

Development of the Pediatric Quality of Life Inventory™ (PedsQL™) Food Allergy Module: An examination of child food sensitivity and health-related quality of life

by

Alana Rose K. Resmini

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Approved by

Michael M. Steele, Chair, Assistant Professor of Psychology
Steven Shapiro, Associate Professor of Psychology
Jennifer Gillis, Associate Professor of Psychology

Abstract

Nearly 10% of U.S. children are affected by food allergy, with peanut allergy being the most common reason for food-induced anaphylaxis. Food allergy has been shown to affect emotional, social, and family functioning; however, a valid English-language health-related quality of life (HRQOL) measure for children with food allergy does not currently exist. Thus, the purpose of this qualitative study was to develop items for the Pediatric Quality of Life Inventory™ (PedsQL™) Food Allergy Module. This study followed the PedsQL™ Module Development MethodologySM which includes conducting a literature review and focus and cognitive interviews with children with food allergy and their parents. After each step of the development process, experts provided feedback about the appropriateness of the items. A literature review of food allergy was conducted to generate open-ended questions for the focus interviews and to develop potential items for the PedsQL™ Food Allergy Module. A total of 30 participants (13 children ages 5-13 and 17 parents of children ages 2-13) with physician-diagnosed food allergy participated in the focus and cognitive interviews. The literature review resulted in 43 items and the focus interviews resulted in 37 items. Modifications made based upon the results of the cognitive interviews included minor wording changes. No items were removed and no new themes were identified based upon the results of the cognitive interviews and expert feedback. The addition of a food allergy-specific module improves the comprehensiveness of the PedsQL™ Measurement System and helps to ensure that valid health outcomes assessment in this population is possible.

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Introduction

Development of a PedsQL™ Module for Children with Food Allergy

Health outcomes assessment includes clinical and patient-reported outcome measures that focus on the evaluation of healthcare procedures, interventions and services (Mariner, 1994). Also known as “health outcomes management,” health outcomes assessment allows physicians and patients to make informed medical decisions based upon how the medical service, procedure, or intervention will affect the patient, and measure whether the procedure, intervention, or service was effective in its intended purpose (Ellwood, 1988; Mariner, 1994). Historically, observable clinical indicators of health such as mortality rates, morbidity rates, number of symptom-free days, and amount of physical symptoms have been utilized to determine health outcomes. More recently, disability, discomfort, and dissatisfaction have been used as alternatives to the aforementioned clinical measures of health (Roach, 2006). Another important approach to the evaluation of health outcomes is the use of patient-reported outcomes (PRO), which is defined as any report given by the patient (Burke, 2000). Such reports can include diaries, event logs, health-related quality of life (HRQOL) measures, and/or measures of treatment satisfaction (Chang, 2007). The use of PROs as a method for assessing health outcomes has been shown to improve quality of life and reduce health care costs by guiding the medical decision making process and involving the patient in his or her care (Higginson & Carr, 2001).

Health Related Quality of Life

As previously mentioned, HRQOL is one type of PRO that can be used for the evaluation of health outcomes. The World Health Organization (WHO, 1948) defines HRQOL as “a state of

complete physical, mental, and social well-being, and not merely the absence of infirmity.”

Thus, HRQOL is described as the assessment of the physical, social and emotional effects of a treatment, service, or intervention and the measurement of the patient’s physical, social, emotional, and school/occupational functioning (Higginson & Carr, 2001; Varni, Burwinkle, Seid, & Skarr, 2003). HRQOL has become a particularly appealing construct for evaluating health outcomes in recent years, with organizations such as the Food and Drug Administration (FDA) requiring the assessment of HRQOL for all drug trials (Johnson & Temple, 1985).

HRQOL assessment is especially applicable to certain diseases, such as arthritis, where there are few physical markers of the condition (Leidy, Revicki, & Geneste, 1999). Additionally, HRQOL assessment can be helpful when trying to decide between potential treatments where multiple options are available, and for examining the side effects of new treatments or procedures relative to existing treatments (Leidy, Revicki, & Geneste, 1999). Because of its multi-faceted and patient-centered approach, HRQOL has been described as the gold standard for understanding patient satisfaction and treatment effectiveness within the context of health outcomes assessment (Eiser & Morse, 2001; Varni, Seid, & Kurtin, 1999).

Health Related Quality of Life: Measures

Of the over 1,000 measures of HRQOL that currently exist (Bullinger, 2002), the majority can be considered “generic” instruments; that is, they are measures that are designed to assess general levels of HRQOL in both healthy populations and various disease groups. For example, the Sickness Impact Profile (SIP), the Nottingham Health Profile, and the Short Form-36 (SF-36) are available internationally and have been validated with norm groups in several countries (Bullinger, 2002). The SIP, developed in the 1970s, was one of the first HRQOL measures and consists of 136 questions that can be self-administered or completed in an

interview format (Damiano, 1996). The SIP includes items such as, “I act nervous or restless.” or “I am going out less to visit people.” for measuring emotional behavior and social interaction, respectively. Another generic measure of HRQOL, the Nottingham Health Profile, is a two-part measure that assesses patients’ feelings and functioning relative to their illness, as well as how their health affects daily activity. The two subscales can be used separately or together to evaluate HRQOL, and the self-administered profile is simple to answer, with a reading age of 9 years (McEwen & McKenna, 1996). Finally, the SF-36 is unique in that its items were derived from several other health outcome assessments, including the General Psychological Well-Being Inventory and the Self-Perceptions Questionnaire (Ware, 1996). Because generic measures of HRQOL are not disease-specific, comparisons can be made between certain disease groups and healthy norms, or between different disease groups. For example, Larsson, Karlsson, and Sullivan (2002) used the SF-36 to compare the quality of life of obese adults to normal weight controls.

A relatively large body of research that supports the use of HRQOL in health outcomes assessment of adults has emerged with some of the first studies examining health outcomes assessment of adult patients with cancer who were undergoing chemotherapy (Bullinger, 2002). In the area of heart disease outcome assessment, quality of life assessment has replaced traditional indicators of health, such as returning to work (Wenger, Naughton & Furberg, 1996). Measures have even been developed to assess HRQOL in adult psychiatric populations, where research is shifting to include patient perceptions of health in these populations (e.g., schizophrenia, depression; Gregoire, de Leval, Mesters, & Czarka, 1994; Hunt & McKenna, 1992; Wilkinson et al., 2000). Additional areas of focus include assessing health outcomes among adults with diabetes, epilepsy and pain-related conditions such as headaches and

abdominal pain (Bott, et al., 1998; Bullinger, 2002; Dahloef, 1995; Kutoba & Awaya, 2010; Wahl et al., 2009).

As evidenced by these studies, a multitude of research exists for the measurement of HRQOL in adult populations. However, pediatric HRQOL assessment is a far newer line of research (Varni, Seid & Kurtin, 1999; Wallender, Schmitt & Koot, 2001) and the need for additional research among child populations is warranted (Matza, Swensen, Flood, Secnik, & Leidy, 2004). For example, mortality rates are unsuitable as outcome measures in children older than 1-year-old, except in cases of accidents, since death during childhood is rare (McGlynn & Halfon, 1998; Singh & Yu, 1996). Further, because of the number of diseases that are exclusive to childhood (McGlynn & Halfon, 1998), and school absences can occur for other reasons (e.g., social reasons; McCowan, Bruce, Neville, Crombie, & Clark, 1996), morbidity rates and school absences can be seen as unreliable outcome measures in pediatric populations (McCowan, et al., 1996). Finally, relying only on morbidity and mortality rates to assess outcome fails to capture all aspects of the WHO's definition of health (WHO, 1948). That is, child comprehensive health outcome measures should include physical, social, emotional, and school functioning, in addition to the health concerns of the child (Forrest, Shipman, Dougherty, & Miller, 2003).

Despite the obvious need for measures designed to evaluate HRQOL among child populations, there are certain challenges that come with efforts in this area. For example, assessing HRQOL in children can be difficult given the differences in the cognitive ability of children at different ages (Varni, Seid & Rode, 1999). Thus, measures of HRQOL must be developmentally appropriate to be considered reliable and valid for the ages targeted. Further, parent proxy-reports are helpful for obtaining relevant clinical information, and are necessary to obtain when children are too young to complete self-report measures (Chang & Yeh, 2005;

Varni, Limbers, & Burwinkle, 2007a). Further, because parents are often responsible for making medical decisions for the child, it is important to assess HRQOL from a parent proxy perspective (Jokovic, Locker & Guyatt, 2004). However, parent proxy-reports alone can be seen as providing limited information about the child and self-report methods should be utilized once the child possesses the cognitive abilities necessary to complete measures (Varni, Limbers, & Burwinkle, 2007a).

Despite the challenges of measuring HRQOL in children, several valid and reliable measures exist that are designed to assess health outcomes in both healthy and unhealthy pediatric populations (Eiser & Morse, 2001). For example, the Child Health Questionnaire (CHQ), modeled after the SF-36, is a generic quality of life measure for children (Landgraf, Abetz & Ware, 1996) that includes parent proxy-report and child self-report forms developed for children ages 10 years and older. Specific items ask about health episodes occurring in the past year, as well as the child's overall health. Another valid and reliable generic HRQOL measure for children is the Child Health and Illness Profile (CHIP), which consists of parent and child forms for children ages 6-11 years, and an adolescent form for ages 11-17 years (Riley et al., 2004; Riley et al., 2004; Starfield, Riley & Green, 1999; Starfield et al., 1995). In addition to measuring current functioning, the CHIP measures domains such as resilience, risk avoidance, and future health and each question on the child form is accompanied by an animated character and a 5-point Likert scale answer. The adolescent version of the CHIP assesses five domains (i.e., satisfaction, discomfort, risk avoidance, resilience, and achievement) with an optional measure of disorders. Although both instruments demonstrate adequate reliability and validity, they lack the developmental specificity of other generic HRQOL measures for children such as the Pediatric Quality of Life Inventory (PedsQLTM).

The Pediatric Quality of Life Inventory

Perhaps the most widely used and well researched measure of HRQOL is the PedsQL™.

This instrument was developed as a result of years of research in test development and validation in pediatric chronic disease populations (Varni, Seid, & Rode, 1999). Devised to be a generic measure of quality of life, the PedsQL™ 1.0 was developed utilizing a sample of pediatric cancer patients (Varni, Seid, & Rode, 1999), with the final version consisting of 15 items. Given the developmental differences between children and adolescents, child (5-12 years of age) and adolescent (13-18 years of age) forms were created. The items on the parent proxy forms are nearly identical to the items on the youth forms, but are in reference to the parent's perception of the child's functioning (i.e., the questions are written in the third person). Additionally, the age-appropriate child forms are written to target the cognitive abilities associated with each form (Varni, Seid, & Rode, 1999).

Further validation of the PedsQL™ 1.0 resulted in the addition of new items and included validation in other disease populations (e.g., pediatric diabetes, rheumatology, cardiology; Varni, Seid, & Kurtin, 2001). For example, the PedsQL™ 2.0 and 3.0 versions included further specified age ranges such as young child (5-7 years of age), child (8-12 years of age), and adolescent (13-18 years of age) forms. The most recent version of the PedsQL™, the Pediatric Quality of Life Inventory 4.0 Generic Core Scales (PedsQL™ Generic Core Scales), parallels each of the aforementioned age ranges and includes a parent proxy-report for toddlers (2-4 years of age). For the child and adolescent self-report versions (i.e., ages 8-18), and all parent proxy-report versions, a 5-point Likert scale is used (0 = never a problem, 4 = almost always a problem). However, a 3-point Likert scale is utilized for the young child version (5-8 years of age), with happy faces corresponding to each response (0 = not at all a problem, 2 = sometimes a

problem, 4 = a lot of a problem). All versions require respondents to rate the items based upon problems experienced in the past 30 days (Varni, Seid, & Kurtin, 2001). All 23 items are reverse scored and linearly transformed (range = 0-100), with higher scores indicating better quality of life. Sample items include “It is hard for me to walk more than one block.” and “I feel sad or blue.” (Varni, Seid, & Kurtin, 2001).

The PedsQL™ Generic Core Scales assess the four components of the WHO’s definition of quality of life (i.e., physical, emotional, social, and role functioning; Varni, Burwinkle, Seid, & Skarr, 2003), as well as school functioning, since children spend a considerable amount of their time in academic settings (Varni et al., 2003). As with other generic measures of HRQOL, the general nature of the PedsQL™ Generic Core Scales allows one to evaluate healthy children, as well as acute and chronic childhood disease populations. This can allow for the comparison of HRQOL levels between specific disease populations and comparisons of children with certain diseases to healthy children (Varni et al., 2003). Further, numerous studies support the reliability and validity of the PedsQL™ Generic Core Scales in a variety of disease populations (Chan, Mangione-Smith, Burwinkle, Rosen, & Varni, 2005; Varni, Seid & Rode, 1999), and several studies have shown that the PedsQL™ Generic Core Scales can reliably differentiate between healthy and ill children (Varni, Seid, & Kurtin, 2001; Varni et al., 2003; Varni et al., 2004; Varni et al., 2006). For example, recent studies have determined the validity of the PedsQL™ Generic Core Scales among children with diabetes (Varni et al., 2003), cerebral palsy (Varni et al., 2006), and asthma (Varni et al., 2004).

In addition to the PedsQL™ Generic Core Scales, several disease-specific PedsQL™ modules exist. For example, there are modules available that assess HRQOL in pediatric cancer patients (Varni, Burwinkle, Katz, Meeske, & Dickinson, 2002), pediatric transplant patients

(Weissberg-Benchell et al., 2010), children with brain tumors (Palmer, Meeske, Katz, Burwinkle, & Varni, 2007), and neurological conditions (Iannaccone, et al., 2009). The disease specific modules are specifically designed to be used in conjunction with the PedsQL™ Generic Core Scales (Varni & Burwinkle, 2004), which allows for disease-specific assessment (i.e., specific symptomatology) and the comparison of children across disease-states (e.g. Ingerski et al., 2010; Varni, Limbers, & Burwinkle, 2007b). In fact, a primary goal of the PedsQL™ Measurement System is to develop disease specific modules to satisfy both research and clinical need for the most common and debilitating illnesses and diseases found in childhood. This will ultimately provide researchers, policy-makers, providers, and health plans with single measure for pediatric health outcomes evaluation.

Pediatric Food Allergy: Prevalence & Statistics

Recently, a great deal of attention has been paid to pediatric food allergy and it is quickly becoming a public health concern (United States Department of Health and Human Services; USDHHS, 2008). This is easily understood when one considers that nearly 10% of U.S. children are affected by food allergy, with peanut allergy being the most common reason for food-induced anaphylaxis (Venter & Arshad, 2011). Furthermore, approximately 3 million children under the age of 18 years (3.9%) of U.S. children were reported to have been diagnosed with food allergy or digestive allergy in the previous 12 months (USDHHS, 2008). Even more concerning, the prevalence of food allergy increased 18% from 1997-2007 among children under 18 years (Sicherer, Munoz-Furlong, Godbold, & Sampson, 2010; Sicherer, Munoz-Furlong, & Sampson, 2004). These statistics become particularly alarming when one considers the fact that children with food allergy are 2-4 times as likely to have other health-related conditions, such as asthma, and that anaphylaxis can be both common and fatal among this population. While many

children outgrow certain types of food allergies, children with more severe forms of allergies, such as those with peanut and tree nut allergies, do not outgrow their allergies by adulthood (Venter & Arshad, 2011).

Pediatric Food Allergy: Disease Facts

Food allergies are adverse immune reactions to food proteins (Johansson et al., 2004), and affect 6-8% of young children and 3-4% of adults (Mansoor & Sharma, 2011). Food allergies occur when the body produces Immunoglobulin-E (IgE) antibodies as a result of the immune system mistakenly identifying the protein as harmful (Mansoor & Sharma, 2011; Sampson 1999; Sicherer, 2006). Once the body begins to react, several responses can occur, such as skin reactions, gastrointestinal distress, or even respiratory distress (Sicherer, 2006). This can sometimes progress to anaphylaxis, a potentially life-threatening condition that also includes an acute muscle and/or skin reaction with reduced breathing and blood pressure (Sampson et al., 2006).

Although other types of allergies, such as seasonal allergies, have treatment options such as injection therapy (i.e., shots of the allergen to increase tolerance), there is no cure for food allergies (Sicherer, 2006). Prior studies attempting to utilize injection therapy for food allergy have resulted in serious side effects such as anaphylaxis and even death (Burks et al., 2003; Sicherer, 2006). Thus, current standards suggest that the strict avoidance of allergens is the safest and most effective way to prevent an allergic reaction for individuals with a food allergy (Sicherer, 2006). However, avoidance may be difficult due to cross-contamination of food products, poor labeling procedures, and other factors (Noimark, Gardner, & Warner, 2009). The prospect of avoiding food allergens for one's entire lifespan becomes particularly concerning when one considers that contact with a food allergen can result in anaphylaxis, skin rashes, and

gastrointestinal distress (Mansoor & Sharma, 2011). In fact, food allergy is the most common cause of anaphylaxis-induced hospital visits (Bohlke, et al., 2004) and requires immediate epinephrine administration typically via intramuscular injection (e.g., EpiPen®; Keet, 2011; Sampson et al., 2006; Sicherer, 2006). Based on this information, it is easy to appreciate the challenges a child may face if suffering from food allergy, and the impact food allergy can have on the entire family system.

Pediatric Food Allergy: Family Functioning.

Previous research has shown that living with food allergy can limit family activities, with parents of children with peanut allergy reporting more family disruption as a result of their child's condition than parents of children who have a rheumatologic disease (Primeau et al., 2000). Parents from this particular study attributed familial disruption to the risk of death associated with their child's allergy, and acknowledged the burden associated with allowing another adult to prepare foods for their child. Consequently, parents were reluctant to allow their child to attend birthday parties and school outings or eat school lunches (Primeau et al., 2000). Similarly, Bollinger and colleagues, (2006) found that children's food allergies significantly affected meal preparation in a survey of young children and their caregivers. Finally, previous research indicates that, in some families, all family members, regardless of a food allergy diagnosis, avoid the specific food allergen for the affected family member (Munoz-Furlong, 2003). Because fatal reactions to food allergens are most common outside of the home (Bock, Munoz-Furlong, & Sampson, 2007), experts recommend strict vigilance towards the ingredients listed in food labels, and the avoidance of consumption of desserts and baked goods that may contain the food allergen when outside of the home (Bock et al., 2007). This can lead many

families of children with food allergy to frequent the same restaurants because they cater to food-allergic individuals (Avery, King, Knight, & Hourihane, 2003).

Pediatric Food Allergy: Psychological Functioning.

The need for hypervigilance around potential food allergens can lead to greater levels of anxiety for children with food allergy, such that children with food allergy may even demonstrate even higher instances of separation anxiety than their nonallergic siblings (King, Knibb, & Hourihane, 2009). Because an allergic reaction is comparable to experiencing a hypoglycemic attack, a recent study by Avery and colleagues (2003) compared the quality of life of children with food allergy to children with type 1 diabetes. Results indicated that children with food allergy evidenced lower levels of HRQOL than their type 1 diabetes counterparts. Specifically, children with food allergy reported higher levels of fear related to experiencing a reaction, and had more anxiety about eating than children with type 1 diabetes. Further research has found that children with nut allergy experience lower social and emotional quality of life than their non-allergic peers (Cummings et al., 2010).

Pediatric Food Allergy: School Functioning.

In addition to family functioning, living with food allergy can also affect school functioning in children. For example, Bollinger et al., (2006) found that food allergy significantly impacted school attendance in 34% of children sampled. In addition to the physical impact food allergy can have on school functioning, a recent study demonstrated how bullying can impact children with food allergy. Specifically, Lieberman and colleagues (2010), report food allergy-related bullying as the reason for 78% of subjects in the sample reporting bullying. For example, children described bullying due to seclusion from others (e.g., having to sit at a separate lunch table), having to keep medications or injections with them at all times, and

receiving special treatment from others. Based on the aforementioned findings, one can appreciate the effect food allergy may have on a child's school functioning.

Existing Food Allergy-Specific Quality of Life Measures.

Although the aforementioned studies have furthered our understanding of how food allergy impacts a child's life in a single domain, a more comprehensive approach to better understanding the quality of life among this population is warranted. Unfortunately, there are few measures that are specifically designed to evaluate HRQOL in children with food allergy. Historically, the HRQOL of children with food allergy has been assessed in several different ways, with some authors simply adapting existing quality of life measures for unrelated adult populations to assess the quality of life of children with food allergy (e.g., adult bee sting; Avery et al., 2003). Other authors have utilized generic HRQOL measures and anxiety measures such as the State-Trait Anxiety Inventory (STAI) for parent proxy-report, and the Spence Child Anxiety Scale (SCAS) for child self-report of anxiety (Cummings et al., 2010; King et al., 2009). As with other situations where no validated tool exists for a specific construct, prior research has been conducted by researchers devising their own measures to assess the quality of life of children with food allergy without fully evaluating the psychometric properties of the instrument. For example, Marklund et al., (2006), developed a parental perception scale for the purposes of their study, and pilot tested the scale on nine patients before giving it to study participants. Other authors have developed and utilized yet to be validated scales for children with peanut-only allergy (Avery et al., 2003) for the purposes of their studies (King et al., 2009).

Other researchers have developed measures to assess constructs similar to pediatric HRQOL for this population, such as the Food Allergy Quality of Life- Parental Burden (FAQL-PB; Cohen, Noone, Munoz-Furlong, & Sicherer, 2004), which was designed to evaluate parental

burden among families with a food allergic child. This measure consists of questions such as “In the past week, how troubled have you been by your concerns for your child’s health because of their food allergy?” and “In the past week, how troubled have you been by anxiety relating to your child’s food allergy?” This questionnaire has been utilized in a study of parents of young Chinese children (Leung, Yung, Wong, Li, & Wong, 2009) and found that 15% of the sample had reduced HRQOL which was more common among children who had more than three food allergies.

Additional research yielded the FAQL-Teen (Resnick et al., 2010), a measure of HRQOL for adolescents ages 13-19, which was validated among a sample of teens involved with the Food Allergy and Anaphylaxis Network (FAAN). This study indicated good discriminant validity by comparing scores for teens with food allergy to healthy teen counterparts. The final measure consists of 17 items, uses a 6-point Likert scale, and includes items such as “If you were planning on going to a restaurant, how much would your choice of restaurant be limited by your food allergy?” Although the measure demonstrates good internal consistency ($\alpha = 0.9$) (Resnick et al., 2010), these study results should be interpreted with caution. Specifically, because the known groups analysis, used to validate this measure, included a group with relatively high illness severity (i.e., FAAN members) and a healthy sample, the sensitivity of the measure is difficult to determine. Specifically, the children used in the validation study may not be representative of the greater food allergy population, which likely limits the external validity of the study.

Another instrument, the Food Allergy Quality of Life Questionnaire-Child Form (FAQLQ-CF), was developed in 2008 by Dutch researchers (Flokstra-de Blok et al., 2008a) who also previously developed the Food Allergy Quality of Life Questionnaire-Parent Form

(FAQLQ-PF; DunnGalvin, Flokstra-de Blok, Burks, Dubois, & Hourihane, 2008) for parents of children with food allergy ages 4-12 years. The FAQLQ-CF consists of 22 questions such as “How troublesome do you find it, because of your food allergy, that you must always watch what you eat?” and “How troublesome is it, because of your food allergy, that the ingredients of a food change?” and is rated on a 7-point Likert scale. The child form is appropriate for children ages 8 to 12 years, and demonstrated adequate construct validity using the Food Allergy Independent Measure ($\alpha=.83\text{-.94}$; FAIM). Furthermore, the measure has excellent internal consistency, and is accurately able to distinguish between the quality of life of children based on severity (i.e., between children with more than two food allergies and those with two or fewer food allergies; Flokstra-de Blok et al., 2008a). The same researchers subsequently developed the Food Allergy Quality of Life Questionnaire Teenager Form (FAQLQ-TF) for adolescents ages 13-17 years, with similar validity results (Flokstra-de Blok et al., 2008b).

One limitation to the FAQLQ-CF and FAQLQ-TF, however, is that the measures have not been validated in an English format. That is, while the forms were written and validated in Dutch, then translated into English utilizing the 2008 WHO guidelines for translation (see http://www.who.int/substance_abuse/research_tools/translation/en/index.html for current guidelines), the psychometric properties of the English version have not been evaluated. Additionally, the authors utilized the FAIM, devised by the same authors for the purposes of testing construct validity, to determine construct validity between measures. Thus, the FAQLQ-CF and FAQLQ-TF are examples of well-validated measures in another language. However, future research is needed to develop and validate an English-language HRQOL questionnaire for children with food allergy who live in the United States.

Rationale for the Current Study

An abundance of research indicates that HRQOL is a reliable and valid means for assessing health outcomes among both healthy child and pediatric populations (Eiser & Morse, 2001; Varni, Seid, & Kurtin, 1999). Because a valid English-language HRQOL measure for children with food allergy does not currently exist, the development of such a measure would fill an important gap in the literature base (King et al., 2009). Because food allergies have been shown to affect the physical, psychological, and social domains of health, this line of research will be important for improving the lives of children with food allergy (Gupta et al., 2011; Sicherer et al., 2010; Sicherer, Munoz-Furlong, & Sampson, 2003). Despite the fact that the PedsQL™ is considered by many to be the gold standard for assessing health outcomes in both healthy and pediatric populations, currently no food allergy module for the PedsQL™ measurement system exists.

Goals of the Current Study

The ultimate goal of the current study is to improve health outcomes for children with food allergy. In an effort to reach this goal, this investigation aims to develop and validate a measure of HRQOL in children with food allergy. Specifically, the addition of a food allergy-specific module will improve the comprehensiveness of the PedsQL™ Measurement System, which will consequently help ensure that valid health outcomes assessment in this population is possible. Thus, the goal of this study is to devise developmentally appropriate child self-report forms that will target children ages 5-18 years and parent proxy-reports that will target parents of children ages 2-18 years.

The current investigation consisted of test development, which involves the following five steps:

1. A review of the literature was conducted for the purposes of generating potential items for the questionnaire.
2. Questionnaire items were generated based upon the literature review.
3. Experts (e.g., pediatric allergist and pediatric psychologists) reviewed the items.
4. Focus interviews consisting of children with food allergy and their parents were conducted.
5. Cognitive interviews were conducted to determine the appropriateness of individual items.

Method

Participants and Settings

Parents of children ages 2-18 years, and children ages 5-18 years with a diagnosis of food allergy were recruited by responding to recruitment emails sent to local food allergy support groups. A total of 30 participants (i.e., 13 children ages 5-18 years, and 17 parents of children ages 2-18 years with food allergy) participated in the focus and cognitive interviewing phases of the study. On average, children reported having 3.07 food allergens, with peanut reported as the most common food allergen (80% of the sample; see Table 1). To be eligible for participation, the child must have had an active food allergy diagnosis for at least six months, both the parent and child must have been willing to participate, and each participating family member must be English speaking. Exclusionary criteria included failure to provide written consent, diagnosis made less than six months prior to the time of data collection, non-English speaking participants, and/or parental report of limited child cognitive ability (e.g., Intellectual Disability, Autism Spectrum Disorder). Participants received \$10 for participating in the focus interviews and \$15 for participating in the cognitive interviews. Prior to the initiation of data collection, all research

activities were approved by Auburn University's Institutional Review Board for the Protection of Human Subjects in Research (IRB).

Procedure

Development of the PedsQL™ Food Allergy Module adhered to the established PedsQL™ Module Development MethodologySM (Varni et al., 2006; Varni et al., 2004; Varni et al., 2002), which involves the following steps:

1. A review of the literature for the purposes of generating potential items for the questionnaire.
2. The generation of questionnaire items based upon the literature review.
3. Expert review of the items.
4. Semi-structured focus interviews of children with food allergy and their parents.
5. Expert review of the items.
6. Cognitive interviews of individual items to determine appropriateness of the items.
7. Expert review of the items.

For the current study, the comprehensive literature review examined the existing research in adult and pediatric patients with food allergy from the past five years using PubMed and Google Scholar to aid in the generation of potential items for the PedsQL™ Food Allergy Module. Next, focus interviews were conducted with children with food allergy and their parents. Finally, cognitive interviews were conducted individually with children and their parents to determine the appropriateness of the items. Three allergists in full time private practice, including a pediatric allergist on the medical advisory board of a pediatric food allergy support group, and a pediatric psychologist provided feedback about the PedsQL™ Food Allergy Module at different stages of development.

Focus interviews, following the PedsQL™ Focus Group MethodologySM, were conducted by a graduate-level researcher with parent-child dyads in a university-based psychological services clinic and consisted of open-ended questions in a semi-structured interview format such as “What is the biggest concern about your child’s health?” and “What symptoms bother your child the most?” which was designed to elicit general information about living with food allergy. The four domains of HRQOL (i.e., physical, social, emotional, and academic functioning) were represented in the focus group questioning with questions such as “In what ways, if any, does having a food allergy keep you from doing physical activities that you want to do?” (i.e., physical), “Does your food allergy affect how you get along with other people? How so?” (i.e., social), “What things, if any, do you worry about because you have a food allergy?” (i.e., emotional), and “What problems, if any, do you have at school because you have a food allergy?” (i.e., academic). Please see Appendix A for child and adolescent focus interview questions and Appendix B for parent focus interview questions.

Children eight years of age and older were interviewed separately from their parents, which is consistent with the PedsQL™ Module Development MethodologySM protocol, and is done to minimize the impact the parent’s presence might have on the child’s responses and vice-versa. Each participant attended only one focus interview session that lasted less than two hours in duration. Participants continued to be recruited until theme saturation was achieved; that is, until no new information was received from children and parents during focus interviews. Items generated during the literature review and focus groups were submitted for review by a pediatric allergy specialist and no changes were made based on feedback.

Cognitive interviews, following the PedsQL™ Cognitive Interviewing MethodologySM, consisted of parents and children who had not previously been involved in the study, meeting

individually with a trained research assistant. The goal of cognitive interviews is to understand the thought processes involved with answering each item and to use the information to ask more useful questions. During the interviews, children and their parents completed the PedsQL™ Food Allergy Module independently and answered general questions about the measure such as “How would you make the directions clearer or easier to understand?” and “Were there any items that you think should be deleted?” Parents and children also answered item-specific questions such as “What does this item mean to you?” about each item. Please see Appendix C for sample interview questions.

Items continued to be added or discarded based upon information gathered during the focus groups, cognitive interviews and expert consultation. Specifically, the PedsQL™ Food Allergy Module included 43 items after the literature review and was reduced to 37 items as a result of information gathered during the focus interviews. Items discarded included “I have allergic reactions often,” “I often have problems as a result of using my EpiPen®,” “I am afraid I/someone else will use my EpiPen® incorrectly,” “I get scared when I have to have blood tests,” “I am scared of needle sticks or shots” and “Going to the doctor’s office often is burdensome.” No items were discarded as a result of the cognitive interviews or expert evaluation. All focus groups and cognitive interviews were audiotaped and transcribed to determine common themes between sessions. Specifically, a trained research assistant transcribed each audiotape and a graduate-level research assistant coded the transcriptions for common themes.

Measures

The Food Allergy and Family Information Form. This form was devised for the purposes of this study. Information collected on this form included the number and types of food allergens for each family member. Other medical information, such as how often the child has

had to use his or her EpiPen® in the past month and how many trips to the emergency room due to a food allergy reaction, was collected. The child's food allergy impact on his or her parents, such as how many days the parent has had to miss work due to his or her child's food allergy, was obtained using this form. Demographic information such as child's date of birth, gender, race/ethnicity, and parental occupation and education level was also collected to examine the demographics of the sample. Please see Appendix D for an example of the form.

Results

Literature Review

An extensive review of peer-reviewed articles was conducted through search engines such as Google Scholar and PubMed in order to identify potential research relevant to the constructs important to evaluating HRQOL in children with food allergy. Examples of terms searched include “Food Allergy,” “Pediatric Food Allergy,” “Health-Related Quality of Life,” and “Anaphylaxis.” During this phase, a list of potential items were generated from themes identified in prior research, items included in other food allergy-specific measures (e.g., FAQLQ-CF; Flokstra-de Blok et al., 2008a), and from items included in other PedsQL™ disease-specific modules (e.g., diabetes, asthma and arthritis modules; Chan et al., 2005; Varni et al., 2002; Varni et al., 2003). Examples of themes identified in the literature review included vigilance toward abstaining from food allergens, worry associated with accidental contact (Bock et al., 2007; Cummings 2010), and deficits in family and academic functioning in children with food allergy (Bollinger et al., 2006; Munoz-Furlong, 2003). Specifically, the aforementioned themes resulted in the development of items such as “I worry about food ingredients changing,” “I worry about trying new foods,” and “It is hard for me to stay away from food allergens.” Ultimately, the literature review resulted in 43 potential items in the areas of General Health (two

items), Treatment (nine items), Worry (14 items), Communication (eight items), and Social Functioning (10 items). Items such as “I am often frustrated due to food restriction” and “I am scared to use my EpiPen®” were generated as a result of themes identified by peer-reviewed journal articles (see Appendix F for a list of items generated during this phase). Potential PedsQL™ Food Allergy Module items generated during the literature review were reviewed by a pediatric allergist and pediatric psychologist and were not modified based upon feedback received.

In addition to developing items, themes generated from the literature review were used to format the focus interview questions for the next phase of the module development. For example, the interview question “Does your food allergy affect or limit you from doing things with your family?” was generated as a result of the finding that parents of children with peanut allergy report more family disruption as a result of their child’s condition than parents of children who have a rheumatologic disease (Primeau et al., 2000). Interview questions such as “In what ways, if any, does being afraid of having a reaction affect what you do?” and “What things, if any, do you worry about because you have a food allergy?” were generated because of findings that indicated that children with food allergy report higher levels of fear than children with other illnesses (Avery, 2003). Finally, interview questions such as “Do you feel different from your classmates because you have a food allergy? How does that make you feel?” and “In what ways, if any, does food allergy affect how you get along with other kids at your school?” were generated based upon the findings of a sample of children who reported experiencing food allergy-related bullying (e.g., taunting the child with the allergen, drawing attention to the child’s EpiPen®, making fun of the child for seclusion during meal times; Lieberman et al., 2010).

Focus Interviews

A total of eight children with food allergy ages 5-13 years and ten parents of children with food allergy participated in ten separate focus interviews (see Table 1), which consisted of parents and children individually answering open-ended questions in a semi-structured interview format designed to elicit qualitative information (e.g., daily impact) about living with a food allergy. Focus interviews have demonstrated their effectiveness in the measure development process, using open-ended questions to gather first-hand information about the topic, learn the vocabulary unique to the population, and discover topics not highlighted in the research literature (Sudman, Bradburn, & Schwarz, 1996). The focus interview phase resulted in themes surrounding management, worry, and social issues and reached theme saturation (i.e., no new themes were discussed) after interviews with 10 families. Specifically, children and parents discussed the importance of vigilance toward ingredient lists and worries about accidental contact with specific allergens. For example, one mother reported that her husband once used the same utensil from the peanut butter jar in the jelly jar, which caused her son to have a reaction the next time he ate a jelly sandwich. Management was also a concern, as many children and parents discussed the unpredictable nature of food labels and difficulties abstaining from foods that other children were eating. For example, one mother reported that she recently discovered a “processed in a facility that produces nut products” disclaimer label on a previously “trusted brand” of cookies. Social aspects of living with a food allergy such as feeling left out at birthday parties and other social events, as well as peers bullying a child for having a food allergy were also indicated as major themes. One participant reported “[We] probably missed 200 [birthday] cakes because of our allergies.” when discussing his and his sister’s peanut and tree nut allergies. These major themes were grouped into Treatment, Emotional Functioning,

and Social Functioning on the next iteration of the PedsQL™ Food Allergy Module, which was reduced from 43 items to 37 items as a result of the focus interviews. Items dropped from the PedsQL™ Food Allergy Module after the focus interview phase included “I have allergic reactions often,” “I often have problems as a result of using my EpiPen®,” “I am afraid I/someone else will use my EpiPen® incorrectly,” “I get scared when I have to have blood tests,” “I am scared of needle sticks or shots” and “Going to the doctor’s office often is burdensome” as these areas were not indicated to be of concern to the families interviewed. For example, when discussing issues related to using an EpiPen®, the parents and children indicated little to no hesitation with its use. Further, families did not report frequent or burdensome visits to allergists as a result of food allergy, nor did they report having frequent allergic reactions.

Impairments of physical functioning were not reported during the focus interviews despite interview questions such as “In what ways, if any, does having a food allergy keep you from doing physical activities that you want to do?” and “In what ways, if any, does having a food allergy get in the way of taking care of yourself?” Most children and parents reported that unless there was a snack or party involved in an activity (e.g., T-ball and soccer), they did not notice an impairment of functioning in this domain as a result of having a food allergy. Additionally, respondents did not indicate that children’s self-care was affected by having a food allergy. At the conclusion of this phase, consultation with the pediatric allergist and pediatric psychologist was conducted to provide feedback related to the PedsQL™ Food Allergy Module, and no revisions were made.

Cognitive Interviews

A total of five children ages 5-9 years with food allergy and seven parents of children with food allergy, who had not been involved in the previous aspects of the study participated in

cognitive interviews designed to elicit specific feedback about the feasibility of the measure (e.g., clarity and intention of questions). Cognitive interviews consist of parents and children independently completing the questionnaire and individually answering follow up questions related to individual items and overall impressions of the questionnaire (e. g., “How would you make the directions clearer or easier to understand?” and “What does this item mean to you?”). Cognitive interviews are an important stage of the measure development process, as they allow developers to directly ask the target population about their perception of each item on the measures. This process helps one identify if there are poorly worded items, confusing terminology, or misconceptions about relevant content of the items that may negatively impact the content validity of the final measure. This phase of the project resulted in minor wording revisions to the study questions, specifically, adding clarification statements to several items. For example, based on respondents’ comments, the item “coming into contact with a food allergen” was changed to “accidentally touching a food allergen,” since accidental contact with an allergen is different and potentially less harmful than accidentally ingesting an allergen. Other revisions included changing the “Treatment” heading to “Management,” since, as one parent remarked while completing the measure, currently there is no cure for food allergy. Further, on the child self-report module, the word “peers” was changed to “people my age.” Parents and children did not indicate missing or unnecessary items as a result of the cognitive interviews, thus, the PedsQL™ Food Allergy Module was maintained at 37 items, with three subscales measuring Management, Emotional Functioning and Social Functioning. See Table 2 for wording changes resulting from cognitive interviews. Experts (i.e., pediatric allergist and pediatric psychologist) were consulted at the conclusion of this phase and no revisions were made based on their feedback.

Final Measure

The PedsQL™ Food Allergy Module began with a total of 43 potential items as a result of the literature search and input from pediatric allergists and a pediatric psychologist. This pool of items was eventually decreased to 37 items after conducting focus interviews with children and parents. Items were generated and modified after receiving feedback from families with a child suffering from a food allergy that described their experiences with this specific diagnosis. For example, wording clarification was provided as a result of the cognitive interviews. The PedsQL™ Food Allergy Module includes three scales labeled Management (five items), About My Feelings (15 items), and How I Get Along with Others (17 items). Specifically, the Management scale includes items such as “I worry about side-effects from using my EpiPen®” and seeks to measure the impact of avoidance and responses to potential allergic reactions. The About My Feelings scale includes items such as “I worry about food ingredients changing” and seeks to measure the emotional impact of having a food allergy. The How I Get Along with Others scale includes items such as “I have trouble convincing others that my food allergies are a serious, life-threatening problem” and seeks to measure the social and communication effects of having a food allergy. The PedsQL™ Food Allergy Module’s format is consistent with other PedsQL™ disease-specific modules and the PedsQL™ Generic Core Scales. For example, the PedsQL™ Arthritis Module (Varni et al., 2002) includes the item “I worry about the side effects from medicines” which is consistent wording with the PedsQL™ Food Allergy Module question “I worry about side-effects from using my EpiPen®.” Similarly, the PedsQL™ Generic Core Scales includes the question “I worry what will happen to me.” Please see Appendix E for the PedsQL™ Generic Core Scales Child Self-Report Form.

Items on the parent proxy PedsQL™ Food Allergy Module are nearly identical to the items on the youth forms, but are in reference to the parent's perception of the child's functioning (i.e., the questions are written in the third person). Parents and children are asked if any of the items have been a problem within the past month. Consistent with the PedsQL™ Measurement System, both parent proxy-report and child self-report scores on the PedsQL™ Food Allergy Module utilize a 5-point Likert scale (0 = never a problem, 1 = almost never a problem, 2 = sometimes a problem, 3 = often a problem, 4 = almost always a problem). Items are reverse scored and linearly transformed to a 0 to 100-point scale (i.e., 0 = 100, 1 = 75, 2 = 50, 3 = 25, 4 = 0), with higher scores indicating better HRQOL. The final version of the child self-report and parent report forms of the PedsQL™ Food Allergy Module can be found in Appendix G and Appendix H, respectively.

Discussion

The present study involved the development of the PedsQL™ Food Allergy Module, a questionnaire designed to evaluate HRQOL among children with food allergy, in an effort to improve health outcomes for children with food allergy. The first step of the process involved conducting a careful review of the literature to identify potential items that may be relevant to evaluating child functioning in each domain of health (i.e., physical, psychological, social) among children with food allergy. Ultimately, this literature review led to the generation of items that could initially be categorized as Treatment, About My Feelings, and How I Get Along With Others. After a review of the list by two pediatric allergy specialists and a pediatric psychologist, the initial prototype of the PedsQL™ Food Allergy Module included a 43 item measure with both parent proxy-report and child self-report forms. Next, because children with food allergy and their parents possess crucial knowledge about the impact this disease has on a child's

HRQOL, families were recruited to participate in focus interviews. Once theme saturation was reached, and the items were reviewed by the pediatric allergy specialists and a pediatric psychologist, the PedsQL™ Food Allergy Module prototype was reduced to 37 items. Finally, cognitive interviews were conducted to ensure that each item was written and formatted in a way that accurately conveyed the meaning intended by the developers of the measure. After cognitive interviews were completed, and the items were again reviewed by the pediatric allergy specialists and a pediatric psychologist, the final prototype of the PedsQL™ Food Allergy Module included a total of 37 items with three scales that were labeled Management, About My Feelings, and How I Get Along with Others. It is important to note the PedsQL™ Food Allergy Module development adhered to the PedsQL™ Module Development MethodologySM, which addresses the FDA standards for HRQOL measure development (Johnson & Temple, 1985).

Consistent with the PedsQL™ Module Development MethodologySM, an extensive review of the current pediatric food allergy and HRQOL literature was conducted. This literature review resulted in themes surrounding the vigilance associated with food allergen avoidance, worry about potential ingestion of food allergens, effects of food allergy on family functioning (e.g., avoidance of food allergen by all members of the family, limits on family activities) and the social impact (e.g., not being able to attend social gatherings due to food allergy, having to bring own food to social events) of having a food allergy. Children's fears about potential ingestion of allergens are reasonable considering the possibility of encountering poor labeling (e.g., "produced in a facility that processes peanuts" or "may contain egg"), incomplete food ingredient lists (i.e., not listing included ingredients), and possible cross-contamination of food ingredients in restaurants. Subsequently, these fears have been reported to prevent family activities from occurring and can make events such as travel difficult due to the

inability to prepare meals for the family while away from home. Finally, it is easy to consider how having a food allergy can impact social functioning, as many leisure activities involve food, and abstaining from eating a food allergen in the presence of peers can lead a child to feel left out, which can be especially detrimental in adolescence. The themes discussed in the literature review lead to the creation of 43 potential items and informed focus interview questions such as “Does your food allergy affect or limit you from doing things with your family? If so, how?” and “In what ways, if any, does being afraid of having a reaction affect what you do?” Potential PedsQL™ Food Allergy Module items generated during the literature review were reviewed by a pediatric allergist and pediatric psychologist and were not modified based on feedback received.

Next, focus interviews were conducted with children with food allergy and their parents until no new themes were discussed. Themes such as frustration due to food restriction, worry about accidental contact with a food allergen, and feeling left out when others eat food allergens were identified during this phase and were consistent with the existing food allergy research literature. Themes such as the frequent difficulties conveying the importance of vigilance toward food allergens to others (i.e., distinguishing between a food allergy and “pickiness”) are important to understanding the daily struggles of this population and may be missed by traditional health outcomes assessment. According to parent and child reports within this sample, deficits in physical functioning were not indicated during the focus interviews and as a result, no items were generated in this area. This finding was consistent with literature in this area (i.e., no prior studies have reported deficits in physical functioning) and is not surprising considering that many children with food allergy do not exhibit physical symptoms except in the rare instances of allergy reactions.

As a result of the focus interviews, the PedsQL™ Food Allergy Module was reduced from 43 items to 37 items. Questions involving burdensome and frequent visits to allergists, and anxiety surrounding frequent blood tests or shots were removed from the measure because they were not indicative of common occurrences or of concern to the families who participated in focus interviews. This modification highlights differences between items on the PedsQL™ Food Allergy Module and other disease-specific modules (e.g., PedsQL™ Arthritis Module; Varni et al., 2002), where blood tests and shots are part of disease management. Reasons for this difference may include the fact that blood tests and skin pricks occur to determine the diagnosis of a food allergy and are not part of the food allergy treatment regimen (Sicherer, 2006). Hence, these data suggest that blood tests that occur infrequently may not impact the child's overall daily functioning. At the conclusion of this phase, the PedsQL™ Food Allergy Module was not modified based upon expert feedback.

Consistent with the PedsQL™ Module Development MethodologySM, cognitive interviews were conducted with children with food allergy and their parents. Minor wording revisions such as changing the “Treatment” heading to “Management” and changing the word “peers” to “people my age” were made based on the results of the cognitive interviews. Specifically, the wording change to “people my age” is consistent with the developmental appropriateness of items within the PedsQL™ Measurement System. The modification of the “Treatment” heading likely better captures the construct of interest (i.e., avoidance of food allergens). During the cognitive interview phase, parents and children did not indicate that there were any missing areas from the questionnaire which suggests that items generated from themes in the literature and as a result of the focus interviews were sufficient. This is not uncommon during the measure development process, especially with populations where disease management

is limited to a relatively small number of options. For example, parents and children with food allergy, when asked about certain elements of treatment and disease management are limited in terms of potential responses due to relatively few treatment\management options. Conversely, parents and children with diabetes may be engaging in a wider range of treatment and management methods for their particular illness (e.g., insulin injections, dietary restrictions, etc.). As a result of the cognitive interviews and expert feedback, the PedsQL™ Food Allergy Module consists of 37 items.

There were several limitations to this study. Specifically, the small age range of participants can be seen as an important limitation for the current investigation. Because the PedsQL™ Measurement System is designed to evaluate the HRQOL in children and adolescents ages 2 years to 18 years, it will be important to validate this measure with a wider range of children and adolescents. Additionally, it is not hard to imagine how adolescents with food allergy, who are in the process of becoming more independent, may face unique challenges when it comes to managing and coping with their food allergy. Therefore, it will be important to include older participants in any future validation efforts for the PedsQL™ Food Allergy Module. Second, participants were recruited through food allergy support groups, which may have resulted in a biased sample that included children with a greater number of, or more severe type of, food allergies than the actual population. Further, the families who participated were self-selected, which suggests that they may be more attune to the issues involving living with a food allergy as is highlighted by their membership in a food allergy support group. Thus, future areas for research include gathering participants from other settings (e.g., school systems, clinical settings) to gain a variety of information related to living with food allergy. Finally, the sample was recruited from two sites within a limited geographic region, thus limiting the generalizability

of the findings. It will be important to include a more geographically and ethnically diverse sample in future research efforts aimed at evaluating the psychometric properties of the PedsQL™ Food Allergy Module.

Once the PedsQL™ Food Allergy Module has been validated, this measure will allow researchers to better understand how living with food allergy impacts a child's HRQOL. This will be particularly important given the fact that this population has received little attention in the literature, while the number of children with this diagnosis continues to increase across the country. When used in conjunction with the PedsQL™ Generic Core Scales, the PedsQL™ Food Allergy Module will also allow researchers to better understand how the HRQOL of children with food allergy compare to children from other illness/disease groups (e.g., Type 1 Diabetes). Finally, the PedsQL™ Food Allergy Module will provide researchers with a tool that will allow them to examine if older children, children with a certain type of food allergy (e.g., peanut or tree nut), or those who have a greater number of food allergies are at the greatest risk for low levels of HRQOL.

As previously stated, HRQOL measurement is determined to be the “gold standard” for understanding patient satisfaction and treatment effectiveness within the context of health outcomes assessment and is especially useful in illnesses such as food allergy, where there are few physical symptoms. Although there is not currently a cure for food allergy, a validated form of the PedsQL™ Food Allergy Module will have the potential to capture response to treatment, facilitate decision making between multiple treatments, and examine the side effects of treatments in future FDA drug trials. Like other disease-specific measures of HRQOL, the PedsQL™ Food Allergy Module has the potential to improve quality of life and reduce health

care costs by guiding the medical decision making process and involving the patient in his or her care.

The current investigation fills a gap in the literature by providing a measure that was designed using a standardized development protocol to specifically capture HRQOL in children with food allergy, a population that is clearly experiencing deficits in daily functioning (Bock et al., 2007; Lieberman et al., 2010; Primeau et al., 2000). Furthermore, the addition of the PedsQL™ Food Allergy Module improves the comprehensiveness of a valid and highly utilized HRQOL measurement system, and helps to ensure that valid health outcomes assessment in this ever-growing population is possible. The availability of such a measure will have both significant clinical and research implications that will ultimately lead to efforts that will improve the HRQOL in children with food allergy.

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Table 1

Demographics of Children with Food Allergy and Their Parents Represented in Focus Interviews and Cognitive Interviews

Total N = 30	Focus Interviews n = 18	Cognitive Interviews n = 12
Child Gender		
Female	4 (50%)	3 (60%)
Male	4 (50%)	2 (40%)
Parent Gender		
Female	8 (80%)	5 (71.4%)
Male	2 (20%)	2 (28.6%)
Child Ethnicity*		
White, Non-Latino	9 (90%)	6 (100%)
Asian or Pacific Islander	1 (10%)	0 (0%)
Child Age Group – Child Report		
5-7 years	5 (62.5%)	3 (60%)
8-12 years	3 (37.5%)	2 (40%)
13-18 years	0 (0%)	0 (0%)
Child Age Group – Parent Report		
2-4 years	2 (20%)	0 (0%)
5-7 years	6 (60%)	6 (75%)**
8-12 years	2 (20%)	2 (25%)**

13-18 years	0 (0%)	0 (0%)
Number of Allergens*		
1	3 (30%)	1 (16.7%)
2	4 (40%)	2 (33.3%)
3	0 (0%)	1 (16.7%)
4	2 (20%)	0 (0%)
7	1 (10%)	0 (0%)
12+	0 (0%)	2 (33.3%)****
Type of Allergens*		
Peanut	9 (90%)	3 (60%)
Tree nut	7 (70%)	1 (20%)
Egg	2 (20%)	4 (80%)
Wheat	1 (10%)	1 (20%)
Oat	1 (10%)	0 (0%)
Soy	1 (10%)	1 (20%)
Bison	1 (10%)	0 (0%)
Pumpkin	1 (10%)	0 (0%)
Dairy	1 (10%)	3 (60%)
Oranges	1 (10%)	0 (0%)
Pineapples	1 (10%)	0 (0%)
Legumes	0 (0%)	1 (20%)
Rye	0 (0%)	1 (20%)
Barley	0 (0%)	1 (20%)

Seeds	0 (0%)	1 (20%)
Salmon	0 (0%)	1 (20%)
Shellfish	0 (0%)	1 (20%)
Tuna	0 (0%)	1 (20%)

*Some demographic and allergen information included for children who did not participate, but parents participated

**One parent in the cognitive interview group provided information for more than one child

***One participant in the cognitive interview group did not indicate specific food allergens but stated that she had only 8 safe foods

Table 2

Wording Changes Resulting from Cognitive Interviews

Original Item	Revised Item
I worry about accidentally <i>coming into contact</i> with a food allergen	I worry about accidentally <i>touching</i> a food allergen
I worry about eating at restaurants	I worry about eating at <i>familiar</i> restaurants
I worry about eating without my parents present	I worry about eating <i>new foods</i> without my parents present
I have trouble telling family members about my food allergy	I have trouble telling family members <i>such as aunts, uncles, and grandparents</i> about my food allergy
I have trouble telling strangers about my food allergy	I have trouble telling strangers <i>such as restaurant workers</i> about my food allergy
<i>I have trouble</i> at birthday parties and other social gatherings where food allergens are present	<i>I feel left out</i> at birthday parties and other social gatherings where food allergens are present
<i>I have difficulty avoiding my food allergens around my friends</i>	<i>I have difficulty not eating foods that I am allergic to when friends eat them</i>

Note. Changes highlighted by italic formatting.

Appendix A
Children/Adolescent Focus Interview Questions

Introduction

1. Introduction- reminder that questions are about food allergy.
2. What is the first thing that comes to mind when you hear the phrase “food allergy”?
3. What is the biggest concern about your health?

Physical

1. In what ways, if any, does having food allergy keep you from doing physical activities that you want to do?
2. In what ways, if any, does having food allergy get in the way of taking care of yourself?
3. What food allergy symptoms bother you most?
4. In what ways, if any, does being afraid of having a reaction affect what you do?
5. In what ways does your food allergy affect your sleep?
6. Is carrying an EpiPen® a problem for you? How so?

Psychological/social

1. Does your food allergy limit you from doing things you want to do?
2. What things, if any, do you worry about because you have a food allergy?
3. Do you worry about death from food allergy?
4. Does your food allergy affect how you get along with other people? How so?
5. In what ways does your food allergy cause problems, if any, in your family?
6. Does it affect or limit you from doing things with your families? Going out to dinner, movies, and other activities?
7. In what ways, if any, does having food allergy make you feel good or bad about who you are?

8. Happy?
9. Unhappy?
10. Afraid?
11. Is the thought of using your EpiPen® a problem for you? How so?

School

1. What problems, if any, do you have at school because you have food allergy?
2. In what ways, if any, does food allergy affect how you get along with other kids at your school?
3. Do you feel different from your classmates because you have a food allergy? How does that make you feel?

Other

1. Is there anything else about your health or your food allergy that is important to your quality of life?

Appendix B

Parent Focus Interview Questions

Introduction

1. What is the first thing that comes to mind when you hear the phrase “food allergy”?
2. What is the biggest concern about your child’s health?
3. What do you think is your child’s biggest concern about his or her health?
4. How does your child’s food allergy affect his/her overall health?
5. Does it affect his/her daily activities?
6. Has your child’s food allergy limited the family activities in any way?
7. What symptoms bother your child the most?
8. Have you changed how your family eats?

Physical

1. In what ways, if any, does having food allergy keep your child from doing physical activities that he/she wants to do?
2. In what ways, if any, does having food allergy get in the way of your child taking care of him/herself?
3. What food allergy symptoms bother your child the most?
4. In what ways, if any, does being afraid of having a reaction affect what your child does?
5. In what ways does your child’s food allergy affect his/her sleeping?
6. Is carrying an EpiPen® a problem for your child? How so?

Psychological/social

1. What things, if any, do you worry about because of your child’s food allergy?
2. Do you worry about death from food allergy?
3. Does your child’s food allergy affect how he/she gets along with other people? How so?

4. In what ways does your child's food allergy cause problems, if any, in your family?
5. How does your child's health make him/her feel emotionally?
6. Is the thought of your child using his/her EpiPen® a problem for you? How so?

School

1. What problems, if any, does your child have at school because of his/her food allergy?
2. What does your child like best about school?
3. What does your child like least about school?
4. In what ways, if any, does food allergy affect how your child gets along with other kids at school?

Other

1. Is there anything else about your child's health or your food allergy that is important to his/her quality of life?

Appendix C

Child and Parent Cognitive Interview Questions

1. Rationale

How would you make the directions clearer or easier to understand?

What does “in the past one month” mean to you?

Was this reference period used to determine your response?

Would your responses be different if the instructions had asked about problems with the following activities “in the past 7 days”?

2. Individual Items

In your own words, what do you think this question is asking? What does this item mean to you?

3. Response Choices

What do you think about these response choices?

How would you make them clearer or easier to understand?

Is there one that describes your situation?

4. Sections

In your own words, what do you think this group of items is measuring?

Do you think these items are related? Are there any that don’t belong?

5. Overall Evaluation

Any comments regarding:

The difficulty of these items?

The importance of these items to having a food allergy?

Any items that were not covered/left out?

Any items that you think should be deleted?

Overall thoughts/opinions of the questionnaire?

Anything that you would change?

Appendix D
PedsQL™ Food Allergy and Family Information Form

<p>What is your relationship to this child (please check and/or circle)?</p> <p><input type="checkbox"/> Mother, Step Mother, Foster Mother <input type="checkbox"/> Grandmother <input type="checkbox"/> Guardian <input type="checkbox"/> Father, Step Father, Foster Father <input type="checkbox"/> Grandfather <input type="checkbox"/> Other _____</p>			
INFORMATION ABOUT THE CHILD			
Date of Birth (month/day/year): _____ / _____ / _____	Are you insured through Medicaid? <input type="checkbox"/> NO <input type="checkbox"/> YES	Age of child now: _____	Child is: <input type="checkbox"/> male <input type="checkbox"/> female
Ethnic Group or Race of Child:	<input type="checkbox"/> Black, Non-Latino <input type="checkbox"/> Asian or Pacific Islander	<input type="checkbox"/> Mexican/Latino <input type="checkbox"/> White, Non-Latino	<input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Other _____
INFORMATION ABOUT MOTHER		INFORMATION ABOUT FATHER	
Marital Status:	<input type="checkbox"/> Single <input type="checkbox"/> Living with someone <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Separated <input type="checkbox"/> Widowed	Marital Status:	<input type="checkbox"/> Single <input type="checkbox"/> Living with someone <input type="checkbox"/> Married <input type="checkbox"/> Divorced <input type="checkbox"/> Separated <input type="checkbox"/> Widowed
Highest Level of Education:	<input type="checkbox"/> 6 th grade or less <input type="checkbox"/> 7 th -9 th grade <input type="checkbox"/> 10 th -12 th grade <input type="checkbox"/> High school graduate <input type="checkbox"/> Some college or certification course <input type="checkbox"/> College Graduate <input type="checkbox"/> Graduate or Professional Degree	Highest Level of Education:	<input type="checkbox"/> 6 th grade or less <input type="checkbox"/> 7 th -9 th grade <input type="checkbox"/> 10 th -12 th grade <input type="checkbox"/> High school graduate <input type="checkbox"/> Some college or certification course <input type="checkbox"/> College Graduate <input type="checkbox"/> Graduate or Professional Degree
Occupation/Job Title:	Occupation/Job Title: _____		
IMPACT SCALE			
<p>What are your child's food allergies?</p>		<p>Do you have food allergy? <input type="checkbox"/> NO <input type="checkbox"/> YES IF YES.... What type(s)?</p> <p>Do any of your other children have food allergy? <input type="checkbox"/> NO <input type="checkbox"/> YES</p>	
<p><i>In the past month</i>, has your child had...</p>			
<p>To use his or her epinephrine pen? <input type="checkbox"/> NO <input type="checkbox"/> YES</p>		<p>IF YES... How many times? _____ IF YES... After eating what food(s)? _____</p>	
<p><i>In the past 6 months</i>, has your child...</p>			
<p>Had a chronic health condition (defined as a physical or mental health condition that has lasted or is expected to last at least 6 months, and interferes with your child's activities)? <input type="checkbox"/> <input type="checkbox"/> NO <input type="checkbox"/> YES</p>		<p>IF YES... What is the name of your child's chronic health condition? _____</p>	

<i>In the past 12 months, has your child had...</i>					
Any OVERNIGHT VISITS to the hospital? <input type="checkbox"/> NO <input type="checkbox"/> YES		IF YES... How many times? _____ What was wrong? _____			
Any EMERGENCY ROOM/URGENT CARE visits? <input type="checkbox"/> NO <input type="checkbox"/> YES		IF YES... How many times? _____ What was wrong? _____			
<i>In the past 30 days...</i>					
How many days did your child miss from school due to physical or mental health? _____					
How many days was your child sick in bed or too ill to play? _____					
How many days did your child need someone to care for him/her due to physical or mental health? _____					
<i>If you work outside of the home, please answer the following questions.</i>					
<i>In the past 30 days</i>, how many days have you missed from work due to your child's physical or mental health?					
IN THE PAST 30 DAYS, HAS YOUR CHILD'S HEALTH INTERFERED WITH...	Never	Almost Never	Sometimes	Often	Almost Always
Your daily routine at work	0	1	2	3	4
Your ability to concentrate at work	0	1	2	3	4

Appendix E
 PedsQL™ Generic Core Scales
 Child Self-Report Form

*In the past **ONE month**, how much of a **problem** has this been for you ...*

About My Health and Activities (PROBLEMS WITH...)		Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard for me to walk more than one block		0	1	2	3	4
2. It is hard for me to run		0	1	2	3	4
3. It is hard for me to do sports activity or exercise		0	1	2	3	4
4. It is hard for me to lift something heavy		0	1	2	3	4
5. It is hard for me to take a bath or shower by myself		0	1	2	3	4
6. It is hard for me to do chores around the house		0	1	2	3	4
7. I hurt or ache		0	1	2	3	4
8. I have low energy		0	1	2	3	4
About My Feelings (PROBLEMS WITH...)		Never	Almost Never	Sometimes	Often	Almost Always
1. I feel afraid or scared		0	1	2	3	4
2. I feel sad or blue		0	1	2	3	4
3. I feel angry		0	1	2	3	4
4. I have trouble sleeping		0	1	2	3	4
5. I worry about what will happen to me		0	1	2	3	4
How I Get Along with Others (PROBLEMS WITH...)		Never	Almost Never	Sometimes	Often	Almost Always
1. I have trouble getting along with other kids		0	1	2	3	4
2. Other kids do not want to be my friend		0	1	2	3	4
3. Other kids tease me		0	1	2	3	4
4. I cannot do things that other kids my age can do		0	1	2	3	4
5. It is hard to keep up when I play with other kids		0	1	2	3	4
About School (problems with...)		Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard to pay attention in class		0	1	2	3	4
2. I forget things		0	1	2	3	4
3. I have trouble keeping up with my schoolwork		0	1	2	3	4
4. I miss school because of not feeling well		0	1	2	3	4
5. I miss school to go to the doctor or hospital		0	1	2	3	4

Appendix F

Items Resulting from Literature Search

Health (*problems with...*)

1. I have allergic reactions often
2. I am often frustrated due to food restrictions

Treatment:

1. I often have problems as a result of using my EpiPen®
2. I am scared to use my EpiPen®
3. I am afraid that using my EpiPen® will hurt
4. I am afraid I/someone else will use my EpiPen® incorrectly
5. I am embarrassed to carry my EpiPen® with me
6. It is hard for me to stay away from food allergens
7. I get scared when I have to have blood tests
8. I am scared of needle sticks or shots
9. Going to the doctor's office often is burdensome

Worry (*problems with...*)

1. I worry about unlisted ingredients
2. I worry about eating at restaurants
3. I worry about eating at new restaurants
4. I worry about eating food at school
5. I worry about eating at friends' houses
6. I worry about not having my EpiPen® available
7. I worry about having an allergic reaction
8. I worry about food ingredients changing
9. I worry about having food allergies for the rest of my life
10. I worry about trying new foods
11. I worry about side-effects from using my EpiPen®
12. I worry about eating without my parents present
13. I am afraid to order school lunches due to my food allergies
14. I worry that I do not obtain enough nutritional value in my meals due to my food allergies

Communication (*problems with...*)

1. I have trouble telling peers about my food allergies
2. I have trouble telling teachers about my food allergies
3. I have trouble telling doctors about my food allergies
4. I have trouble telling family members about my food allergies
5. I have trouble telling strangers about my food allergies
6. I have trouble telling friends' parents about my food allergies
7. I have trouble convincing others that my food allergies are a serious, life-threatening problem
8. I often argue with family members about my food allergies

Social (*problems with...*)

1. Peers often make fun of me for having food allergies
2. Peers often taunt me with food that I am allergic to
3. Peers often bully me for having food allergies
4. I have trouble at birthday parties where food allergens are present
5. I often feel different from peers due to food allergies
6. I often feel left out when others eat foods I cannot eat
7. I have trouble with food restrictions around my friends
8. I often avoid social situations because of my food allergies
9. I have trouble making friends because I am embarrassed of my food allergies
10. I am embarrassed by the rashes caused by my food allergies

Appendix G
 Items Resulting from Focus and Cognitive Interviews
 PedsQL™ Food Allergy Module
 Child Self-Report

*In the past **ONE month**, how much of a **problem** has this been for you ...*

Management (PROBLEMS WITH...)	Never	Almost Never	Sometimes	Often	Almost Always
1. I worry about side-effects from using my EpiPen	0	1	2	3	4
2. I am afraid that using my EpiPen will hurt	0	1	2	3	4
3. I am embarrassed to carry my EpiPen with me	0	1	2	3	4
4. I am scared to use my EpiPen	0	1	2	3	4
5. It is hard for me to stay away from food allergens	0	1	2	3	4

About My Feelings (PROBLEMS WITH...)	Never	Almost Never	Sometimes	Often	Almost Always
1. I worry about eating food at school	0	1	2	3	4
2. I worry about eating at friends' houses	0	1	2	3	4
3. I worry about not having my EpiPen available at a time when I may need it	0	1	2	3	4
4. I worry about having an allergic reaction	0	1	2	3	4
5. I worry about accidentally touching a food allergen	0	1	2	3	4
6. I worry about unlisted ingredients	0	1	2	3	4
7. I worry about food ingredients changing	0	1	2	3	4
8. I worry about having food allergies for the rest of my life	0	1	2	3	4
9. I worry about trying new foods	0	1	2	3	4
10. I am frustrated due to food restrictions	0	1	2	3	4
11. I worry that I do not obtain enough nutritional value in my meals due to my food allergies	0	1	2	3	4
12. I worry about eating at familiar restaurants	0	1	2	3	4
13. I worry about eating at new restaurants	0	1	2	3	4
14. I am afraid to order school lunches due to my food allergies	0	1	2	3	4
15. I worry about eating new foods without my parents present	0	1	2	3	4

How I Get Along with Others (PROBLEMS WITH...)	Never	Almost Never	Sometimes	Often	Almost Always
1. I have trouble telling people my age about my food allergies	0	1	2	3	4
2. I have trouble telling teachers about my food allergies	0	1	2	3	4
3. I have trouble telling family members such as aunts, uncles and grandparents about my food allergies	0	1	2	3	4
4. I have trouble telling strangers such as restaurant workers about my food allergies	0	1	2	3	4
5. I have trouble telling friends' parents about my food allergies	0	1	2	3	4
6. I have trouble convincing others that my food allergies are a serious, life-threatening problem	0	1	2	3	4
7. I have trouble turning down food when people try to share with me	0	1	2	3	4
8. People my age make fun of me for having food allergies	0	1	2	3	4
9. Others try to touch me with food that I am allergic to	0	1	2	3	4
10. People my age bully me for having food allergies	0	1	2	3	4
11. I feel left out at birthday parties and other social gatherings where food allergens are present	0	1	2	3	4
12. I often feel different from people my age due to my food allergies	0	1	2	3	4
13. It bothers me that I cannot attend sporting games due to my food allergies	0	1	2	3	4
14. It bothers me that I cannot eat dinner at my friends' houses because of my food allergies	0	1	2	3	4
15. I often feel left out when others eat foods I cannot eat	0	1	2	3	4
16. I have difficulty not eating foods that I am allergic to when friends eat them	0	1	2	3	4
17. I often avoid social situations because of my food allergies	0	1	2	3	4

Appendix H
 Items Resulting from Focus and Cognitive Interviews
 PedsQL™ Food Allergy Module
 Parent Report

In the past **ONE month**, how much of a **problem** has your child had with...

Treatment (PROBLEMS WITH...)	Never	Almost Never	Sometimes	Often	Almost Always
1. Feeling frustrated due to food restrictions	0	1	2	3	4
2. Feeling afraid that using an EpiPen will hurt	0	1	2	3	4
3. Feeling embarrassed to carry an EpiPen	0	1	2	3	4
4. Feeling scared to use his or her EpiPen	0	1	2	3	4
5. Staying away from food allergens	0	1	2	3	4

Emotional Functioning (PROBLEMS WITH...)	Never	Almost Never	Sometimes	Often	Almost Always
1. Worrying about eating food at school	0	1	2	3	4
2. Worrying about eating at friends' houses	0	1	2	3	4
3. Worrying about not having an EpiPen available at a time when he or she may need it	0	1	2	3	4
4. Worrying about having an allergic reaction	0	1	2	3	4
5. Worrying about accidentally coming into contact with a food allergen	0	1	2	3	4
6. Worrying about unlisted ingredients	0	1	2	3	4
7. Worrying about food ingredients changing	0	1	2	3	4
8. Worrying about having food allergies for the rest of his or her life	0	1	2	3	4
9. Worrying about trying new foods	0	1	2	3	4
10. Worrying about side-effects from using an EpiPen	0	1	2	3	4
11. Worrying about obtaining enough nutritional value in meals due to food allergies	0	1	2	3	4
12. Worrying about eating at restaurants	0	1	2	3	4
13. Worrying about eating at new restaurants	0	1	2	3	4
14. Feeling afraid to order school lunches due to food allergies	0	1	2	3	4
15. Worrying about eating without parents present	0	1	2	3	4

Social functioning (PROBLEMS WITH...)	Never	Almost Never	Some- times	Often	Almost Always
1. Telling peers about food allergies	0	1	2	3	4
2. Telling teachers about his or her food allergies	0	1	2	3	4
3. Telling family members about his or her food allergies	0	1	2	3	4
4. Telling strangers about his or her food allergies	0	1	2	3	4
5. Telling friends' parents about his or her food allergies	0	1	2	3	4
6. Convincing others that his or her food allergies are a serious, life-threatening problem	0	1	2	3	4
7. Turning down food when people try to share with him or her	0	1	2	3	4
8. Peers making fun of child for having food allergies	0	1	2	3	4
9. Peers taunting child with food allergens	0	1	2	3	4
10. Peers bullying child for having food allergies	0	1	2	3	4
11. Having trouble at birthday parties and other social gatherings where food allergens are present	0	1	2	3	4
12. Feeling different from peers due to food allergies	0	1	2	3	4
13. Not attending sporting games due to food allergy	0	1	2	3	4
14. Turning down invitations to eat at friends' houses because of food allergies	0	1	2	3	4
15. Feeling left out when others eat foods he or she cannot eat	0	1	2	3	4
16. Having difficulty avoiding food allergens around friends	0	1	2	3	4
17. Avoiding social situations because of food allergies	0	1	2	3	4