylaxis than those who had not, for those reporting children with past epinephrine use vs no prior use, for those with peanut or tree nut allergy vs milk or egg allergy, and for those reporting more than 3 food allergies vs 1 or 2 food allergies, similar to the trends reported for the full index. Overall, group A had lower mean FASEQ scores and individual domain-specific FASEQ scores, which differed significantly ($P < .05$) compared with group B (Fig 3). A similar pattern (significantly lower scores in group A vs group B) was noted for total FASEQ scores (and 6 of 8 individual domains) when stratified by reported anaphylaxis, reported epinephrine use, and 1 to 2 reported total food allergens vs more than 3 allergens. Significant differences ($P < .05$) between group A and group B (lower scores in group A vs group B) were also noted in all 8 domains when additionally stratified by caregivers of peanut or tree nut allergic individuals and milk or egg allergic individuals (data not shown).

A linear regression model that used the total FASEQ score as the main outcome score showed a significant but weak associations with FAQL-PB score (ICC = 0.13, $P > .001$; 95% CI, 0.06–0.19; adjusted $R^2 = 0.006$), demonstrating (as expected) that the constructs are related but distinct in food allergy. Our model, which includes independent variables FAQL-PB, age of initial reaction, group A vs group B, and age explains 35% of the variance in FASEQ score, adjusted for anaphylaxis, epinephrine use, history of emergency department treatment for a reaction, allergen type, type of practitioner making the diagnosis, income, race, food allergic siblings, parental educational level, and geographic region. Of those independent variables, score on FAQL-PB (standardized $\beta = 0.21$), clinic population (standardized $\beta = 0.58$), and child's current age (standardized $\beta = -0.4$) had the most statistically significant contribution. Hence, for every 1-unit increase in scores on the FAQL-PB scale, we can expect an increase of 0.13 in the FASEQ score (Table 3).

Associations between the 2 individual FASEQ domains and the FAQL-PB score were stronger than any association to a single item (model-adjusted $R^2 = 0.05$; medical care ICC, -0.29 ; 95% CI, -0.36 to -0.22 ; $P < .001$; social function ICC = 0.49; 95% CI, 0.4–0.58; $P < .001$). Individually, 6 of the 8 FASEQ items had significant associations with FAQL-PB score (recognition, labeling, safety, control, teaching, support; model-adjusted $R^2 = 0.13$; ICC range, -0.17 to 0.3; P range = .004 to $<.001$). There were weak but significant associations between individual FAQL-PB domains and total FASEQ score, with 10 of 17 domains having significant associations (vacation, dining, mealtime, trust others, appreciate severity, sadness, ability to help, eating around others; model-adjusted $R^2 = 0.08$; ICC range, -0.09 to 0.05; P range = .05 to .001). Comparison of FAQL-PB individual items with the 2 FASEQ domains noted similar associations (8 of 17 items were significantly associated with medical care; model-adjusted $R^2 = 0.06$; ICC range, -0.09 to 0.05; P range = .03 to $<.001$; and of 17 items with social functioning; model-adjusted $R^2 = 0.08$; ICC range, -0.1 to 0.06; P range = .047 to $<.001$).

Discussion

We present evidence supporting the preliminary psychometric soundness of the FASEQ as a tool to assess caregiver self-efficacy and self-management in food allergy. These 8 self-efficacy items comprise 2 domains that cover medical care and social functioning aspects, which can differentiate reaction severity, epinephrine use, race, allergen type, and number of allergens. The FASEQ has a MCID of 0.3. In multivariable analysis, the FAQL-PB score is an independently associated predictive variable of FASEQ score (and the reverse has been demonstrated previously). Because they covary, if self-efficacy improves, HRQL will also improve, and good total FAQL-PB scores are predictive of good total FASEQ scores. The

Table 1
Demographic Trends^a

Demographic	Total (N = 2,308)	Group A (n = 2,003)	Group B (n = 305)	P value
Current age, mean (SD), y	7 (3.8)	6.9 (3.8)	7.5 (3.8)	.03
Age of initial reaction, mean (SD), y	2.4 (2.4)	2.5 (2.4)	1.9 (2.2)	<.001
Peanut allergic (n = 1,538)	66.6	73	24.6	<.001
Tree Nut allergic (n = 487)	21.1	20	28.2	.002
Milk allergic (n = 107)	4.6	1.3	26.9	<.001
Egg allergic (n = 176)	7.6	5.7	20.3	<.001
Reported history of anaphylaxis	58.6	61.9	37.5	<.001
White race	87.9	89.3	79.5	<.001
Income >\$100,000	55.3	54.6	59.6	NS
College graduate	83.3	83.3	83.3	NS
Allergist made initial diagnosis	78.3	76.9	86.9	<.001

Abbreviation: NS, nonsignificant.

^aData are expressed as percentage of patients unless otherwise indicated.

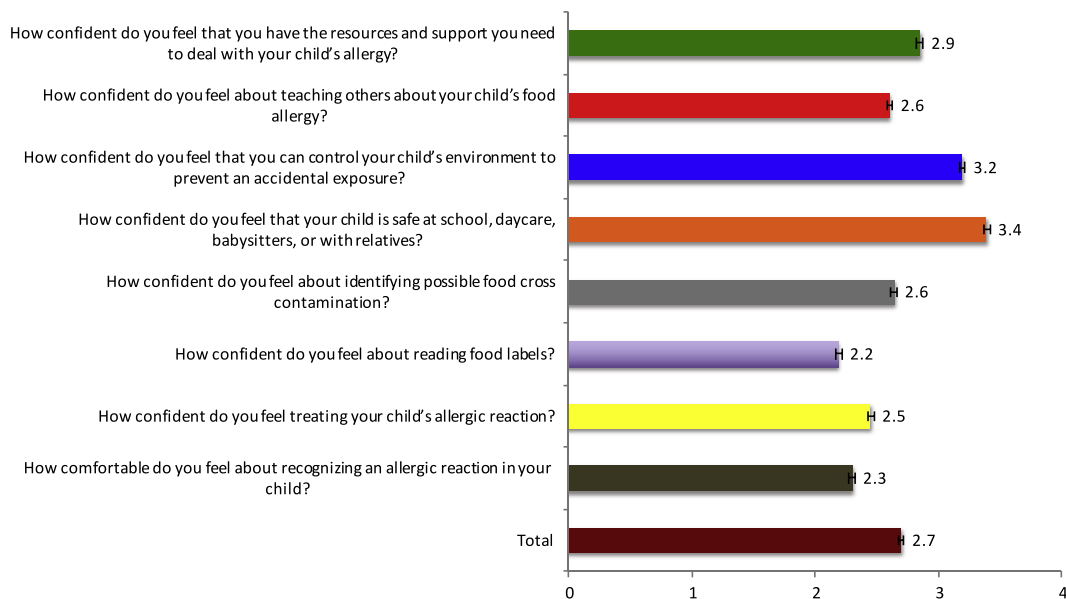


Figure 1. Total and domain-specific Food Allergy Self-efficacy Questionnaire scores for the combined referral center and self-selected population ($n = 2,308$). Mean item scores are shown. Error bars represent SE.

model also shows that FASEQ is an important but not sufficient predictor of HRQL and other variables, such as age and population type, which must be taken into consideration. Future research should examine economic factors more closely because these influence HRQL and self-efficacy and may strongly affect coping behaviors. In addition, individual differences, such as personality and illness perception, are known to influence HRQL and are likely to moderate or mediate the association with self-efficacy. Although we found a significant association between the total scores on the

2 measures, not all individual items on the FAQL-PB were related to the FASEQ. This can be expected because it is the items together that explain the construct being examined. Previous research has also found that some concepts related to self-efficacy are associated with HRQL and some are not.^{50,51}

The ability of the FASEQ to distinguish key features of known groups (reaction severity, treatment, allergen type or number) indicate the strong discriminative power of the FASEQ. These findings with respect to self-efficacy further enhance our

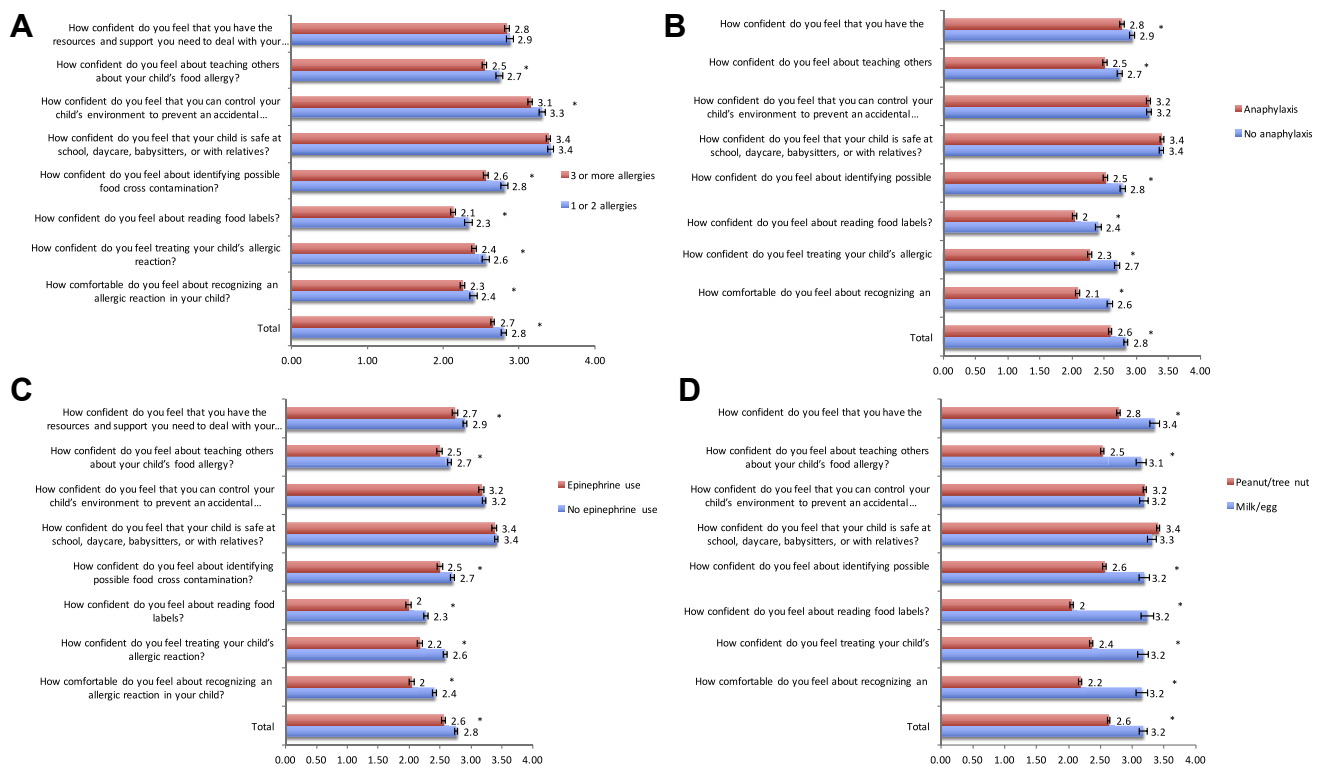


Figure 2. Total and domain-specific Food Allergy Self-efficacy Questionnaire scores for the overall population ($n = 2,308$). A, Scores by allergen number; B, scores by reaction severity; C, scores by epinephrine use; and D, scores by allergen type. Mean item scores are shown. Asterisks indicate significant difference ($P < .01$). Error bars indicate SE.

Table 2
Psychometric Properties of the Food Allergy Self-efficacy Questionnaire^a

FASEQ psychometric property	Factor 1 (medical care)	Factor 2 (social function)
How confident do you feel that you have the resources and support you need to deal with your child's allergy?	0.5	0.58
How confident do you feel about teaching others about your child's food allergy?	0.58	0.45
How confident do you feel that you can control your child's environment to prevent an accidental exposure?	0.23	0.67
How confident do you feel that your child is safe at school, daycare, babysitters, or with relatives?	0.04	0.66
How confident do you feel about identifying possible food cross contamination?	0.61	0.39
How confident do you feel about reading food labels?	0.82	0.2
How confident do you feel treating your child's allergic reaction?	0.82	0.19
How comfortable do you feel about recognizing an allergic reaction in your child?	0.87	0.08

Abbreviation: FASEQ, Food Allergy Self-Efficacy Questionnaire.

^aCronbach $\alpha = 0.87$; intraclass correlation coefficient = 0.75 ($n = 37$); Food Allergy Quality of Life Parental Burden correlation (discriminant validity): $\rho = 0.12$, $P < .001$; minimal clinical important difference = 0.3. Bolded values represent items related to factor loading.

knowledge base not only on the effect of food allergy on everyday life but also on how food allergy is perceived and experienced differently based on what particular food is being avoided. The burden may be disproportionate in some individuals compared with others based on independent variables relating to distinct subgroups, which can be predicted and hence potentially targeted for support. An increased understanding of the interplay between HRQL and self-efficacy may potentially enhance patient-clinician communication and allow for the clinician to select interventions that are appropriate and targeted specifically to that patient. HRQL measures together with the FASEQ might be used as tools to focus communication on coping with food allergy or in difficulties in managing risk and exploring adaptive strategies. Coping skills training and techniques and communications skills might be particularly useful. Further evidence-based research aimed at

exploring the effects of interventions on outcomes in food allergy are needed. The theory of behavioral change is motivated by experience. High perceived self-efficacy can predict performance on preparation and coping. Strong self-efficacy intensifies and sustains efforts needed to master optimal performance of difficult tasks—in this case, the task would be the caregiver's perception of the difficulty of life with a food allergic child. An index measuring self-efficacy in food allergy may therefore have potential applicability as a patient-reported outcome to measure coping and resiliency and denote change induced by emerging treatment modalities currently under investigation (eg, oral, sublingual, or epicutaneous immunotherapy) aimed to alter the course of a child's (or individual's) food allergy.

This study is limited by several factors, similar to our group's other studies within these cohorts. We used self-administered questionnaires to collect data; this measure type is inherently limited and open to response bias. Although the FASEQ and FAQL-PB data were collected prospectively, covariates used to help understand the differences in FASEQ score were collected by survey and subject to some reporting and recall bias, although the effect of this limitation is mitigated in some respect in group B, given trends were verified by medical record review. However, group A was recruited via an internet sample using e-mail and social media from national food allergy advocacy groups and thus suffers from potential selection bias and recall bias. Multiple clinic sites were not used for group A, which would enhance the strength of that sample. Validation of a clinical outcomes measure cannot be established in a single study, as mentioned earlier, and further work is required to achieve this goal. A 2-week recall reliability assessment was performed in a sample at the lower limit of acceptability. Given that this study was cross-sectional, the long-term stability of these findings requires further inquiry. Future research should also explore the effect of age-, culture-, and sex-related variables. This sample also represents a largely white, middle class, and educated population, which may not fully represent the general food allergic community, although it is unclear precisely what the demographics of this population are. Further longitudinal and prospective studies are required to elucidate the nature of these associations and interactions among different levels (eg, biological, psychological, environmental). The FASEQ will be further validated for convergent validity against other measures, including a measure of general

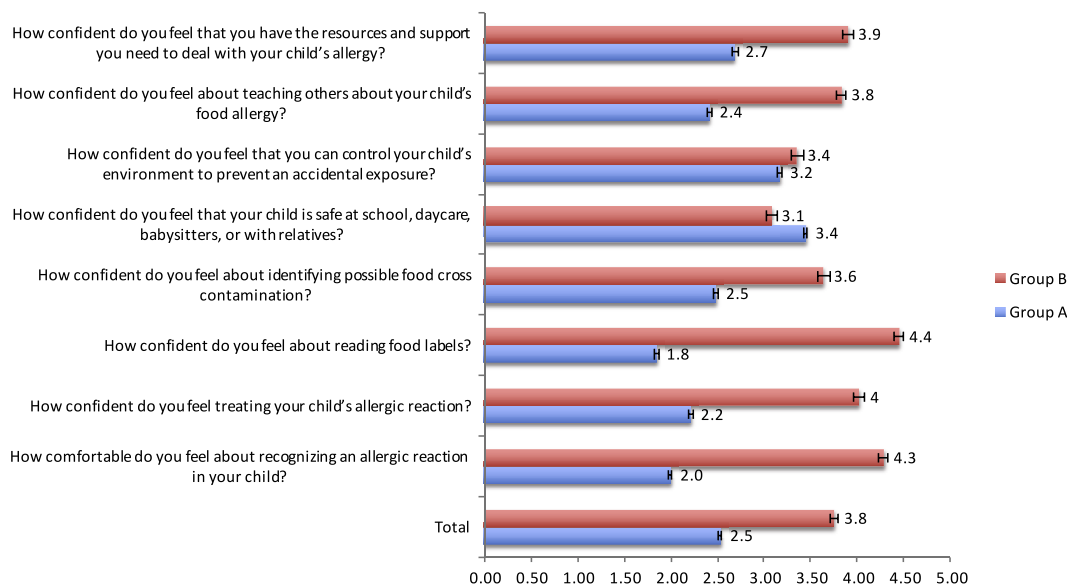


Figure 3. Total and domain-specific Food Allergy Self Efficacy Questionnaire scores stratified by referral center vs self-selected population ($n = 305$ referral center, $n = 2003$ self-selected). Mean item scores are shown. Error bars represent SE. All differences noted between the groups above are significant ($P < .05$).

Table 3
Multivariable Linear Regression Model of Factors Predictive of Self-efficacy Score^a

Self-efficacy score	ICC	P value
FAQL-PB score	0.13 (0.1 to 0.16)	<.001
Age of initial reaction	0.04 (0.02 to 0.06)	<.001
Clinic population	1.47 (1.3 to 1.6)	<.001
Age	−0.09 (−0.1 to −0.06)	<.001
Age ² (age × age)	0.003 (0.0007 to 0.01)	.01
Intercept	2.47 (2.2 to 2.7)	<.001

Abbreviations: FAQL-PB, Food Allergy Quality of Life Parental Burden; ICC, intraclass correlation coefficient.

^aLinear regression model adjusted for anaphylaxis, epinephrine use, allergen type, allergist diagnosis, income, race, other food allergic siblings, educational level, geographic region, and emergency department treatment.

self-efficacy and the Food Allergy Independent Measure. Continued comparison to other measures, as well as longitudinal validation, is needed to comprehensively validate and enhance the psychometric and clinical utility of the FASEQ. Lastly, this study is limited in that self-efficacy is being tested against only external factors associated with disease, as opposed to using inherent psychological characteristics of the caregivers. This is something we seek to explore in a future study because it may be a key determinant of the concept.

To our knowledge, this is the first description of food allergy self-efficacy in a diverse US caregiver population and reveals that the FASEQ is a potentially reliable and valid patient-reported outcome measure for assessing this concept. Self-efficacy is distinct from food allergy quality of life, but there is a significant predictive association among these constructs. The index is able to discriminate multiple food allergy traits related to reaction severity, treatment, and allergen type and number. Further work is planned to continue to better demonstrate the validity of the FASEQ as an outcome measure, including work into exploring convergent validity, further analysis of this index using item-response theory, validation for longitudinal use, and validation of its use in other countries and related food allergic disorders, with an aim that self-efficacy could become a patient-reported outcome of interest for future food allergy interventional therapies.

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