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Development and validation of a self-administered Food Allergy Quality of Life Questionnaire for children

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Summary

Background Having a food allergy may affect health-related quality of life (HRQL). Currently, no validated, self-administered, disease-specific HRQL questionnaire exists for children with food allergy.**Objective** The aim of this study was to develop and validate the Food Allergy Quality of Life Questionnaire – Child Form (FAQLQ-CF) in the Dutch language.**Methods** Interviews with food-allergic children ($n = 13$, 8–12 years) generated 139 HRQL items. The most important items were identified by 51 food-allergic children using the clinical impact method. This resulted in the FAQLQ-CF containing 24 items (total score range 1 'not troubled' to 7 'extremely troubled'). The FAQLQ-CF, the Food Allergy Independent Measure (FAIM) and a generic HRQL questionnaire (CHQ-CF87) were sent to 115 food-allergic children for cross-sectional validation of the FAQLQ-CF.**Results** Construct validity was demonstrated by the correlation between the FAQLQ-CF and the FAIM ($\rho = 0.60$, $P < 0.001$). The FAQLQ-CF had an excellent internal consistency (Cronbach's $\alpha = 0.94$) and discriminated between children who differed in number of food allergies (> 2 food allergies vs. ≤ 2 food allergies; total FAQLQ-CF score, 4.3 vs. 3.6; $P = 0.036$), but did not discriminate between reported anaphylaxis or not. The total FAQLQ-CF score correlated with 8 of the 11 CHQ-CF87 sub-scales which demonstrated convergent/discriminant validity.**Conclusion** The FAQLQ-CF is the first self-administered disease-specific HRQL questionnaire for food-allergic children. This questionnaire has a strong internal consistency and cross-sectional validity. It discriminates between children who differ in number of food allergies, and it was short and easy to use in the population studied. Therefore, the FAQLQ-CF may be a useful tool in clinical research.**Keywords** children, EuroPrevall, food allergy, health-related quality of life

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Introduction

Avoidance of foods causing allergic reactions and emergency treatment are the only proven forms of treatment of food allergy [1]. Children with food allergy and their families thus need to be continuously alert with regard to food in numerous situations and settings, and this may have an impact on daily life [2]. The avoidance of implicated foods along with the fear of an allergic reaction following possible exposure may have a negative impact on the quality of life of food-allergic children.

Quality of life can be measured with generic or disease-specific questionnaires. While generic questionnaires are useful and allow for comparison of quality of life between different diseases, their limitation is that they are generally less sensitive than disease-specific questionnaires, so that potentially important differences or changes may be missed. This is particularly true in the case of food allergy, where unless they are exposed to the relevant food, patients will have no symptoms other than those related to the need to avoid foods or fear of accidental ingestion. In addition, generic questionnaires are sensitive

to co-morbidities, whereas disease-specific questionnaires allow assessment of a single disease. This is also relevant to allergic diseases such as food allergy where many patients also have atopic dermatitis, asthma and/or allergic rhinoconjunctivitis.

There are a few studies that have investigated the impact of food allergy on health-related quality of life (HRQL) in children and all found that HRQL was impaired. However, these studies used generic HRQL questionnaires [3–6] or disease-specific HRQL questionnaires which were not validated [7–9]. By using generic questionnaires [Child Health Questionnaire – Parent Form (CHQ-PF28)], it was found that the quality of life was more impaired in children with food allergy than in children with allergic diseases other than food allergy or non-allergic children [3], and that food allergy by itself was associated with a deterioration of children's quality of life, regardless of additional allergic diseases [4]. Moreover, general health perception, emotional impact on the parent and limitation of family activities of parents with food-allergic children were found to be impaired compared with established norms, using the CHQ-PF50 [5]. By using the Impact on Family Scale (IFS), it has been shown that daily life is significantly more disrupted in peanut-allergic children than in children with a rheumatic disease [6].

A few studies describe the development of preliminary disease-specific questionnaires to assess the parental adjustment to and coping with children's food allergy [7], to determine the impact of food allergy on the daily activities of food-allergic children and their families [8] and to compare the quality of life of food-allergic children with children with diabetes mellitus [9]. The first two questionnaires were completed by the parents, the last one by the child. However, these questionnaires have not been validated which is critical in order to determine whether the questionnaire is measuring that part of quality of life which is determined by the target disorder [10]. The only validated disease-specific HRQL questionnaire for food allergy which is currently available is administered to parents and measures the parental burden associated with having a child with food allergy [11].

Because no validated food allergy-specific HRQL questionnaire exists which can be administered to children, we developed such a questionnaire. We targeted children old enough to complete the questionnaire themselves (≥ 8 years) but not yet teenage (≤ 13 years), where social and developmental differences were likely to result in differences in the content of the questionnaire. This questionnaire was developed as part of the EuroPrevall project, a European multi-centre research project on food allergy [12]. This article will describe the development and cross-sectional validation of the Food Allergy Quality of Life Questionnaire – Child Form (FAQLQ-CF) in the Dutch language. Validation was accomplished by ascertaining construct validity between the items of the FAQLQ-CF and

the Food Allergy Independent Measure (FAIM) as well as a generic quality of life instrument, the Children's Health Questionnaire – Child Form (CHQ-CF87). In both cases, only moderate correlations were expected, as disease-specific questionnaires cover a wider range of issues than most independent measures can capture [13], and generic instruments cover a wider range of issues than disease-specific instruments can capture [14]. In addition, the FAQLQ-CF was tested to see if it could discriminate between children who had previous anaphylactic reactions and those who had not as well as children allergic to many foods and those allergic to only a few foods.

Methods

Participants

During all stages of questionnaire development and validation, children aged 8–12 years were included. All common food allergies and different types and severities of symptoms were represented. During the item generation, children were recruited from our outpatient paediatric allergy clinic. During the item reduction and cross-sectional validation, children were recruited from our outpatient paediatric allergy clinic or were recruited through food allergy support organizations (the Dutch Foundation for Food Allergy and the Dutch Anaphylaxis Network) and by advertisement in local newspapers.

Procedure

During the item reduction and cross-sectional validation phase, children and their parents were instructed that the children should fill out the questionnaire by themselves. Parents were allowed to explain a question when needed, but they were not allowed to tell the child which answer to give. In addition, during all stages of questionnaire development, descriptive characteristics were asked on age, sex, type and number of food allergies, type of symptoms, time since most severe allergic reaction, and diagnosis. For completing these descriptive questions, parents were allowed to help their child when needed.

Item generation. Potential items for the new questionnaire were assembled during the item generation phase. A semi-structured interview was administered to 13 food-allergic children (aged 8–12 years). Such interviews are flexible while a framework of themes, concerning unpleasant or troublesome things about having a food allergy in daily life, is explored. Additional sources for items were literature review and expert opinion. This resulted in an extended item list of 139 items. The items were divided into the following themes: shopping/labelling (five items), food preparing (five items), eating in general (10 items),

eating out (20 items), social activities (29 items), emotions (35 items), holidays (21 items), school/leisure activities (10 items) and medication (four items).

Item reduction. Subsequently, item reduction was carried out by using the clinical impact method [15, 16]. The clinical impact method asks patients to identify the impairments that are most important to them in their everyday lives. Items identified most frequently and rated the most important are selected for the final questionnaire. The extended item list was sent to a different group of 54 food-allergic children (aged 8–12 years). Items were formulated as questions to which the answer was 'yes' or 'no'. For example, 'Do you read labels because of your food allergy?' The children could indicate whether an item was applicable to them or not and, if applicable, they were asked to indicate on a five-point scale ranging from 'not' to 'extremely' the impact of that item on their life. The five-point scale was illustrated by drawings of faces (smileys) ranging from a smiling face to a sad face. For each item, we counted the number of times that an item was applicable (i.e. *frequency*). Frequency divided by the total number of children gives the *percentage* by which an item was identified as being important. Then, we calculated the mean importance (MI) for each item. The MI of an item is the sum of impact scores (based on the five-point scale) divided by the *frequency*. The overall importance (OI) of each item was calculated by multiplying the *percentage* with the MI. The maximum possible OI score was 5.0 [17, 18].

The items with the greatest OI were selected for the FAQLQ-CF. To prevent redundancies, one of any pair of items with an inter-item correlation >0.85 and/or overlapping content (face validity) was eliminated. Our goal was to create a brief questionnaire that could be administered within half an hour, taking into account that it takes 1 min to complete one item [19]. The selected items were worded as questions with a seven-point response scale ranging from 'not troubled' to 'extremely troubled' [16, 18] and were illustrated by drawings of faces (smileys) ranging from a smiling face to a sad face. A consultant/teacher for sick children and a linguist reviewed the FAQLQ-CF for clarity and ease of use.

Cross-sectional validation. The complete questionnaire packages, containing the FAQLQ-CF, the FAIM and a generic HRQL questionnaire (CHQ-CF87), were pre-tested in three children (aged 8, 10 and 12 years). No major problems emerged during this pre-test. The 8-year-old child reported that her parents read the questions aloud and that she marked the right answers herself. The questionnaire packages were then sent by mail to 115 food-allergic children. A part of these children had participated in the item generation (10%) or item reduction phase (45%). For the children recruited from our clinic, we

checked the patient records to determine whether or not the food allergy was diagnosed by a double-blind, placebo-controlled food challenge (DBPCFC).

Reliability. The internal consistency of the FAQLQ-CF and the domains was measured by calculating Cronbach's α . An alpha greater than 0.70 indicates good internal consistency [20].

The test-retest reliability of the FAQLQ-CF was assessed by administering the questionnaire to 28 children on two occasions 10–14 days apart, and the intraclass correlation coefficient (ICC) of the repeated FAQLQ-CF measurement was calculated. An ICC greater than 0.70 indicates good test-retest reliability [21].

Cross-sectional validation

Construct validity. In order to demonstrate the construct validity of the FAQLQ-CF, correlations were calculated between the FAQLQ-CF and an FAIM. The FAIM was developed for this study and includes four expectation of outcome (EO) questions and two independent measure (IM) questions. The use of EO and IM questions to validate disease-specific HRQL questionnaires has already been successfully implemented to validate HRQL questionnaires [11, 18], and it is of special use in anaphylactic disorders where no objective measurement of the extent or severity of disease exists [13]. The four EO questions concern the chance of accidental exposure, chance of having a severe reaction when accidentally exposed, chance of dying when accidentally exposed and chance of not acting effectively when accidentally exposed. Children could indicate their answer on a seven-point scale ranging from 'never' (0% chance) to 'always' (100% chance). The two IM questions concern the number of foods one needs to avoid (question 5) and the impact of food allergy on social life (question 6). Children could indicate their answer on a seven-point scale ranging from 'almost none' to 'almost all' (question 5) and ranging from 'so little I do not actually notice it' to 'a very great deal' (question 6). We expected a moderate correlation coefficient (0.40–0.70) [22] between the FAQLQ-CF and the FAIM.

Discriminative ability. In order to establish the discriminative ability of the FAQLQ-CF, we compared the total FAQLQ-CF score for children who reported anaphylaxis vs. children who did not. Anaphylaxis was defined as children who reported two or more of the following cardiovascular symptoms: dizziness, feeling your heart beat fast, loss of vision, inability to stand, light-headedness, collapse, loss of consciousness/passing out. In addition, we compared the total FAQLQ-CF score for children who reported many food allergies vs. children who reported fewer food allergies. We investigated which

cut-off in number of reported food allergies revealed a significant difference in the total FAQLQ-CF score. Additionally, the total FAQLQ-CF score was compared for girls vs. boys, because gender may influence the quality of life [23]. Finally, we compared the total FAQLQ-CF score for children who were recruited from our clinic vs. children who were recruited by advertisement.

Convergent and discriminant validity. In order to demonstrate convergent and discriminant validity, a generic HRQL questionnaire was administered: the CHQ-CF87. The CHQ-CF87 was developed in the USA and has since been validated in several other countries and languages [24, 25]. This questionnaire is self-administered by the child and contains 87 items divided into 12 sub-scales: physical functioning, role functioning – emotional, role functioning – behaviour, role functioning – physical, bodily pain, general behaviour, mental health, self-esteem, general health perceptions, change in health (single item), family activities and family cohesion. The Dutch version was found to be reliable and valid with good internal consistency (only one sub-scale had a Cronbach's α below 0.70) and with good test–retest reliability (only two sub-scales had non-significant ICCs). Finally, all sub-scales were able to differentiate between subgroups with and without two or more reported chronic conditions [25]. We expected a low correlation coefficient (0.10–0.30) between the FAQLQ-CF and the CHQ-CF87, because the FAQLQ-CF is a disease-specific quality of life questionnaire, whereas the CHQ-CF87 measures generic quality of life.

Translation

The Dutch FAQLQ-CF was translated into English using the guidelines of the World Health Organization [26]. The Dutch FAQLQ-CF and the FAIM were translated into English by a native English speaker and back translated by a native Dutch speaker. The original Dutch version was compared with the back-translated Dutch version. No important differences in content or meaning of questions emerged. The English version of the FAQLQ-CF and the FAIM may be found in Appendices A and B.

Statistical analyses

The raw FAQLQ-CF and FAIM scores 0–6 were recoded as 1–7. The total FAQLQ-CF score is the mean score of all items with a range of 1 'no impairment' to 7 'maximal impairment'. The dataset was not normally distributed; therefore, non-parametric tests were used. In order to demonstrate construct validity, Spearman's correlation coefficients were calculated for the individual items and total FAQLQ-CF scores with the individual FAIM questions and the mean of the FAIM. The items of the FAQLQ-CF were allocated to domains based on factor analysis

(principal component analysis with Varimax rotation) [27] and face validity determined by a clinical expert panel (B.M.J.F.dB., J.N.G.O.E. and A.E.J.D.) [28, 29]. The discriminative ability of the FAQLQ-CF was analysed by using the Mann–Whitney test. Finally, convergent and discriminant validity was demonstrated by calculating Spearman's correlation coefficients for the domain and total FAQLQ-CF scores with the CHQ-CF87 sub-scales. Statistical analyses were performed with SPSS for Windows (version 14).

Ethical approval

The study was approved by the local medical ethics review commission (METc 2005/051) who deemed that permission from the commission was not required. Parents and children received written information, indicating that participation in the study was voluntary.

Results

Item generation and item reduction

Descriptive characteristics of the children involved in the item generation and item reduction are shown in Table 1. The extended item questionnaire was returned by 51 children (response rate 94%). The OI scores of all 139 items of the extended item questionnaire ranged from 0.00 to 3.22. The 25 non-overlapping most important items ($OI \geq 1.57$) were selected for the FAQLQ-CF (Table 2). These selected items came from the following original themes: shopping/labelling (four items), food preparing (one item), eating in general (five items), eating out (four items), social activities (four items), emotions (six items), holidays (zero item), school/leisure activities (one item) and medication (zero item). Although children did bring up items concerning sadness, embarrassment and teasing, most of these items did not reach a high enough OI for inclusion in the questionnaire.

Cross-sectional validation

Participants. The FAQLQ-CF with the FAIM and the CHQ-CF87 were returned by 84 children (response rate 73%). The questionnaires of three children were excluded from the analysis because no current food allergies were reported, and one questionnaire was excluded because the descriptive characteristics were missing. For one child, the CHQ-CF87 was missing. Forty-eight children (60%) were recruited from our clinic, of which 25 (31%) had a food allergy confirmed by a DBPCFC. The other children from our clinic had a physician-diagnosed food allergy (skin prick and/or blood test) and the majority was awaiting DBPCFC. All children recruited by

Table 1. Descriptive characteristics of the children involved in the item generation, item reduction and cross-sectional validation

	Item generation	Item reduction	Cross-sectional validation
Patients (<i>n</i>)	13	51	80
Sex, (m/f)	9/4	29/22	46/34
Age, mean in years (SD)	10.1 (1.3)	9.8 (1.3)	10.2 (1.3)
Food allergy, <i>n</i> (%)			
Peanut	10 (76)	33 (65)	60 (75)
Tree nuts	11 (85)	38 (75)	58 (73)
Egg	8 (62)	19 (37)	30 (38)
Milk	5 (38)	17 (33)	22 (28)
Fish	1 (8)	3 (6)	2 (3)
Shell fish	0	6 (12)	7 (9)
Wheat	4 (31)	6 (12)	10 (13)
Sesame	2 (15)	7 (14)	15 (19)
Soy	2 (15)	6 (12)	12 (15)
Celery	0	1 (2)	1 (1)
Number of food allergies, <i>n</i> (%)			
1 food	1 (8)	12 (24)	20 (25)
2 foods	3 (23)	16 (31)	22 (28)
3 foods	3 (23)	8 (16)	18 (24)
> 3 foods	6 (46)	15 (29)	20 (25)
Type of symptoms, <i>n</i> (%)			
Cardiovascular*	2 (15)	10 (20)	15 (19)
Respiratory tract†	8 (62)	28 (55)	40 (50)
Gastrointestinal tract‡	2 (15)	8 (16)	14 (18)
Skin§	1 (8)	5 (9)	8 (10)
Other¶	0	0	3 (4)

*Dizziness, feeling your heart beat fast, loss of vision, inability to stand, light headedness, collapse, loss of consciousness/passing out.

†Tightening throat, difficulty swallowing, hoarseness/hoarse voice, difficulty breathing in, shortness of breath, wheezing, cough.

‡Sick to your stomach, stomach cramps, vomiting, diarrhoea.

§Itchy skin, red rash, hives, worsening eczema, swelling of the skin.

¶Oral allergy, swollen tongue or lips, symptoms of the nose or eyes.

advertisement (40%) reported physician-diagnosed food allergies. Descriptive characteristics of the children involved in the cross-sectional validation are shown in Table 1. There were no significant differences in descriptive characteristics between boys and girls or between children who were recruited from our clinic and children who were recruited by advertisement.

Construct validity. Most items of the FAQLQ-CF correlated significantly with at least one of the FAIM questions, and most items correlated significantly with the mean of the FAIM questions. One item ('Jealous of other people who do not have a food allergy') did not correlate with any of the FAIM questions and was therefore excluded. The validated FAQLQ-CF therefore consists of 24 questions. The total FAQLQ-CF score correlated significantly with the mean FAIM ($\rho = 0.60$, $P < 0.001$) and with the individual FAIM

Table 2. Selected items for Food Allergy Quality of Life Questionnaire – Child Form

Item	%	MI	OI
Can eat fewer things	94	3.42	3.22
Must always watch what you eat	98	3.04	2.98
The ingredients of a food change	76	3.77	2.88
Limited in buying things you like	80	3.22	2.59
Frightened of an allergic reaction	65	3.88	2.51
Tasting or trying fewer things when eating out	84	2.95	2.49
Frightened of eating the wrong food by accident	69	3.43	2.35
Hesitate eating certain foods when you doubt that it is safe	90	2.59	2.33
Concerned that you will never get rid of your food allergy	57	3.79	2.16
The label states: 'May contain traces of ...'	67	3.15	2.10
Disappointed when people do not take your food allergy into account	59	3.53	2.08
Not knowing how things taste which you cannot eat	67	3.06	2.04
Frightened of eating something you have never eaten before	69	2.94	2.02
Less easily stay for a meal with someone	53	3.74	1.98
Checking yourself whether you can eat something when eating out	80	2.46	1.98
Having to read labels	86	2.16	1.86
Jealous of other people who do not have a food allergy	51	3.62	1.84
Others can eat the food you are allergic to when you do things with other people	82	2.24	1.84
Do not get anything when someone is giving treats at school	47	3.88	1.82
Feeling disappointed because you have a food allergy	59	3.03	1.78
Having to tell beforehand about what you are not allowed to eat when eating out	73	2.43	1.76
Having to explain to people around you that you have a food allergy	88	2.00	1.76
Watching out when touching certain foods	59	2.87	1.69
People around you forget that you have a food allergy	55	3.04	1.67
Refusing food when you do things with others	49	3.20	1.57

MI, mean importance; OI, overall importance.

questions (Table 3). The correlation coefficients for the FAQLQ-CF with the FAIM were the same for children with a food allergy diagnosed by DBPCFC and children with a physician-diagnosed food allergy (total FAQLQ-CF score with the mean FAIM, $\rho = 0.56$, $P = 0.003$ and $\rho = 0.59$, $P < 0.001$, respectively). These results demonstrated the construct validity of the FAQLQ-CF, i.e. the FAQLQ-CF is measuring the quality of life that is affected by food allergy.

Domain structure. The 24 items of the FAQLQ-CF were subjected to factor analysis (principal component analysis) and revealed five components with eigenvalues > 1 . To aid in the interpretation of these components, Varimax rotation was performed for five, four and three factors. An expert panel reviewed these groupings, and based on face validity, the grouping of four factors made the most sense, explaining 66% of the variance. This revealed the

Table 3. Spearman correlation coefficients for the FAQLQ-CF with the FAIM and internal consistency (Cronbach's α) of the FAQLQ-CF

	FAIM							α
	EO1	EO2	EO3	EO4	IM1	IM2	Mean	
Total FAQLQ-CF	0.34	0.35	0.46	0.38	0.43	0.56	0.60	0.94
<i>Allergen avoidance (AA)</i>								0.88
Checking yourself whether you can eat something when eating out	0.12	0.07	0.11	0.34	0.29	0.25	0.21	
Having to tell beforehand about what you are not allowed to eat when eating out	0.13	0.14	0.17	0.29	0.28	0.28	0.25	
Hesitate eating certain foods when you doubt that it is safe	0.22	0.07	0.14	0.15	0.23	0.21	0.23	
Less easily stay for a meal with someone	0.29	0.26	0.28	0.35	0.52	0.48	0.47	
Having to read labels	0.27	-0.02	0.08	0.38	0.17	0.18	0.15	
Tasting or trying fewer things when eating out	0.26	0.26	0.24	0.35	0.35	0.47	0.42	
Having to explain to people around you that you have a food allergy*	0.18	0.42	0.41	0.36	0.31	0.49	0.50	
<i>Risk of accidental exposure (RAE)</i>								0.82
People around you forget that you have a food allergy	0.18	0.42	0.45	0.15	0.32	0.54	0.57	
Others can eat the food you are allergic to when you do things with other people	0.22	0.34	0.40	0.32	0.42	0.47	0.52	
The label states: 'May contain traces of ...'	0.19	0.18	0.41	0.06	0.21	0.33	0.37	
The ingredients of a food change	0.37	0.36	0.45	0.09	0.23	0.32	0.49	
Watching out when touching certain foods [†]	0.13	0.31	0.51	0.34	0.30	0.58	0.51	
<i>Emotional impact (EI)</i>								0.87
Frightened of an allergic reaction	0.37	0.42	0.53	0.29	0.29	0.34	0.55	
Frightened of eating the wrong food by accident	0.31	0.49	0.60	0.28	0.28	0.43	0.60	
Concerned that you will never get rid of your food allergy	0.36	0.40	0.40	0.40	0.27	0.44	0.53	
Feel disappointed because you have a food allergy	0.32	0.27	0.29	0.46	0.25	0.40	0.43	
Frightened of eating something you have never eaten before	0.24	0.43	0.52	0.27	0.23	0.51	0.56	
Disappointed when people do not take your food allergy into account [‡]	0.25	0.31	0.43	0.28	0.31	0.45	0.49	
<i>Dietary restriction (DR)</i>								0.83
Can eat fewer things	0.12	-0.01	0.01	0.16	0.30	0.33	0.19	
Refusing food when you do things with others	0.05	0.10	0.10	0.28	0.34	0.32	0.28	
Not knowing how things taste which you cannot eat	0.23	0.05	0.06	0.37	0.13	0.21	0.18	
Must always watch what you eat	0.25	0.17	0.29	0.28	0.27	0.45	0.40	
Limited in buying things you like	0.22	0.30	0.36	0.29	0.41	0.41	0.45	
Do not get anything when someone is giving treats at school	0.19	0.17	0.15	0.29	0.28	0.25	0.33	

Bold indicates $P < 0.05$.

*Based on face validity, the expert panel allocated item from EI to AA.

[†]Based on face validity, the expert panel allocated item from AA to RAE.

[‡]Based on face validity, the expert panel allocated item from RAE to EI.

FAQLQ-CF, Food Allergy Quality of life Questionnaire – Child Form; FAIM, Food Allergy Independent Measure; EO1, chance of accidental exposure; EO2, chance of severe reaction when accidentally exposed; EO3, chance of dying when accidentally exposed; EO4, chance of not acting effectively when accidentally exposed; IM1, number of foods one needs to avoid; IM2, impact of food allergy on social life.

domains: allergen avoidance (AA), risk of accidental exposure (RAE), emotional impact (EI) and dietary restrictions (DR). All factors showed a number of strong loadings (AA, 0.807–0.578; EI, 0.818–0.516; RAE, 0.768–0.611 and DR, 0.877–0.497). Based on face validity, the expert panel allocated three items to a more appropriate domain (Table 3). The domains correlated significantly ($P < 0.001$) with the mean FAIM (AA, ρ 0.42; RAE, ρ 0.60; EI, ρ 0.68 and DR, ρ 0.38).

Reliability. The FAQLQ-CF and the domains had excellent internal consistency with Cronbach's α exceeding 0.70 (Table 3). The total FAQLQ-CF score ICC was 0.91 (95% confidence interval, 0.81–0.96), indicating excellent test–retest reliability.

Discriminative ability. The HRQL of children who reported more than two food allergies was clinically (i.e. > 0.5 which is the minimal importance difference [30]) and statistically significantly more impacted than the HRQL of children who reported two or less food allergies (total FAQLQ-CF score 4.3 vs. 3.6; $P = 0.036$). There was no difference in the total FAQLQ-CF score between children who reported anaphylaxis (i.e. cardiovascular symptoms) and children who did not report anaphylaxis (4.2 vs. 3.9; $P = 0.315$). If children with respiratory symptoms were added to the group of children with cardiovascular symptoms, the difference in total FAQLQ-CF score was still not significant ($P = 0.267$). In addition, no difference in total FAQLQ-CF score was found between boys and girls (3.8 vs. 4.1; $P = 0.397$) and between children who were recruited

Table 4. Spearman's correlation coefficient for the total FAQLQ-CF score and domains of the FAQLQ-CF with the CHQ-CF87 sub-scales

CHQ-CF87 sub-scales	Total FAQLQ-CF	Domains of the FAQLQ-CF			
		AA	RAE	EI	DR
Physical functioning	-0.13	-0.03	-0.10	-0.14	-0.14
Role functioning – emotional	-0.29*	-0.21	-0.24*	-0.17	-0.32**
Role functioning – behaviour	-0.15	-0.12	-0.13	-0.05	-0.17
Role functioning – physical	-0.26*	-0.18	-0.21	-0.26*	-0.24*
Bodily pain	-0.23*	-0.13	-0.21	-0.27*	-0.19
General behaviour	-0.31**	-0.34**	-0.12	-0.22	-0.29*
Mental health	-0.29*	-0.22	-0.09	-0.25*	-0.32**
Self-esteem	-0.29*	-0.24*	-0.14	-0.24*	-0.31**
General health perceptions	-0.36**	-0.27*	-0.35**	-0.44***	-0.15
Family activities	-0.45***	-0.39***	-0.35**	-0.41***	-0.32**
Family cohesion	-0.19	-0.12	-0.04	-0.18	-0.25*

* $P < 0.05$.** $P < 0.01$.*** $P < 0.001$.

Correlation coefficients are negative because a high score on the FAQLQ-CF indicates maximal impairment of quality of life, whereas a high score on the CHQ-CF87 indicates better health status.

FAQLQ-CF, Food Allergy Quality of Life Questionnaire – Child Form; AA, allergen avoidance; RAE, risk of accidental exposure; EI, emotional impact; DR, dietary restrictions.

from our clinic and children who were recruited by advertisement (3.7 vs. 4.3; $P = 0.057$).

Convergent and discriminant validity. The FAQLQ-CF correlated weakly with 8 of the 11 CHQ-CF87 sub-scales. The highest correlation was found with the CHQ-CF87 sub-scale 'Family activities'. In addition, the FAQLQ-CF domains AA, RAE, EI and DR correlated with four, three, six and seven CHQ-CF87 sub-scales, respectively (Table 4). The presence of some correlation, albeit low, indicates that both questionnaires are measuring constructs partly related (i.e. convergent validity). On the other hand, these low correlations indicate that the generic CHQ-CF87 is not as sensitive as the disease-specific FAQLQ-CF, and therefore justifies the need of a disease-specific quality of life instrument in food-allergic children (i.e. discriminant validity).

Discussion

This report describes the development and cross-sectional validation of the first self-administered disease-specific HRQL questionnaire for food-allergic children: the FAQLQ-CF. The content of this questionnaire measures the most important issues that food-allergic children have to deal with in their daily life and consequently impair their quality of life. By using the clinical impact method

for selection of the items for the FAQLQ-CF, this questionnaire consists exclusively of items that are regarded as important by children.

In addition, the items of the FAQLQ-CF point to important issues for health care providers, catering industries, food manufacturers and governments to develop and implement regulations that may improve the quality of life of food-allergic children [12]. The impact on the quality of life of items such as 'Must always watch what you eat' and 'Having to explain to people around you that you have a food allergy' may be reduced if awareness of food allergy is enhanced in the general public. Although recently, the labelling legislation has been improved for food-allergic patients in Europe and USA [31], the use of precautionary labelling has also increased. The impact of this phenomenon on the quality of life is shown by the item 'The label states; 'May contain traces of ...'. Items such as 'Able to eat fewer things' and 'Limited in buying things you like' indicate the desirability of developing new therapeutic interventions which may allow food-allergic children to eat the food to which they are allergic and consequently improve the quality of life.

In order to validate the FAQLQ-CF, we developed the FAIM, which includes four EO questions and two IM questions. The FAIM measures the child's perception of the severity of his/her condition. The FAIM is based on the approach of expectation of outcome questions that has already been successfully implemented to validate disease-specific HRQL questionnaires [11, 18], and these HRQL questionnaires were able to measure relevant and plausible changes over time (i.e. longitudinal validity) [32]. The method of expectation of outcome questions as independent measure is of special use in anaphylactic disorders where no objective measurement of the extent or severity of disease exists [13]. Moreover, purely symptom-based clinical measures would be less applicable to food-allergic patients who only experience symptoms when they are exposed to a food to which they are allergic while their HRQL is continuously affected by their condition [4]. The EO questions are based on the perceived expectation of patients of what will happen following exposure which is likely to be a driving force of the quality of life [13]. The IM questions are based on the same principle and ask about the perceived impact on the social life. The correlation coefficient we found between the FAQLQ-CF and FAIM (0.60) is in accordance with other studies using solely EO questions to validate the disease-specific HRQL questionnaires, which found correlation coefficients of 0.69 [18] and 0.41 [11], respectively. Finally, validation of the FAQLQ-CF was carried out in the Dutch language and carefully translated into English using the guidelines of the World Health Organization. The validity of the questionnaire in English and eight other European languages is currently being investigated.

The items for the FAQLQ-CF were selected by using the clinical impact method which reveals items that are clinically most important as perceived by food-allergic children. This is in contrast to the method of selecting items based on mathematical linkage between items by performing factor analyses. The latter method has the potential drawback that it may result in excluding items with a high clinical impact [29]. However, because we included items based on clinical importance rather than mathematical linkage between the items, the allocation of items into domains revealed by the factor analysis did not always make intuitive sense. Therefore, the allocation of items into domains was based on factor analysis supplemented by allocation based on face validity determined by an expert panel. Calculation of Cronbach's α showed that these domains were internally consistent, because they all had a Cronbach's α exceeding 0.70.

In the current study, the clinical impact method may also have some limitations. The number of children included in the item reduction was relatively small compared with the number of items of the extended item questionnaires. If the sample size was larger, it may be that other items gained more impact and would possibly be included in the questionnaire. However, although the sample size was relatively small, it was a representative sample, and therefore we think that the extended item questionnaire was reduced to the correct items. Another limitation of the clinical impact method may be that the selected items cover a relatively narrow range of items, resulting in a very high overall Cronbach's α .

Typically, HRQL questionnaires inquire about events during a specific period, e.g. 1 week or 1 month. However, such a restricted reporting period may result in missing important issues outside the reporting period. Moreover, many patients verbalized discontent with the short and framed reporting period of 1 week of the Food Allergy Quality of Life – Parental Burden (FAQL-PB) questionnaire [11]. Therefore, we used a less restricted reporting period. Patients were asked to complete the questionnaire according to their current state. This method will allow for before–after comparison in intervention studies and analysing changes over time without loss of important information by a restricted reporting period.

The FAQLQ-CF discriminates well between children who reported more than two food allergies and children who reported two or fewer food allergies, but there was no difference in total FAQLQ-CF score in children who reported anaphylaxis (i.e. cardiovascular symptoms) and children who did not report anaphylaxis. There may be two possible explanations for this finding. The first possibility is that many children may not remember an anaphylactic reaction well [33]. Indeed, in our patient group with a mean age of 10.2 (SD 1.3) years, we found that the most severe reaction occurred a mean of 4.2 (SD 3.4) years ago. However, we could not find any relation

between the time since the most severe reaction and the total FAQLQ-CF score ($\rho = -0.08$, $P = 0.490$), making this explanation unlikely. We thus speculate that children may be too young to realize the potentially life-threatening consequences of severe anaphylactic reactions to food. This suggests that in children, the day-to-day consequences of the food allergy itself, including the avoidance requirements and the possibility of an allergic reaction, impair the quality of life irrespective of the severity of symptoms in the past.

It is known from the literature that the minimal importance difference (MID) of HRQL questionnaires with a seven-point scale is approximately 0.5. The MID is the smallest difference in score which patients perceive as beneficial and which would mandate, in absence of troublesome side-effects and excessive cost, a change in the patient's management [30]. Therefore, the difference in total FAQLQ-CF score between children who reported more than two food allergies and children who reported two or less food allergies was not only a statistically significant difference but also a clinically significant difference. Although the MID of 0.5 is a robust estimate for HRQL questionnaires with a seven-point scale, the specific MID of the FAQLQ-CF remains to be estimated in a longitudinal survey.

The FAQLQ-CF is the first disease-specific HRQL questionnaire for food-allergic children that asks children to assess their own quality of life. It is important to ask children themselves about their quality of life, because children and parents differ in their views and judgments about the quality of life [34]. In general, parents are less able to make judgments regarding the experience of symptoms, relationships with peers or worries about the future [35]. On the other hand, it is obvious that in very young children, one can only make use of the proxy ratings of the parents. A parent-administered instrument has been developed in the context of the EuroPrevall project (FAQLQ-PF) [36], and studies are in progress to determine in which age groups one or both of these questionnaires may be used to obtain optimal measurements of HRQL in food-allergic children. Possible drawbacks of a self-administered questionnaire for children are that the result may be affected by reading limitations of children or that parents may interfere with the completion of the questionnaire. However, it has been reported that children aged 8–12 years can self-report reliably on their health status [37]. In addition, children are likely to express a level of concern regarding their food allergy that is in keeping with their usual level of concern in the home environment, and we therefore asked them to complete questionnaires at home. This also made the study less burdensome for these children and thus more feasible. To reduce unwanted parental influence as much as possible, we emphatically instructed parents and children that the children should fill out the questionnaire by themselves.

In summary, we have described for the first time a disease-specific HRQL questionnaire for food-allergic children. The FAQLQ-CF is valid, reliable and short, and it measures the most important issues that food-allergic children have to face. In addition, it discriminates between children who differ in number of food allergies and was easy to use in the population studied. Therefore, the FAQLQ-CF is a suitable questionnaire for studies of food-allergic children in which HRQL is the outcome of interest. Examples include investigation of the effect of emerging treatments such as oral immunotherapy and anti-IgE therapy on the quality of life. The instrument may be accessed directly from this publication and is available in numerous European language translations from the author.

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Appendix A: Food Allergy Quality Of Life Questionnaire – Child Form (8–12 years)

Instructions

The questions are about the influence of your food allergy on your quality of life. It is important that you fill out the answers yourself. You may ask your parents for help, but they are not allowed to tell you which answer to give. Answer every question by putting an 'x' in the proper box. You may choose from the following answers.



not



barely



a little bit



fairly



quite



very



extremely

How **troublesome** do you find it, because of your food allergy, that you ...

- 1 must always watch what you eat?
- 2 can eat fewer things?
- 3 are limited in buying things you like?
- 4 have to read labels?
- 5 have to refuse food when you do things with others?
- 6 can less easily stay for a meal with someone?
- 7 can taste or try fewer things when eating out?
- 8 have to tell beforehand about what you are not allowed to eat when eating out?
- 9 have to check yourself whether you can eat something when eating out?
- 10 hesitate eating certain foods when you don't know if it is safe?
- 11 must watch out when touching certain foods?
- 12 don't get anything when someone is giving treats at school?

☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐

How **troublesome** is it, because of your food allergy, ...

- 13 that the ingredients of a food change?
- 14 that the label states: 'May contain traces of ...'?
- 15 that you have to explain to people around you that you have a food allergy?
- 16 that people around you forget that you have a food allergy?
- 17 that others can eat the food you are allergic to when you do things with other people?
- 18 that you don't know how things taste which you can't eat?

☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐

How **frightened** are you because of your food allergy ...

- 19 of an allergic reaction?
- 20 of eating the wrong food by accident?
- 21 to eat something you have never eaten before?

☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐

Answer the following questions:

- 22 How **concerned** are you that you will never get rid of your food allergy?
- 23 How **disappointed** are you when people don't take your food allergy into account?
- 24 How **disappointed** do you feel because you have a food allergy?

☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐
☐	☐	☐	☐	☐	☐	☐

Appendix B: Food Allergy Independent Measure – Child Form (8–12 years)

The following four questions are about the chance that you think you have of something happening to you because of your food allergy. Choose one of the answers. This is followed by two more questions about your food allergy. Answer every question by putting an 'x' in the box next to the proper answer.

0 1 2 3 4 5 6
 never (0% chance) very small chance small chance fair chance big chance very big chance always (100% chance)

How big do you think the chance is that you . . .		0	1	2	3	4	5	6
a.	will accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
b.	will have a severe reaction if you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
c.	will die if you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐
d.	can <u>not</u> do the right things for your allergic reaction should you accidentally eat something to which you are allergic?	☐	☐	☐	☐	☐	☐	☐

e.	How many foods are you unable to eat because of your food allergy?	f.	Everyone does things with other people, such as; playing with friends, going to a birthday party, visiting, staying over with someone for a meal or eating out. How much does your food allergy affect things you do with others?
☐ almost none		☐ so little I don't actually notice it	
☐ very few		☐ very little	
☐ a few		☐ a little	
☐ some		☐ moderately	
☐ many		☐ a good deal	
☐ very many		☐ a great deal	
☐ almost all		☐ a very great deal	