

## Original Article

# An Examination of the Food Allergy Quality of Life Questionnaire Performance in a Countrywide American Sample of Children: Cross-Cultural Differences in Age and Impact in the United States and Europe

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**What is already known about this topic?** The development of age and country norms for health-related quality of life (HRQOL) in food allergy is essential to ensure measurement precision in clinical and research settings and for cross-country and subgroup comparison.

**What does this article add to our knowledge?** HRQOL in children with food allergy has been measured across the United States in a cross-sectional study for the first time. We have shown correspondence and difference in impact between American and European samples.

**How does this study impact current management guidelines?** Precision in measurement is vital for evaluation of health care interventions, and assessment of best practice from the patients' perspective, with potential impact on the provision of resources and on health and regulatory policy.

**BACKGROUND:** It is important to ensure that tools are valid and reliable in the context in which they are used. The development of age and country norms is part of this process.

**OBJECTIVES:** The primary aim of the present study was to examine the performance of the Food Allergy Quality of Life Questionnaire – Parent Form (FAQLQ-PF) in a countrywide

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Conflicts of interest: E. Koman is an unpaid member of the Food Allergy Support Group of Tidewater volunteer board and is employed by Capella University. J. O'B. Hourihane is on the board for and has received consultancy fees from Aimmune Corporation; has received research support from Aimmune Corporation and DBV Technologies; has received lecture fees from ThermoFisher, Danone, and DBV Technologies; and has received travel support from the Clemens von Pirquet Foundation. U. Thisanayagam has received research support from Lincoln Medical Ltd. M. Greenhawt has received research support from the Agency for Healthcare Research and Quality (1K08HS024599-01, Career Development

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*Abbreviations used**EI- Emotional impact**FA- Food anxiety**FAIM- Food Allergy Independent Measure**FARE- Food Allergy Research and Education**FAQLQ- Food Allergy Quality of Life Questionnaire**FAQLQ-PF- Food Allergy Quality of Life Questionnaire – Parent Form**HRQOL- Health-related quality of life**SDL- Social/dietary limitations*

**American sample of children with food allergy. The secondary aim was to compare age differences in impact across 9 European countries.**

**METHODS:** In a cross-sectional quantitative design, questionnaires were completed by the parents of 1029 food-allergic children (0-12 years). Participants were recruited via support groups and allergists. Data were analyzed by using multivariate analysis of variance and tests for internal consistency and validity. The average score was calculated for each age group in 15 studies in Ireland, Switzerland, the Netherlands, Spain, Portugal, Germany, Italy, Denmark, Israel, and the United Kingdom.

**RESULTS:** The FAQLQ-PF has high convergent validity (child:  $r = 0.49$ ,  $n = 695$ ,  $P = .01$ ; parent:  $r = 0.36$ ,  $n = 696$ ,  $P = .01$ ) and discriminant validity, parent:  $t(719) = 4.67$ ,  $P = .001$  (anaphylaxis yes vs no);  $t(513)$ ,  $P = .009$  (single vs multiple allergens). Internal consistency was excellent ( $r = 0.96$ ). US health-related quality of life was worse than European health-related quality of life, as indicated by higher FAQLQ-PF scores in US samples. Burden increased with age in all populations.

**CONCLUSIONS:** The FAQLQ-PF is appropriate for use in an American population. Findings will form the basis for further work in the development of an online manual with food allergy-normed age scores to allow for precise measurement, interpretation of scores, and comparison across countries and cultures, in clinical and research settings. © 2016 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2016;■:■-■)

**Key words:** Food Allergy; Quality of life Questionnaire; Quality of life; Measurement precision; Normed scores

Food allergy has become a global health concern affecting between 5% and 10% of children and 3% to 4% of adults.<sup>1,2</sup> The chronicity of the disease coupled with the constant although rare threat of fatality means that measures of health-related quality of life (HRQOL) in individuals with food allergy are increasingly viewed as a meaningful outcome measure.<sup>3,4</sup> Measures of HRQOL can be used in the evaluation and monitoring of health care interventions, in the assessment of best practice from the patients' perspective, and in screening for potential psychological problems. The results generated from research can have an impact on the provision of resources and on health and regulatory policy.<sup>3-5</sup>

The Food Allergy Quality of Life Questionnaire – Parent Form (FAQLQ-PF) is a parent proxy age-appropriate measure that captures the impact of everyday social and dietary limitations and assesses the emotional impact that such restrictions have on the lives of children with food allergy.<sup>6,7</sup> Eiser and Morse<sup>8</sup> outlined recommendations on the development of tools to assess

**TABLE I.** Sample questions from the 3 domains of the FAQLQ-PF: EI, FA, and SDL

Subscale	Sample question
EI	Because of food allergy, my child experiences emotional distress
FA	Because of food allergy, my child feels afraid to try unfamiliar foods
SDL	Because of food allergy, my child feels frustrated by dietary restrictions

HRQOL in children with chronic diseases, including the importance of taking developmental processes into account. In food allergy, previous research has found differences in impact depending on age.<sup>6,7,9</sup> The Food Allergy Quality of Life questionnaires (FAQLQ) were developed and validated under the aegis of Europrevall, and subsequently translated and validated in more than 10 countries across Europe.<sup>10</sup>

That a questionnaire is suitable in the context in which it is being used is vital to ensure the validity, reliability, and interpretation of results.<sup>8</sup> Although the FAQLQ-PF has previously been validated in the United States,<sup>7</sup> the purpose of the present study was to examine the performance of the questionnaire in a large population sample (we recruited participants from 48 out of 50 states). The present study represents one aspect in work to develop an online manual of normed scores that will allow clinicians and researchers to evaluate a child's HRQOL with reference to age, sex, severity, number of foods avoided, and country. This will ensure greater precision in measurement in future studies in Europe and the United States and throughout the world.

## METHODS

### Design

The design of the present study was a prospective cross-sectional quantitative design. The sample consisted of children between the ages of 0 and 12 years with a food allergy clinical diagnosis. Parents were used as proxy responders; that is, parents responded from the child's perspective.

### Materials

The FAQLQ-PF is a questionnaire that assesses the HRQOL of children with food allergy. It is completed by the parents of the food-allergic child on a 7-point scale ranging from 1 (not at all) to 7 (extremely). The higher the total FAQLQ-PF score, the greater the negative impact on HRQOL. It has been found to have excellent reliability ( $\alpha > 0.9$ ), and construct, cross-cultural, content, and longitudinal validity.<sup>6,7</sup> The questionnaire items assess quality of life on 3 domains that have been found to be central to capturing the impact of food allergy, namely, general emotional impact (EI), food anxiety (FA), and social and dietary limitations (SDL). Sample questions from each domain are presented in Table I. The FAQLQ-PF also includes questions on demographic and clinical characteristics relevant to a child's food allergy and items assessing the impact of the food allergy on the health, emotional well-being, and stress of the parent, their partner, and family (presented in separate sections A-F).

**Sample questions from the 3 domains of the FAQLQ-PF.** The Food Allergy Independent Measure (FAIM) – Parent Form was developed to evaluate whether the FAQLQ

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