

Letter to the Editor

A validated index to measure health-related quality of life in patients with food protein-induced enterocolitis syndrome*To the Editor:*

Food protein-induced enterocolitis syndrome (FPIES) is a non-IgE-mediated food allergy characterized by severe gastrointestinal symptoms of severe protracted vomiting, lethargy, diarrhea, and hypovolemic shock occurring 1 to 4 hours after food ingestion.^{1,2} Accompanying findings can include metabolic acidosis, methemoglobinemia, thrombocytosis, neutrophilia, and increased gastric juice leukocyte levels.³⁻⁷ Unlike IgE-mediated food allergy (FA), the diagnosis is based solely on clinical criteria. Food triggers cannot be tested for, antihistamine and epinephrine are ineffective, and there are no patient-administered treatments that can stop an FPIES reaction.⁵ FPIES responds to vigorous intravenous fluid resuscitation, and the vomiting might respond to 5-HT₃ antagonists.⁸⁻¹⁰

FPIES is most often triggered by cow's milk, soy, rice, and oat but can be triggered by grains, meats, poultry, vegetables, legumes, and even seafood.^{3,4,6,E1-E4} Coreactivity among multiple foods is common and complicates food avoidance. A child's nutrition can be compromised without appropriate substitutions for foods that must be avoided.^{3,6,E2} Altogether, the avoidance issues and lack of patient-administered treatment might predispose caregivers of children with FPIES (CCFs) to high anxiety, low self-efficacy, and poor health-related quality of life (HRQL).^{5,E5} No disease-specific HRQL index for FPIES or prior FPIES HRQL studies exist.

The Food Allergy Quality of Life-Parental Burden (FAQL-PB) index measures HRQL in caregivers of children with IgE-mediated food allergy (CFAs) up to age 12 years.^{E6} FA and FPIES are distinct diseases but share several clinical features. Affected subjects must avoid the inciting food allergen and are generally in good health until a reaction occurs, and acute reactions are potentially life-threatening.^{E7} Given these similarities, we sought (1) to determine whether the FAQL-PB is a reliable and valid HRQL measure among CCFs and (2) to compare differences in HRQL scores between CCFs and CFAs.

Participating CCF were recruited at the International Association for Food Protein Enterocolitis advocacy group national conference in October 2013. Five self-report measures were coadministered, including a survey containing background screening questions regarding the family demographics and child's FPIES illness, the FAQL-PB, the Food Allergy Self-Efficacy Questionnaire (FASEQ), the Food Allergy Independent Measure (FAIM),^{E8} and the PedsQL Family Impact Module (PedsQL-FIM).^{E9} CCF FAQL-PB data were compared with those of a nested cohort of 305 caregivers of patients with milk, egg, peanut, and tree nut allergy.^{E10} Data were analyzed with Stata SE software (version 13; StataCorp, College Station, Tex). Additional methodology is described in the [Methods](#) section in this article's Online Repository at www.jacionline.org.

Sixty-eight CCFs participated in this study. The sample demographics are shown in [Table I](#). [Fig 1](#) (blue bars) displays CCF mean and domain-specific FAQL-PB scores. CCFs with dual liquid/solid food FPIES had significantly higher mean

TABLE I. Demographics of the FPIES population

Trend	No. (68)	Percent
White race	63	92.6
College education	48	70.6
No siblings with FPIES or food allergy	54	79.4
Commercial/private insurance	52	76.5
Maternal caregiver	46	67.6
Allergist made diagnosis of FPIES	55	80.9
Liquid and solid food FPIES	52	76.5
Has an allergic comorbidity	12	17.6
Income <\$100,000	32	47.1

FAQL-PB scores (worse quality of life [QoL]) than those with a single trigger (3.3 [95% CI, 3-3.6] vs 2.45 [95% CI, 1.81-3.09]; difference, 0.85; $P = .01$), as well as significant differences in 5 of 17 individual domain scores. Female caregivers had significantly higher mean FAQL-PB scores (worse QoL) than male caregivers (3.5 [95% CI, 3.2-3.84] vs 2.3 [95% CI, 1.93-2.7]; mean difference, 1.2; $P < .001$), as well as significant differences in 11 of 17 individual domain scores. No differences in HRQL scores were noted based on allergist diagnosis, income, insurance, or caregiver education.

Among CCFs, there were significant correlations between outcome measures (see [Table E1](#) in this article's Online Repository at www.jacionline.org). CCF PedsQL-FIM scores correlated strongly with FAQL-PB scores ($r = 0.73$, $P < .001$), and FAIM scores correlated moderately with FAQL-PB scores ($r = 0.39$, $P = .001$). Individual FAQL-PB domain scores correlated strongly with PedsQL-FAIM scores but correlated weakly (although significantly) with FAIM scores. These correlations demonstrate the FAQL-PB has good criterion validity in patients with FPIES. FASEQ scores were moderately correlated with FAQL-PB and PedsQL-FIM scores but not with FAIM scores. The FAQL-PB had excellent split-half reliability in CCFs, with a Cronbach α value of .91 and no item redundancy. Exploratory factor analysis with oblique rotation noted a 3-factor structure (general health concerns, social interactions, and public travel/dining). Comparatively, factor analysis within the CFAs revealed only 2 factors (ie, general health concerns and social interactions; see [Table E2](#) in this article's Online Repository at www.jacionline.org). The estimated index minimal clinically important difference (MCID) in CCFs, as determined by using the standard error of measurement method, was 0.34.

The FAQL-PB score was significantly different between CCFs and CFAs. Mean total and all individual domain scores were significantly higher (worse QoL) in CCFs than in CFAs (3.1 [95% CI, 2.9-3.4] vs 1.9 [95% CI, 1.7-2]; difference, 1.29; $P < .001$; [Fig 1](#)). [Table E3](#) in this article's Online Repository at www.jacionline.org details a multivariable linear regression model for FAQL-PB scores, showing significantly worse scores for CCFs and with allergic comorbidity but an improved score with advancing child age and worsening self-efficacy scores.

In this exploratory study our findings show evidence supporting the FAQL-PB as a valid and reliable index to assess caregiver HRQL among those caring for patients with FPIES. The index discriminates HRQL differences based on single-item versus dual liquid and solid food FPIES and based on respondent sex. The

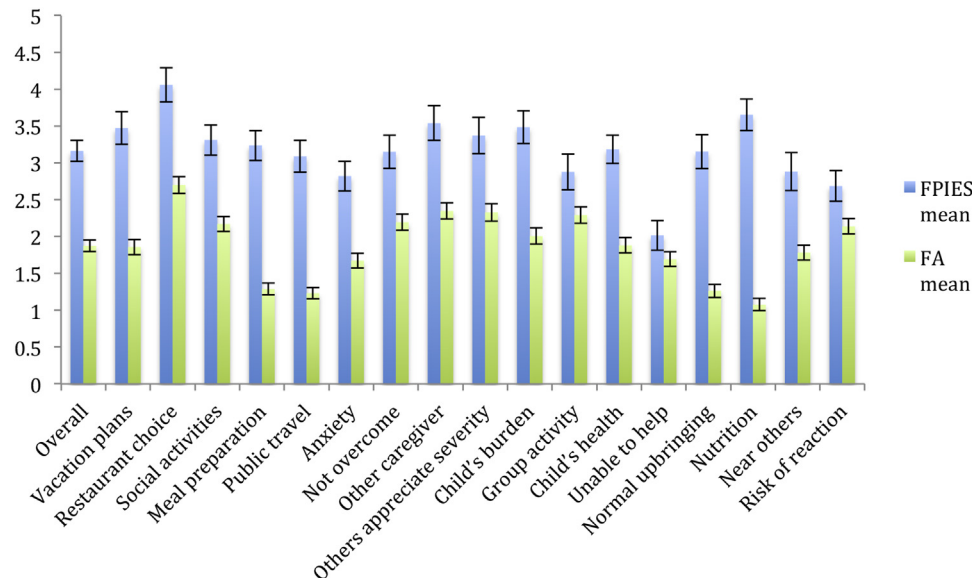


FIG 1. Comparison of mean total FAQL-PB scores between CCFs and CFAs. The difference was statistically significant ($P < .05$) in all QoL domains. Error bars represent SEs.

FAQL-PB has distinct dimensionality (number of relevant themes) in the setting of FPIES versus FA (3 vs 2 dimensions) and has an MCID of 0.34. Thus the FAQL-PB can serve as a patient-reported outcome measure in the setting of FPIES for clinical and research applications.

Our findings that caregiver burden of disease is different for FPIES and FA is novel. However, despite higher (worse) HRQL in the setting of FPIES, self-efficacy was better. This highlights an interesting contrast, suggesting that perception of disease management in CCFs is indicative of underlying HRQL. FPIES and FA differ with regard to timing and age of resolution, number of foods involved and perceived degree of cross-reactivity (worse in FPIES), ability to self-treat a reaction (nonexistent in FPIES), and provider awareness (poor nonallergist FPIES awareness).^{5,8,E11,E12} One of this study's main objectives was to determine whether HRQL might be different between these illnesses. We are planning future studies that will explore motivating factors that better explain this difference.

There are several limitations to this study. This was a small exploratory study examining the feasibility, validity, and reliability of the FAQL-PB in the setting of FPIES for cross-sectional use. Power analysis for many comparisons within CCFs was limited, although we had power to make comparisons between CFAs and CCFs. CCF enrollment was from an FPIES advocacy conference and used caregiver report for data regarding illness history, which might not be a representative population and is limited by selection and recall bias. CFA data were taken from a largely white, well-educated population at a tertiary referral center, which also might be poorly representative.

In conclusion, we demonstrate evidence supporting the FAQL-PB as reliable and valid for assessing HRQL in the setting of FPIES. It is the first such FPIES measure. Furthermore, we show that HRQL among CCFs is worse than among CFAs, a highly novel finding. The utility of the FAQL-PB in the setting of FPIES has potential application in future treatment or intervention, longitudinal disease monitoring, and clinical assessment. Further research is needed to better understand why such large differences in HRQL might exist between these diseases, to further validate the

FAQL-PB within a more representative FPIES population, and to validate the FAQL-PB for longitudinal use in the setting of FPIES.

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METHODS

Outcome measures

The FAQL-PB is a validated, 17-item, self-administered questionnaire that measures the effect of pediatric FA on caregiver HRQL.^{E6} It has an intraclass correlation coefficient (ICC) of 0.93 and a Cronbach α value of .95, indicating both excellent validity and reliability for the cross-sectional assessment of QoL. Caregiver HRQL was not assessed at a uniform time from diagnosis during the formulation and validation of this scale. The 17 questions are each 7-point Likert items scored as a summated rating scale, with a higher FAQL-PB score indicating a worse QoL. The clinical significance of changes in QoL measures is assessed through evaluating the MCID, the smallest difference in score that patients perceive as beneficial, and would mandate, in the absence of troublesome side effects and effective cost, a change in the patient's management. For 7-point Likert scales analyzing QoL, prior studies have used an approximate measure of 0.5 as an MCID based on work in the setting of cardiac and pulmonary disease.^{E13} However, 0.5 is a speculative and not an absolute number adaptable to any 7-point scale because the MCID is specific to the particular QoL index and population being studied.^{E14}

The FAIM is a validated, 6-item, self-administered questionnaire designed to assess the perception of FA severity and related risk, measuring the likelihood and perceived expectation of outcome regarding accidental allergen exposure. It was purposefully designed as an independent measure of criterion validity in developing FA HRQL scales and has been used for both cross-sectional and longitudinal validation of the Food Allergy Quality of Life Questionnaire series in Europe.^{E8,E15-E17} It has an ICC of greater than 0.7 and a concordance correlation coefficient of greater than 0.7, indicating strong validity and reliability.^{E8} For this study, in consultation with the FAIM developers, the term "food allergy" was changed to "FPIES" without other text changes for its use in FPIES (Audrey DunnGalvin, personal communication).

The PedsQL is a reliable and validated family of modular generic and disease-specific pediatric HRQL measures developed by Varni et al.^{E18} The PedsQL-FIM is a generic caregiver self-administered index measuring the effect of a child with a chronic medical condition on caregiver HRQL. It contains 36 items covering 8 distinct domain subscales. The index has a Cronbach α value of greater than 0.9, indicating strong reliability, and has strong criterion validity in multiple pediatric chronic illnesses, including asthma, sickle cell disease, diabetes, bronchiolitis, and eosinophilic esophagitis, among multiple other illnesses.^{E19-E22}

The FASEQ is an 8-item caregiver self-efficacy questionnaire measuring confidence in the self-management of FA. The 8 questions are all 5-point Likert items, and the index is scored as a summated rating scale, with a lower score indicating better self-efficacy. It has a Cronbach α value of 0.88, an ICC of 0.75, and a unidimensional factor structure. It has good discriminant validity and concurrent validity to differentiate allergen type, history of anaphylaxis, and epinephrine use (Greenhawt, data submitted for publication).

The surveys were administered to CCFs in person, and written informed consent was obtained. When possible, male and female caregivers were both surveyed. All caregiver information was obtained in a deidentified manner. Results were transcribed to an MS Excel spreadsheet for data cleaning and uploaded to a statistical package. The CCFs were compared with a previously described cohort of 304 CFAs with children with milk, egg, peanut, and tree nut allergy cared for at the University of Michigan Food Allergy Center and Allergy/Immunology clinics who had been administered the FAQL-PB, FASEQ, and identical demographic and history of illness questionnaires for FA.^{E10}

Statistical analyses

Data were analyzed with Stata SE software (Version 13, StataCorp) for descriptive statistics, correlations between domain and total scores of outcome measures, unpaired independent *t* tests for mean score differences, and regression analysis to explore factors predictive of FAQL-PB scores. Descriptive statistics were used to describe the trends within CCFs. For psychometric validation, FAQL-PB split-half reliability testing was performed in CCFs, and total and domain-specific scores were correlated to FAIM and

PedsQL-FIM to assess criterion, convergent, and discriminant validity. Mean and domain-specific FAQL-PB score differences within CCFs and between the CCF and CFA cohorts were compared by using unpaired independent-samples *t* tests for concurrent validation. Multiple linear regression models were constructed to explore which variables predicted QoL scores. Model specification was assessed by using the Ramsey reset test for omitted variables, and collinearity was assessed through the inspection of variance inflation factor. Factor analysis was performed to determine preliminary index dimensionality in the FPIES cohort by using the iterative principal factor method and oblique and orthogonal rotation. Screeplots were examined for the number of factors to retain with a prespecified eigenvalue of greater than 1. The Bartlett test of sphericity and Kaiser-Meyer-Olkin measure of sampling adequacy were tested to show adequate variable correlation for factor analysis. Based on an α value of .05, the study had 80% power to detect a 0.5-point difference in QoL scores between the CCF and CFA groups, with 65 patients per arm. This study was approved by the University of Michigan Medical School's institutional review board.

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TABLE E1. Correlations between FAQL-PB total and domain scores and PedsQL-FIM, FAIM, and FASEQ total scores in CCFs

FAQL-PB domain	PedsQL-FIM	FAIM	FASEQ
Total FAQL-PB score	0.73	0.39	0.4
Limitation in choice of vacation plans	0.32	−0.01	−0.02
Limitation in choice of restaurant	0.25	0.02	0.003
Limitation in participation in social activities	0.48	0.02	0.11
Troubled by need to spend extra time preparing meals	0.44	0.09	0.14
Troubled by need to take precaution before leaving home	0.48	0.06	0.24
Troubled by anxiety	0.55	0.32	0.31
Troubled that child might not overcome their food allergy	0.57	0.4	0.25
Troubled by possibility of leaving child in care of others	0.51	0.43	0.47
Troubled that others lack appreciation of severity	0.57	0.32	0.41
Troubled by the sadness of the burden your child carries	0.61	0.42	0.33
Troubled by your child attending group activities	0.56	0.27	0.2
Troubled by possibility of concerns for your child's health	0.54	0.22	0.12
Troubled you would be unable to help treat a reaction	0.49	0.36	0.38
Troubled your child will not have a normal upbringing	0.48	0.28	0.21
Troubled by concerns for your child's nutrition	0.51	0.25	0.16
Troubled by fear of child being near others while eating	0.45	0.27	0.62
Troubled with the thought your child will have a reaction	0.51	0.36	0.46
Individual FAQL-PB domain correlation average	0.49	0.25	—
Mean index score (95% CI)	1.86 (1.6-2.1)	2.3 (2.1-2.6)	2.87 (2.6-3.2)

Boldface values indicate a significant correlation ($P < .05$).

TABLE E2. Factor analysis with loadings for the FAQL-PB in CCFs with comparison with CFAs

	Health concerns	Social interactions	Public travel/dining	Uniqueness
FPIES population*				
Risk of reaction	0.4761	0.4711	−0.2398	0.3635
Child's health	0.5579	0.2396	0.1620	0.3834
Not overcome	0.6326	0.0655	0.1408	0.4651
Unable to help	0.4351	0.3725	−0.2029	0.5388
Child's burden	0.7146	0.0628	−0.0652	0.4660
Anxiety	0.6556	0.0617	0.1675	0.4138
Normal upbringing	0.9136	−0.0820	−0.0639	0.2758
Nutrition	0.5805	0.2541	−0.0497	0.4586
Meal preparation	0.5971	−0.3099	0.4662	0.3824
Near others	−0.1014	0.8095	−0.0138	0.4265
Group activity	0.1188	0.5561	0.3518	0.3905
Others appreciate severity	0.2148	0.4820	0.0710	0.5818
Other caregiver	−0.0474	0.8711	0.1093	0.2462
Public travel	0.4450	−0.0337	0.5834	0.3008
Vacation plans	0.0017	−0.0339	0.7516	0.4410
Restaurant choice	−0.1474	0.1364	0.8638	0.2882
Social activities	−0.0678	0.1197	0.7020	0.5045
Factor correlation	0.5474 (1 and 2)	0.1554 (2 and 3)	0.3506 (1 and 3)	
Food allergy population*				
Risk of reaction	0.9447	−0.086		0.211
Others appreciate severity	0.8108	−0.0056		0.349
Not overcome	0.8054	0.0678		0.272
Group activity	0.79	0.0864		0.275
Other caregiver	0.7952	0.1082		0.238
Child's burden	0.795	0.05		0.311
Child's health	0.777	0.1039		0.275
Unable to help	0.7457	−0.0471		0.49
Near others	0.7055	0.1369		0.352
Anxiety	0.6565	0.2149		0.33
Normal upbringing	0.5046	0.3449		0.389
Nutrition	0.3503	0.2649		0.68
Restaurant choice	−0.0645	0.9122		0.244
Vacation plans	−0.0375	0.8693		0.287
Social activities	0.0838	0.769		0.314
Meal preparation	0.1871	0.627		0.411
Public travel	0.3277	0.5326		0.371
Factor correlation	0.6832			

Boldface values denote the item loading factors that load to each factor.

*Iterated principal factor method with oblique rotation used in both populations.

TABLE E3. Adjusted regression model of factors predictive of FAQL-PB scores

FAQL-PB score	Coefficient	P value	95% CI
Child has FPIES (vs food allergy)	0.91	.03	0.07 to 1.75
Child has an allergic comorbidity	0.48	.03	0.06 to 0.91
FASEQ score	−0.26	.01	−0.47 to −0.06
Child's age (mo)	−0.02	.02	−0.04 to −0.004
Intercept	3.18	.00	1.99 to 4.37

Adjusted for income greater than \$100,000, race, education level, insurance status, allergist's diagnosis, presence of other child with food allergy or FPIES, and age $\times$ age (age²) interaction.