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Food allergy QoL questionnaire for children aged 0–12 years: content, construct, and cross-cultural validity

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Summary

Background To date, there is no food allergy-specific questionnaire that allows parents to report children's health-related QoL (HRQL) *from the child's perspective*.

Objective The aim of this study was to develop a sensitive, multi-dimensional measure to assess parental perception of HRQL in children aged 0–12 years with food allergy.

Methods The Food Allergy QoL – Parent Form (FAQLQ-PF) was developed and validated in four stages: (1) item generation using focus groups, expert opinion, and literature review; (2) item reduction, using clinical impact and factor analysis; (3) internal and test–retest reliability and construct validity were evaluated using relevant scales of the Child Health Questionnaire (CHQ)-28 and the disease-specific food allergy independent measure (FAIM); and (4) cross-cultural and content validity was examined by administering the questionnaire in a US sample.

Results *Stage 1:* Saturation was reached at 110 items.

Stage 2: The reduced instrument has 14 items for children < 4 years and 26 and 30 items for children aged 4–6 years and 7–12 years, respectively. Factor analysis revealed three subscales: emotional impact, food anxiety, and social and dietary limitations, accounting for 68% of the variance.

Stage 3: Cronbach's $\alpha > 0.7$ for subscales and total score. Construct validity was demonstrated by significant correlations between relevant scales of the CHQ-28 and FAQLQ-PF subscales ($r = 0.69$ – 0.77 , $P < 0.01$), and between FAQLQ-PF subscales and the FAIM. Sensitivity was shown by significant within-group differences in a sample of 124 food-allergic children.

Stage 4: The FAQLQ-PF was validated in a sample of US children, Cronbach's $\alpha > 0.7$ for subscales and total score. Construct validity was demonstrated by significant correlations between FAQLQ-PF and the FAIM (parent report) and between the FAQLQ-PF and the FAIM (child report). No differences were observed between the US and Irish scores.

Conclusion The FAQLQ-PF is psychometrically robust, with excellent reliability and validity.

Keywords disease-specific measure, EuroPrevall, food allergy, health-related QoL, parents and children

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Background

Health-related QoL (HRQL) is an increasingly important outcome measure, particularly in the case of chronic diseases such as food allergy, for which there is no treatment at present [1]. Interventions such as double-blind placebo-controlled food challenges [2] or emerging

treatments such as oral immunotherapy and anti-IgE therapy may alter QoL but valid and reliable instruments are needed to measure such changes. The results may also be used to inform the allocation of healthcare funds and decisions about treatments for certain patient groups and individual patients [3].

HRQL is a multi-dimensional construct, consisting of physical, psychological, and social components [4, 5]. Food allergy is only sporadically symptomatic, and hence anxiety associated with a potential reaction has more profound effects on a child's everyday life [6–9]. Most studies to date have used generic HRQL questionnaires to investigate the impact of food allergy on QoL [10]. However, a disease-specific questionnaire is necessary because generic measures, although useful for comparing HRQL across diseases, do not incorporate issues directly related to the patient's condition and therefore lack the sensitivity necessary to detect changes as a result of treatment interventions [5]. Furthermore, generic measures lack the detail that is required to assess how different subgroups are impacted by food allergy.

Currently, there is only one well-validated HRQL food allergy specific measure, the Food-Allergy QoL – Parental Burden (FAQL-PB) questionnaire [11]. The FAQL-PB measures the parental burden associated with having a child with food allergy. To date, there is no fully validated food allergy specific questionnaire that allows parents to report children's HRQL from the child's perspective. In developing the Food Allergy QoL Questionnaire – Parent Form (FAQLQ-PF), we felt it was important to include not only the limitations in children's lives caused by food safety concerns, but the negative emotions that are elicited by such restrictions. Both aspects should be measured in order to provide a comprehensive and sensitive measure [12].

While allowing for the importance of measuring parental burden and asking children themselves about health and illness, many reviewers argue strongly for obtaining information from both children and parents whenever possible [13–15]. Difficulties in assessing HRQL in children may arise because of age, lack of insight, cognitive limitations, differences in language ability and understanding and sensitivity to social threat, or normative pressures [16] (Supplementary Material).

Therefore, parents are asked to imagine items relating to HRQL from their child's point of view. Furthermore, as a control measure and as a method for more in-depth analysis, the FAQL-PF also contains items on parental concern for their child's physical and emotional health, parental and family stress, and impact on family activities, as a result of food allergy.

The questionnaire was developed and validated under the aegis of EuroPrevall, a European multi-centre research project funded by the European Union (EU), which aims to improve the QoL for children, adults, and families living with food allergy, www.europrevall.org

Methods

The design of the questionnaire was based on the following principles:

- (1) The questionnaire must have content validity in the view of parents and clinicians involved in its development.
- (2) The questionnaire must be developmentally appropriate.
- (3) The questionnaire should be short, simple, and capable of being self-administered by parents of food-allergic children.

The process of the questionnaire development consisted of the following steps, used successfully in many studies [16]:

- (1) Item generation – focus groups, expert opinion, and literature review (Group A, $n = 50$);
- (2) Item reduction – clinical impact (Group B, $n = 70$).
- (3) Scale generation – factor analysis (Group B, $n = 70$).
- (4) Cross-sectional validation – psychometric analysis (Group C, $n = 124$)
- (5) Cross-cultural validation – US sample (Group D, $n = 60$).

Identification of patient population

The inclusion criteria were: (a) the presence of physician-diagnosed food allergy (skin prick and/or blood test), (b) children aged between 0 and 12 years, (c) a signed parental consent form. Parents completed a detailed survey before taking part in the study. All children had been prescribed an epipen/anapen. In order to be sure that we were tapping HRQL impact of food allergy only, children were excluded if another major illness was present, both atopic and non-atopic (e.g. asthma, eczema, diabetes), that substantially influenced children's QoL. Participants were recruited via a press release in the national print media, Irish Anaphylaxis Campaign (IAC) files (Group A) and directly during visits to the only specialist paediatric allergy clinic in Ireland (Groups B and C). Participants completed questionnaires in the clinic or in University College Cork. Participants (Group D) whose children had previously attended the Duke Clinical Research Unit in North Carolina were contacted and asked to complete the questionnaire. Consent for the study was obtained from the Clinical Research Ethics Committee of the Cork Teaching Hospitals and from the Duke University Medical Ethics Committee.

Stage 1: item generation and content validity Content validity of the questionnaire was established by gathering items that accurately captured parental concerns about their food-allergic children through focus groups (held from October 2005 to February 2006), co-ordinators of support groups, discussions with experienced clinicians (JH&AD), and examination of relevant clinical and HRQL literature. The end-point for item generation was when no significant new items were generated. Parents of food-

allergic children were the most important source for possible items. Focus groups were audio-recorded, transcribed verbatim, and content analysed [17]. Participants' comments were coded to highlight key concepts and categories and, finally, grouped into domains, so that we could be sure that we were addressing all possible aspects of food allergy. This work resulted in an extended list of items with attention to age, sex, food type, symptoms type and number, and the '*extended prototype instrument*'.

Stage 2: item reduction and scale generation The *extended prototype instrument* was sent by post to a new group of participants (Group B) in the form of a list of 110 randomly ordered items. Participants had been contacted previously by phone to enquire about their willingness to take part in the study. A pre-paid envelope and covering letter was included in the package sent.

Four principles guided item reduction. First, the primary criterion for including the item was its 'clinical impact' on children's QoL [18, 19]. Second, to decrease the variability and idiosyncrasy of the response, each domain must include at least four items. Third, face and content validity would be optimized by including parent and clinician review of the questionnaire [20]. Finally, factor analysis was used, not to reduce items, but rather to help develop subscales [21].

Statistical analysis

(A) The clinical impact methodology [18, 19] was used to reduce the number of items in the questionnaire. *Frequency* (the proportion of parents endorsing a particular item), *importance* (the mean importance score attached with that item), and *overall importance* (frequency $\times$ mean importance) of each item were evaluated, resulting in a reduced number of items. Items with the highest overall importance (OI) were selected. We selected an OI cut-off point of 2.0 [21]. However, in order to ensure sensitivity, we determined that additional items would be included that clinicians (JH&AD) identified as important and that had an impact score of 1.8 in two or more subgroups, each of which included at least 10 patients. Subgroups were defined in terms of *age, gender, severity, number of symptoms experienced, and number of food types avoided*. In addition, items would be dropped if they were found to have low inter-item and/or item-total correlations, or that would increase Cronbach's α if removed [22, 23].

(B) The items were then subjected to factor analysis to discover the underlying dimensions (scales) of the questionnaire [22]. The criteria for factor selection were based on interpretation of the Scree plots (looking for the point of inflection); each scale would have at least 4 items, items should load ≥ 0.4 on only one factor and scales should be theoretically coherent [19].

Stage 3: cross-sectional reliability and validity The psychometric properties of the FAQLQ-PF were evaluated

in Stage 3. Multivariate ANOVA was used to explore any differences in our sample population with regard to the scores obtained. To measure the reliability of the questionnaire, both internal consistency reliability and test-retest reliability were assessed. The reduced measure, covering letter, and pre-paid envelope were sent to 124 parents of food allergic children (Group C). In addition, a sub-set of parents completed a second form 18 days after they had completed the first. Parents also reported any change in their child's health between completing the first and the second questionnaires; test-retest analysis was only undertaken on those who reported 'no change at all' in their health status.

Construct validity [24] is evaluated by testing the instrument against hypotheses concerning the scores in a test. In the absence of a disease-specific, age-appropriate, validated questionnaire, the Child Health Questionnaire (CHQ-28) [25] and the Food Allergy Independent Measure (FAIM) were chosen. The CHQ-28 is a validated, parent-administered, *generic* health questionnaire [11]. The CHQ was developed in the USA, and has since been cross-culturally validated in 21 languages and 32 countries. The CHQ-PF28 has four, five, or six response options, divided over eight multi-item scales and five single-items concepts. The multi-item scales consist of physical functioning, social and physical functioning, general health, bodily pain, family activities, social/emotional/behaviour, parent impact, self-esteem, mental health, behaviour and family cohesion.

The FAIM has been used to validate several previous disease-specific questionnaires, including food allergy [11, 25], and consists of four questions, rated on a six-point Likert scale that assesses the parent's expectation of outcome for the child with food allergy, and is therefore *disease-specific*. Subjective *expectation of outcome* is a strong predictor of perception of physical and mental health status and QL [12, 13]. Both these measures and the FAQLQ-PF were completed simultaneously by participants (Group C).

Food Allergy Independent Measure (FAIM)

What chance do you think **your child** has of...?

... accidentally ingesting the food to which they are allergic?

... having a severe reaction if food is accidentally ingested?

... dying from his/her food allergy following ingestion in the future?

... effectively treating him/herself, or receiving effective treatment from others (including epipen administration), if he/she accidentally ingests a food to which he/she is allergic?

Finally, discriminant validity (the sensitivity of the questionnaire to detect within-group differences), which is very important to determine change following clinical intervention or child development, was examined.

Statistical analysis

To measure the internal consistency reliability of the questionnaire, Cronbach's α was used. Scores > 0.7 indicate that scale items measure related concepts [26, 27]. Item-total consistency was also calculated to check the internal reliability of each subscale. Intra-class correlation (ICC) coefficients were computed to examine the relationship between scale scores at times 1 and 2 [28].

Two hypotheses were generated to evaluate construct validity. In order to test convergent validity, a number of *a priori* predictions were generated concerning associations of FAQLQ-PF subscales with subscales of the CHQ-28. It was hypothesized that scales of the FAQLQ-PF would correlate most highly with those scales that are tapping a similar construct (e.g. emotional functioning) and would not correlate with a scale tapping a dissimilar construct. Secondly, we expected that the FAIM would correlate significantly with the FAQLQ-PF items, scale scores and total score.

Discriminant validity was examined by means of linear regression to evaluate both the combined and the individual impact of severity of symptoms, allergic food type, and number of foods avoided, on the overall score.

Stage 4: cross-cultural validity Following validation of the FAQLQ-PF in an Irish sample of food-allergic children, we sought to validate the questionnaire in a US sample of children. Sixty mothers of food-allergic children (Group D) who had previously attended the Duke Clinical Research Unit in North Carolina were asked to complete the questionnaire. All children were confirmed by skin and/or blood test as being food allergic and had been issued with an anapen/epipen. All parents and 30 of the children aged > 6 years completed the FAIM. The wording was adapted for children. Consent was obtained from the Duke University Medical Ethics Committee

Food Allergy Independent Measure (FAIM)

What chance do you think you have of... ?

- ... accidentally eating the food to which you are allergic?
- ... having a severe reaction if you eat the food to which you are allergic?
- ... dying if you eat the food to which you are allergic in the future?
- ... doing the right things for your allergic reaction if you accidentally eat something?

Statistical analysis. Cronbach's α was used to measure the internal consistency reliability of the questionnaire. Item-total consistency was also calculated to check the internal reliability of each subscale. The FAQLQ-PF was also subjected to factor analysis. Validity was assessed by means of correlation between the FAQLQ-PF and the FAIM for both parents and children. A two-way between-subjects ANOVA was used to examine any score differences between Groups C and D.

Results

All statistical analyses were performed using SPSS v 14.0. The results were considered to be significant if $P < 0.05$. Children in all groups (A–D) displayed typical features of food allergy with regard to severity, range of foods, and experience of anaphylaxis, and were aged between 0 and 12 years (Table 1).

Stage 1: item generation

Content analysis of five focus groups composed of 50 parents (where both parents attended were counted as one unit) produced 110 items on a wide range of concerns related to food allergy including: *physical distress, emotional functioning, personality and social development, behaviour, social activities, and diet*. These were rewritten as items to form the extended prototype questionnaire. For example, the following quote 'my child said to me. "when will I be normal" ... and I was shocked because I didn't realise that he felt different because of food allergy' became 'my child feels different from other children of his/her age because of food allergy'.

Stage 2: item reduction and scale generation

Seventy parents (85% response rate) completed the prototype questionnaire (Group B), of whom 96% were mothers. Initially, 36 items were identified as problematic ($OI > 2.1$); 17 items were identified as important for 0–3 years. Each item in the overall scale was deleted in turn and item/scale reliability was checked to determine whether alpha was improved/disimproved. Three items were dropped at this point. In order to ensure face and content validity, 15 mothers of food-allergic children and two clinicians were interviewed. Both groups also proposed changes to the wording and structure of the items. Three items were dropped because they were not deemed food allergy specific. The remaining 30 items of the core questionnaire were subjected to factor analysis. Before performing the analysis, the suitability of the data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of 0.3 or above. The Kaiser–Meyer–Oklin value was 0.85, exceeding the recommended value of 0.6 [20], and Bartlett's

Table 1. Clinical features of Groups A–D, presented as percentage of total

Variable	Group A (%)	Group B (%)	Group C (%)	Group D (%)
Sex				
M	54	47	52	50
F	46	53	48	50
Age (years)				
0–3	25	28	30	10
3–6	35	45	36	40
6–12	40	27	34	50
Anaphylaxis				
Yes	72	62	65	40
No	28	38	45	60
Diagnosis				
General practitioner	54	52	50	42
Paediatrician	36	40	38	45
Consultant allergist	10	8	12	13
Symptoms				
Single				
Skin	12	18	17	10
Oral	10	9	10	14
Gastrointestinal	15	12	10	20
Cardiovascular	15	5	7	8
Multiple				
Excluding cardiovascular	19	16	14	17
Including cardiovascular	29	40	42	41
No. of symptoms				
1–4	28	32	30	35
5–10	36	20	25	30
10+	32	48	45	65
Food types				
Single				
Peanut	8	9	8	7
Nut	3	3	2	4
Milk	8	12	10	11
Egg	9	15	12	17
Fish	5	3	3	6
Shellfish	1	2	2	5
Soya	2	3	1	3
Wheat	3	2	2	5
Sesame	2	1	3	3
Fruits	5	2	2	2
Vegetables	4	2	1	1
Multiple				
Excluding peanuts	14	12	10	12
Including peanuts	38	35	44	32

Test of Sphericity [20] reached statistical significance ($P=0.00$), further supporting the factorability of the matrix.

Analysis identified seven factors with eigenvalues > 1 ; however, only the first four factors were meaningful. Because only one item, relating to symptoms '*my child experiences physical distress because of symptoms*' loaded 0.4 on the fourth factor, we placed it in Factor 1. Two

distinct analyses were undertaken, one on the whole sample, with the second repeating the analysis on splitting the file into tertiles, based on age (0–3 years, 4–6 years; and 7–12 years) and establishing an item structure that was consistent across all three age bands. Using the Scree plot and a factor loading of 0.4 to determine a cut-off point, we chose three factors to form the domains: *emotional impact* (13 items), *food anxiety* (8 items), *social and dietary limitations* (9 items)

Factor 1 – emotional impact: items concern psychological phenomena such as feeling different from other children, frustration, control and generalized anxiety stemming from food allergy; 'My child feels different from other children because of food allergy'.
Factor 2 – food anxiety: items concern anxiety relating to food; 'My child is afraid to try new foods because of food allergy'.
Factor 3 – social and dietary limitations: items concern everyday dietary and social restrictions; 'My child's ability to take part in pre/school events involving food (class parties, treats, lunchtime) is limited by food allergy'.

Stage 3: psychometric evaluation of the Food Allergy Quality of Life – Parent Form

Distribution and reliability of the subscales. The questionnaire was administered to 124 parents (Group C). There was a 92% response rate, of whom 96% were mothers. Table 2 shows the mean scale scores for the three domains. Children aged 3–6 years had higher mean scores in the *food anxiety* scale ($M=4.1$, $SD=3.1$), whereas parents of children aged 6–12 years reported greater impact on HRQL ($M=4.1$, $SD=2.6$) than children aged 3–6 years in the *social and dietary limitations* scale ($M=3.8$, $SD=2.2$). Overall, parents of boys reported higher mean scores up to the age of 6 years; parents of girls reported higher mean scores in the 6–12 year age group. These differences approached, but did not reach significance.

A two-way between-groups multivariate ANOVA was used to further investigate sex and age differences in the FAQLQ-PF total and subscales. The four dependent variables used were: total score, emotional impact, food anxiety and social/dietary limitations. The independent variables were sex and age group. Preliminary assumption testing was conducted to check for normality, linearity, univariate and multivariate outliers, homogeneity of variance-covariance matrices, and multicollinearity, with no violations noted. There were no statistically significant main or interaction effects noted for the total score. However, when the results for the subscales were considered

separately, the only difference to reach statistical significance, using an adjusted Bonferroni α level of 0.013, was that of the interaction between sex and age group for emotional impact [$F(1,120) = 4.112$, $P = 0.010$, Wilks $\lambda = 0.870$, partial $\eta^2 = 0.157$]. Parents of boys reported higher mean scores up to the age of 6 years; parents of girls reported higher mean scores in the 6–12 year age group.

We next evaluated the reliability of the scales. The reliability coefficients, as measured by Cronbach's α , were high for all subscales and total scale, with coefficients ranging from 0.89 to 0.94 for the 3 age groups (Table 2). High intra-class correlations (ICC's), exceeding 0.7, were found between the questionnaires completed at times 1 and 2, indicating high test–retest reliability [28, 29].

Construct validity. The relationships between the FAQLQ-PF scale scores and CHQ-28 scale scores and between the FAQLQ-PF scale scores and the FAIM scores are shown in Table 3. All correlations were significant at $P < 0.05$ ($N = 124$). As hypothesized, strong positive correlations were found between *emotional impact* (FAQLQ-PF) and *role social/emotional/behavioural* (CHQ-28) ($r = 0.71$) and between *food anxiety* (FAQLQ-PF) and *mental health* (CHQ-28) ($r = 0.72$). There was a strong correlation between *social and dietary limitations* (FAQLQ-PF) and *family activities* (CHQ-28) ($r = 0.77$). There were negative or no statistically significant correlations between dissimilar scales. For example, the CHQ physical functioning scale assessed a child's physical disability, which was not

Table 2. Clinical impact score and factor score of the FAQLQ-PF for children aged 0–12 years

Item	Clinical impact	Factor score
Because of food allergy my child ...		
Emotional impact (13 items)		
... feels different from other children*	2.6	0.713
... is negatively affected by receiving more attention*	2.3	0.574
... experiences physical distress because of symptoms*	3.7	0.522
... experiences emotional distress because of symptoms*	2.1	0.492
... is negatively affected by restrictions on his/her environment*	3.6	0.494
... wishes his/her food allergy would go away	3.7	0.593
... is more anxious in general than other children of his/her age	2.9	0.781
... does not feel as confident as other children in social situations	2.5	0.452
... is more cautious in general than other children of his/her age	3.9	0.564
... had to grow up more quickly than other children of his/her age	2.6	0.529
... feels worried about the future (opportunities/relationships) [†]	2.4	0.697
... feels worried about the future (opportunities/relationships) [†]	2.4	0.697
... feels that many people do not understand the serious nature of food allergy [†]	2.1	0.792
... feels that food allergy restricts his/her life in general [†]	2.2	0.765
Food-related anxiety (8 items)		
... is afraid to try new foods*	2.9	0.557
... is concerned that I am worried that he/she will have a reaction*	3.1	0.539
... feels anxious when going to new places	3.6	0.683
... feels anxious about eating an ingredient to which he/she is allergic	2.7	0.674
... feels anxious about food	2.9	0.660
... is anxious when eating with unfamiliar children/adults	3.1	0.657
... is concerned that he/she must always be cautious about food	3.2	0.534
... feels anxious by poor labelling on food products [†]	1.8	0.653
Social & Dietary Limitations (9 items)		
... lack of variety in his/her food*	2.6	0.615
... ability to take part in social activities (sleepovers, parties, playtime) is limited*	2.8	0.556
... feels frustrated by dietary restrictions*	2.6	0.634
... is restricted because of limitations on restaurants we can safely go to*	3.2	0.546
... is restricted because of limitations on holiday destinations we can safely go to*	2.9	0.582
... ability to take part in preschool/school events involving food is limited	2.4	0.500
... feels frustrated by social restrictions	2.9	0.615
... feels 'left out' in activities involving food	2.4	0.552
... is upset that family social outings have been restricted by the need to plan ahead	3.1	0.461

*FAQLQ (PF) for children aged 0–3 years (14 items).

[†]Only for children aged +7 years (four items).

FAQLQ-PF, food allergy QoL questionnaire – parent form.

Table 3. Score distribution and internal consistency of FAQLQ-PF scales in 124 children aged 0–3 years, 4–6 years and 7–12 years

FAQLQ-PF Scale	Age group (years)	Mean (SD)	% min/max (floor/ceiling)	Cronbach's α	Test–retest reliability (intra-class correlation*)
Total score	0–3#	3.6 (3.2)	4.2/5.0	0.89	0.78
	3–6	3.9 (4.3)	3.4/7.3	0.93	0.80
	6–12	4.0 (3.7)	5.6/2.1	0.91	0.82
General impact (bio/psycho/social)	3–6	3.8 (2.4)	1.2/6.0	0.93	0.75
	6–12	3.9 (2.5)	3.3/3.2	0.94	0.77
Food anxiety	3–6	4.1 (3.1)	0.0/1.2	0.89	0.89
	6–12	4.0 (3.4)	0.5/3.7	0.94	0.85
Social & dietary limitations	3–6	3.8 (2.2)	2.2/0.1	0.92	0.74
	6–12	4.1 (2.6)	1.8/3.1	0.90	0.73

* $P < 0.05$ for all values.

#14 items only.

FAQLQ-PF, food allergy QoL questionnaire – parent form.

Table 4. Pearson correlations between CHQ-28, FAQLQ-PF and FAIM.

CHQ-28*	Bodily pain	Family activities	Role (social, emotional, behavioural)	Mental health	FAIM*
FAQLQ-PF					
Emotional impact	0.521	0.510	0.711	0.417	0.577
Food anxiety	0.421	0.562	0.453	0.728	0.614
Social & dietary limitations	0.126	0.770	0.584	0.469	0.549

Highest significant correlations for each FAQLQ-PF scale are in bold.

* $P < 0.05$ for all scales.

FAQLQ-PF, food allergy QoL questionnaire – parent form; FAIM, food allergy independent measure.

relevant to a food allergic child. The FAIM correlated strongly with individual items and scales of the FAQLQ-PF ($0.63 < r < 0.74$, $P < 0.05$) (Table 4).

Discriminant validity. The ability of the FAQLQ-PF to discriminate between objective impact variables associated with food allergy in children was examined.

A two-way between-groups ANOVA was conducted to explore the impact of number of symptoms experienced and number of foods on HRQL scores. There was a statistically significant main effect for both independent variables [$F(4,120) = 8.510$, $P = 0.01$] and [$F(4,120) = 7.860$, $P = 0.01$], respectively. *Post-hoc* comparisons using the Tukey HSD test showed that the mean score for children with one to five symptoms (excluding cardiovascular) ($M = 3.2$, $SD = 1.3$) was significantly different than that for children with 5–10 symptoms (including cardiovascular) ($M = 4.3$, $SD = 1.1$). The mean score for children allergic to a single food (excluding peanut) ($M = 3.1$, $SD = 1.2$) was significantly different from the mean score for children allergic to a single food (including peanut) ($M = 3.7$, $SD = 2.1$) and children allergic to multiple foods (including peanut) ($M = 4.1$, $SD = 1.4$).

Stage 4: cross-cultural and construct validity

Sixty mothers (Group D) of food-allergic children (1 : 1, M : F) aged between 0 and 11 years ($M = 5$ years, $SD = 4.2$) completed the questionnaire in the Duke Clinical Research Unit. Thirty children ($M = 8$ years, $SD = 2.4$) completed the FAIM. Table 5 shows the score distribution and internal consistency of the FAQLQ-PF scales in 124 children (Ireland), and 60 children (US) aged 0–3 years, 3–6 years and 6–12 years. Reliability coefficients were high, with Cronbach's $\alpha > 0.8$ for subscales and total score.

ANOVA showed that there were no significant differences between Irish and US scores on the three subscales or the total score.

Construct validity (Table 6) was demonstrated by significant correlations between FAQLQ-PF subscales ($r = 0.52$ – 0.73 , $P < 0.01$) and the FAIM (parent form) and between FAQLQ-PF subscales ($r = 0.44$ – 0.71 , $P < 0.01$) and the FAIM (child form).

Factor analysis performed on US data confirmed earlier findings, in an Irish sample, of a three-factor construct: *emotional impact* (13 items), *food anxiety* (eight items), *social and dietary limitations* (nine items) accounting for 85% of the variance. Pearson correlation coefficients

Table 5. Score distribution and internal consistency of FAQLQ-PF scales in 124 children (Ireland) and 60 children (USA) aged 0–3 years, 3–6 years, and 6–12 years

FAQLQ-PF	Age group (years)	Mean (SD) (Irish sample)	Cronbach's α^*	Mean (SD) (US sample)	Cronbach's α^*
Total score	0–3 [†]	3.6 (3.2)	0.89	3.4 (3.1)	0.92
	4–6	3.9 (4.3)	0.93	3.7 (5.3)	0.91
	7–12	4.0 (3.7)	0.91	4.0 (4.1)	0.94
Emotional impact	4–6	3.8 (2.4)	0.93	3.7 (3.1)	0.92
	7–12	3.9 (2.5)	0.94	3.9 (3.5)	0.90
Food anxiety	4–6	4.1 (3.1)	0.89	3.9 (2.3)	0.89
	7–12	4.0 (3.4)	0.94	4.0 (4.2)	0.90
Social & dietary limitations	4–6	3.8 (2.2)	0.92	3.7 (3.8)	0.89
	7–12	4.1 (2.6)	0.90	4.1 (2.5)	0.88

* $P < 0.05$ for all values.

[†]14 items only.

FAQLQ-PF, food allergy QoL questionnaire – parent form.

Table 6. Spearman P correlations between scale scores of the FAQLQ-PF in a US sample and the FAIM (parent report) and the FAIM (child report)

FAQLQ-PF*	General emotional impact	Food anxiety	Social & dietary limitations	No. of allergic foods*
FAIM (parent report)				
Q1	0.654	0.501	0.452	0.594
Q2	0.577	0.533	0.437	0.573
Q3	0.522	0.764	0.584	0.601
Q4	0.512	0.569	0.632	0.715
FAIM (child report)				
Q1	0.649	0.383	0.435	0.732
Q2	0.543	0.640	0.569	0.787
Q3	0.561	0.415	0.723	0.653
Q4	0.539	0.384	0.558	0.629

* $P < 0.05$ for all values.

FAQLQ-PF, food allergy QoL questionnaire; FAIM, food allergy independent measure.

Table 7. Pearson correlations between FAIM (parent report) and the FAIM (child report)

	Q1	Q2	Q3	Q4
Q1	0.732	0.477	0.459	0.531
Q2	0.559	0.601	0.516	0.476
Q3	0.526	0.419	0.623	0.612
Q4	0.458	0.442	0.575	0.635

$P < 0.05$ for all scales.

FAQLQ-PF, food allergy QoL questionnaire; FAIM, food allergy independent measure.

(Table 7) show a strong relationship between each of the subscales and the number of foods to which a child is allergic ($r=0.57$ – 0.78). Finally, we found a positive association between the number of foods to which a child is allergic and impact on HRQL.

Discussion

We sought to develop a multi-dimensional measure that allows parents to report children's HRQL *from the child's*

perspective. Valid and reliable instruments are needed to measure changes following clinical or therapeutic interventions. Furthermore, growing recognition of the importance of developmental trajectories in many areas of health research [17] suggests the need to create developmentally appropriate measures to track children's progress.

We developed and validated the FAQLQ-PF in four pre-planned stages. Internal consistency reliability and test–retest reliability were confirmed. Factor analysis was used to place items in three subscales: *emotional impact* (13 items), *food anxiety* (eight items), and *social and dietary limitations* (nine items) explaining 68% of the variance. As hypothesized, there were significant correlations between the generic CHQ-28 and FAQLQ-PF scales that tap similar, food allergy-relevant issues such as impact on emotional functioning and social restrictions and no or very low correlations between scales that were not relevant to food allergy. Also, as expected, there were significant correlations between parents expectation of outcome for their child and the items and subscales of the FAQLQ-PF. Furthermore, we established that the FAQLQ-

PF was sensitive to within-group differences in a sample of food allergic children with a wide range of symptoms and allergy to various foods. Finally, we found that the FAQLQ-PF was relevant in a non-Irish population. Taken together, these results provide evidence of the validity and reliability of the questionnaire.

Our findings of a severe impact of food allergy on HRQL in relation to psychosocial aspects of children's everyday lives concur with, and, goes beyond, findings from other previous studies. For example, the results suggest that the anxiety associated with the risk of a potential reaction has more profound effects on the emotional and social aspects of a child's everyday life than clinical reactivity induced by food intake (6–9, 30–31). In focus groups, parents emphasized the key impact of children's anxiety about food issues. The importance of a subscale assessing this aspect of anxiety was subsequently confirmed using clinical impact and factor analytic methodologies.

Multivariate analysis showed an interaction between sex and age group for the impact of general emotional impact on the HRQL scale; in effect, parents of boys reported higher mean scores up to the age of 6 years and parents of girls reported higher mean scores in the 6–12 years age group. Cognitive development during the middle childhood years provides the foundation for simultaneous social and emotional changes [32]. Children learn about the world outside their family, match themselves against the expectations of others, compare their performance against that of their peers, and develop customary ways of responding to challenges and learning opportunities, and therefore the impact of gender may be increasingly observed. In the general population, self-reported general ill-health and physical symptoms, as well as psychological distress, have been found to increase significantly from pre-adolescence to age 15 for females compared with males [33]. Research also shows an excess of psychological vulnerability in adolescent girls with chronic conditions when compared with boys suffering from the same conditions, including epilepsy and asthma [34], insulin-dependent diabetes mellitus [35], cerebral palsy [36], and self-reported food allergy [9].

Another interesting finding relates to the impact of peanut allergy on HRQL in children. We found that children with peanut allergy obtained higher scores than children with either allergy to single foods or multiple foods, other than peanut. This may be because peanut is very difficult to avoid compared with other foods, entailing higher levels of vigilance and consequent higher levels of anxiety.

The FAQLQ-PF is presented in a single form and is therefore 'user-friendly'. The core questionnaire for the 0–3 year, 4–6 year and 7–12 year age groups has 14, 26, and 30 items, respectively, with three subscale scores, calculated as the mean of each scale. The total score is calculated as the mean of the three subscales. The assess-

ment of different factors within the same measure (food anxiety vs. generalized anxiety) allows direct comparison of their individual or cumulative contribution to HRQL impact. RHR, the simple yet comprehensive format of the FAQLQ-PF, has been designed to be used in clinical practice by clinicians or health professionals, or in research designs.

The FAQLQ-PF has been translated into nine languages, and is undergoing longitudinal validation in Europe, the USA and Singapore. The questionnaire and scoring key is available as an online supplement or may be obtained by contacting the corresponding author.

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Supplementary material

Food Allergy QoL Questionnaire – Parent Form (0–12 years)

This material is available as part of the online article from <http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2222.2008.02978.x>

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FAQLQ-PF

Food Allergy Quality of Life Questionnaire – Parent Form (0-12 years)

Please return the completed questionnaire to:

Audrey DunnGalvin,
Clinical Investigation Unit,
Department of Paediatrics and Child Health,
Cork University Hospital,
Ireland

Tel. 00353-21-4901262
Email : a.dunngalvin@ucc.ie

This questionnaire is part of the EuroPrevall project, a European multidisciplinary study of the prevalence, costs and basis of food allergy in Europe.

Food Allergy Quality of Life Questionnaire-Parent Form (FAQoL-PF) Children aged 0-12 years

Instructions to Parents

- The following are scenarios that parents have told us affect children's quality of life because of food allergy.
- Try to imagine each scenario from your child's viewpoint.
- Please indicate how much of an impact each scenario has on **your child's quality of life** by placing a tick or an x in one of the boxes numbered 0-6.

Response Options

0 = not at all
1 = a little bit
2 = slightly
3 = moderately
4 = quite a bit
5 = very much
6 = extremely

All information given is completely confidential.

This questionnaire will only be identified by a code number.

There are 4 sections to this questionnaire : A, B, C, and D.

- If your child is aged 0 to 3 years, please answer Section A
- If your child is aged 4 to 6 years, please answer Section A and Section B
- If your child is aged 7 years and over, please answer Section A, Section B, and Section C.

Section D : For all age groups.

SECTION A : For all age groups

	Not at all		Extremely				
	→						
Because of food allergy, my child feels.....	0	1	2	3	4	5	6
1 Anxious about food	☐	☐	☐	☐	☐	☐	☐
2 Different from other children	☐	☐	☐	☐	☐	☐	☐
3 Frustrated by dietary restrictions	☐	☐	☐	☐	☐	☐	☐
4 Afraid to try unfamiliar foods	☐	☐	☐	☐	☐	☐	☐
5 Concerned that I am worried that he/she will have a reaction to food	☐	☐	☐	☐	☐	☐	☐

	Not at all		Extremely				
	→						
Because of food allergy, my child.....	0	1	2	3	4	5	6
6 Experiences physical distress	☐	☐	☐	☐	☐	☐	☐
7 Experiences emotional distress	☐	☐	☐	☐	☐	☐	☐
8 Has a lack of variety in his her diet	☐	☐	☐	☐	☐	☐	☐

	Not at all		Extremely				
	→						
Because of food allergy, my child has been negatively affected by.....	0	1	2	3	4	5	6
9 Receiving more attention more attention than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
10 Having to grow up more quickly than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
11 His/her environment being more restricted than other children of his/her age	☐	☐	☐	☐	☐	☐	☐

	Not at all		Extremely				
	→						
Because of food allergy, my child's social environment is restricted because of limitations on.....	0	1	2	3	4	5	6
12 Restaurants we can safely go to as a family	☐	☐	☐	☐	☐	☐	☐
13 Holiday destinations we can safely go to as a family	☐	☐	☐	☐	☐	☐	☐

	Not at all		Extremely				
	→						
Because of food allergy, my child's ability to take part has been limited.....	0	1	2	3	4	5	6
14 In social activities in other people's houses (<i>sleepovers, parties, playtime</i>)	☐	☐	☐	☐	☐	☐	☐

SECTION B : For children aged 4 to 12 years.

	Not at all	Extremely →					
Because of food allergy, my child's ability to take part has been limited.....	0	1	2	3	4	5	6
15 In preschool/school events involving food (<i>class parties/treats/lunchtime</i>)	☐	☐	☐	☐	☐	☐	☐

	Not at all	Extremely →					
Because of food allergy, my child feels.....	0	1	2	3	4	5	6
16 Anxious when going to new places	☐	☐	☐	☐	☐	☐	☐
17 Concerned that he/she must always be cautious about food	☐	☐	☐	☐	☐	☐	☐
18 'Left out' in activities involving food	☐	☐	☐	☐	☐	☐	☐
19 Upset that family social outings (<i>eating out, celebrations, days out</i>) have been limited by food allergy	☐	☐	☐	☐	☐	☐	☐
20 Anxious about accidentally eating an ingredient to which he/she is allergic	☐	☐	☐	☐	☐	☐	☐
21 Anxious when eating with unfamiliar adults/children	☐	☐	☐	☐	☐	☐	☐
22 Frustrated by social restrictions	☐	☐	☐	☐	☐	☐	☐

	Not at all	Extremely →					
Because of food allergy, my child.....	0	1	2	3	4	5	6
23 Is more anxious in general than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
24 Is more cautious in general than other children of his/her age	☐	☐	☐	☐	☐	☐	☐
25 Is not as confident as other children of his/her age in social situations	☐	☐	☐	☐	☐	☐	☐
26 Wishes his/her food allergy would go away	☐	☐	☐	☐	☐	☐	☐

SECTION C : For children aged 7 to 12 years

	Not at all	Extremely →					
Because of food allergy, my child feels.....	0	1	2	3	4	5	6
27 Worried about his/her future(opportunities, relationships)	☐	☐	☐	☐	☐	☐	☐
28 That many people do not understand the serious nature of food allergy	☐	☐	☐	☐	☐	☐	☐
29 Concerned by poor labelling on food products	☐	☐	☐	☐	☐	☐	☐
30 That food allergy limits his/her life in general	☐	☐	☐	☐	☐	☐	☐

Thank you for completing the questionnaire. I would be grateful if you would now answer some questions on your child's food allergy.

SECTION D: For all age groups

Part 1 : My child's food allergy.

Q1. What sex are you ? Male ☐ Female ☐

Q2. What sex is your child? Male ☐ Female ☐

Q3. What age is the child with food allergy? Years _____ Months _____

☐ ☐

Q4. What type of food(s) is your child allergic to? Tick where applicable.

Peanut	☐	Nut	☐	Milk	☐	Egg	☐
Wheat	☐	Soya	☐	Sesame	☐	Fish	☐
Shellfish	☐	Fruits	☐	Vegetables	☐	Other	☐

Please specify 'Other'

Q5. After ingesting which food, did your child have his/her most severe reaction?

Q6. Has your child had an anaphylactic reaction? Yes ☐ No ☐

Q7. If 'Yes', how recent was the reaction? Tick where applicable.

Very recently ☐

6 to 12 months ago ☐

Approximately 1 yr ago ☐

Approximately 2yrs ago ☐

More than 2 years ago ☐

Q8(a). Has your child been issued with an anapen/epipen? Yes ☐ No ☐

Q8(b). Does the provision of an anapen/epipen cause?**(1) Reassurance ...**For you ☐For your child ☐**(2) Anxiety ...**For you ☐For your child ☐**Q9. Who diagnosed your child with food allergy? Tick where applicable**G.P. ☐Consultant Allergist ☐Consultant Paediatrician ☐Dermatologist ☐Dietician ☐Alternative Practitioner ☐**Q10. What Symptoms does your child have? Tick where applicable.**

Itching in the mouth	☐	Throat tightening	☐	Urticaria/Hives	☐
Itching in the throat	☐	Difficulty swallowing	☐	Skin swelling	☐
Itching in the ears	☐	Hoarseness	☐	Nausea	☐
Itching of the lips	☐	Difficulty breathing	☐	Abdominal cramps	☐
Runny nose	☐	Shortness of breath	☐	Vomiting	☐
Stuffy nose	☐	Wheeze	☐	Diarrhoea	☐
Sneeze	☐	Cough	☐	Light-headedness	☐
Itchy eyes	☐	Itching of the skin	☐	Palpitations	☐
Tears	☐	Redness of the skin	☐	Inability to stand	☐
Red eyes	☐	Increase eczema	☐	Loss of consciousness	☐

Q11. How often does your child meet another child with food allergy?Never ☐Rarely ☐Sometimes ☐Often ☐

SECTION D: For all age groups

Part 2 : You and your child's worries about food safety

Please answer the following questions with reference to the 6-point scale on the right

0 = extremely unlikely
1 = very unlikely
2 = somewhat unlikely
3 = likely
4 = quite likely
5 = very likely
6 = extremely likely

Q1. What chance **do you think your child has of?**

	Question	6-point Scale						
		0	1	2	3	4	5	6
1	accidentally ingesting the food to which they are allergic ?							
2	having a severe reaction if food is accidentally ingested ?							
3	dying from his/her food allergy following ingestion in the future ?							
4	effectively treating him/herself, or receiving effective treatment from others (including Epipen administration), if he/she accidentally ingests a food to which he/she is allergic ?							

Q2. What chance **does your child think he/she has of?**

	Question	6-point Scale						
		0	1	2	3	4	5	6
1	accidentally ingesting the food to which they are allergic ?							
2	having a severe reaction if food is accidentally ingested ?							
3	dying from his/her food allergy following ingestion in the future ?							
4	effectively treating him/herself, or receiving effective treatment from others (including Epipen administration), if he/she accidentally ingests a food to which he/she is allergic ?							

Q3. How many foods **does your child have to avoid ?**

0-2	
3-6	
7-10	
10+	

SECTION D: For all age groups

Part 3: Your concerns as a parent

Q1. How would you describe ...

(A) Your general health?

Excellent	
Very Good	
Good	
Fairly Good	
Not So Good	
Poor	
Very Poor	

(B) Your child's general health?

Excellent	
Very Good	
Good	
Fairly Good	
Not So Good	
Poor	
Very Poor	

Q2. Because of food allergy, how much worry/concern does each of the following cause you?

(A) your child's physical health

None at all	
A little bit	
Some	
Quite a bit	
A lot	

(B) your child's emotional well-being

None at all	
A little bit	
Some	
Quite a bit	
A lot	

Q3. What level of stress does your child's food allergy cause ...

(A) You?

None at all	
A little bit	
Some	
Quite a bit	
A lot	

(B) Your Partner?

None at all	
A little bit	
Some	
Quite a bit	
A lot	

(C) Your Family?

None at all	
A little bit	
Some	
Quite a bit	
A lot	

Q4. How much has food allergy limited the type of activities.....

(A) you can do as a family ?

None at all	
A little bit	
Some	
Quite a bit	
A lot	

(B) your child can take part in ?

None at all	
A little bit	
Some	
Quite a bit	
A lot	

Q5. Are you Mother _____ Father _____

Thank you for taking the time to complete this questionnaire. Your participation in our research is sincerely appreciated.