

Validation of a Disease-Specific Questionnaire for Measuring Parent-Reported Health-Related Quality of Life in Children with Allergies

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Scand J Caring Sci; 2012

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Purpose: To evaluate the properties and suitability of a disease-specific questionnaire to assess parent-reported health-related quality of life (HRQL) of children and parents of children suffering from food hypersensitivity (FHS) or allergy to furred pets (AFP).

Methods: The parents of 202 children with FHS and of 131 children with AFP filled in questionnaires comprising the CHQ-PF28 and the Food-Pet-Allergy in Children (FPAC) Questionnaire. Psychometric properties of the FPAC questionnaire were evaluated separately for FHS and AFP.

Results: Analyses resulted in five proposed scales: Limitations of Family/Child Activities (I), Parents' Distress (II),

Child's Emotions (III), Child in School (IV) and Family Conflicts (V). Convergent/discriminant validity for scales I, II and III of both questionnaires was high; for scale IV it was moderate. All five FHS and four AFP scales were able to distinguish significantly between children with and without clinical allergy symptoms (known-group validity). Internal consistency reliability was good for scales I, II and III, but poor for scale IV.

Conclusion: Three valid scales were determined for both FHS and AFP (Limitations of Family/Child Activities, Parents' Distress and Child's Emotions) and can be used in clinical research.

Keywords: quality of life, childhood, furred pet allergy, food hypersensitivity.

Submitted 10 April 2011, Accepted 30 January 2012

Introduction

Among children and adolescents, the prevalence of allergies to furred pets (AFP) has been estimated to 15–18% (1) and the corresponding figure for perceived food hypersensitivity (FHS) has been estimated to 20–35% (2–4), of which 6–8% can be diagnosed as food allergies (5). In order to make it possible to investigate the health-related quality of life (HRQL) in children suffering from AFP and/or FHS, we designed a disease-specific questionnaire: The Food-Pet-Allergy in Children (FPAC) Questionnaire. In this study, we present the psychometric characteristics of the FPAC questionnaire.

The concept of HRQL involves the respondents' perceptions of their own well-being and functioning in physical, emotional, mental, social and everyday life areas (6, 7). Today, assessment of self- or parent-reported HRQL has become an important outcome measure in paediatric nursing and medical research and an important tool in estimating the burden of a disease for a child and/or family (8, 9).

Several generic instruments measuring parent-/proxy-reported HRQL in children have been developed and validated, for example, The Child-Health Questionnaire Parental Form 28 (CHQ-PF28) (10). Generic questionnaires allow comparisons of the burden of a disease across different medical diseases/conditions (11). However, disease-specific issues of importance affecting the HRQL may go undetected owing to the general phrasing in generic instruments (11, 12). Therefore, as generic instruments are fairly blunt for the purpose of capturing detailed HRQL information regarding a certain disease/condition, disease-specific questions add valuable research and clinical

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information on specific areas of importance to the respondent in relation to the disease/condition. Furthermore, a disease-specific questionnaire is better in detecting small but important differences in HRQL (13). Therefore, a combination of generic and disease-specific questionnaires is recommended, in order to provide data of both breadth and depth (14, 15).

We have performed studies where the parent-reported HRQL in children with FHS or with AFP was investigated (16, 17). At the time when these studies were planned, no disease-specific questionnaires for children with food hypersensitivity or allergic reactions to furred pets were available. To elucidate the parental perceptions of limitations in daily life, as well as consequences and/or emotional impact of the child's condition on the child's and the parents' life situation, the Food-Pet-Allergy in Children (FPAC) Questionnaire was developed. The development of the questionnaire was based on clinical experience, scientific literature and interviews with children and their parents.

During recent years some new disease-specific HRQL instruments concerning food allergy in children have been developed (9, 18–20). However, no disease-specific questionnaire has yet been presented for children with allergic reactions to furred pets.

A validated disease-specific HRQL questionnaire for children suffering from FHS or AFP would be of great importance for longitudinal and comparative evaluations, but also in order to provide benchmarks to assess the effectiveness of nursing and medical interventions developed to mitigate the impact of disease on the HRQL of children and parents. The aim of this study was therefore to evaluate the psychometric characteristics of the FPAC questionnaire.

Methods

Subjects and procedure

The Swedish birth cohort project BAMSE from which our subjects were recruited has been described in detail elsewhere (21, 22). In brief, background data on 4089 infants born in predefined areas of the Stockholm region between 1994 and 1996 were ascertained from parents when their children were approximately 2 months old. During a 4-year follow-up period, parents were requested for data about symptoms of allergic diseases. At the age of 4 years, 328 children were identified as having AFP and 689 children having FHS. When the children were 9 years old, the parents were sent the FPAC questionnaire and the generic HRQL Child-Health Questionnaire, Parental Form 28 (CHQ-PF28) (10). The response rates reached 74% for parents of children with FHS and 79% for parents of children with AFP. An analysis of the incoming questionnaires showed that 202 children still suffered from FHS and 131 from AFP, according to their parents (16, 17).

For the present evaluation of the psychometric characteristics of the FPAC questionnaire, we have used questionnaire data from the 202 identified children with FHS and the 131 children with AFP.

FPAC

The FPAC Questionnaire was developed by the authors for measuring HRQL among children with parent-reported AFP and/or FHS. To develop the questionnaire, we interviewed both children with reactions to food and/or pets and their parents in order to identify important areas of their daily life. Based on these interviews, scientific literature and our own clinical knowledge, we developed a first version of the FPAC. The questionnaire was divided into two similar sections to be filled in by parents of children considered to have FHS (section 1, 67 items) or AFP (section 2, 67 items), respectively. The sections directed to parents whose child reacted to food or pets were similar, except for the wording.

A first test version of the FPAC was distributed to parents ($n = 10$) who had 8–9-years-old children with food and/or pet allergies but were not part of the BAMSE study. Their comments prompted only minor revisions.

For the core validation part (e.g. factor analysis), the 67 original items in section 1 and 2 of the FPAC were reduced to 24 FHS and 29 AFP items, respectively, in order to concentrate mainly on indicator variables for the child's/parents' HRQL: aspects of daily life (child/parents), limitations in social activities (child/parents), limitations in school work or in school activities (child), the child's feelings and worry experienced by the parents, conflicts within the family (child/parent) and overall measure of the child's HRQL. Assessments for each of the items were made on a 4-point Likert scale. Items are summarized in Table 1. Items not included in the core validation part captured the disease (FHS, AFP) including symptoms, medications and the economic situation of the family.

Moreover, three global questions (G1, G2, G3) in each of the two questionnaires were used to elicit a global appraisal of the parents' concern about the child's allergy (G1) and also of their perception of their own (G2) and the child's HRQL (G3). Clinical symptoms were used to evaluate known-group validity.

CHQ-PF28

The Child-Health Questionnaire (CHQ) Parental Form (PF) 28 captures parents' or caregiver's views of a child's HRQL. This version has been translated into Swedish and validated in children aged 9–16 years (23, 24). It encompasses 28 items, focusing on the physical and psychosocial functioning and well-being of the child and its family, and it aggregates to 13 subscales: Physical Functioning (three items), Role/social limitations-Emo-

Table 1 Areas and items covered by the FPAC (food-pet-allergy in children) questionnaire and used for the evaluation of psychometric characteristics (only abbreviated item stems are presented)

<i>Items included to evaluate psychometric characteristics of FHS section of the FPAC questionnaire (total: 24 items)</i>	<i>Items included to evaluate psychometric characteristics of AFP section of the FPAC questionnaire (total: 29 items)</i>
1. Family has adjusted the diet 2. Family has to abandon from activities/change plans 3. Family must plan vacations/travels carefully 4. Social interactions with friends are negatively impacted Due to the food allergy the child cannot: 5. eat in a friend's house 6. stay overnight in a friend's house 7. eat in restaurants 8. The child can participate in all school activities without having any symptoms 9. The parents feel confident that school staff can cope with child's food allergy symptoms Parents are concerned about: 10. child's acute symptoms 11. child's acute symptoms when they are not around 12. food allergy will worsen in future 13. that they will overprotect the child 14. leaving the child with a babysitter for an evening 15. the negative impact on child's future health 16. how to teach the child what food he/she has to avoid 17. that the child will not get the nourishment required 18. The child ponders about the food allergy 19. The child feels sad about having food allergy 20. The child is worried about having acute symptoms of food allergy 21. The child feels different from others 22. The child believes that the food allergy will disappear later in life 23. The child feels restricted in its daily life 24. Family conflicts due to child's food allergy	Family avoids meeting furred pets: 1. due to the child's furred pet allergy 2. because other family members have allergy to furred pets 3. because relatives/friends have allergy to furred pets 4. Family members have to abandon contact with horses due to child's pet allergy 5. Family has to abandon from activities/change plans 6. Family must plan vacations/travels carefully 7. Social interactions with friends are negatively impacted Due to the furred pet allergy the child cannot: 8. play in a friend's house who has pets 9. play outside with friends who have pets 10. stay overnight in a friend's house who has pets 11. have contact with horses 12. The child can participate in all school activities without having any symptoms 13. The school has made arrangements to protect the child from getting symptoms 14. The child can sit to pet owning friends without having symptoms 15. The parents feel confident that school staff can cope with child's symptoms 16. The child ponders about the furred pet allergy 17. The child feels sad about having furred pet allergy 18. The child is worried about having acute symptoms of furred pet allergy 19. The child feels different from others 20. The child believes that the furred pet allergy will disappear later in life 21. The child is disappointed 22. The child feels restricted in its daily life Parents are concerned about: 23. child's acute symptoms 24. child's acute symptoms when they are not around 25. furred pet allergy will worsen in future 26. that they will overprotect the child 27. leaving the child with a babysitter for an evening 28. the negative impact on child's future health 29. Family conflicts due to child's furred pet allergy

tional/Behavioural (one item), Role/social limitations-Physical (one item), Bodily Pain (one item), Behaviour (four items), Mental Health (three items), Self-Esteem (three items), Perceptions of General Health (four items), Change in Health (one item), Parental impact–Emotional (two items), Parental impact–Time (two items), Family Activities (two items) and Family Cohesion (one item).

Generally, items and scales were scored so that a higher score indicated better HRQL. All parents filled in the CHQ-PF28.

Ethical permission for the 9 years follow-up of the BAMSE cohort was obtained from the Ethical Committee at Karolinska Institutet, Stockholm, before any participant was informed and enrolled.

Statistical methods

Food hypersensitivity, AFP and the CHQ-PF28 scales were transformed into a common 0–100 scale. Global questions were rated on a 10-cm visual analogue scale. Recoding and calibration of CHQ-PF28 items were performed according to the author's recommendations (10). Generally, higher scores indicated greater well-being or HRQL.

The psychometric validation of both FHS and AFP questionnaires followed generally accepted guidelines (25). The items of both questionnaires consisted of a mixture of causal and indicator variables. Indicator variables were chosen with a view to tapping into the presumed underlying concept of HRQL, whereas causal variables refer to phenomena that cause a change in HRQL (26). We used exploratory factor analysis (EFA) as a means of exploring the structure of the new questionnaires. EFA assumes that the underlying construct is reflected by the items in the factors and it is known that the presence of causal variables may elicit misleading results (26, 27). Therefore, we ran our EFA on the 24 and 29 indicator variables of FHS and AFP, respectively. Causal items were used to assess known-group variability. Varimax rotation and the mineigen criterion (i.e. eigenvalues greater than 1) were used to extract factors. Factor loadings above 0.5 were used to assess the importance of the items in each factor. EFA results were used as a starting point for further rearrangement of factors. Global questions were not part of the EFA.

Multitrait-scaling analysis was employed to address convergent and discriminant validity (28). Correlations between FHS and AFP scales, respectively, and the global questions were evaluated. Furthermore, convergent validity was examined by correlating FHS and AFP scales, respectively, with CHQ-PF28 scales, using Pearson's product moment correlation coefficients; statistical tests were two-tailed two-tests.

Evidence of known-group validity was assessed by comparing children suffering from breathing difficulties or persistent cough (which are common symptoms of asthma in childhood if they are present in the absence of common cold) with children who were free of these symptoms.

Reliability in terms of internal consistency was analysed by means of Cronbach's α . An α above 0.7 was regarded as acceptable (28). We employed SAS software (SAS Institute Inc. Cary, NC, USA version 9.1) for all analyses.

Results

Patient characteristics

A total of 202 children with FHS and 131 with AFP were included in the study. Nearly 80% of the children in both groups suffered from typical clinical symptoms, most com-

Table 2 Children's demographic and disease characteristics

	FHS	AFP
No. of patients	202	131
Age (years)		
Mean (range)	9 (8–10)	9 (7–10)
Sex (%)		
Boys/Girls	58/42	62/38
Proportion (%) of children with symptoms		
Any	79.3	80.5
Breathing difficulties/persistent cough	15.8	45.7
Runny nose/sneezing	27.9	55.5
Itching/watery eyes	28.2	66.4
Eczema	45.8	21.0
Urticaria	74.8	10.6
Other allergic symptoms	28.5	5.1
Frequency of symptoms (% of children)		
Rarely	66.2	69.5
Often	34.7	30.5
Proportion (%) of children who have family members with FHS/AFP	62.5	62.8
Proportion (%) of children taking medication to treat/prevent symptoms from FHS/AFP in last 12 months	56.5	78.2

monly urticaria (74.8%) in both groups. Eczema (45.8%) and itching/watery eyes (66.4%) were frequently reported in the FHS cohort, and runny nose/sneezing (55.5%) in the cohort with children suffering from AFP.

For the majority of the children, other family members also suffered from FHS or AFP. Further details are shown in Table 2.

Construct validity

Food hypersensitivity. Five factors were extracted by EFA, explaining 51%, 9%, 6%, 6%, 5% of the total variance, respectively. Factor 1 (seven items) addressed limitations of family and child activities (items 1–7, see Table 1 left panel for content of items). After reassigning three items from factor 3 to factor 2, factor 2 (eight items) addressed parents' distress (items 10–17, Table 1 left panel) very well. Some items, which also loaded on factor 1, were finally merged with factor 3 (six items) to represent child's emotions (items 18–23, Table 1 left panel). Factor 4 (two items) covered the two items related to the child in school (items 8, 9, Table 1 left panel), and factor 5 was again a single item factor representing family conflicts (item 24, Table 1 left panel).

Allergy to furred pets. Exploratory factor analysis resulted in seven factors, explaining 41%, 9%, 7%, 6%, 5%, 4%, 4% of the total variance, respectively. Factors 1 and 3 mainly covered items related to limitations of the family and the

child's activities (items 1–11, Table 1 right panel). Therefore, it was decided to combine the two factors to a new one (factor I, 11 items). Factor 2 (items 23–28, Table 1 right panel) was clearly associated with items addressing the distress experienced by parents (factor II, six items). Factor 4 (items 16–22, Table 1 right panel) covered items related to child's emotion (factor III, seven items), and factor 5 and 6 (items 12–15, Table 1 right panel) were combined to a new factor addressing the child's problems in school (factor IV, four items). Finally, item 29 proved to be a stand-alone item tapping into 'family conflicts'.

Food hypersensitivity and Allergy to furred pets scales. By summing up item values within a factor, and transforming them into scores ranging from 0 to 100, the following scales were generated for both questionnaires:

- I** Limitations of Family/Child Activities;
- II** Parents' Distress;

- III** Child's Emotions;
- IV** Child in School; and
- V** Family Conflicts

Convergent and discriminant validity

Multitrait-scaling analyses were conducted for the five scales of each questionnaire. Table 3 summarizes convergent and discriminant scaling rates and the scaling success rate. Almost all items were more highly correlated with their own scale than with other scales, leading to a scaling success rate higher than 89% for the first three scales of both questionnaires. For the fourth scale, the scaling success rate was only 50%.

The correlation between the three global items and the scales was used to address convergent validity of the five scales. As expected, significant ($p < 0.05$) positive correlations were found for all three global items and the FHS

Table 3 Multitrait-scaling analysis for the FHS and AFP scales

Scale	FHS				AFP			
	#Items	Corr. with own scale ^a	Corr. with other scales ^b	Scaling success ^c	#Items	Corr. with own scale ^a	Corr. with other scales ^b	Scaling success ^c
Limitations of Family/Child Activities	7	0.34–0.78	0.00–0.54	27/28 (96.4%)	11	0.31–0.76	0.07–0.58	42/44 (95.5%)
Parents' Distress	8	0.27–0.70	0.02–0.62	30/32 (93.8%)	6	0.52–0.73	0.10–0.56	24/24 (100%)
Child's Emotions	6	0.17–0.66	0.00–0.55	23/24 (95.8%)	7	0.26–0.61	0.00–0.62	25/28 (89.3%)
Child in School	2	0.31	0.14–0.48	4/8 (50%)	4	0.05–0.36	0.11–0.53	8/16 (50%)
Family Conflicts	1	–	0.16–0.20	–	1	–	0.12–0.26	–

^aRange of item–scale correlations (corrected for overlap).

^bRange of absolute correlations between an item and other scales.

^cPercentage of cases in which an item correlates higher with its own scale (corrected for overlap) than with other scales.

Table 4 Pearson's correlations between global items and FHS and AFP scales

Scale	FHS			AFP		
	Global Items			Global Items		
	G1 ^a	G2 ^b	G3 ^c	G1 ^a	G2 ^b	G3 ^c
Limitations of Family/Child Activities	0.55***	0.42***	0.28***	0.55***	0.32***	0.29**
Parents' Distress	0.78***	0.37***	0.25***	0.63***	0.46***	0.31***
Child's Emotions	0.58***	0.40***	0.16*	0.49***	0.39***	0.25**
Child in School	0.38***	0.36***	0.27***	0.36***	0.21*	0.18*
Family Conflicts	0.15*	0.16*	0.13	0.08	0.29**	0.31***

* $p < 0.05$ (two-tailed); ** $p < 0.01$ (two-tailed); *** $p < 0.001$ (two-tailed).

^aParents' concern about the child's allergy (G1).

^bParents' perception of their HRQL (G2).

^cParents' perception of the child's HRQL (G3).

scales, except for G3 and scale 5. Similar results were obtained for the five AFP scales and the global items, except for G1 and scale 5 (Table 4).

Fifty-three out of 75 correlations between the CHQ-PF28 and FHS scales were significant ($p < 0.05$); 19 of them showed a correlation coefficient larger than or equal to 0.3, and correlations above 0.4 were achieved for three sub-scales: General Health and factor I, Parental Time and factor I, and Parental Impact–Emotional and factor II. Significant correlations between AFP and CHQ-PF28 scales were found in 45 of 75 cases; 18 were larger than or equal to 0.3, and four were at least 0.4: between General Health and factor I, II and III and between Parental Impact–Emotional and factor II (data not shown).

Reliability and scale score distribution

Table 5 shows the scale score distribution and internal consistency characteristics of the FHS and AFP scales. The mean score values of FHS scales ranged between 73.4 and 93.0, whereas mean AFP scale values tend to be lower and ranged between 62.6 and 91.3. Cronbach's α was acceptable (≥ 0.7) for scales I and II of both questionnaires, indicating reasonable scale coherence, and was low for scales III and IV. The skewness was negative in all cases, indicating left skewed data. The ceiling effect was low for the FHS scales II and III ($< 19\%$), moderate for scales I, II and IV, but high for scale V. For the AFP scales, the ceiling effect was high for scale V, but low for the other scales.

Known-group validity

Evidence for known-group validity was obtained by comparing FHS scale scores as well as AFP scales between children with and without breathing difficulties/cough (Table 6). For all five FHS scales and two global questions

Table 6 Comparison of children with/without breathing difficulties/persistent cough (known-group validity)

Scales ^a	FHS		APF	
	Breathing difficulties/cough		Breathing difficulties/cough	
	Without	With	Without	With
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
I	90.2 (16.0)	78.6 (26.1)***	74.0 (2.8)	58.8 (21.3)***
II	80.7 (18.9)	69.3 (23.1)**	73.5 (21.9)	66.1 (20.3)*
III	75.3 (15.0)	64.6 (18.0)***	66.7 (13.9)	57.7 (15.1)***
IV	86.3 (19.3)	78.1 (19.6)*	68.1 (18.8)	60.9 (17.4)*
V	94.3 (16.4)	86.0 (18.8)*	93.1 (13.6)	88.5 (18.4)
G1	76.2 (26.4)	58.0 (31.9)**	77.3 (22.9)	62.9 (26.3)**
G2	88.3 (12.7)	79.1 (18.6)***	86.1 (13.6)	83.1 (14.0)
G3	80.7 (18.7)	75.7 (21.7)	83.5 (14.1)	79.4 (18.3)

* $p < 0.05$ (two-tailed); ** $p < 0.01$ (two-tailed); *** $p < 0.001$ (two-tailed).

^aLimitations of Family/Child Activities (I), Parents' Distress (II), Child's Emotions (III), Child in School (IV), Family Conflicts (V);¹ Parents' concern about the child's allergy (G1); Parents' perception of their HRQL (G2); Parents' perception of the child's HRQL (G3).

of the FHS section and for the first four APF scales and the first global question of the APF section of the questionnaire, children who were free of breathing difficulties/cough displayed significantly higher scores than patients with these symptoms. Similar results were obtained for urticaria and eczema (data not shown).

Discussion

This study presents a new instrument developed from a population-based sample for measuring the HRQL for children with allergies and their families, and gives the psychometric properties of the instrument.

Table 5 Score distribution and internal consistency of the FHS and AFP scales

Scales ^a	FHS					AFP				
	#Items	Mean (sd)	Cronbach's alpha	Skewness	%Ceiling ^b	#Items	Mean (sd)	Cronbach's alpha	Skewness	%Ceiling ^b
I	7	88.4	0.86	−2.31	45.4	11	66.8	0.87	−0.34	9.2
II	8	79.1	0.84	−1.13	18.7	6	69.6	0.85	−0.48	14.0
III	9	73.4	0.65	−1.13	3.5	7	62.6	0.63	−0.41	1.5
IV	2	85.4	0.47	−1.77	49.5	4	64.4	0.40	−0.69	3.9
V	1	93.0	–	−2.89	82.6	1	91.3	–	−1.64	75.4
G1	1	74.2	–	−1.09	6.8	1	77.0	–	−0.83	3.2
G2	1	86.4	–	−1.58	9.6	1	84.8	–	−1.46	4.1
G3	1	79.8	–	−1.36	6.1	1	81.8	–	−1.42	3.3

^aLimitations of Family/Child Activities (I), Parents' Distress (II), Child's Emotions (III), Child in School (IV), Family Conflicts (V); Parents' concern about the child's allergy (G1); Parents' perception of their HRQL (G2); Parents' perception of the child's HRQL (G3).

^bProportion of parent-reported results showing maximum scale value.

Research on HRQL has become an increasingly important issue within nursing and medical research during the past few years, but it is associated with methodological difficulties (14, 15, 29–31). The clinical importance of a statistically significant change in HRQL is not obvious. This is why the concept of minimal clinically important difference (MCID) has been developed (32), something that must be investigated separately once an instrument is fully developed and tested.

It has been shown that allergic diseases including FHS in children can affect their and their families' health-related quality of life negatively (9, 12, 18, 32–35), but little is known of what factors are of importance in this context. To investigate this, the importance of disease-specific questions/questionnaires has been highlighted (15, 34, 35). This is not the least important knowing that FHS in most cases is characterized by the absence of physical symptoms, but instead often is presented as living with a constant fear for suffering from symptoms. Other groups of researchers have added valuable knowledge in this field by developing disease-specific questionnaires regarding FHS, but as pointed out by others (18, 19, 35), no such studies has before our study been published on a population-based material. Furthermore, no studies on how and whether allergy to furred pets in children affects their HRQL have to our knowledge yet been published. By using data obtained from the BAMSE cohort, we aimed at evaluating the psychometric characteristics of a new, disease-specific questionnaire whose two sections can be used to collect HRQL data.

The evaluation of construct validity by exploratory factor analysis revealed no unambiguous structure for either the FHS or the AFP questionnaire. Reassignment of some items and combining factors led to similar satisfactory 5-scale solutions (I Limitations of Family/Child Activities, II Parents' Distress, III Child's Emotions, IV Child in School, V Family Conflicts) for both questionnaires, enabling a meaningful interpretation. Scale III ('Child's Emotions') in the FPAC can be found also in other validated instruments (9, 19), but has never been investigated in this age group why this study adds valuable new knowledge.

The scaling success rates of scales I, II and III in both the questionnaires were very high ($\geq 89\%$), whereas for scale IV only a value of 50% could be achieved. The items forming scale IV were only weakly intercorrelated, suggesting that they might tap into different underlying constructs instead of just one.

The statistically significant positive correlations (>0.4) between the General Health scale of the CHQ-PF28 and scale I of the FHS questionnaire, and scales I (Limitations of Family/Child Activities), II (Parents' Distress) and III (Child's Emotions) of the AFP questionnaire indicate that, apart from disease-specific components, these scales also ascertain the parents' perception of their children's general health. For both questionnaires, the significant correla-

tions between the CHQ-PF28 scale PE (Parental Impact-Emotional) and scale II (Parents' Distress) suggest that scale II aims at the parents' distress regarding the child's physical health and emotional well-being. Moreover, the limitations in personal time owing to the child's disease and the related emotional and physical problems are emphasized in the significant correlation between the CHQ-PF28 scale Parental Impact-Time and scale I (Limitations of Family/Child Activities).

There was evidence with regard to the important concept of known-group validity for both questionnaires. Breathing difficulties/cough, but also eczema and urticaria, are known problems for children suffering from food or furred pet allergy (36,37). Almost all scales of both questionnaires were able to distinguish in the predicted direction between groups of patients with or without these clinical symptoms.

The ceiling effect for scales I, II, III and IV was moderate ($\leq 50\%$ for FHS, $\leq 15\%$ for AFP), whereas a high (82.6% for FHS, 75.4% for AFP) ceiling effect was observed for scale V, which represents a stand-alone item addressing family conflicts related to the choice of the child's medication but also regarding how to avoid the child's exposure to the allergens. The questionnaire could be further strengthened, either by dropping the entire scale because there is obviously no conflict between family members or by adding more specific questions to expand the whole domain. For both questionnaires, Cronbach's alpha was quite high for scales I, II and III, indicating that item coherence was strong within the scales (≥ 0.63) and moderate for scale IV.

Conclusions

In conclusion, this work added psychometric validity results to the FPAC questionnaire, which addresses parent-reported HRQL of children suffering from AFP and/or FHS. The first three scales capturing limitations of family/child activities, parents' distress and child's emotions can be regarded as valid and possible to use in clinical research, whereas scales IV and V of both questionnaires need further refinement.

Authors' contribution

A Gardulf, A-C Egmar, E Östblom and G Nordström developed the FPAC questionnaire, and A-C Egmar and E Östblom collected the data. U Nicolay was responsible for all the data analyses and is the main author of the manuscript together with A Gardulf. All the authors have read, contributed to and approved the manuscript.

Acknowledgements

The study was supported financially by the Centre for Allergy Research, Karolinska Institutet; the Swedish

Asthma and Allergy Foundation; the Swedish Heart and Lung Foundation; the Vardal Foundation for Health Care Sciences and Allergy Research; Mjölkdroppen; The Red Cross University College; and the Stockholm County

Council, Stockholm, Sweden. The authors are grateful to all parents for taking the time to answer the FPAC. We are also very grateful for help with the language revision by Ms Hilary Hocking, Östersund, Sweden.

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