

Development of a questionnaire to measure quality of life in families with a child with food allergy

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Background: Food allergy is potentially severe, affects approximately 5% of children, and requires numerous measures for food avoidance to maintain health. The effect of this disease on health-related quality of life (HRQL) has been documented by using generic instruments, but no disease-specific instrument is available.

Objective: To create a validated, food allergy-specific HRQL instrument to measure parental burden associated with having a child with food allergy: the Food Allergy Quality of Life-Parental Burden questionnaire.

Methods: After identification of 74 items affecting families with children with food allergy, 88 families were approached for effect scoring. Final items were generated by score results, elimination of redundancies, and content review. Resulting high-effect areas were queried for validation with a 7-point Likert scale. A final instrument including 17 items and 2 expectation of outcome questions was distributed to 352 families for validation.

Results: Areas of effect included family/social activities (restaurant meals, social activities, child care, vacation), school, time for meal preparation, health concerns, and emotional issues. Validation steps showed strong internal validity (Cronbach α , 0.95) and good correlation with expectation of outcome questions ($r = 0.412$; $P < .01$) and scores on a generic HRQL instrument, the Children's Health Questionnaire-PF50 ($r = -0.36$ to -0.4 ; $P < .01$). The instrument showed the ability to discriminate by disease burden: parents whose children had multiple (>2) food allergies were more affected than parents whose children had fewer allergies (scores, 3.1 vs 2.6; $P < .001$). **Conclusions:** The Food Allergy Quality of Life-Parental Burden demonstrates strong internal and cross-sectional validity. Its discriminative ability suggests that it will be a useful tool to measure outcomes in treatment studies of food allergy for children. (J Allergy Clin Immunol 2004;114:1159-63.)

Key words: Food allergy, quality of life

Food allergies are increasing in prevalence¹ and are a group of disorders that include potentially fatal anaphylactic reactions.² No cure is currently available, and affected patients, many of them children, must carefully avoid the causal foods. Therefore, affected patients and their caretakers are burdened with a variety of tasks in daily living, including careful label reading of manufactured products, concern about cross-contamination of foods with allergens in a variety of settings, and potential limitations on common social activities associated with eating.³⁻⁵ Accidental exposure may occur and compromise the health of an ostensibly well individual, suddenly and with potentially tragic outcomes, sometimes creating an additional burden of fear for patients. Therefore, living with food allergy may be expected to have an adverse effect on quality of life.

Only a few studies have measured health-related quality of life (HRQL) specifically in patients with food allergy and their caretakers. Sicherer et al⁶ showed that parents of children with food allergy scored low on quality of life measures in domains of family activities, general health perception, and parental emotional effect. Primeau et al⁷ studied adults with peanut allergy and parents of children with peanut allergy and also documented a reduced HRQL. Both studies used generic instruments designed to measure disease effect without regard to specific issues inherent to disorders of food allergy. In contrast with the generic instruments, disease-specific HRQL instruments focus on the domains that are most relevant to the disease being studied and are therefore significantly more sensitive than the generic ones.^{8,9}

It is now well-recognized in health care outcomes research that the effect of disease on HRQL is an important facet to consider in measuring response to treatment and in appreciating the general burden of disease.⁸ This may be particularly relevant for disorders such as food allergy that may not be associated with specific ongoing signs or symptoms. Disease-specific HRQL instruments have been validated and used as an outcome measure in many allergic conditions including asthma,¹⁰ rhinoconjunctivitis,¹¹ multisystem allergic disease,¹² and yellow jacket allergy,¹³ but none have been created for use in food allergy. In this study, we used principles previously established in the development and validation of disease-specific HRQL instruments¹²⁻¹⁴ and focused on the parental burden of having a child with food allergy to

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Abbreviations used

CHQ-PF50: Children's Health Questionnaire–PF50
 FAAN: Food Allergy and Anaphylaxis Network
 FAQL-PB: Food Allergy Quality of Life–Parental Burden
 HRQL: Health-related quality of life

develop a disease-specific instrument for food allergy, the Food Allergy Quality of Life–Parental Burden (FAQL-PB) Questionnaire.

METHODS

Item generation and reduction

Interviews, focus groups, and questionnaires were undertaken with parents of children with food allergy and controls with informed consent. No identifiable personal health information was collected, and the study was approved by the Mount Sinai Institutional Review Board. These subjects were recruited in some cases by approaching consecutive families attending the Allergy Practice at Mount Sinai. For validation studies, members of the Food Allergy & Anaphylaxis Network (FAAN) were contacted by mail. Initial lists of potentially important items were generated by literature review, by the experience of the authors, and through a focus group with 6 parents. An initial list of 74 items spanning a variety of HRQL domains was generated. These items were evaluated by a different group of 88 parents with a child with food allergy attending the Mount Sinai pediatric allergy clinics. Parents were asked to indicate which of the items were troublesome (yes/no) in regard to their child's food allergy and to rate how troubling the item was on a 5-point scale (1, very little; 5, very much).¹³ For each item, the proportion of subjects who labeled the item as troublesome (frequency), the mean importance score in those subjects indicating an item to be troublesome (mean importance), and the product of the frequency and the mean importance (effect) were calculated.^{10,11,13} The maximum possible effect for an item was 5.0. To create a brief instrument, the 16 highest-effect items were selected (effect scores >2). Item similarity (face validity) and Pearson correlations were performed to eliminate high-scoring but redundant items. Items selected for the final questionnaire were converted to questions with a 7-point worded response scale. Previous work suggests that 7-point scales combine excellent responsiveness with ease of administration and subject understanding.¹⁵ The questions were presented within the context of effect of disease over the period of the preceding week. The proposed instrument was reviewed by 18 parents and 1 of the authors (A. M. F.) for comments on clarity and ease of use and revised accordingly.

Validation

Validation steps were adapted from guidelines established in previous quality of life studies.^{10,11,13} Subjects included 450 randomly selected FAAN members (recruited with Institutional Review Board–approved waiver of signed consent) who received mailings and additional Mount Sinai patients approached during clinical visits. In most HRQL studies, independent measures generally include symptoms scores and medication use. Like patients with insect venom allergy,¹³ most patients with food allergy do not have frequent anaphylactic reactions. Although severe reactions for a particular patient may be infrequent because of avoidance, the lasting effects on quality of life may be significant. Therefore,

a variety of means were used to determine validity, presuming that scores would reflect features of the disorder (number of food allergies) and previous experience or expectation.

Subjects answered 2 questions regarding their expectation of future reactions (expectation of outcome): (1) "How great do you think your child's chance is of having a serious reaction upon ingesting the food to which he/she is allergic?" and (2) "How great do you think your child's chance is of dying if your child should they ingest the food(s) to which he/she is allergic?" Responses were recorded on a 7-point scale (no chance, very small chance, small chance, moderate chance, large chance, very large chance, and always). The total score of the FAQL-PB was compared with the mean of the expectation of outcome questions.

A randomly selected subset of participants with children age 5 to 18 years also completed the Children's Health Questionnaire–PF50 (CHQ-PF50). This is a generic health status tool validated on parents of children age 5 to 18 years, focusing on physical and psychosocial functioning. It has been used to measure pediatric HRQL from the parent's perspective in several diseases since its release in 1996 and is useful for determining the relative burden of disease.¹⁶ One previous study concerning the effect of childhood food allergy on quality of life used the CHQ-PF50 as its outcome measure.⁶ The score of the FAQL-PB was compared with the domains of the CHQ-PF50 (general health, parental emotional effect, and family activities) previously identified to be significant in food allergy. Only a moderate degree of association was expected ($0.3 < r < 0.6$) because this instrument is generic.

Additional validation assessments included the following:

Comparison of FAQL-PB scores of families with children with food allergy against those of controls (families with atopic children but no food allergies) with the expectation that disease-free families would have low/no effect.

Comparison of FAQL-PB scores of families whose children had 1 to 2 food allergies with families whose children had 3 or more food allergies with the expectation that burden was greater for persons with more food allergies.

Comparison of FAQL-PB scores of families whose children had had an anaphylactic reaction (by self-report) against families whose children had not had an anaphylactic reaction with the expectation that such events would lead to a greater effect on HRQL.

Cronbach α was used to assess the consistency of the FAQL-PB by looking at all questions. An acceptable Cronbach α has been identified in the literature as $\alpha > 0.7$.¹⁷ It was expected that there should be excellent overall agreement ($\alpha \geq 0.9$). Spearman correlation coefficients and Mann-Whitney tests were used for comparisons of nonparametric data. Reliability was assessed by administering the FAQL-PB to families 2 separate times, 1 week apart, over which time we would not expect there to be a change in the child's condition. The intraclass correlation coefficient for the repeated FAQL-PB measurements is presented as a measure of repeatability.¹⁸ Analyses were performed with SPSS for Windows (version 12; SPSS, Chicago, Ill).

RESULTS

Item generation and reduction

The effect scores of 74 items evaluated by 88 parents of children with food allergy ranged in value from 0.16 to 3.5 (median, 1.2) and were ordered accordingly. Items with similar topics whose scores were highly correlated (>.85) were eliminated to result in 16 questions formatted on

a Likert scale as described. After review by the authors and pretesting on 18 additional families, 2 changes were made. A question directly addressing school and daycare was added that was previously not included but had an effect value near that of the accepted questions. Every family participating in the pretest interviews indicated that school issues should be a part of the final instrument despite this addition resulting in a lengthier instrument. Also, the wording of an existing question about food preparation was considered vague and was clarified to include time spent reading ingredient labels. The final instrument is shown as Fig E1 in the Journal's Online Repository (www.mosby.com/jaci).

Validation

Subjects. The validation phase of the study included participants from 352 families. Ninety-three consecutive parents (26% of the total participants) were recruited while attending Mount Sinai pediatric allergy clinics (only 1 parent declined), and 259 (74%) were recruited through mailings to FAAN members. Of the 150 families who were mailed the instrument with the CHQ-PF50, 71 (47%) responded within 4 weeks, and 188/300 (62.7%) families who received only the FAQL-PB form responded in the same period. The demographic characteristics of the participants and their children are summarized in Table I. Of the 352 questionnaires completed, 13 (3.7%) did not answer 1 or 2 questions.

Validation. Intrinsic validity and reliability were determined in 2 ways. The Cronbach α coefficient for the FAQL-PB was 0.95, indicating excellent agreement between the individual questions in the instrument. To determine the test-retest reliability of the FAQL-PB, 11 families were queried 2 times, 1 week apart, over which time no change in their child's food allergy was expected. The mean question score intraclass correlation coefficient was 0.93 ($P < .01$), indicating excellent reliability.

Correlation with expectation outcomes and a generic instrument was determined for cross-sectional validation. All but 1 question was significantly ($P < .01$) correlated with the mean value of the expectation of outcome questionnaire. The Spearman correlation coefficient for the mean of all of the questions with the mean of the expectation of outcome questionnaire was 0.412 ($P < .01$). There was also moderate but significant ($P < .01$) correlation between the mean FAQL-PB question score and the CHQ-PF50 scale scores previously noted to be important in food allergy⁶: general health ($r = -0.36$), emotional effect ($r = -0.4$), and family activities ($r = -0.4$).

Discriminative ability of the instrument was evaluated in 3 ways. The number of families having children with 2 or fewer food allergies was 183, whereas 168 families had children with 3 or more allergies (1 missing data). Jaeschke et al¹⁹ delineate 0.5 as the minimal clinically important difference for a quality of life instrument when responses are presented on a 7-point Likert scale. The mean question score on the FAQL-PB for families whose children had 3 or more food allergies compared with those

TABLE I. Demographics for participants in validation phase (N = 352)

Parent completing	
Mother, 96%	
Father, 3.4%	
Ethnicity and race	
Hispanic, 2.8%	
Not Hispanic, 96%	
Asian, 4%	
African American, 3.4%	
White, 90.8%	
Family income	
>\$30,000, 4.3%	
\$30,000-\$39,999, 2.8%	
\$40,000-\$69,999, 15.6%	
\$70,000-\$99,999, 19.9%	
>\$100,000, 49.4%	
FAAN members	
Yes, 86.9%	
No, 13.1%	
Number of children with food allergy	
1, 86.6%	
2, 12.5%	
3, 0.9%	
Age of children	
Mean, 6.2 y	
Median, 5.8 y	
Range, 2 mo-17 y	
Children with parent-reported anaphylactic food allergy	
Yes, 46.9%	
No, 53.1%	
Allergic disease	
Atopic dermatitis, 67%	
Asthma, 56%	
Allergic rhinitis, 34%	
Food allergies	
Peanut, 80%	
Tree nut, 51%	
Milk, 42%	
Egg, 41%	

with 2 or fewer was 0.5 higher (3.1 vs 2.6; $P < .001$). The mean scores are shown in Fig 1. The mean score of the expectation of outcome questionnaire, the mean score for 13 of 17 individual questions (eg, all except numbers 2 [$p = .5$], 3 [$p = .7$], 8 [$p = .07$], and 13 [$p = .13$]), and the overall mean question score were all significantly different in these 2 populations ($P < .05$). In the study population, 165 parents reported a previous anaphylactic reaction to food, and 187 families did not. The mean question score on the FAQL-PB for families reporting anaphylaxis was 3.0, versus a mean score of 2.7 for families not reporting anaphylaxis; the difference was statistically ($P = .05$) significant but not as strongly clinically important as the number of food allergies. We enrolled 13 families who had children with atopic disease but not food allergy as controls. All control subjects scored 0 (no effect) on the FAQL-PB compared with the average question score of 2.8 in families with food allergy.

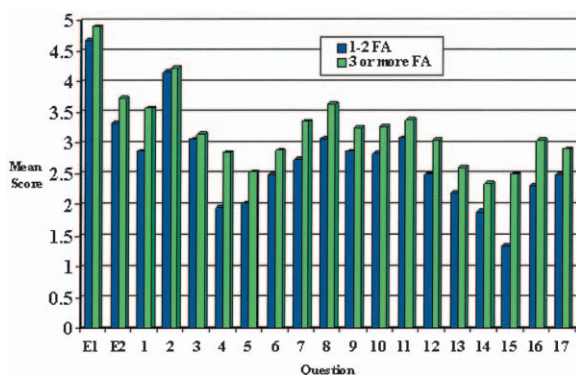


FIG 1. Comparison of scores for parents with children avoiding 1 to 2 foods versus 3 or more foods. Questions E1 and E2 are the expectation of outcome questions. Questions E2, 1, 4 to 8, 10, and 12 to 17 show statistically significant differences between groups ($P < .05$). FA, Food allergy.

DISCUSSION

We have devised and validated a brief, self-administered instrument to measure disease-specific effect of food allergy on HRQL of parents of children with food allergy. The instrument demonstrates excellent internal validity (Cronbach α coefficient, 0.95) and test-retest reliability. Cross-sectional validity is evident by the expected correlation with a validated generic instrument (CHQ-PF50) used to measure parental effect on quality of life ($r = 0.36/0.4$; $P < .01$) and with parental expectation of outcome ($r = 0.4$; $P < .01$). Validation of the instrument for longitudinal studies will require definitive treatments for food allergy that are not yet available. However, the discriminative ability of the instrument in regard to patients with few compared with several food allergies, demonstrated here by a cross-sectional analysis with clinically and statistically different scores on the FAQL-PB, indicates a strong potential for the instrument to be useful in longitudinal studies. This notion is further supported by the observation that families with atopic children but not children with food allergy scored 0 on the instrument (eg, subjects cured would not have a measurable burden).

The study also reveals the numerous HRQL domains affecting families with food allergy. Family and social activities are affected, such as school and camp, social activities that involve food, vacation, restaurant meals, leaving children in the care of others, and children being near others who are eating. Time is affected for meal preparation and precautions when leaving the home. Parents have health and nutritional concerns for their child and worry that they may not be able to help them in the event of a reaction. Emotional issues include anxiety about reactions, frustration in dealing with others, sadness, and worry that their child may not overcome the allergy and not have a normal upbringing. This study has clearly indicated that food allergy affects the family in a variety of ways aside from what may be otherwise considered typical

health related outcomes such as episodes or severity of allergic reactions per year.

There were several inherent limitations in establishing the FAQL-PB instrument. Disease-specific instruments to measure HRQL typically query symptoms over a specific period, eg, 1 week. It was decided for convention to proceed in this manner, but many participants verbalized discontent with this aspect of the instrument. For example, participants might not have planned a social event or dealt with a school issue in the preceding week but were strongly affected by such issues weeks or months previously. One parent voluntarily indicated extreme anxiety about the child's food allergy, was on medications to control the anxiety, and indicated that this was the reason for a low effect score for that question (eg, no anxiety while on medications). Unfortunately, framing questions within a brief time for a disorder such as food allergy is not ideal and may underrepresent specific effect. However, this approach is technically unavoidable for the creation of valid instruments able to discriminate change over time (otherwise, the response could refer to any time a problem occurred, even after improvement in the condition).

Disease-specific instruments are limited by the scope of the subjects on whom they are validated. We attempted to recruit subjects with diverse ethnicity, race, and socioeconomic status (and did so locally), but members of the FAAN are predominantly white and of high socioeconomic status. Studies on more diverse patient populations will be needed to determine validation and effect for nonwhite and impoverished populations. In addition, this study may be biased by the fact that nearly 87% of our subjects were FAAN members. FAAN members may be biased to a more severe form of food allergy with a greater effect on quality of life or may benefit from membership in a support group, lessening the effect on quality of life. However, we used a large group (FAAN) for the purposes of making validation studies representative of participants in future research studies of food allergy therapies. Additional instruments for use in adults, adolescents, and children with food allergy are under development.

In summary, this is the first disease-specific HRQL instrument for food allergy. For the first time, we have documented several areas of HRQL affected by this disorder and created a brief self-administered instrument that can measure this effect that has been validated through cross-sectional study. Its discriminative ability indicates that it will be a useful tool to measure outcomes in treatment studies of food allergy for children. Final validation will require its use during such studies when treatments become available.

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