Development, validation and outcome of health-related quality of life questionnaires for food allergic patients

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Chapter 8

Quality of life in food allergy: valid scales for children and adults

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Anthony E.J. Dubois

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Abstract

Purpose:
The purpose of this review is to give an overview of how health-related quality of life (HRQL) can be measured in food allergy and to explore recent findings on how food allergy might impact HRQL.

Recent findings:
In addition to the more familiar burdens of having a food allergy, the psychosocial impact of food allergy and information gaps concerning food allergy have received much attention in the recent literature. Recently, reliable and valid disease-specific HRQL questionnaires have become available to measure the impact of food allergy on HRQL in food allergic patients of all ages.

Summary:
Assessment of HRQL could be used by clinicians to get insight in the specific problems patients have to face. In addition, HRQL measurements may be used to measure the effects of an intervention on the patient’s quality of life. Finally, HRQL is the only available measure reflecting the ongoing severity of food allergy, since no objective disease parameters are available.
Introduction

Living with a food allergy is increasingly being recognised as being more difficult than is generally appreciated. Management of food allergy includes avoidance of the culprit food in numerous situations which may interfere with daily life. In addition, there is always a chance of accidental exposure which may lead to a (severe) allergic reaction. This may in turn be a source of anxiety. When a severe allergic reaction occurs, prompt and accurate administration of epinephrine may be required which by itself may provoke anxiety about being able to respond adequately. Therefore, food allergy may have a considerable impact on quality of life.

What is quality of life?

Although there is no consensus on the definition of quality of life, a constructive definition has been drawn up by the World Health Organisation (WHO): “the individual’s perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.” The component of overall quality of life that concerns an individuals’ health is called health-related quality of life (HRQL) and may be defined as “the effects of an illness and its consequent therapies upon a patient as perceived by the patient.” HRQL is a multidimensional concept that consists of bio-psycho-social domains such as physical and psychological status and social interaction.

How might food allergy influence HRQL?

Since there is no cure available for food allergy, the only form of treatment is strict avoidance of foods causing allergic reactions and provision of emergency treatment. The difficulty of this treatment is that it may take considerable effort in daily life and that success is not guaranteed. There is always a chance of accidental exposure. Consequently, this might influence HRQL.

Allergen avoidance and allergic reactions

Allergen avoidance, aiming to prevent allergic reactions, may include numerous actions in different settings in daily life in which food allergic patients have to relay on external factors for their safety. It has been reported that ingredients lists were insufficient for the needs of food allergic patients and that ingredients of pre-packed products were frequently changed which was perceived as frustrating. In addition, it was shown that a considerable percentage of restaurant personnel have insufficient knowledge about food allergy. Despite this, they expressed relatively
high comfort levels in providing safe meals to food allergic patients. The premise that accidental exposure may occur in any situation is underlined by a study that showed that 9% of food allergic patients who had been on board of an airplane reported experiencing an allergic reaction there. Even more alarming was the finding that the information about flying with food allergies was in some cases incomplete or inaccurate. Therefore, in addition to the need of food allergic patients to be vigilant in various situations involving food, they are often reliant on external information which may very well be unreliable.

**Anxiety and psychological impact**
Food allergy may be a psychological burden with high levels of stress and anxiety for the food allergic patient and, in the case of children, also for their parents. Mothers with a food allergic child reported that they experienced parenting such a child as “living with risk.” The pervading theme expressed by adolescents with food allergy was “striving to normalise the experience of being food allergic.” These adolescents experienced deprivation, insecurity and fear of severe allergic reactions, but most of them ultimately felt competent in dealing with their food allergy. Lastly, it has been reported that adolescents perceived anaphylaxis as “no big deal” whereas their parents described a large impact on their own day-to-day life. Thus, food allergy may have a considerable psychological impact and may provoke anxiety in food allergic patients and in parents of food allergic children. The lower levels of anxiety sometimes reported by adolescents may not be justified.

**Uncertainty and information gaps**
Having a food allergy implies being “at risk” for an allergic reaction and this inevitably invokes uncertainty. Moreover, no biological markers are available to predict who will or who will not have an anaphylactic reaction in the future. Uncertainties concerning food allergy may arise from a lack of information. One way to deal with uncertainties caused by lack of information is to join a patient organisation. Recently, it was shown that parents themselves had a solid foundation of food allergy knowledge, but that they had concerns about the food allergy knowledge of primary care physicians. The general public had a wide variation in knowledge of food allergy with many misconceptions. Such knowledge gaps, especially among physicians and the general public, may have a negative impact on the HRQL of food allergic patients and parents of food allergic children.

**Why is HRQL measurement important?**
The importance of measuring HRQL may be addressed from different points of view. First of all, measurement of HRQL gives insight in the impact of disease
from the patient’s perspective. It is, for example, possible that two patients with the same objective clinical impairment may have very different degrees of impairment in their HRQL. HRQL assessment could be used by clinicians to get insight in the specific problems patients have to face and to help them coping with those issues. HRQL questionnaires can usually be completed by the patient in less than 15 minutes and are thus suitable for administration just before the clinical interview (e.g. in the waiting room). During the clinical interview, the clinician could discuss areas most affecting HRQL with the patient and help them to manage the mentioned problems. Follow-up measurement over time gives the clinician and patient insight in the effect on HRQL of the chosen management.

In research, HRQL measurements may be used to measure the effects of interventions generally on patients’ quality of life, which could help improve the quality of patients’ treatment and outcome. HRQL measurements may also be used to compare the effect of different interventions and to compare the impact of different diseases on HRQL. Such HRQL studies may be used by policy makers to improve the allocation of health care resources. Ultimately, combining HRQL data with epidemiologic data on prevalence may give insight in the societal impact of a disease.

Finally, with regard of food allergy, it is important to note that there are no objective disease parameters available to measure the ongoing severity of food allergy, such as FEV1 in asthma. One could measure the severity of a food allergic reaction, but allergic reactions occur only when a patient is exposed to a culprit food. Despite the absence of actual symptoms, food allergy has an ongoing severity due to the allergen avoidance requirements and resulting psychosocial burden. HRQL is the only available measure reflecting this ongoing severity of food allergy.

How to measure HRQL?

HRQL can be measured with questionnaires, also called as instruments or scales. There are two types of HRQL questionnaires; generic and disease-specific questionnaires. The major psychometric properties of questionnaires are reliability and validity.

**Generic and disease-specific questionnaires**

Generic questionnaires are developed for use in different diseases and general populations. Thus, these questionnaires allow comparison between different diseases. The disadvantage is that they may not focus adequately on problems specific to a particular disease and that they also measure the impact of comorbid diseases. Disease-specific instruments are developed for use in a specific population. These questionnaires are much more likely to detect clinically important changes in patients’ impairments. The disadvantage is that do not allow comparison between different diseases.


**Reliability and validity**

Reliability refers to the extent to which the questionnaire is repeatable and consistently produces the same results. Reliability is most commonly evaluated by assessment of internal consistency and test-retest analysis (Table 1). Validity is the degree to which the questionnaire measures what it is intended to measure. There are two types of validity: internal and external validity. Internal validity refers to the internal structure of the questionnaires and is usually evaluated by factor analysis, inter-item correlations and floor- and ceiling effects. External validity is the relationship between the questionnaire and an external criterion (e.g. other measures of the same or different dimensions of health) and the most common types are face, content, convergent/discriminant and construct validity.

**Table 1. Types of reliability and validity commonly used to evaluate HRQL questionnaires.**

<table>
<thead>
<tr>
<th>Reliability</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal consistency</strong></td>
<td>Refers to how well the items of a questionnaire relate to each other and to the total questionnaire. It is most commonly evaluated by Cronbach's alpha. An alpha $\geq 0.70$ indicates good internal consistency.</td>
</tr>
<tr>
<td><strong>Test-rest reliability</strong></td>
<td>It estimates the reproducibility of the questionnaire over time. The questionnaire is completed on two occasions by the same patients in whom no change in the condition has taken place. It is most commonly evaluated by the intraclass correlation coefficient (ICC). An ICC $\geq 0.70$ indicates good test-rest reliability.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Validity</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal</strong></td>
<td></td>
</tr>
<tr>
<td>Factor analysis</td>
<td>Is used to identify groups of items within the questionnaire that relate with each other.</td>
</tr>
<tr>
<td>Inter-item correlations</td>
<td>Correlation between items. Should not be greater than 0.85 to prevent redundancy.</td>
</tr>
<tr>
<td>Floor and ceiling effects</td>
<td>Percentage of patients with minimal or maximal score on the questionnaire, respectively. Floor- and ceiling effects should be minimal.</td>
</tr>
<tr>
<td><strong>External</strong></td>
<td></td>
</tr>
<tr>
<td>Face validity</td>
<td>A subjective judgement of whether the questionnaire appears to measure what it is supposed to measure.</td>
</tr>
<tr>
<td>Content validity</td>
<td>The extent to which a questionnaire represents all dimensions of a construct. It is also a judgment, but it may be evaluated by the correlation between the questionnaire and the symptom content of a disease.</td>
</tr>
<tr>
<td>Convergent and discriminant validity</td>
<td>The extent to which the questionnaire correlates with measures designed to measure similar constructs and does not correlate with measures designed to measure dissimilar constructs.</td>
</tr>
<tr>
<td>Construct validity</td>
<td>Refers to whether a questionnaire measures the theorized psychological construct (e.g. HRQL). It is evaluated by the correlation between the questionnaire and an independent measure known to be related with the construct or for which there are theoretical grounds for expecting it to be related.</td>
</tr>
</tbody>
</table>
These types of external validity may be ranked based on the rigor of the method of ascertainment. Face validity is determined by expert opinion as to whether the questionnaire seems to measure HRQL related to the disease in question. Since this assessment is subjective, face validity may be considered the least rigorous form of validity. Content validity is also based on subjective assessment of the extent to which a questionnaire represents all dimensions of a construct, but more systematic assessments may be used as well. Therefore, it may be considered to be more rigorous than face validity. Convergent/discriminant validity is assessed by calculating the correlation between the questionnaire and measures of similar or dissimilar constructs. As this is a systematic assessment, this type of validity may be considered as more rigorous than content validity. Finally, since no “gold standard” exists to measure HRQL and to compare a new HRQL questionnaire with, the best achievable form of validity is construct validity, which is ascertained by calculating the correlation between the questionnaire and an independent measure which reflects the severity of the disease in question. As this is a systematic assessment with measures known to be related with the construct, this type of validity may be considered as more rigorous than convergent/discriminant validity (Table 1).

Construct validity is thus usually evaluated by comparing the HRQL questionnaire with an objective measurement of the extent or severity of the disease, and often such an independent measure is directly or indirectly related to the burden of symptoms characterising the disease in question. However, in disorders not characterized by chronic symptoms, as in food allergy, such an independent measure is not available. Therefore is has been shown that the perceived expectation of what will happen following exposure can be used as independent measure to evaluate construct validity as this will be the driving force determining HRQL, and instruments developed in this way have proved to be useful and consistent in measuring HRQL.39

Finally, for a questionnaire to be reliable and valid in a specific population (e.g. children), it is very important to include patients of the target population in the development of the questionnaire (i.e. item generation and item selection).30 This ensures that the questions are of importance for the target population. In addition, the wording of the question should be age appropriate.

**Measurement of HRQL in children and adults with food allergy**

Measurement of HRQL in food allergy is relatively new research area. The first study on this topic was published in 200031 and the interest in HRQL of food allergy has increased ever since. A few studies reported HRQL of food allergic patients measured with generic questionnaires. However, reliable and valid disease-specific questionnaires to measure HRQL in food allergy have become available only recently.
Table 2. Generic HRQL questionnaires used in food allergic patients.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>No. of items</th>
<th>Domains/ Subscales</th>
<th>Completed by</th>
<th>Used by (Authors, year, country, reference)</th>
<th>Age in years of included food allergic patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child Health Questionnaire- Child Form (CHQ-CF87)</td>
<td>87</td>
<td>Physical functioning Role functioning-emotional Role functioning-behaviour Role functioning-physical Bodily pain General behaviour Mental health Self-esteem General health Family activities Family cohesion Change in health</td>
<td>Child</td>
<td>Flokstra-de Blok et al., 2009, the Netherlands 13 Flokstra-de Blok et al., 2008, the Netherlands 14</td>
<td>8-12</td>
</tr>
<tr>
<td>Medical Outcome Trust Short Form 36 Health Survey (SF-36) or (RAND-36)</td>
<td>36</td>
<td>Physical functioning Social functioning Role functioning-physical Role functioning-emotional Mental health Vitality Bodily pain General health Change in health</td>
<td>Patient</td>
<td>Primeau et al., 2000, Canada 9 Marklund et al., 2004, Sweden 11 Flokstra-de Blok et al., 2009, the Netherlands 13</td>
<td>18-45</td>
</tr>
<tr>
<td>Impact on Family scale (IOF)</td>
<td>24</td>
<td>Familial/social Personal strain Financial Burden Mastery</td>
<td>Patient/parent</td>
<td>Primeau et al., 2000, Canada 9</td>
<td>18-45 / ≤ 18</td>
</tr>
<tr>
<td>Visual Analogue Scale (VAS) (i.e. thermometer)</td>
<td>1</td>
<td>n.a.</td>
<td>Patient/parent</td>
<td>Primeau et al., 2000, Canada 9</td>
<td>18-45 / ≤ 18</td>
</tr>
</tbody>
</table>

n.a. not applicable
Generic HRQL questionnaires used in food allergic patients

Table 2 gives an overview of the generic HRQL questionnaires used in the field of food allergy. The Child Health Questionnaires (CHQ-CF28, CHQ-CF50 and CHQ-CF87) and the Medical Outcome Trust Short Form 36 Health Survey (SF-36 or RAND-36) are generic HRQL questionnaires for children and adults, respectively, that are reliable and well validated in many languages and that have extensively been used in social-medical research.

The Impact on Family (IOF) scale has been developed to assess the impact of chronic childhood conditions on the family. The original questionnaire has shown to be internally consistent with an acceptable factor structure. More recently, the IOF has been revised and has shown an acceptable level of construct validity.

The Visual Analogue Scale (VAS) has been adapted from the EQ-5D. The VAS is a vertical line (i.e. thermometer) with the end-points labelled 'no disruption' (score 0) and 'most disruption imaginable' (score 100) and patients are asked to rate how much disruption they experience in their daily activities due to their disease.

As can be seen in Table 2, only two studies investigated the generic HRQL of food allergic adults.

Disease-specific HRQL questionnaires available for use in food allergic patients

During the last years a few disease-specific HRQL questionnaires have been developed and used in food allergy research. However, not all questionnaires have been extensively validated and therefore sometimes caution is needed when interpreting results obtained with these questionnaires. Table 3 summarises disease-specific HRQL questionnaires for use in food allergic patients that are available in the literature. Other disease-specific HRQL questionnaires that were not available from the publication are described in the text only.

The first study of disease-specific HRQL in food allergy was done by Avery and colleagues. A questionnaire specially developed for this study and an adapted version of the Vespid Allergy Quality of Life Questionnaire (VQLQ) were completed by the children aged 7-12 years. However, the first questionnaire was not validated. The second questionnaire has been validated in vespid allergy but not in food allergy and it was not described how this questionnaire was adapted.

Thereafter, Arslan and colleagues investigated HRQL in food allergic adults (aged 19-80 years) with the Short-Form Nepean Dyspepsia Index (SF-NDI). This questionnaire was developed and validated in patients with functional dyspepsia, but showed satisfactory test-retest reliability in food allergic patients. Construct validity was evaluated by correlating the SF-NDI with two gastrointestinal symptom rating scales. Relatively high correlations were found, since all three questionnaires are targeted to gastrointestinal problems. However, food allergic patients may experience symptoms of other systems as well (e.g. skin, respiratory tract, cardiovascular). Moreover, food allergic patients experience symptoms only when they are exposed to a culprit food. Otherwise they are symptom free, but the
<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>No. of items</th>
<th>Domains/ Subscales</th>
<th>Targetage group (years)</th>
<th>Completed by</th>
<th>Reliability</th>
<th>Validity</th>
<th>Patients/ parents included in development</th>
<th>Developed by (Authors, year, country, reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Allergy Quality of Life-Parental Burden (FAQL-PB)</td>
<td>17</td>
<td>n.a.</td>
<td>0-17</td>
<td>Parent</td>
<td>Internal consistency</td>
<td>Test-retest</td>
<td>Yes</td>
<td>Cohen et al., 2004, US 45</td>
</tr>
<tr>
<td>Food Allergy Impact Scale (FAIS)</td>
<td>32</td>
<td>Meal preparation, Family social activities, Caregiver-supervised child social activities, Family relations, Stress and free time, School and structured activities, Autonomous social activities, Employment and finances</td>
<td>0-18</td>
<td>Parent</td>
<td>Internal consistency</td>
<td>Not tested</td>
<td>Yes</td>
<td>Bollinger et al., 2006, US 46</td>
</tr>
<tr>
<td>Food Allergy Parent Questionnaire (FAPQ)</td>
<td>18</td>
<td>Parental anxiety/stress, Psychosocial impact of allergies, Parental coping/competence, Family Support</td>
<td>0-18</td>
<td>Parent</td>
<td>Internal consistency</td>
<td>Factor analysis</td>
<td>No</td>
<td>LeBovidge et al., 2006, US 47</td>
</tr>
<tr>
<td>Food allergy specific questions</td>
<td>23</td>
<td>Items concerning the child, Items concerning the patents or entire family</td>
<td>9</td>
<td>Parent</td>
<td>Not tested</td>
<td>Not tested</td>
<td>Yes</td>
<td>Östblom et al., 2008, Sweden 48</td>
</tr>
<tr>
<td>Food Allergy Quality of Life Questionnaire-Parent Form (FAQLQ-PF)</td>
<td>30</td>
<td>Emotional Impact, Food-related anxiety, Social and dietary limitations</td>
<td>0-12</td>
<td>Parent</td>
<td>Internal consistency</td>
<td>Test-retest</td>
<td>Yes</td>
<td>DunnGalvin et al., 2008, Ireland 49</td>
</tr>
</tbody>
</table>
Table 3. Continued.

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>No. of items</th>
<th>Domains/ Subscales</th>
<th>Targetage group (years)</th>
<th>Completed by</th>
<th>Reliability</th>
<th>Validity</th>
<th>Patients/ parents included in development</th>
<th>Developed by (Authors, year, country, reference)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food Allergy Quality of Life Questionnaire-Child Form (FAQLQ-CF)</td>
<td>24</td>
<td>Allergen avoidance&lt;br&gt;Risk of accidental exposure&lt;br&gt;Emotional impact&lt;br&gt;Dietary restrictions</td>
<td>8-12</td>
<td>Child</td>
<td>Internal consistency Test-retest</td>
<td>Internal: Inter-item correlations Factor analysis External: Face, Content, Convergent/discriminant, Construct *</td>
<td>Yes</td>
<td>Flokstra-de Blok et al., 2009, the Netherlands</td>
</tr>
<tr>
<td>Food Allergy Quality of Life Questionnaire-Teenager Form (FAQLQ-TF)</td>
<td>23</td>
<td>Allergen avoidance and dietary restrictions&lt;br&gt;Emotional impact&lt;br&gt;Risk of accidental exposure</td>
<td>13-17</td>
<td>Child</td>
<td>Internal consistency Test-retest</td>
<td>Internal: Inter-item correlations Factor analysis External: Face, Content, Convergent/discriminant, Construct *</td>
<td>Yes</td>
<td>Flokstra-de Blok et al., 2008, the Netherlands</td>
</tr>
<tr>
<td>Food Allergy Quality of Life Questionnaire-Adult Form (FAQLQ-AF)</td>
<td>29</td>
<td>Allergen avoidance and dietary restrictions&lt;br&gt;Emotional impact&lt;br&gt;Risk of accidental exposure&lt;br&gt;Food allergy related health</td>
<td>≥18</td>
<td>Adult</td>
<td>Internal consistency Test-retest</td>
<td>Internal: Inter-item correlations Factor analysis External: Face, Content, Convergent/discriminant, Construct *</td>
<td>Yes</td>
<td>Flokstra-de Blok et al., 2009, the Netherlands</td>
</tr>
</tbody>
</table>

* longitudinal validation and validation in different languages underway
n.a. not applicable
considerable efforts they have to make to avoid the culprit food influences their daily life. This impact on daily life is not captured by the SF-NDI.

The first validated disease-specific HRQL questionnaire for food allergy became available in 2004: the Food Allergy Quality of Life-Parental Burden (FAQL-PB) 45. This questionnaire is administered to parents and measures the parental burden associated with having a food allergic child. The questionnaire has shown to be reliable and valid (Table 3). While being useful and well designed, this instrument is not able to measure HRQL of the food allergic children, which may be an important outcome measure in clinical research.

Recently, the Food Allergy Impact Scale (FAIS) and the Food Allergy Parent Questionnaire (FAPQ) were developed. The FAIS measures the impact of food allergy on daily activities of food allergic children and their families and is completed by the parent 46. It showed acceptable internal consistency and preliminary support for the external validity (face and content validity), but internal validity was not tested (Table 3). Further study of construct validity and internal validity is desirable to investigate the degree to which the FAIS measure what it is intended to measure.

The FAPQ measures the parental adjustment to and coping with children’s food allergy and is completed by the parent 47. The subscales ‘parental anxiety/stress’ and ‘psychosocial impact of allergies’ showed good internal consistency, but the subscales ‘parental coping/competence’ and ‘family support’ did not. Internal validity evaluated by factor analysis was acceptable and preliminary support for the external validity (face and content validity) was shown (Table 3). Another limitation was that the items of the FAPQ were generated based only on the clinical experience of the authors and that no patients/parents were included during the development. Also the FAPQ needs further study of the construct validity in order to investigate the degree to which the FAIS measure what it is intended to measure.

More recently, two studies were published on the impact of food allergy on quality of life in children and the impact on daily life in food allergic adults. The first study used disease-specific questions that were specially developed for this study and these questions were completed by the parents 48. However, these questions were not tested for reliability or validity (Table 3). The second study investigated the impact of food allergy on daily life of adults with two self-designed questions (influence on daily life at home and outside the home) 2. Again, these questions were not tested for reliability or validity.

Very recently, disease-specific HRQL questionnaires for food allergic patients of all ages (i.e. parents, children, adolescents and adults) have been published 42,49-51. All four questionnaires have shown to be reliable (internal consistency and test-retest) with an acceptable level of internal validity (factor analysis, inter-item correlation) and external validity (face, content, convergent/discriminant and construct validity) (Table 3). During the development of these questionnaires, patients of the target age group were the most important source for items generation and item selection. Investigation of the ability to measure differences over time (i.e. longitudinal validation) and validation in different languages of these questionnaires are underway.
Conclusion

Food allergy may negatively impact HRQL of food allergic patients and families with a food allergic child in numerous ways. To investigate this impact on HRQL, generic or disease-specific questionnaires may be used. Generic HRQL questionnaires may be not specific enough to measure disease-specific impairments and they also measure the impact of comorbid diseases. Recently, reliable and valid disease-specific questionnaires have become available to measure HRQL in patients with food allergy of all ages. These questionnaires may be used by clinicians to get insight in the specific problems of food allergic patients and in clinical research where HRQL is the outcome of interest.

Acknowledgements
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