



# Preliminary psychometric analyses and clinical performance of a caregiver self-efficacy scale for food allergy self-management

Matthew Greenhawt, MD, MBA, MSc<sup>\*,†,‡</sup>; Audrey DunnGalvin, PhD<sup>§</sup>

<sup>\*</sup> Division of Allergy and Clinical Immunology, Department of Internal Medicine, University of Michigan Medical School, Ann Arbor, Michigan

<sup>†</sup> Department of Pediatrics, Child Health Evaluation and Research Unit, University of Michigan Medical School, Ann Arbor, Michigan

<sup>‡</sup> Department of Pediatrics, Section of Allergy and Immunology, Children's Hospital Colorado, University of Colorado School of Medicine, Aurora, Colorado

<sup>§</sup> Department of Pediatrics & Child Health, University College Cork, Cork, Ireland

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## ABSTRACT

**Background:** Food allergy health-related quality of life has been defined, but self-efficacy is poorly described.

**Objective:** To examine the preliminary reliability, validity, and clinical performance of a novel food allergy self-efficacy index.

**Methods:** An 8-item Food Allergy Self-Efficacy Questionnaire (FASEQ) was adapted for food allergy–related themes and coadministered with the Food Allergy Quality of Life Parental Burden (FAQL-PB) index to caregivers self-reporting a food allergic child (group A) and those with children followed up at a food allergy referral center clinic (group B). FASEQ split-half reliability, 2-week recall, factor analysis, and construct and discriminative validity were assessed. Multiple linear regression was used to explore predictive associations between the FAQL-PB and the FASEQ.

**Results:** Among 2,308 caregivers, the mean FASEQ score was 2.69 (95% CI, 2.66–2.73) and was lower (better) among group A (mean FASEQ score, 2.52; 95% CI, 2.49–2.56) vs group B (mean FASEQ score, 3.75; 95% CI, 3.66–3.84;  $P < .001$ ). The FASEQ Cronbach  $\alpha$  was 0.87, and the 2-week intraclass correlation coefficient (ICC) was 0.75. Total and 6 of 8 individual FASEQ domain scores were significantly lower among caregivers with children having anaphylaxis or epinephrine use vs none and peanut or tree nut allergy vs milk or egg allergy, demonstrating good discriminative validity. Total FASEQ score was associated with FAQL-PB score (ICC, 0.13; 95% CI, 0.06–0.19;  $P < .001$ ), with 6 of 8 FASEQ individual domains significantly associated (ICC range, –0.17 to 0.3;  $P < .01$  for all). Factor analysis revealed 2 domains (medical care and social functioning) with construct validity.

**Conclusion:** We present preliminary evidence the FASEQ is a valid tool to assess caregiver food allergy self-efficacy. Self-efficacy is a distinct but related concept that captures aspects of self-management that are an important companion to health-related quality of life.

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## Introduction

Food allergy is major public health disorder that affects nearly 15 million Americans, including 8% of children in the United States, at an estimated cost of \$24.8 billion annually.<sup>1–3</sup> Allergic reactions

may occur on initial food exposure, and ability to predict reaction severity is poor, with reactions ranging from mild to highly severe. Several promising food allergy treatments are under development, although currently no therapy exists beyond allergen avoidance.<sup>4</sup> Research has found an adverse effect of food allergy on health-related quality of life (HRQL) for the child, teen, adult, and parent.<sup>5–7</sup> Caregiver HRQL in food allergy has been well described, and food allergy–specific indexes measure the perceived difficulty of living with the burden of illness.<sup>5,8</sup> Overall, research using disease-specific measures demonstrates worse HRQL associated with epinephrine use, reported anaphylaxis, multiple food allergies, multiple food allergic children in the family, lower reported family income, certain allergen types, and emergency department visits for food allergy. Research using generic HRQL measures found worse HRQL in food allergy compared with other pediatric chronic diseases, such as type 1 diabetes or rheumatoid arthritis. Negative

**Reprints:** Matthew Greenhawt, MD, MBA, MSc, Department of Pediatrics, Section of Allergy and Immunology, Children's Hospital Colorado, University of Colorado School of Medicine, 13123 E 16th Ave, Box 518, Anschutz Medical Campus, Aurora, CO 80045; E-mail: [Matthew.Greenhawt@childrenscolorado.org](mailto:Matthew.Greenhawt@childrenscolorado.org).

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associations also have been noted with epinephrine device provision and use, increased food allergy–related health services, older age, and female sex. Significant differences in how teens perceive their food allergy compared with their parents have also been found.<sup>6,9–33</sup> However, HRQL measures are developed to capture the burden of living with food allergy and are not designed to assess the individual's perception of control over management or their ability to make behavioral changes to better manage the disease.<sup>34,35</sup>

Self-efficacy describes an individual's perceived capabilities for learning or performing actions to manage a situation.<sup>36</sup> Thus, the perceived ability or perception of control to make changes that can influence an outcome is a key coping mechanism. Self-efficacy is a powerful influence on motivation and achievement.<sup>36,37</sup> In other health care fields, self-efficacy has been associated with successful chronic disease management but has been minimally explored in food allergy.<sup>38–42</sup> It is important to understand how self-efficacy influences HRQL (and vice versa); therefore, the development of a validated outcome measure for food allergic families could help better monitor life with the disease, as well as evaluate emerging food allergy therapies, both clinical and educational. The main aim of this study was to perform a preliminary psychometric validation of a measure of caregiver food allergy self-efficacy. A secondary aim was to assess how self-efficacy relates to caregiver food allergy HRQL.

## Methods

This was a cross-sectional, observational study conducted within a large cohort of individuals drawn from 2 populations to provide as robust a sampling of potential segments of the food allergic community as possible. Group A consisted of caregivers who self-reported having a food allergic child and were recruited nationally for participation in an online survey during summer and fall 2012 via e-mail contact, social media feeds, and the websites of Kids with Food Allergies (now a division of the Allergy and Asthma Foundation of America) and the Food Allergy and Anaphylaxis Network (since renamed Food Allergy Research and Education), 2 large, national food allergy advocacy groups. The details of the questions asked and methods of this process have been previously described.<sup>10,11</sup> Eligible participants included caregivers older than 18 years with at least one food allergic child with a physician-diagnosed food allergy. Caregivers with more than one food allergic child were asked to retake the survey based on their experience with each child independently. Analysis was restricted to cases with milk, egg, peanut, or tree nut allergy, the 4 most commonly reported allergens in the cohort.

Group B consisted of caregivers of food allergic children evaluated and managed for milk, egg, peanut, or tree nut allergy at the Division of Allergy and Clinical Immunology, University of Michigan clinics from 2009 to 2011. These individuals were identified by review of a divisional food allergy patient database and were recruited for participation in this study in clinic, by mail, or by telephone between November 2011 and August 2012. These 4 allergens represented those most commonly seen in the practice. Selection process and survey data details for this cohort are described elsewhere.<sup>11,24</sup>

Both cohorts (groups A and B) separately completed an online series of identical questions that contained 3 sections. Section 1 consisted of an internally developed measure of caregiver self-efficacy, named the Food Allergy Self-Efficacy Questionnaire (FASEQ). In section 2, each caregiver also completed the Food Allergy Quality of Life Parental Burden (FAQL-PB) index.<sup>11</sup> A survey section (section 3) collected information on the most severe reaction to the diagnosed allergen, reaction treatment, follow-up care, allergic and nonallergic comorbidities, emergency management training, and sociodemographic information, adapted from a divisional food allergy registry form. Information obtained from the

clinic cohort questionnaire data (group B) was additionally verified through medical record review of the patient's medical record to account for potential recall bias. National Institutes of Allergy and Infectious Diseases/Food Allergy and Anaphylaxis Network anaphylaxis criteria were applied to both the parent-reported symptoms and those detailed through medical record review.<sup>43</sup>

The FAQL-PB is a 17-item, self-administered questionnaire that measures the effect of pediatric food allergy on caregivers, developed by Cohen et al,<sup>6</sup> with excellent validity and reliability (intra-class correlation coefficient [ICC] = 0.93 and Cronbach  $\alpha$  = 0.95) to assess cross-sectional HRQL. The index has not been validated for longitudinal use. Caregiver HRQL was not assessed at a uniform time from diagnosis during the formulation and validation of this scale. Each index item is 7-point Likert-style response scale, and the index is scored as a summated rating scale, with a higher FAQL-PB score indicating worse HRQL.<sup>6</sup> The index was recently determined to have 2 domains and a minimal clinically important difference (MCID) (eg, the smallest difference in score that patients perceive as beneficial, and would mandate, in absence of troublesome adverse effects and effective cost, a change in the patient's management) of 0.3, although elsewhere an MCID of 0.5 has been estimated.<sup>11,44</sup>

The FASEQ consists of 8 Likert-item questions designed to evaluate caregiver confidence in managing food allergy. Short yet reliable instruments have been emphasized as important for the health care professionals as a tool to be used on a regular basis in clinical practice.<sup>45</sup> Content was developed through the adaptation of a self-efficacy measure designed for use in asthma, with wording of certain items changed to reflect terms used for food allergy.<sup>36</sup> This content was assessed for face validity internally within the Division of Allergy and Clinical Immunology, in conjunction with team members from the University of Michigan School of Public Health's Center for Managing Chronic Disease, who have expertise in self-regulatory behavior.<sup>35</sup> The index was then briefly piloted as part of a secondary outcome measure in small, blinded randomized clinical trial of a self-regulation intervention for anaphylaxis management.<sup>34</sup> Items in the FASEQ are scored similarly to the FAQL-PB, as a summated rating scale with lower score reflective of better self-efficacy, using a 5-point scale (range, 0–4). Wording reflects comfort with the 8 items listed.

Data distribution was analyzed using descriptive statistics. Next, we performed a series of analyses to explore the reliability and validity of the FASEQ. FASEQ split-half reliability testing was performed to test for any item redundancy. Construct validity was explored through factor analysis, a data reduction method that seeks to define latent traits (eg, domains) within a data set. We used the iterative principal factor method with oblique and orthogonal rotation separately for groups A and B and together to ensure construct validity across different groups. The Bartlett test of sphericity and Kaiser-Meyer-Olkin Measure of Sampling Adequacy were performed to show adequate variable correlation for factor analysis. Scree plots were used to determine the number of relevant factors to be retained. The  $\chi^2$ , Fisher exact, or unpaired independent-samples *t* test for bivariate inferential comparisons was performed to examine discriminative or known groups validity (eg, the ability of the FASEQ to discriminate between subgroups where a difference would be expected).<sup>46</sup> The MCID for the FASEQ was calculated using the SE of measurement method within the individual and total populations by the following formula: SE of measurement = SD  $\times$  square root [(1 – reliability)].<sup>47–49</sup>

We performed multiple linear regressions between total and domain specific FAQL-PB and FASEQ scores to explore whether an association existed between HRQL and self-efficacy. We expected a significant but low to moderate association because the 2 measures purport to assess different, although related, constructs. Adjusted multiple linear regression was performed to explore the cross-

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