Validation of the Pediatric Quality of Life Inventory™ (PedsQL™) Food Allergy Module- Parent Report

by

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A dissertation submitted to the Graduate Faculty of
Auburn University
in partial fulfillment of the
requirements for the Degree of
Doctor of Philosophy

Auburn, Alabama
August 6, 2016

Keywords: Pediatric Food Allergy, Health-Related Quality of Life,
Assessment, Patient-Reported Outcomes

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Abstract

Food allergy has been shown to affect approximately 8% of children in North America and Europe, with peanut allergy being the most common and severe allergen. A diagnosis of food allergy has been shown to affect emotional, social, and family functioning; however, a valid and developmentally-appropriate English-language health-related quality of life (HRQOL) measure for children with food allergy does not currently exist. Thus, the purpose of this study was to validate the Pediatric Quality of Life Inventory™ (PedsQL™) Food Allergy Module-Parent Report. Parents were recruited from food allergy benefit walks and online. Parents completed several forms in reference to their child's functioning. A total of 168 parents of children ages 2-18 with physician-diagnosed food allergy participated. Results indicated that a 3-factor model consisting of 37 items was appropriate. The measure evidenced adequate content validity with the PedsQL™ Generic Core Scales and internal consistency. Hypotheses related to discriminant validity were not supported. Future examinations should seek to validate the PedsQL™ Food Allergy Module- Child Self Report and consider measuring parent-child agreement. The addition of a valid food allergy-specific module for parents helps to ensure that valid health outcomes assessment in this population is possible and improves the comprehensiveness of the PedsQL™ Measurement System.

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Food allergy has been shown to affect approximately 8% (approximately 5.9 million) of children in North America and Europe (Gaspar-Marques et al., 2014; Gupta et al., 2011; National Institute for Health and Clinical Excellence, 2011). These rates include common food allergens, such as peanut, which affects 25% of children with food allergy. Milk and shellfish allergies are the next most prevalent, affecting 21.1% and 17.2% of children with food allergy, respectively. In addition to differing prevalence rates, allergens can differ in severity. For example, children with peanut and tree nut allergies evidence higher rates of severe reactions to food allergens (Gupta et al., 2011). Compounding these rates is the finding that 30% of children have multiple food allergies (Gupta et al., 2011). Food allergy has been shown to differentially affect children, with the greatest risk for diagnosis occurring in the 3 to 5 year old age group. Despite this finding, adolescents are at the greatest risk for severe reactions, perhaps because severity increases with age (Gupta et al., 2011) and tendency for parental involvement declines with child age.

Research has shown that food allergy rates are on the rise. For example, Branum and Lukacs (2009) found an 18% increase in food allergy prevalence from 1997 to 2007 using population-based data. This rate is consistent with other studies that have found rates increasing from 2009 to 2011 (Jackson, Howie, & Akinbami, 2013), especially among non-Hispanic children. These findings are concerning because of the health implications of having a food allergy. For example, food allergy is associated with a significant risk for comorbid diagnoses such as asthma (29% of children) and eczema (27% of children). Moreover, the increase in food allergy prevalence has also been associated with an increase in hospitalizations as a result of severe reactions (Branum & Lukacs, 2009).

Food Allergy Reactions

Ingestion of a food allergen can quickly lead to food-induced anaphylaxis, which is defined as “a serious allergic reaction that is rapid in onset and may cause death” (Sampson et al., 2006). Criteria for anaphylactic reactions include sudden onset of symptoms such as respiratory distress, decreased blood pressure, swelling of the tongue, and gastrointestinal symptoms. Severity of reactions can be impacted by the amount of allergen consumed, how the food was processed (e.g., cooked or raw), and the presence of asthma (NIAID Panel, 2010).

Unfortunately, there is no cure for food allergy. Instead, abstaining from contact with allergens is the only treatment. Avoiding food allergens can be challenging because of cross-contamination and inconsistent labeling procedures (Noimark, Gardner, & Warner, 2009). In the event of accidental ingestion of food allergens, prompt epinephrine administration via intramuscular injection is necessary (Muraro et al., 2014; NIAID Panel, 2010).

Pediatric Food Allergy and Psychological Functioning

Given the risks associated with food allergy reactions, one can imagine its impact on daily activities. Hypervigilance associated with abstaining from allergen contact can lead to increased rates of anxiety among children with food allergy, even when compared to children with other chronic illnesses. For example, children with food allergy have endorsed significantly higher symptoms of anxiety than their peers with type 1 diabetes (Avery, King, Knight, & Hourihane, 2003). Specifically, children with food allergy reported fears of accidental ingestion, fears of reactions, and concern about food. In another study, adolescents with food allergy evidenced significantly worse physical functioning and higher rates of mental health problems, bodily pain and self-esteem than their peers with type 1 diabetes (Flokstra-de Blok et al., 2010).

High rates of anxiety in youth with food allergy could be seen as protective, but could also hinder the child's functioning if avoidance becomes debilitating (Avery et al., 2003).

These findings are consistent with other studies that have compared children with food allergy to healthy peers. For example, children with food allergy endorsed lower emotional and social health-related quality of life (HRQOL) than age-based norms on generic measures of HRQOL (King, Knibb, & Hourihane, 2009). Similarly, children with food allergy evidenced greater rates of separation anxiety and poorer generic HRQOL than their siblings without food allergy (King et al., 2009).

Pediatric Food Allergy and School and Social Functioning

Considering the amount of time that children spend in school, it is not surprising that several studies have documented the effects of food allergy on school attendance and peer interactions. For example, one study found that 10% of parents chose to homeschool their children because of their food allergy (Bollinger et al., 2006). Relatedly, 26% of parents reported restricting their children's involvement in activities such as field trips, summer camps and school parties because of the child's food allergy. Qualitative analysis of the social effects of having a food allergy has shown avoidance of food consumption at birthday parties, school events and family gatherings (Resmini, 2012).

One aspect of school functioning that is particularly concerning includes reports of bullying due to having a food allergy. For example, Shemesh et al. (2013) found that over 31% of children reported being bullied for having a food allergy. This is consistent with findings of parental awareness of childhood bullying in a sample of children with food allergy (Lieberman, Weiss, Furlong, Sicherer, & Sicherer, 2010). Bullying acts reported include being teased with the food allergen (30%), being forced to come into contact with the allergen (12%) and throwing the food allergen at the respondent (10%). As might be expected, bullying for any reason was associated with child-report of poorer generic HRQOL and increased levels of anxiety (Shemesh et al., 2013). These findings are particularly concerning because of the health implications associated with potential contact with a food allergen.

Pediatric Food Allergy and Family Functioning

In addition to the effect of food allergy on youth, research has demonstrated the impact of food allergy on families. For example, food allergy has been shown to increase parental burden and limit family activities because of the risks associated with potential accidental exposure (Bollinger et al., 2006; Cohen, Noone, Muñoz-Furlong, & Sicherer, 2004; Primeau et al., 2000; Sicherer, Noone, & Muñoz-Furlong, 2001). Primeau et al. (2000) found significantly higher rates of family disruption reported by parents of children with food allergy when compared with families with children with rheumatic diseases. Similarly, studies have shown that pediatric food allergy is associated with greater parental burden and significant rates of parental concern. For example, parents of children with food allergy report a hesitation to allow other adults to prepare food or host playdates because of their child’s food allergy (Bollinger et al., 2006; Howe, Franxman, Teich, & Greenhawt, 2014; Sicherer et al., 2001). This results in an avoidance of restaurants (16% of families) and visiting relatives’ houses (10%). Moreover, family social activities, such as going on vacation, were also found to be impacted by a child’s food allergy (Bollinger et al., 2006).

Consistent with other studies, greater numbers of food allergens were associated with greater avoidance of familial activities. The authors speculate that having multiple allergen affects family functioning because of the need for increased vigilance with each added allergen

(Howe et al., 2014). Thus, food allergy can have a negative familial impact compared to those without food allergy and children with other chronic illnesses.

Health-Related Quality of Life

As discussed previously, food allergy can adversely affect youth’s emotional, academic, social, and family functioning. Broadly, this contributes to their HRQOL, which includes the status of an individual’s physical, mental, social and occupational functioning (Higginson & Carr, 2001; Varni, Burwinkle, Seid, & Skarr, 2003). The multifaceted concept of HRQOL is consistent with the World Health Organization’s (WHO) definition of health (i.e., “the state of complete physical, mental and social well-being and not merely the absence of disease or infirmity;” WHO, 1948). By replacing traditional indicators of health status, such as disease severity or mortality rates, HRQOL shifts the focus from the illness to the patient (Higginson & Carr, 2001).

There are several instances in which HRQOL assessment can be especially helpful. First, HRQOL assessment can be conducted to meet the requirements of patient-reported outcomes (PRO) assessment as part of Food and Drug Administration (FDA) drug trials (FDA, 2009). Second, HRQOL measurement can be beneficial in measuring the effect of an intervention on illnesses where there are few clinical indicators, such as chronic pain (Higginson & Carr, 2001). Finally, HRQOL can be an important measure to consider during end of life care, when treatment has shifted to providing comfort rather than prolonging life (Higginson & Carr, 2001).

Health-Related Quality of Life: Measures

There are two types of HRQOL measures available, generic and disease-specific. Generic HRQOL measures assess general functioning regardless of the respondent’s health status, whereas disease-specific measures assess functioning while considering the symptoms of the illness. Several measures of generic HRQOL have been created for use in children and adolescents. One is the Child Health Questionnaire (CHQ), an assessment of child self- and parent proxy-report of symptoms (Landgraf, Abetz, & Ware, 1996). The CHQ child self-report includes 87 items for children ages 10 and older. The parent proxy-report includes full length (50 items) and short (28 items) forms. Unfortunately, there are limitations related to the use of the CHQ, including lengthy administration time (up to 25 minutes for the child form), lack of available norms, and variable recall times (e.g., in the “past four weeks” and “in general”). Finally, the items on the child and parent forms do not correspond, making direct comparisons of responses difficult (Landgraf et al., 1996).

One instrument that addresses these limitations is the PedsQL™ Generic Core Scales (Varni, Seid, & Kurtin, 2001), a valid and reliable measure of child HRQOL. The PedsQL™ Generic Core Scales assess general HRQOL in children ages 5-18 and parent-proxy report of children ages 2-18. The scales are more feasible than the CHQ, with each form consisting of 28 items across four scales (e.g., Physical, Emotional, Social and School Functioning). Moreover, comparison of ratings across respondents is facilitated by the PedsQL™ wording. Parent-proxy report forms employ similar wording as the child report forms, but are written from the viewpoint of the third person. Finally, the scales include a consistent time reference of the past month (Varni et al., 2001).

While generic instruments are advantageous for comparing HRQOL across groups (e.g., healthy and ill), they may neglect unique information. Thus, disease-specific instruments are warranted. Specifically, disease-specific instruments are beneficial for measuring response to intervention and capturing disease-specific symptoms. They may be especially useful in determining negative treatment side-effects and be more sensitive to clinical changes than generic instruments (Guyatt, Feeny, & Patrick, 1993; Varni, Burwinkle, & Lane, 2005).

Food Allergy-Specific HRQOL Measures

As discussed previously, disease-specific HRQOL measures capture unique information that may be neglected by generic measures. Several sources cite the use of disease-specific and generic instruments in tandem as best practice for HRQOL measurement (Guyatt et al., 1993; Varni et al., 2005). The existence of a food-allergy specific instrument helps to ensure that the effects of disease-specific symptoms are being measured appropriately and has the potential to be more sensitive to clinical changes in disease status (Patrick & Deyo, 1989). Additionally, future food allergy drug trials can benefit from the inclusion of a disease-specific measure, as required by the FDA (FDA, 2009).

Currently, there are few measures appropriate for this task, especially for use with youth in the United States. One example of an international measure is the Food Allergy Quality of Life Questionnaire-Child Form (FAQLQ-CF; Flokstra-de Blok et al., 2009). The instrument was developed in 2008 as part of a group of disease-specific measures for children, adolescents and adults in the Netherlands (DunnGalvin, de BlokFlokstra, Burks, Dubois, & Hourihane, 2008; Flokstra-de Blok et al., 2008). Strengths of the measures include their strong development and validation techniques. The instruments were developed through interviews with parents and youth, item rankings, and expert feedback (Flokstra-de Blok et al., 2009). The measures demonstrated appropriate internal consistency and test-retest reliability. Finally, factor analysis indicated the importance of five factors. Interestingly, the FAQLQ-CF correlated weakly with the CHQ, a generic measure of HRQOL. The authors hypothesized that the weak correlation provides evidence of a need for a disease-specific measure of HRQOL in children with food allergy (Flokstra-de Blok et al., 2009). However, an alternative hypothesis is that concurrent validity of the measure cannot be confirmed.

There are several limitations to the FAQLQ group of questionnaires. First, there are no measures available for child self- or parent proxy-report of symptoms in children younger than eight years old and there is no parent proxy-report available for children older than age 13. Second, the measures were developed and validated in Europe, with the exception of the FAQLQ-Parent Form (FAQLQ-PF), which included a validation sample of 60 parents from the United States. Items on the FAQLQ-CF and FAQLQ-Teen Form (FAQLQ-TF) were originally written in Dutch and were translated into English using the WHO guidelines for measure translation (i.e., the items were written in Dutch, translated into English and were subsequently back translated into Dutch to determine structural differences between the two versions). Thus, the child and teen forms are examples of measures that have been developed and validated in differing cultural samples and may not be appropriate for youth in the United States. Furthermore, items differ across measures, making cross-informant and longitudinal comparison difficult. Finally, the measures lack a retrospective time frame, making it difficult to determine a temporal reference for ratings.

Development of the PedsQL™ Food Allergy Module

In an effort to create a feasible and empirically-based measure of food allergy-specific HRQOL, the PedsQL™ Food Allergy Module- Parent Report was developed (Resmini, 2012). Consistent with the PedsQL™ Methodology, the instrument was devised as a result of a literature review, focus groups, cognitive interviews, and expert input. Specifically, 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- Parent Report. Children with physician-diagnosed food allergy and their parents participated in the focus interviews until theme saturation (i.e., the discussion of no new food allergy-related themes) was reached. The focus groups resulted in a reduction of six items on the questionnaire. Modifications made based upon the results of the cognitive interviews included minor wording changes. No new items were generated as a result of the cognitive or focus interviews. The resulting measure consists of 38 items across three scales (i.e., "Emotional Functioning," "Management," and "Social Functioning"). Items are rated on a five-point Likert scale and include "Worrying about eating food at school" (i.e., Emotional Functioning), "Worrying about side-effects from using his or her EpiPen" (i.e., Management) and "Trouble telling kids his or her age about food allergies" (Social Functioning). Items are reverse-scored and linearly transformed (range = 0-100) such that higher scores indicate better HRQOL (Resmini, 2012). Prior to Resmini (2012), no disease-specific HRQOL measure for children with food allergy existed within the English language.

Consistent with the future directions recommended by Resmini (2012), additional research is needed to validate the PedsQL™ Food Allergy Module- Parent Report within a sample from the United States. The purpose of the current study is to fulfill this goal. Specifically, the psychometric properties of the PedsQL™ Food Allergy Module- Parent Report were examined to determine whether the module measures the construct that it intends to measure (i.e., HRQOL) in its targeted population. As with the administration of any psychometric measure, the findings of a measure should be regarded with caution unless validation has been supported within its intended population. As a result, the reliability and psychometric validity of the PedsQL™ Food Allergy Module- Parent Report were examined in this study so that clinical and empirical conclusions about the results of the measure can be reached.

Rationale for the Study

There are a multitude of research studies demonstrating the reliability and validity of assessing health outcomes in child and adolescent populations through HRQOL measurement. The addition of a valid and reliable English-language measure will ensure that the PedsQL™ Food Allergy Module- Parent Report is appropriate for clinical and empirical use within this population. The psychometric examination of the PedsQL™ Food Allergy Module fills a gap in the literature by providing the means to measure response to potential interventions, including fulfilling the FDA requirements for PROs in drug trials. In contrast to the information provided by generic instruments, a valid and reliable food allergy-specific instrument has the potential to measure disease-specific symptoms, capture potential negative treatment side-effects and to be more sensitive to clinical change. Finally, the validated PedsQL™ Food Allergy Module- Parent Report will provide a feasible instrument consisting of developmentally appropriate parent proxy-report forms. This will allow for appropriate longitudinal comparison of disease-specific HRQOL.

Goals of the Current Study

The primary goal of the study was to improve the availability of health outcomes assessment for children with food allergy. The addition of a valid and reliable multidimensional measure of food allergy specific HRQOL adds to the existing literature by adding support for the validity of an assessment of patient and parent perspectives of HRQOL. To address the current gap in the literature, we examined an existing measure, the PedsQL™ Food Allergy Module- Parent Report, in parents of children ages 2-18.

Aims and Hypotheses

Aim 1: To confirm the factor structure of the PedsQL™ Food Allergy Module- Parent Report for use in parents of youth ages 2 to 18.

Hypothesis 1: Consistent with the scales of other PedsQL™ modules, items on the PedsQL^{TM} Food Allergy Module would load onto three factors (i.e., “Emotional Functioning,” “Management,” and “Social Functioning”).

Aim 2: To establish construct validity of the PedsQL ™ Food Allergy Module.

Hypothesis 2: The PedsQL^{TM} Food Allergy Module will demonstrate appropriate construct validity with the PedsQL^{TM} Generic Core Scales, such that scores on the PedsQL^{TM} Food Allergy Module will be significantly related to scores on the PedsQL^{TM} Generic Core Scales.

Aim 3: To establish discriminant validity of the PedsQL™ Food Allergy Module.

Hypothesis 3a: The PedsQL^{TM} Food Allergy Module will discriminate between those with one food allergy and those with two or more food allergies, such that those with two or more food allergies will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with one food allergy.

Hypothesis 3b: The PedsQL^{TM} Food Allergy Module would discriminate between those with nut allergy and those with other allergies, such that those with nut allergy will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with other food allergies.

Hypothesis 3c: The PedsQL^{TM} Food Allergy Module will discriminate between those with higher perceived severity from those with lower perceived severity such that those with higher perceived severity will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with lower perceived severity.

Aim 4: To establish internal consistency of the PedsQL™ Food Allergy Module.

Hypothesis 4: The PedsQL^{TM} Food Allergy Module will evidence acceptable internal consistency, as defined as having a Cronbach's alpha > 0.70.

Method

Participants

One hundred sixty eight parents of children with food allergy participated in the study. To be eligible for participation, their child must: 1) have had an active, physician-diagnosed food allergy for at least six months prior to study initiation, 2) have parent willingness to participate and, 3) be English-speaking. Exclusion criteria included: participation in prior phases of the study (e.g., participation in the focus or cognitive interviews utilized in the development of the PedsQL™ Food Allergy Module items), and/or parent report of limited child cognitive ability or severe developmental delay. In the event that families had more than one child with a food allergy, parents were asked to answer the questionnaires in reference to the oldest child (between the ages of 5 and 18). Parents of children (ages 2-18) with food allergy were recruited from sponsorship booths at the Food Allergy Research and Education (FARE) Walk for Food Allergy (43 families) and via online food allergy support groups (125 families). 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

FARE walk sample.

FARE hosts over 65 walks annually in 37 states with the goal of raising awareness and funding for food allergy research, education, and advocacy. Eligible families were recruited at the FARE Annual Walk for Food Allergy to learn more about the study and determine whether they were interested in participating. A trained research assistant provided each family with a brief description of the study and reviewed parental consent information prior to providing families with pen and paper questionnaires. Participation took approximately 30 minutes per family.

Online sample.

Invitations to participate in the study were emailed to support group moderators for the 132 support groups listed on the FARE website. The primary investigator submitted requests to post on support group websites, Facebook groups, and e-mail list-serves for parent completion. The online surveys were identical to those administered to parents in person (i.e., measures in reference to the child and one measure in reference to their own functioning), but were completed electronically via Qualtrics, an online survey software. Consent for parent completion was collected via an informational letter at the beginning of the survey.

Participant Compensation.

Each family, regardless of recruitment method, had the opportunity to enter a raffle (one entry per family) as compensation for participation. Parents submitted their name, phone number and email address for raffle entry. There were 25 drawings of $25 across all samples (i.e., all participants who provided their contact information were entered into the sample raffle, where 25 entries were drawn). Parents who participated online were directed to a separate webpage (that was not linked to their survey responses) to provide their contact information upon completion of the study. Winning raffle participants received their check by mail after the conclusion of the study.

Measures

PedsQL^{TM} Food Allergy Module. The PedsQL^{TM} Food Allergy Module is a disease-specific measure of HRQOL. The distributed module contained 38 items comprised of Emotional Functioning (15 items), Management (4 items), and Social Functioning (19 items). Consistent with the PedsQL^{TM} Measurement System, items are rated on a five-point Likert scale and instruct respondents to use a one-month reference. Items are reverse-scored so that lower scores demonstrate higher rates of symptoms, and thus lower food allergy HRQOL.

As with the other forms of the PedsQL^{TM} Measurement System, the PedsQL^{TM} Food Allergy Module consists of developmentally-appropriate child and parent proxy-report parallel forms (i.e., questions are written in the first and third person, respectively). Parent proxy-report forms include toddler (ages 2-4), young child (5-7), child (8-12), and adolescent (13-18) forms for parent report of their perceptions of their children’s functioning (Appendix A).

The PedsQL™ Food Allergy Module and Generic Core Scales items were scored following the PedsQL™ Measurement System Scoring Protocol. That is, items were reverse scored and linearly transformed to a 0 to 100-point scale with higher scores indicating better HRQOL (Varni, Seid, & Kurtin, 2001). Consistent with the PedsQL™ Scoring Criteria, in the event of missing item endorsements, total and scale scores were computed by averaging the scores of the items completed. Scales with more than 50% missing data were not scored (Varni, 2014) .

Food Allergy Family Information Form (Demographics). This form was devised for the purposes of the study. Parents completed questions about their education levels and occupation. Information about the child's demographics and the academic impact of food allergy (e.g., number of days the child missed from school as a result of food allergy) was also collected (Appendix C).

Food Allergy Family Information Form (Medical Information). Parents provided medical information, such as the participating youth's types of food allergens on this form. Other information, such as perceived severity of food allergy and the number of trips to the emergency room in the past 30 days were also collected (Appendix C).

PedsQL^{TM} 4.0 Generic Core Scales. The PedsQL^{TM} Generic Core Scales (Varni, Seid, & Kurtin, 2001) assess general parent proxy-report of health-related quality of life of children ages 2-18. The scales are developmentally appropriate, with Toddler (ages 2-4) Young Child (ages 3-5), Child (ages 8-12), and Adolescent (ages 13-18) forms. The parent-proxy report forms employ similar wording as the child report forms, but are written from the viewpoint of the third person. The PedsQL^{TM} Generic Core Scales consist of four scales (e.g., Physical, Emotional, Social and School Functioning) for a total of 23 items.

Sample parent-proxy report items include "In the past month, how much of a problem has your child had with running?" (i.e., Physical Functioning scale) and "In the past month, how much of a problem has your child had with trouble sleeping?" (i.e., Emotional Functioning scale; Appendix D).

PedsQL^{TM} Family Impact Module (Daily Activities and Family Relationships Scales). The PedsQL^{TM} Family Impact Module (Varni, Sherman, Burwinkle, Dickinson, & Dixon, 2004) consists of 36 items across eight scales. For the purposes of this study, the eight items of the

Family Functioning subscales (i.e., the Daily Activities and Family Relationships scales) were administered to parents of youth with food allergy. Sample items include “Family activities taking more time and effort” (Daily Activities scale) and “Stress or tension between family members” (Family Relationships scale). The Family Functioning subscales achieved appropriate levels of reliability in prior studies of children with cerebral palsy and their parents ($\alpha = 0.90$) and have been used to demonstrate the impact of pain and other chronic illnesses on families (Mano, Khan, Ladwig, & Weisman, 2009; Panepinto, Hoffmann, & Pajewski, 2009). Administering these scales allows for an exploratory assessment of functioning of families with food allergy.

Data Analytic Plan

All analyses were run in Statistical Package for the Social Sciences, Version 22 (IBM SPSS 22, Armonk, New York).

Demographic Data. Descriptive statistical analysis was conducted to determine the characteristics of the sample (e.g., child age, gender, and ethnicity) and nature of participants’ food allergy (e.g., number and types of food allergy). Rates of comorbid medical diagnoses (e.g., Asthma) were calculated.

Factor Structure. To examine the factor structure of the PedsQL™ Food Allergy Module, Hypothesis 1 (i.e., that items on the PedsQL^{TM} Food Allergy Module will load onto three factors) was examined through the use of principal component factor analysis with promax rotation. This technique is consistent with the PedsQL™ Measure Development Methodology (Steele, Steele, & Varni, 2009; Varni et al., 2014). Specifically, the first step was to determine whether the data were appropriate for a principal component factor analysis. This was conducted through the use of three tests, 1) Bartlett's Test of Sphericity, 2) the Kaiser-Meyer-Olkin Measure of Sampling Adequacy and 3) a visual examination of the scree plot.

Construct Validity. To examine the construct validity of the PedsQL™ Food Allergy Module, Hypothesis 2 (i.e., that scores on the PedsQL$^{\text{TM}}$ Food Allergy Module will be significantly associated with scores on the PedsQL$^{\text{TM}}$ Generic Core Scales) was examined by calculating the relationship between scores on the PedsQL™ Generic Core Scales and scores on the PedsQL™ Food Allergy Module using Pearson correlation.

Discriminant Validity. To examine the discriminant validity of the PedsQL™ Food Allergy Module, Hypothesis 3a (i.e., that those with two or more food allergies will evidence worse scores on the PedsQL$^{\text{TM}}$ Food Allergy Module than children with one food allergy) was examined through the use of an Analysis of Variance (ANOVA) to determine whether there are differences in HRQOL scores based upon between those with one allergy versus two or more allergies. Similarly, Hypothesis 3b (i.e., that youth with nut allergy will evidence worse scores on the PedsQL$^{\text{TM}}$ Food Allergy Module than youth with other food allergies) was examined through the use of an ANOVA to determine whether there are differences in HRQOL scores based upon between those with nut allergy versus youth with other food allergies. Hypothesis 3c (i.e., that youth with higher perceived severity will evidence worse scores on the PedsQL$^{\text{TM}}$ Food Allergy Module than youth with lower perceived severity) was examined through the use of an ANOVA to determine whether there are differences in HRQOL scores based upon between those with severity ratings of 7 and above versus those with ratings below 7.

Internal Consistency. To examine the internal consistency of the PedsQL™ Food Allergy Module, Hypothesis 4 (i.e., that Cronbach's alpha will be > 0.70) was examined through calculation of Cronbach's alpha for the total score and Module subscales.

Results

Demographic Data

Sample characteristics are presented in Table 1. As seen in Table 1, the sample was primarily Caucasian, consisted of mostly male children and entailed a small representation of teenagers ($M = 7.73$ years). Although almost all of the children exhibited a tree nut and/or peanut allergy, all of the common food allergens were represented within the sample (e.g., milk, eggs, shellfish). On average, the children experienced over three allergens ($M = 3.79$, SD = 3.08). A minority of the sample endorsed child comorbid medical diagnoses (e.g., Eczema and Asthma; Table 2).

Characteristics reported about caregivers. A small amount of caregivers reported having food allergies. The majority of respondents were Caucasian Mothers, Step Mothers or Foster Mothers. On the PedsQL™ Family Impact Module, caregivers reported food allergies significantly affecting their daily activities (M = 58.13, SD = 32.06) and family relationships (M = 70.92, SD = 27.43).

Identification of Potential Covariates and Confounding Variables

There were no significant differences in the PedsQL™ Food Allergy Module total scores based upon administration method (i.e., online versus in person sample), $R^2 = 0.03$, $p = 0.72$. Thus, future results will be presented as one sample. Rates of comorbid medical diagnoses (e.g., Asthma) were not significantly related to HRQOL scores, $R^2 = 0.06$, $p = 0.47$. Furthermore, PedsQL™ Food Allergy Module- Parent Report Total Scores were not significantly associated with child sex ($R^2 = -0.07$, $p = 0.37$), child age, ($R^2 = -0.11$, $p = 0.60$), child race/ethnicity ($R^2 = -0.06$, $p = 0.44$), or parent report of support group membership ($R^2 = 0.09$, $p = 0.28$). Thus, these variables were not controlled for in subsequent analyses. Finally, data were reviewed for normality and no outliers were present.

Average PedsQL ™ Food Allergy Module- Parent Report Scores

The average score for the PedsQL Food Allergy Module- Parent Report was 62.45 (20.45). Total scores ranged from 58.48 (18.04) to 66.82 (22.73). Scale and total scores by age group are provided in Table 3.

Examination of Study Aims & Hypotheses

> **Hypothesis 1.** Consistent with the scales of other PedsQL™ modules, items on the PedsQL^{TM} Food Allergy Module- Parent Report will load onto three factors (i.e., Emotional Functioning, Management, and Social Functioning).

Factor Structure. To examine the factor structure of the PedsQL™ Food Allergy Module- Parent Report, a principal component factor analysis with promax rotation was conducted. The data were considered suitable for such analysis based upon the Kaiser-Meyer-Olkin value of 0.928 (0.60 is considered the minimum), significant findings from the Bartlett's Test of Sphericity, ($p < 0.001$) and visual inspection of the scree plot (Figure 1).

Upon visual inspection of the scree plot, it was determined that a three-factor solution was appropriate for the model. This information was substantiated by a Monte Carlo PCA for Parallel Analysis Test, which compares the Eigenvalues of the data with the Eigenvalues of a randomly generated comparison sample of 100 replications, 38 variables and 163 subjects (O'Connor, 2000). Because the first three Eigenvalues from the existing dataset were greater than the first three randomly generated Eigenvalues, a model consisting of three components was retained. Additionally, 73.02% of the variance was explained within a three-factor model. Finally, the pattern matrix determined that 18 items fell on Component 1 (i.e., Social

Functioning), indicating that they measure how a child's food allergy affects his or her relationships with others. Fifteen items fell on Component 2 (i.e., Emotional Functioning), indicating that they measure how a child's food allergy affects their worries and emotions and 4 items fell on Component 3 (i.e., Management), indicating that they measure psychosocial functioning in relation to the child's management of his or her allergies.

After confirming the 3-factor model (Table 4) with the above-mentioned tests, the model was restricted to three components and analyzed again with the intention of determining whether any items with extraction values < 0.30 should be removed. Upon inspection of the communalities, it was determined that the Social Functioning item "Trouble telling friends about his or her food allergy" should be omitted from the Module due to an extraction value of 0.255. No other items evidenced extraction values lower than 0.30. Thus, all other items were retained. After removing the item "Trouble telling friends about his or her food allergy," the 3-factor model explained 74.60% of the data. Thus, subsequent analyses were conducted with the final 37-item measure as determined above (Figure 2).

The Component Correlation Matrix is provided in Table 5. According to this Matrix, Component 1 (i.e., Social Functioning) is not correlated with Components 2 or 3 (Emotional Functioning and Management). Components 2 and 3 have a low correlation with each other. Taken together, the analyses suggest that a three-factor structure is appropriate for the 37-item questionnaire.

Hypothesis 2. The PedsQL^{TM} Food Allergy Module will demonstrate appropriate construct validity with the PedsQL^{TM} Generic Core Scales, such that scores on the PedsQL^{TM} Food Allergy Module will be significantly associated with the PedsQL^{TM} Generic Core Scales.

Construct Validity. To examine the construct validity of the PedsQL™ Food Allergy Module, the relationship between scores on the PedsQL™ Generic Core Scales and scores on the PedsQL™ Food Allergy Module was calculated using Pearson correlation. Results indicated a medium correlation between the total score of the PedsQL™ Food Allergy Module and the total score of PedsQL™ Generic Core Scales ($r = 0.47$, $p < 0.001$). Individual scale score correlations are provided in Table 6. The correlations between scales ranged from 0.16 (association between the Generic Core Scales Social Functioning Scale and the Food Allergy Module Management Scale) to 0.54 (association between the Generic Core Scales Social Functioning Scale and the Food Allergy Module Social Functioning Scale). All correlations were significant at the $p < 0.05$ level.

> **Hypothesis 3a.** The PedsQL^{TM} Food Allergy Module will discriminate between those with one food allergy and those with two or more food allergies, such that those with two or more food allergies will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with one food allergy.

Discriminant Validity. An Analysis of Variance (ANOVA) was conducted to determine whether there were group differences between children with one food allergy versus those with two or more. Results indicated that there were no significant differences in PedsQL™ Food Allergy Module- Parent Report Total scores, $F(1, 156) = 0.57$, $p = 0.45$.

> **Hypothesis 3b.** The PedsQL^{TM} Food Allergy Module will discriminate between those with a nut allergy and those with other allergies, such that those with nut allergy will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with other food allergies.

Discriminant Validity. An ANOVA was conducted. Results indicated that there were no significant differences in PedsQL™ Food Allergy Module- Parent Report total scores between parents of children with nut allergy to those without, *F*(1, 157) = 2.18, *p* = 0.14.

Hypothesis 3c. The PedsQL^{TM} Food Allergy Module will discriminate between those with higher perceived severity from those with lower perceived severity such that those with higher perceived severity will evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with lower perceived severity.

Discriminant Validity. An ANOVA was conducted. Results indicated that there were no significant differences in PedsQL™ Food Allergy Module- Parent Report Total scores based upon groupings of parental perceived severity between those with severity ratings of 7 and above versus those with ratings below 7, *F*(1, 158) = 3.62, *p* = 0.06. However, the discrepancy could be due to uneven group sizes (Table 7). Further analyses with more than two groups of severity were unable to be conducted due to the low frequency of severity ratings less than six. When exploring other dichotomies, two trends appeared. First, the PedsQL™ Food Allergy Module- Parent Report discriminates between those who rated their child’s allergy severity as a score of eight through ten versus those who rated their perceived severity as zero through seven, *F*(1, 158) = 7.52, $p < 0.01$. Second, the PedsQL ™ Food Allergy Module- Parent Report discriminates between those who rated their child’s allergy as a zero through nine and those who rated their child’s food allergy as a ten, *F*(1, 158) = 4.71, $p < 0.05$ (Table 7). Taken together, these analyses suggest that the discriminant validity of the PedsQL™ Food Allergy Module- Parent Report is related to greater severity ratings within our sample.

Exploratory Analyses. To further investigate the discriminant validity of the Module, we conducted follow up analyses. For example, the number of past reactions requiring the use of an

EpiPen significantly predicted the PedsQL™ Food Allergy- Parent Report total score, $R^2 = 0.23$, $F(1, 155) = 8.94$, $p < .001$.

Hypothesis 4. The PedsQL^{TM} Food Allergy Module will evidence acceptable internal consistency, as defined as having a Cronbach's alpha > 0.70.

Internal Consistency. To examine the internal consistency of the PedsQL™ Food Allergy Module, Hypothesis 4 (i.e., $\alpha > 0.70$) was examined through calculation of Cronbach's alpha for the total score and Module subscales. Internal consistency for the PedsQL™ Food Allergy Module total score was high ($\alpha = 0.95$) as were scores for all subscales (Table 8).

Discussion

The primary goal of the study was to improve the availability of health outcomes assessment for children with food allergy. The addition of a valid and reliable measure of food allergy specific HRQOL adds to the existing literature by adding support for the validity of an assessment of parent perspectives of HRQOL. To address the current gap in the literature, we examined the psychometric properties of the PedsQL™ Food Allergy Module- Parent Report (Appendix A) for parent perspective of their children's functioning. Specifically, we examined the factor structure, construct and discriminant validity, and internal consistency of the Module.

Our hypothesis that items on the PedsQL^{TM} Food Allergy Module- Parent Report would load onto three factors (i.e., Emotional Functioning, Management and Social Functioning) was supported. After omitting one item, we found results consistent with a three-factor model, including 18 items associated with the Social Functioning scale, 15 items associated with the Emotional Functioning scale, and 4 items associated with the Management scale. This suggests that the three scales each capture unique information about a child's HRQOL. For example, the Emotional Functioning scale, with items such as "Worrying about food ingredients changing," measures how food allergies can affect emotions. The Management scale, with items such as “Feeling afraid to use his or her EpiPen” measures the psychosocial effects of managing one’s food allergies. Finally, the Social Functioning scale measures the relational impact of having a food allergy through items such as “Feeling left out when others eat food he or she cannot eat.”

In addition to these findings, one item (“Trouble telling friends about his or her food allergy”), originally included on the Social Functioning scale, was omitted from the Module due to its lack of association with any scale on the measure. One reason for its lack of association could be that children with food allergy do not struggle with telling friends about their food allergy, indicating that their friends are aware of, and may look out for, the child’s food allergy. Alternatively, it is possible that they do not tell their friends about their health. This finding is interesting considering that another item (i.e., “Trouble telling kids his or her age about food allergies”) was significantly associated with the Social Functioning scale, suggesting that children’s difficulties sharing their diagnosis with peers, but not friends, affects their overall HRQOL. Finally, due to the nature of parent proxy-report, future testing is necessary to determine whether these findings are consistent with child self-report of functioning.

We found a medium association between scores on the PedsQL™ Food Allergy Module- Parent Report Total Score and the PedsQL™ Generic Core Scales- Parent Report Total Score. This suggests that the PedsQL™ Food Allergy Module- Parent Report evidences adequate construct validity. This finding is interesting considering that prior studies have found that children with food allergy are less affected physically by their food allergy, a construct measured by the Generic Core Scales but not the PedsQL™ Food Allergy Module- Parent Report (King, Knibb, & Hourihane, 2009; Resmini, 2013). Thus, perhaps the association between the PedsQL™ Generic Core Scales (which includes a physical functioning scale) and the PedsQL™

Food Allergy Module- Parent Report would be even stronger if solely the corresponding scales were included.

When examining internal consistency on a Scale level, the strongest correlation was between the Social Functioning Scales of the Generic Core Scales and Food Allergy Module. In a parent sample, this finding makes sense considering that social functioning can be more easily observed in children than other types of functioning such as emotional functioning. The PedsQL™ Food Allergy Module's Social Functioning Scale also moderately correlated with the School Functioning Scale of the Generic Core Scales, which highlights social aspects of attending school.

We hypothesized that the PedsQL^{TM} Food Allergy Module would discriminate between those with one food allergy and those with two or more food allergies, such that those with two or more food allergies would evidence worse scores on the PedsQL^{TM} Food Allergy Module than children with one food allergy. Our findings did not support this hypothesis. Perhaps the dichotomy between the number of food allergens is artificial. Alternatively, our uneven sample sizes prohibited us from further examination of this effect. Future research may consider examining whether more than two food allergies is associated with worse HRQOL or whether there are other explanations for this finding.

Because of prior research indicating that children with nut allergies experience more severe reactions to food allergens than children with other types of allergies (Gupta, 2011), we hypothesized that the PedsQL^{TM} Food Allergy Module would discriminate between those with nut allergy and those with other allergies. Our findings did not support this hypothesis. Reasons for this could include the large proportion of children with nut allergies in our sample (89% of children with a current tree nut and/or peanut allergy), which is consistent with epidemiological findings that peanut allergies are the most common pediatric food allergen (Gupta, 2011).

It is possible that HRQOL is better tied to the actual number of prior severe reactions, rather than the number or types of food allergens. In fact, our study showed that the number of past allergic reactions requiring EpiPen use significantly predicted the PedsQL™ Food Allergy Module- Parent Report total score. This suggests that the Module has predictive validity and it is possible that something as salient as prior reactions better discriminates between HRQOL groups than number or types of food allergens. Future research should consider a more diverse sample of food allergens, and may consider matching participants on other demographics to determine whether HRQOL is worse for those with tree nut and/or peanut allergies.

We found that the PedsQL$^{\text{TM}}$ Food Allergy Module- Parent Report discriminated between those with higher perceived severity from those with lower perceived severity such that those with higher perceived severity evidenced worse scores on the PedsQL$^{\text{TM}}$ Food Allergy Module- Parent Report than children with lower perceived severity. We originally hypothesized that the dichotomy would be between those with a severity score of seven or greater, as opposed to those with scores below seven. However, we found that the PedsQL™ Food Allergy Module- Parent Report differentiated between severity scores of eight through ten compared with those with ratings of less than eight. This suggests that parents who perceive their child's food allergy as more severe than average also perceive their child's food allergy to affect their daily functioning. It is worth examining which factors have the greatest effect on perceived severity. Resmini et al. (2015) found that past EpiPen use was the only factor that significantly affected perceived severity in a sample of families with food allergies when examining child age, types of food allergens, and number of food allergens.

Our results indicate that the PedsQL™ Food Allergy Module total and separate scale scores demonstrate excellent internal consistency. This suggests that the overall and separate scale items are measuring the same construct, HRQOL, and provides further evidence of the psychometric integrity of the module.

In summary, the goal of this study was to examine the psychometric properties of the PedsQL™ Food Allergy Module- Parent Report. Based upon the results of the principal components analysis, we determined that a three-factor structure was appropriate. Also consistent with the results of the principal components analysis, one item was removed from the module, resulting in a 37-item measure. The Module's construct validity and internal consistency were supported by the findings of this study. Results indicated that the measure is unable to discriminate between those with nut allergies from those with other allergies and between those with one allergy when compared to those with more than one allergy, but other group differences were found.

Strengths and Limitations

The findings of this study should be considered in light of study strengths and limitations. Its strengths involve the inclusion of a geographically diverse sample, which helps to increase the generalizability of the measure. Further, by recruiting participants outside of clinical settings such as hospitals we hope to have captured the day-to-day HRQOL of the participants, rather than during a health emergency. Keeping these strengths in mind, by recruiting participants through in-person and online support groups, it is possible that we have included participants who have a greater number of or more severe food allergens. Like other in-person and online studies, another limitation of this study includes its self-selected sample. It is possible that we missed potential participants due to lack of food allergy support group membership, by opting out of study participation or due to a lack of resources (e.g., access to a computer, time to participate in a benefit walk). For these reasons, future studies should consider collecting data with families in a variety of settings (e.g., schools, clinics, camps).

Future Directions

Participant turn-out for the benefit walks was lower than expected and IRB policies prohibited us from collecting child data online. As a result, child self-report data were omitted within our sample. Thus, it will be crucial to expand upon this study by validating the PedsQL™ Food Allergy Module- Child Report forms within a large sample of children. Because research has shown the benefits of multi-informant reports of HRQOL when feasible (Cremeens, Eiser, & Blades, 2006; Eiser & Morse, 2001), the addition of a valid and reliable child self-report form will ensure that cross-informant information can be collected and analyzed. Similarly, future examinations should consider recruiting higher rates of fathers to allow for the collection of further cross-informant reports.

Future examinations of the PedsQL™ Food Allergy Module- Parent Report should consider investigating the longitudinal effects of food allergy on HRQOL. For example, it has been shown that adolescents are at greater risk for more severe reactions (Gupta et al., 2011), partially due to a decline in parental involvement. Future investigations should determine whether adolescents' HRQOL is affected similarly.

Additionally, many children outgrow milk and shellfish allergies. As a result, those who are still affected during adolescence tend to have more severe forms of food allergies (Gupta et al., 2011). Thus, it would be beneficial to see how HRQOL is affected longitudinally between those who outgrow their food allergies and those who do not. Finally, future investigations of the PedsQL™ Food Allergy Module may consider examining the factor structure of the Module within each age group. Information collected from such studies could provide details about the progression of social and emotional functioning across childhood and give rationale for the developmental appropriateness of the Module.

Now that the PedsQL™ Food Allergy Module- Parent Report has been validated, the next steps include using it in conjunction with the PedsQL™ Generic Core Scales to examine HRQOL across time and in comparison with other illness groups. By adding a disease-specific measure to HRQOL measurement, more information can be collected about daily functioning and response to clinical intervention. Finally, an analysis of the test-retest consistency of the PedsQL™ Food Allergy Module- Parent Report will provide further information about the reliability of the measure and stability of HRQOL across a short period of time.

Clinical Implications

Research studies have demonstrated the reliability and validity of assessing health outcomes in youth through HRQOL measurement. The results of this study indicate that the PedsQL™ Food Allergy Module- Parent Report is appropriate for clinical use within this population. By administering a brief measure of daily functioning, clinicians can determine where deficits in functioning may occur. As a result, they can refer families to appropriate resources, such as support groups or clinical intervention, which can impact adjustment and long-term functioning. Finally, measurement of HRQOL is a required component of treatment clinical trials. Thus, by utilizing a measure such as the PedsQL™ Food Allergy Module- Parent Report, clinicians can ensure that side effects of potential future treatments do not outweigh the benefits.

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Table 1

Participant Demographics

Variable	Percentage
Age	---
Toddler (ages 2-4)	22.8%
Young Child (ages 5-7)	30.5%
Child (ages 8-12)	32.9%
Teen (ages 13-18)	13.8%
Child Gender	
Male	61.1%
Female	38.9%
Child Ethnicity	
White, Non-Latino	79.6%
American Indian/ Alaskan Native	1.8%
Mexican/Latino	1.2%
Asian/Pacific Islander	1.2%
Black, Non-Latino	4.6%
Other or Multiple Ethnicities	12%
Respondent Type	
Mother, Step Mother, Foster Mother	95.2%
Father, Step Father, Foster Father	4.8%
Respondent Ethnicity	
White, Non-Latino	87.3%
Mexican/Latino	1.8%
Asian/Pacific Islander	1.8%
Black, Non-Latino	5.5%
Other or Multiple Ethnicities	3.6%
Child Insured by Medicaid	7.2%
Siblings with Food Allergy	17.6%

Table 2

Child Food Allergy Demographics

Variable	Percentage
Type of food allergies	
Peanut	89.60%
Egg	42.90%
Milk/Dairy	35.70%
Number of food allergens	
1	19.60%
2	24.50%
3	19.00%
4	6.10%
5	8.60%
6	5.50%
7	6.10%
8+	10.40%
Age at diagnosis	
12 months or younger	58.50%
13 to 23 months	15.90%
24 to 47 months	18.30%
48 months or older	7.30%
Physician diagnosis	
Allergist	80.60%
Emergency Room Physician	6.10%
Multiple Physicians	5.50%
Pediatrician	4.20%
Other Physician	3.60%
EpiPen Use during Prior Month	4.20%
Support Group Participation	61.00%
Respondent with Food Allergy	16.50%
Child Other Chronic Illness	
Asthma	14.90%
Eczema	5.40%
Other	3.00%

Table 3

Scores across age groups

Scales	Toddler		Young Child		Child		Adolescent		Total	
	M	SD	M	SD	M	SD	M	SD	M	SD
Emotional Functioning	53.76	32.08	51.43	24.05	44.70	23.80	45.57	20.46	48.89	25.49
Management	82.11	23.81	70.22	24.89	67.48	30.07	66.58	26.96	71.59	27.18
Social Functioning	64.58	25.58	69.36	19.33	67.65	21.61	64.06	17.51	67.20	21.36
Total	66.82	22.73	63.67	19.10	59.59	20.91	58.48	18.04	62.45	20.45

Table 4

Component Matrix after Restricting to Three Factors

	1	2	3
Feeling left out at birthday parties and other social gatherings because of his or her food allergies	0.98		
Avoiding social situations because of his or her food allergies	0.98		
Bothers child that he or she cannot eat dinner at friends' houses because of his or her food allergies	0.98		
Bothers child that he or she cannot attend sporting games due to his or her food allergies	0.98		
Feeling different from peers due to his or her food allergies	0.98		
Feeling left out when others eat foods he or she cannot eat	0.98		
Having difficulty not eating foods that he or she is allergic to when friends eat them	0.98		
Trouble convincing others that his or her food allergies are a serious problem	0.98		
Trouble telling strangers such as restaurant workers about his or her food allergies	0.98		
Trouble telling teachers about his or her food allergies	0.98		
Trouble telling kids his or her age about food allergies	0.98		

Hard for child to stay away from food allergens	0.97		
Peers try to touch child with food that he or she is allergic to	0.97		
Trouble telling family members such as aunt, uncle and grandparents about his or her food allergies	0.93		
Peers bullying child for having food allergies	0.93		
Peers making fun of child for having food allergies	0.93		
Trouble telling friends' parents about his or her food allergies	0.91		
Trouble turning down food from others	0.87		
Worrying about having an allergic reaction		0.80	
Worrying about unlisted ingredients		0.79	
Worrying about food ingredients changing		0.76	
Worrying about eating at familiar restaurants		0.74	
Worrying about eating at friends' houses		0.73	
Worrying about trying new foods		0.72	
Worrying about trying new foods without parents present		0.72	
Worrying about having food allergies for the rest of his or her life		0.71	
Worrying about accidentally touching a food allergen		0.71	
Worrying about eating at new restaurants		0.69	
Worrying about not having an EpiPen available when needed		0.63	

Worrying about eating food at school		0.61	
Feeling frustrated due to food restrictions		0.57	
Worrying about ordering school lunches		0.56	
Worrying about getting enough nutritional value from meals		0.54	
Feeling scared to use his or her EpiPen		0.55	0.64
Feeling afraid that it will hurt to use his or her EpiPen		0.56	0.63
Worrying about side effects from using his or her EpiPen		0.51	0.52
Feeling embarrassed to carry his or her EpiPen		0.41	0.50
~~Trouble telling friends about his or her food allergy~~			~~0.41~~

Table 5

Component Correlation Matrix

Component	1	2	3
1	1.00	0.12	0.06
2	0.12	1.00	0.50
3	0.06	0.50	1.00

Table 6

Construct Validity by Scale

	FA Emotional	FA Management	FA Social
GCS Physical	0.28***	0.23**	0.28***
GCS Emotional	0.35***	0.34***	0.45***
GCS Social	0.30***	0.16*	0.54***
GCS School	0.24**	0.22**	0.36***

* $P < 0.05$, **$P < 0.01$, ***$P < 0.001$. GCS = PedsQL ™ Generic Core Scales; FA = Food Allergy; based upon parent-report

Table 7a

Discriminant Validity by Scale, One Allergen versus Two or More

		Sum of Squares	df	Mean Square	F	*p*
Emotional Functioning	Between Groups	94.151	1	94.151	.141	.708
	Within Groups	105352.677	158	666.789		
	Total	105446.828	159			
Management	Between Groups	1132.500	1	1132.500	1.517	.220
	Within Groups	117927.802	158	746.378		
	Total	119060.303	159			
Social Functioning	Between Groups	30.890	1	30.890	.067	.795
	Within Groups	71408.500	156	457.747		
	Total	71439.390	157			
Total	Between Groups	243.351	1	243.351	.571	.451
	Within Groups	66542.624	156	426.555		
	Total	66785.976	157			

Table 7b

Discriminant Validity by Scale, Nut Allergens versus Other Allergens

		Sum of Squares	df	Mean Square	F	*p*
Emotional Functioning	Between Groups	2050.552	1	2050.552	3.140	.078
	Within Groups	103831.191	159	653.026		
	Total	105881.743	160			
Management	Between Groups	568.030	1	568.030	.762	.384
	Within Groups	118501.264	159	745.291		
	Total	119069.293	160			
Social Functioning	Between Groups	398.126	1	398.126	.875	.351
	Within Groups	71441.095	157	455.039		
	Total	71839.221	158			
Total	Between Groups	913.074	1	913.074	2.176	.142
	Within Groups	65874.268	157	419.581		
	Total	66787.342	158			

Table 7c

Discriminant Validity by Scale, Perceived Severity, 0-6 Versus 7-10

		Sum of Squares	df	Mean Square	F	*p*
Emotional Functioning	Between Groups	1031.593	1	1031.593	1.583	.210
	Within Groups	104251.816	160	651.574		
	Total	105283.409	161			
Management	Between Groups	3588.287	1	3588.287	4.918	.028
	Within Groups	116739.887	160	729.624		
	Total	120328.173	161			
Social Functioning	Between Groups	493.353	1	493.353	1.127	.290
	Within Groups	69140.412	158	437.598		
	Total	69633.765	159			
Total	Between Groups	1489.177	1	1489.177	3.618	.059
	Within Groups	65029.840	158	411.581		
	Total	66519.017	159			

Table 8

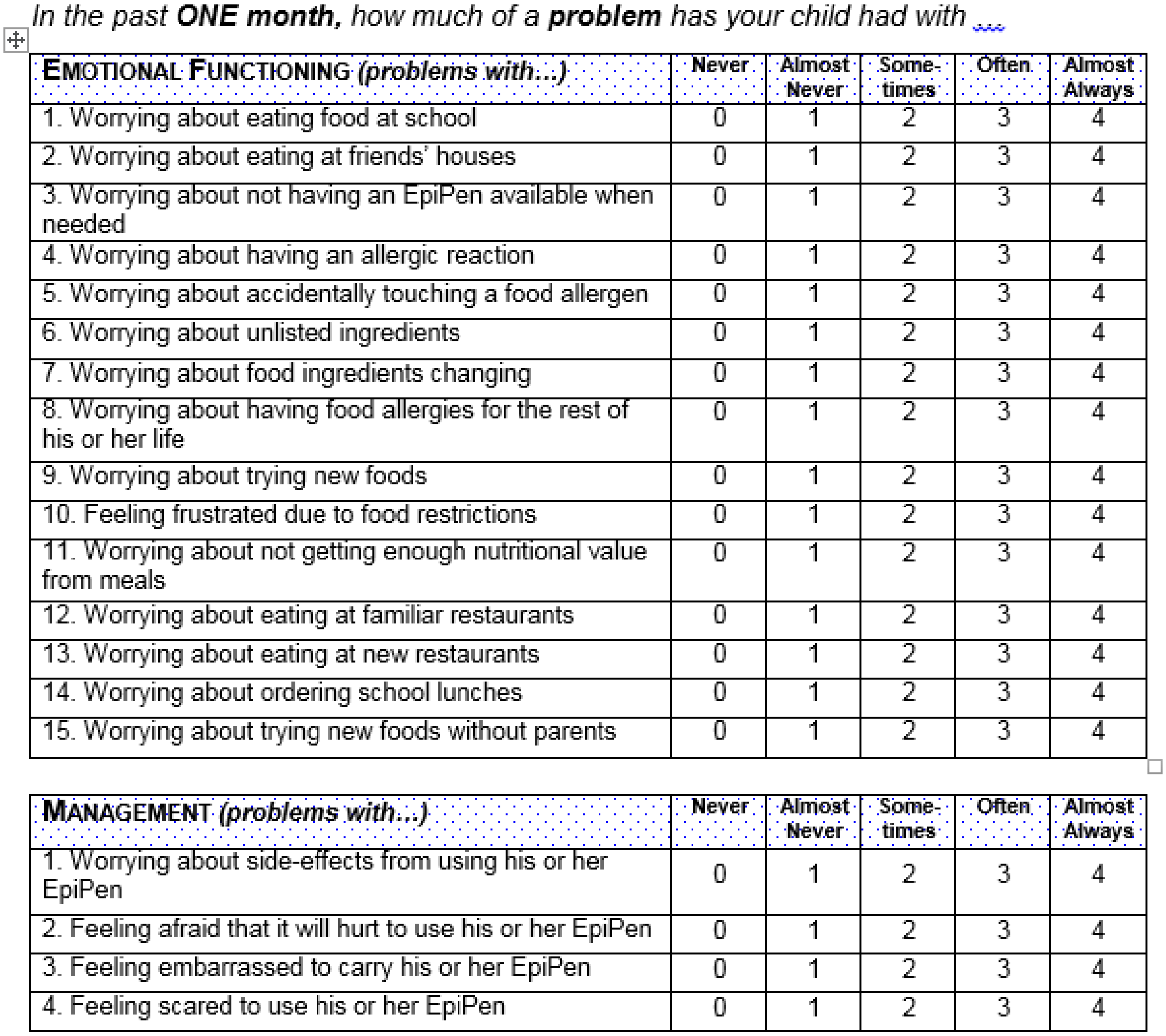
Internal Consistency by Age Group

	Toddler	Young Child	Child	Adolescent	Total
Emotional Functioning	0.96	0.91	0.92	0.89	0.93
Management	0.86	0.73	0.85	0.83	0.81
Social Functioning	0.95	0.91	0.94	0.89	0.93
Total	0.97	0.95	0.96	0.94	0.95

Appendix A

PedsQL^{TM} Food Allergy Module (As administered)

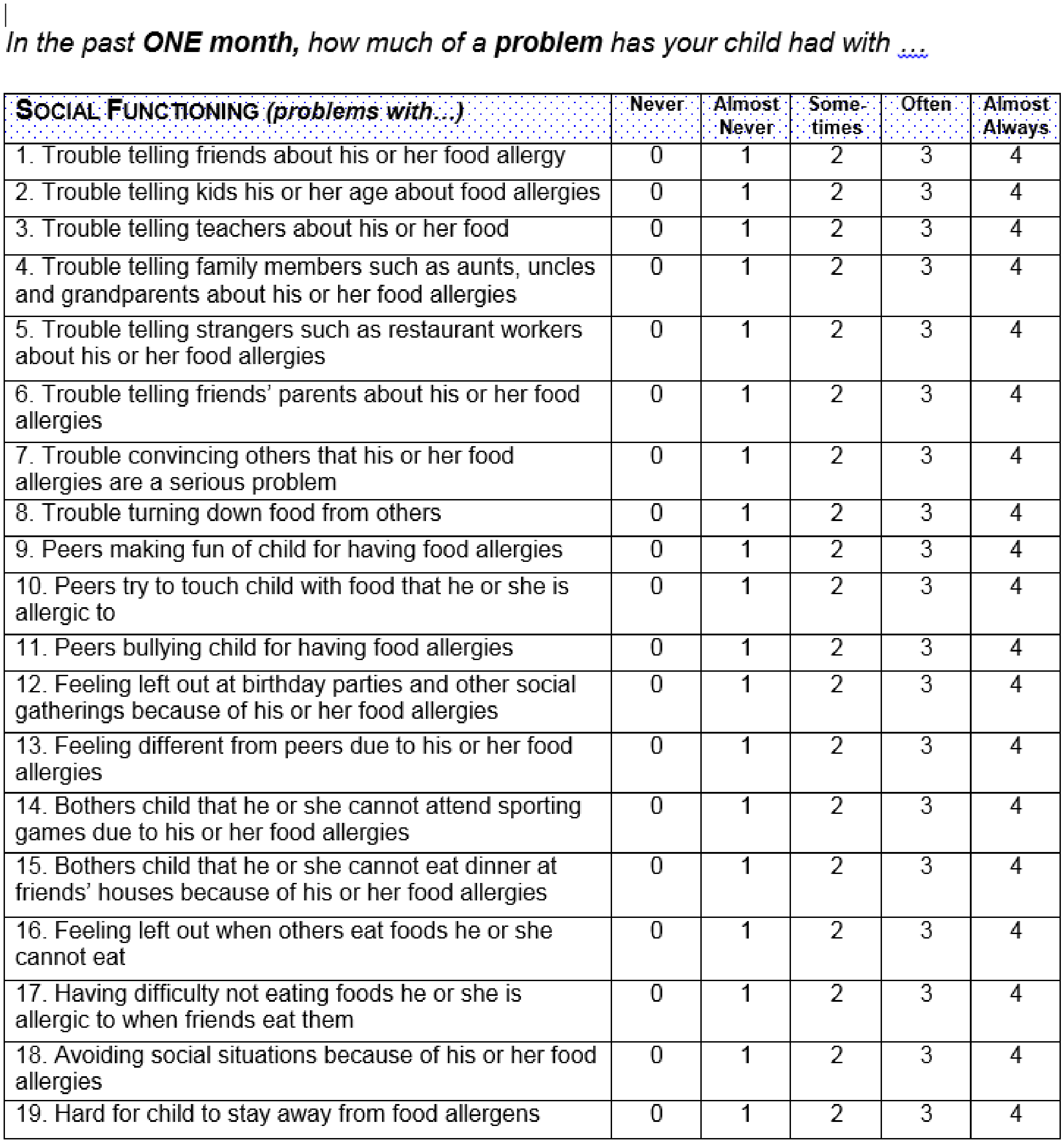
Parent Report



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

EMOTIONAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**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 when needed	0	1	2	3	4
4. Worrying about having an allergic reaction	0	1	2	3	4
5. Worrying about accidentally touching 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. Feeling frustrated due to food restrictions	0	1	2	3	4
11. Worrying about not getting enough nutritional value from meals	0	1	2	3	4
12. Worrying about eating at familiar restaurants	0	1	2	3	4
13. Worrying about eating at new restaurants	0	1	2	3	4
14. Worrying about ordering school lunches	0	1	2	3	4
15. Worrying about trying new foods without parents	0	1	2	3	4

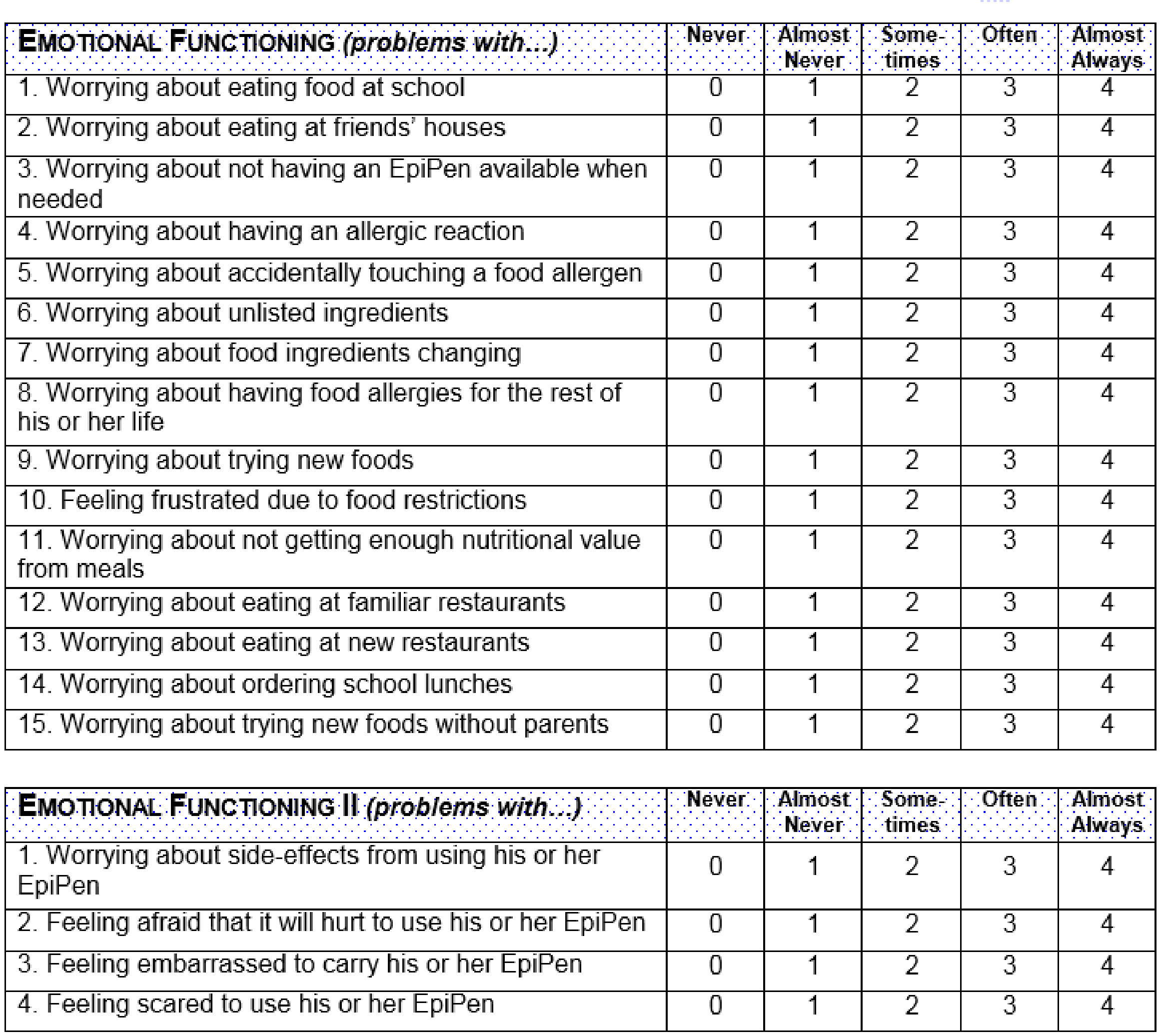
MANAGEMENT ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Worrying about side-effects from using his or her EpiPen	0	1	2	3	4
2. Feeling afraid that it will hurt to use his or her EpiPen	0	1	2	3	4
3. Feeling embarrassed to carry his or her EpiPen	0	1	2	3	4
4. Feeling scared to use his or her EpiPen	0	1	2	3	4



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

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Trouble telling friends about his or her food allergy	0	1	2	3	4
2. Trouble telling kids his or her age about food allergies	0	1	2	3	4
3. Trouble telling teachers about his or her food	0	1	2	3	4
4. Trouble telling family members such as aunts, uncles and grandparents about his or her food allergies	0	1	2	3	4
5. Trouble telling strangers such as restaurant workers about his or her food allergies	0	1	2	3	4
6. Trouble telling friends' parents about his or her food allergies	0	1	2	3	4
7. Trouble convincing others that his or her food allergies are a serious problem	0	1	2	3	4
8. Trouble turning down food from others	0	1	2	3	4
9. Peers making fun of child for having food allergies	0	1	2	3	4
10. Peers try to touch child with food that he or she is allergic to	0	1	2	3	4
11. Peers bullying child for having food allergies	0	1	2	3	4
12. Feeling left out at birthday parties and other social gatherings because of his or her food allergies	0	1	2	3	4
13. Feeling different from peers due to his or her food allergies	0	1	2	3	4
14. Bothers child that he or she cannot attend sporting games due to his or her food allergies	0	1	2	3	4
15. Bothers child that he or she cannot eat dinner at friends' houses because of his or her food allergies	0	1	2	3	4
16. Feeling left out when others eat foods he or she cannot eat	0	1	2	3	4
17. Having difficulty not eating foods he or she is allergic to when friends eat them	0	1	2	3	4
18. Avoiding social situations because of his or her food allergies	0	1	2	3	4
19. Hard for child to stay away from food allergens	0	1	2	3	4

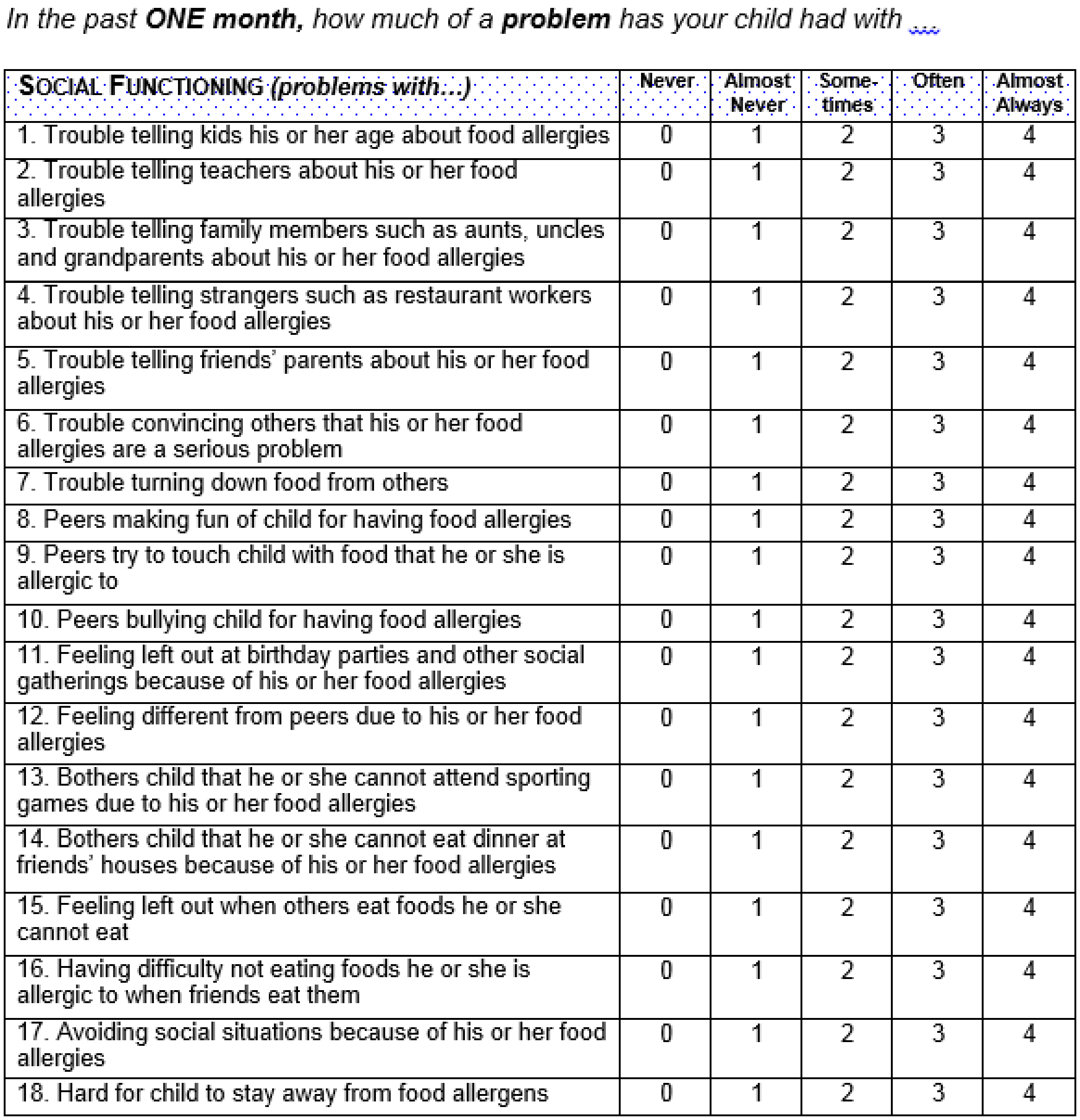
Appendix B
PedsQL^{TM} Food Allergy Module (Final Version)
Parent Report



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

EMOTIONAL FUNCTIONING ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**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 when needed	0	1	2	3	4
4. Worrying about having an allergic reaction	0	1	2	3	4
5. Worrying about accidentally touching 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. Feeling frustrated due to food restrictions	0	1	2	3	4
11. Worrying about not getting enough nutritional value from meals	0	1	2	3	4
12. Worrying about eating at familiar restaurants	0	1	2	3	4
13. Worrying about eating at new restaurants	0	1	2	3	4
14. Worrying about ordering school lunches	0	1	2	3	4
15. Worrying about trying new foods without parents	0	1	2	3	4

EMOTIONAL FUNCTIONING II ***(problems with…)***	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Worrying about side-effects from using his or her EpiPen	0	1	2	3	4
2. Feeling afraid that it will hurt to use his or her EpiPen	0	1	2	3	4
3. Feeling embarrassed to carry his or her EpiPen	0	1	2	3	4
4. Feeling scared to use his or her EpiPen	0	1	2	3	4



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

SOCIAL FUNCTIONING *(problems with…)*	**Never**	**Almost Never**	**Some-times**	**Often**	**Almost Always**
1. Trouble telling kids his or her age about food allergies	0	1	2	3	4
2. Trouble telling teachers about his or her food allergies	0	1	2	3	4
3. Trouble telling family members such as aunts, uncles and grandparents about his or her food allergies	0	1	2	3	4
4. Trouble telling strangers such as restaurant workers about his or her food allergies	0	1	2	3	4
5. Trouble telling friends' parents about his or her food allergies	0	1	2	3	4
6. Trouble convincing others that his or her food allergies are a serious problem	0	1	2	3	4
7. Trouble turning down food from others	0	1	2	3	4
8. Peers making fun of child for having food allergies	0	1	2	3	4
9. Peers try to touch child with food that he or she is allergic to	0	1	2	3	4
10. Peers bullying child for having food allergies	0	1	2	3	4
11. Feeling left out at birthday parties and other social gatherings because of his or her food allergies	0	1	2	3	4
12. Feeling different from peers due to his or her food allergies	0	1	2	3	4
13. Bothers child that he or she cannot attend sporting games due to his or her food allergies	0	1	2	3	4
14. Bothers child that he or she cannot eat dinner at friends' houses because of his or her 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 not eating foods he or she is allergic to when friends eat them	0	1	2	3	4
17. Avoiding social situations because of his or her food allergies	0	1	2	3	4
18. Hard for child to stay away from food allergens	0	1	2	3	4

Appendix C
PedsQL™ Food Allergy and Family Information Form

What is your relationship to this child (please check and/or circle)?

☐ Mother, Step Mother, Foster Mother	☐ Grandmother	☐ Guardian
☐ Father, Step Father, Foster Father	☐ Grandfather	☐ Other ____________________

INFORMATION ABOUT THE CHILD

Child date of birth (month/day/year): ____ / ____ /____	Are you insured through Medicaid? ☐ NO ☐ YES	Age of child now: ________	Child is: ☐ male ☐ female

Ethnic Group or	☐ Black, Non-Latino	☐ Mexican/Latino	☐ American Indian or Alaskan Native
Race of Child:	☐ Asian or Pacific Islander	☐ White, Non-Latino	☐ Other________________________
Race of Parent:	☐ Black, Non-Latino	☐ Mexican/Latino	☐ American Indian or Alaskan Native
	☐ Asian or Pacific Islander	☐ White, Non-Latino	☐ Other________________________

INFORMATION ABOUT MOTHER		**INFORMATION ABOUT FATHER**	
Marital Status:	☐ Single ☐ Living with someone ☐ Married ☐ Divorced ☐ Separated ☐ Widowed	Marital Status:	☐ Single ☐ Living with someone ☐ Married ☐ Divorced ☐ Separated ☐ Widowed
Highest Level of Education:	☐ 6th grade or less ☐ 7th-9th grade ☐ 10th-12th grade ☐ High school graduate ☐ Some college or certification course ☐ College Graduate ☐ Graduate or Professional Degree	Highest Level of Education:	☐ 6th grade or less ☐ 7th-9th grade ☐ 10th-12th grade ☐ High school graduate ☐ Some college or certification course ☐ College Graduate ☐ Graduate or Professional Degree
Occupation/Job Title: ____________________________		Occupation/Job Title: ____________________________	

IMPACT SCALE	
What are your child's food allergies?	***Do** you **have food allergy?*** ☐**NO** ☐**YES** **IF YES**…. What type(s)? Do any of your other children have food allergy? ☐**NO** ☐**YES**
How was your child's food allergy diagnosed?	
☐**Skin Prick Test** ☐**Blood Test** ☐**Oral Food Challenge** ☐**None of the above** ☐**Other: ______________________**	
Who diagnosed your child's food allergy?	
☐**Allergist** ☐**Pediatrician** ☐**Emergency Room Physician** ☐**Ear, Nose, Throat Specialist** ☐**Other:_____________________**	
How old was your child when he/she was diagnosed?	
Please circle below what you perceive the severity of your child's food allergy to be.	
Not at all severe 0 1 2 3 4 5 6 7 8 9 Extremely severe	
*In the past **month**, has your child had…*	
To use his or her epinephrine pen? ☐**NO** ☐**YES**	***IF YES**… How many times?* _________________________ ***IF YES**… After eating what food(s)?* ___________________
*How many times **in your child's life** has he/she had to use his/her epinephrine pen?*	
__________________________________	After eating what food? _____________________________
*In the past **6 months**, has your child…*	
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)? ☐ NO ☐YES	**IF YES…** What is the name of your child's chronic health condition? ____

In the past ***12 months****, has your child had…*	
Any **OVERNIGHT VISITS** to the hospital? ☐ NO ☐ YES	**IF YES**… How many times? _______ What was wrong? _______________________________
Any **EMERGENCY ROOM/URGENT CARE** visits? ☐ NO ☐ YES	**IF YES**… How many times? _______ What was wrong? _______________________________

In the past ***30 days****…*

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? _____

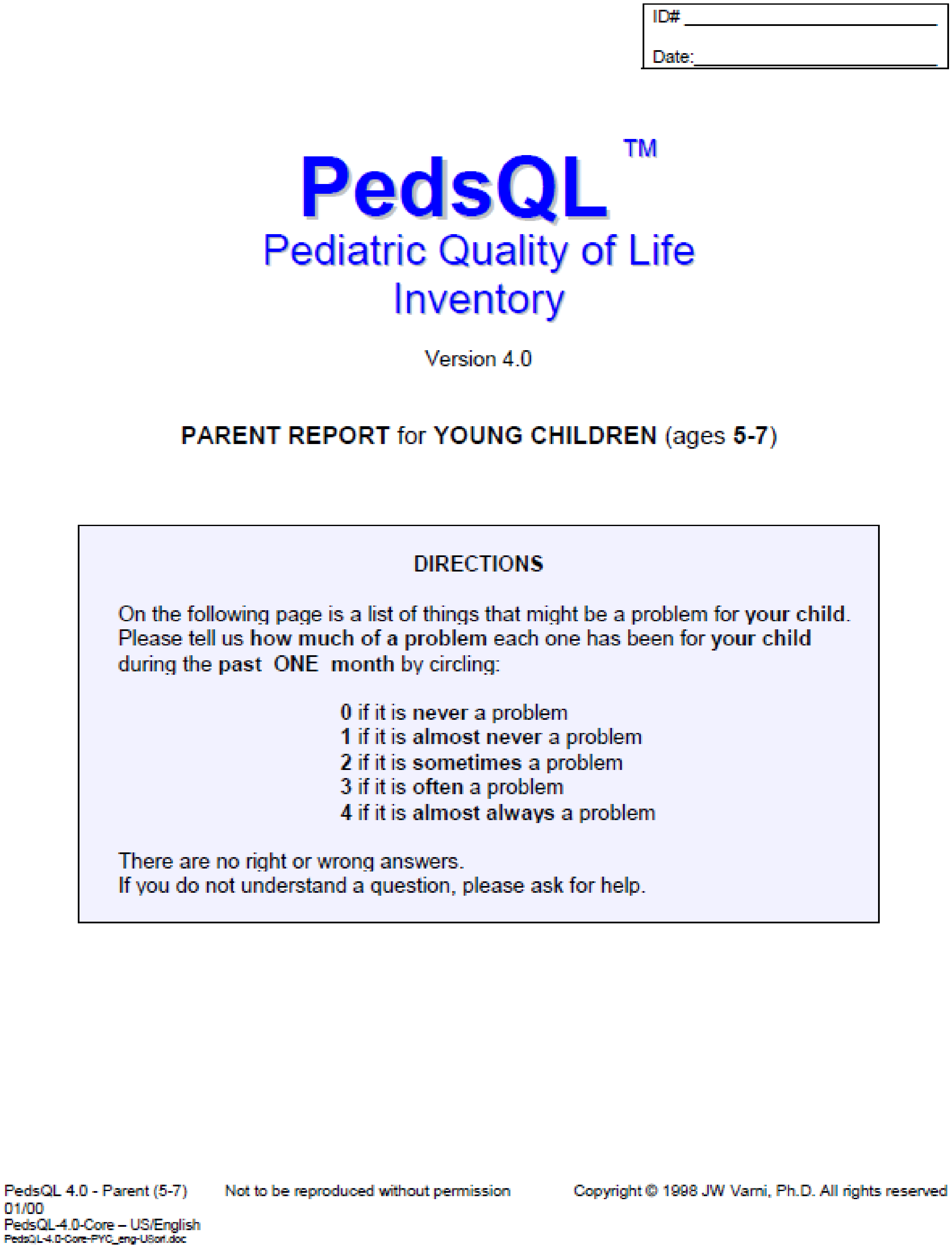
How many days did your child need someone to care for him/her due to physical or mental health? _____

If you work outside of the home, please answer the following questions.

In the past *30 days*, **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	Some-times	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 D
PedsQL™ Generic Core Scales
Parent Report



ID# ____________________

Date:____________________

PedsQL™
Pediatric Quality of Life
Inventory

Version 4.0

PARENT REPORT for **YOUNG CHILDREN** (ages **5-7**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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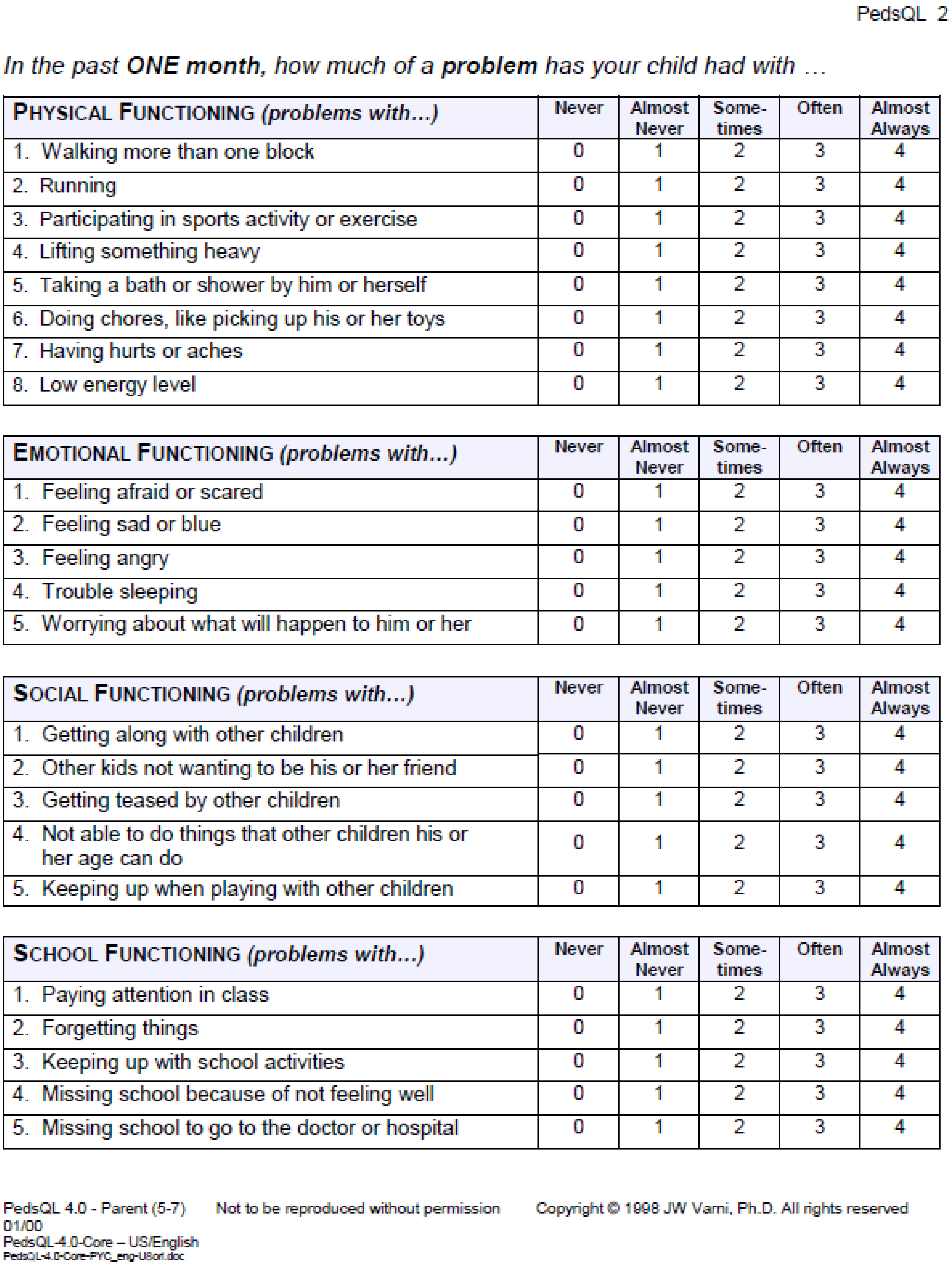
01/00
PedsQL-4.0-Core – US/English
PedsQL-4.0-Core-PYC_eng-USori.doc



PedsQL 2

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

PHYSICAL FUNCTIONING ***(problems with…)***	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores, like picking up his or her toys	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING ***(problems with…)***	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING ***(problems with…)***	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING ***(problems with…)***	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with school activities	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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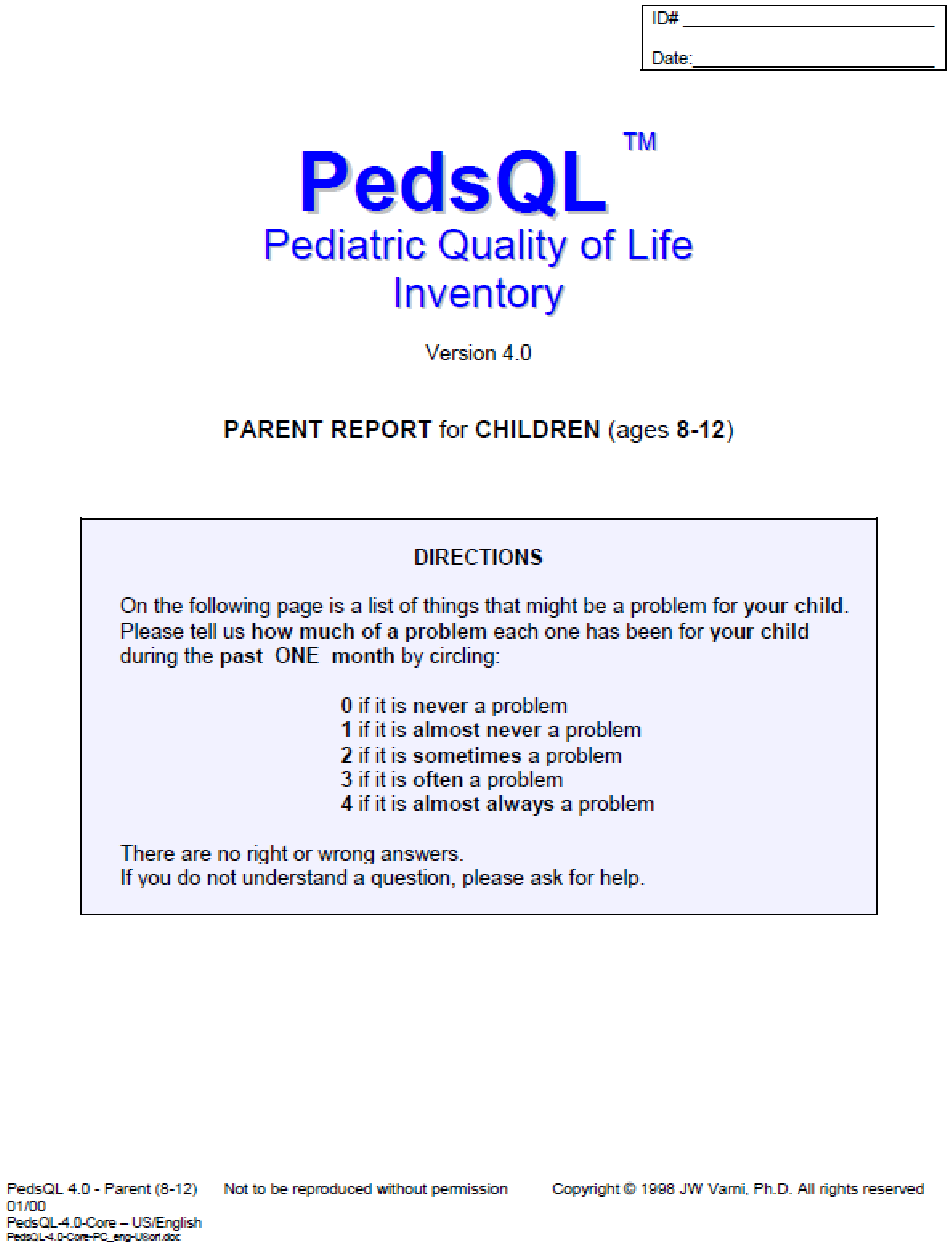

ID# ____________________

Date:____________________

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for **CHILDREN** (ages **8-12**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your child**. Please tell us **how much of a problem** each one has been for **your child** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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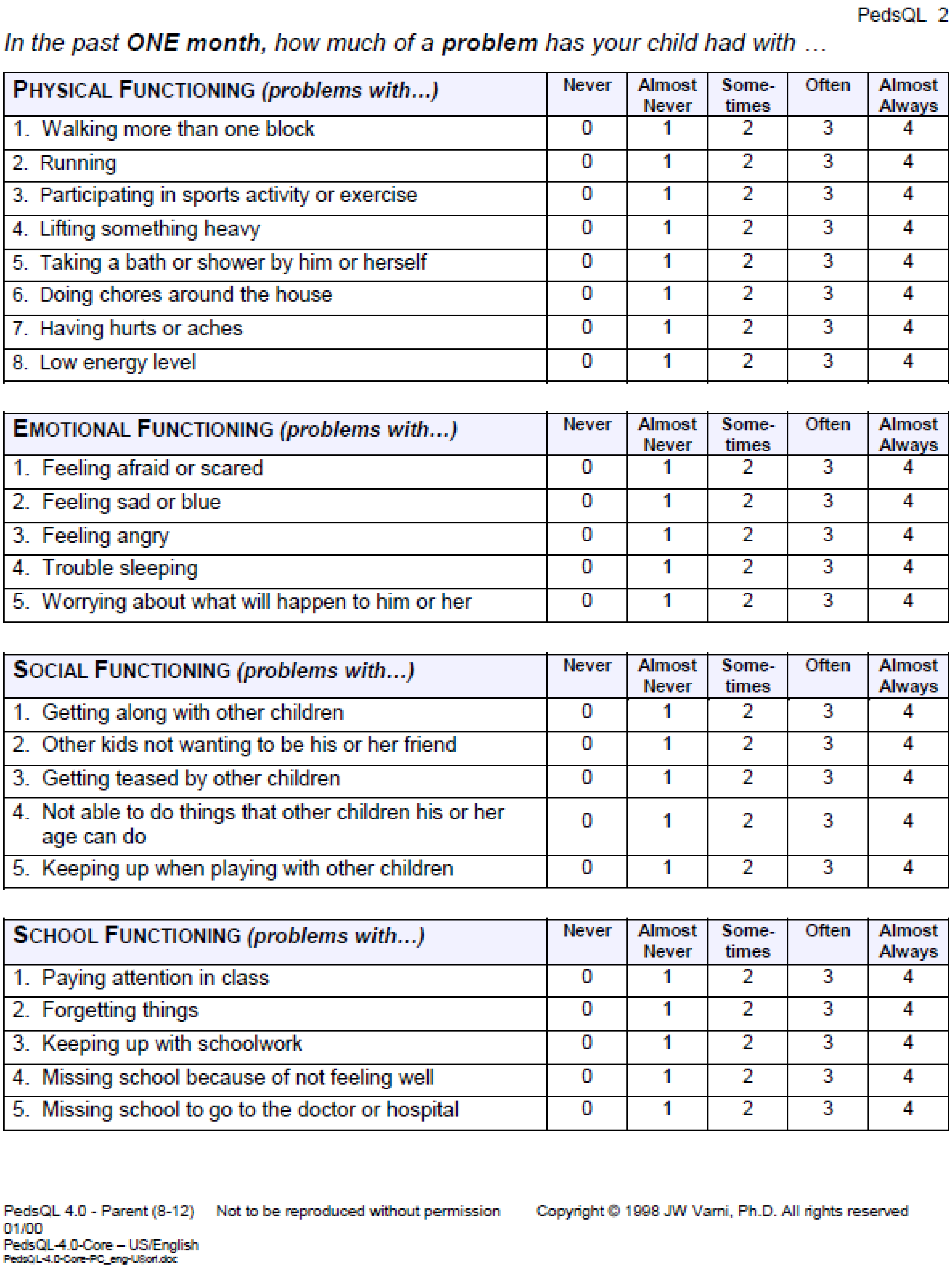

PedsQL 2

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

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other children	0	1	2	3	4
2. Other kids not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other children	0	1	2	3	4
4. Not able to do things that other children his or her age can do	0	1	2	3	4
5. Keeping up when playing with other children	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

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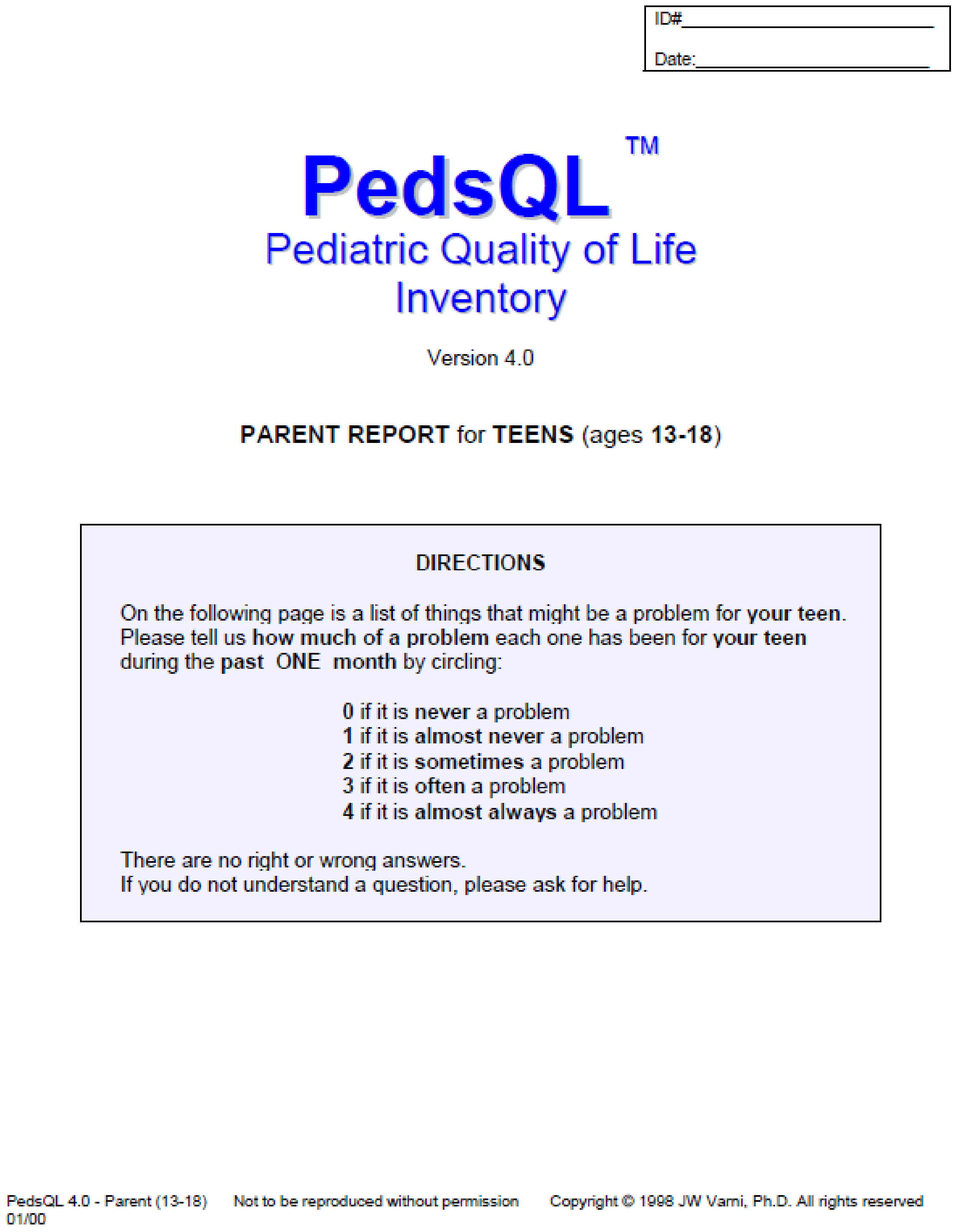

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Date:____________________

PedsQL™

Pediatric Quality of Life Inventory

Version 4.0

PARENT REPORT for **TEENS** (ages **13-18**)

DIRECTIONS

On the following page is a list of things that might be a problem for **your teen**. Please tell us **how much of a problem** each one has been for **your teen** during the **past ONE month** by circling:

0 if it is **never** a problem
1 if it is **almost never** a problem
2 if it is **sometimes** a problem
3 if it is **often** a problem
4 if it is **almost always** a problem

There are no right or wrong answers.
If you do not understand a question, please ask for help.

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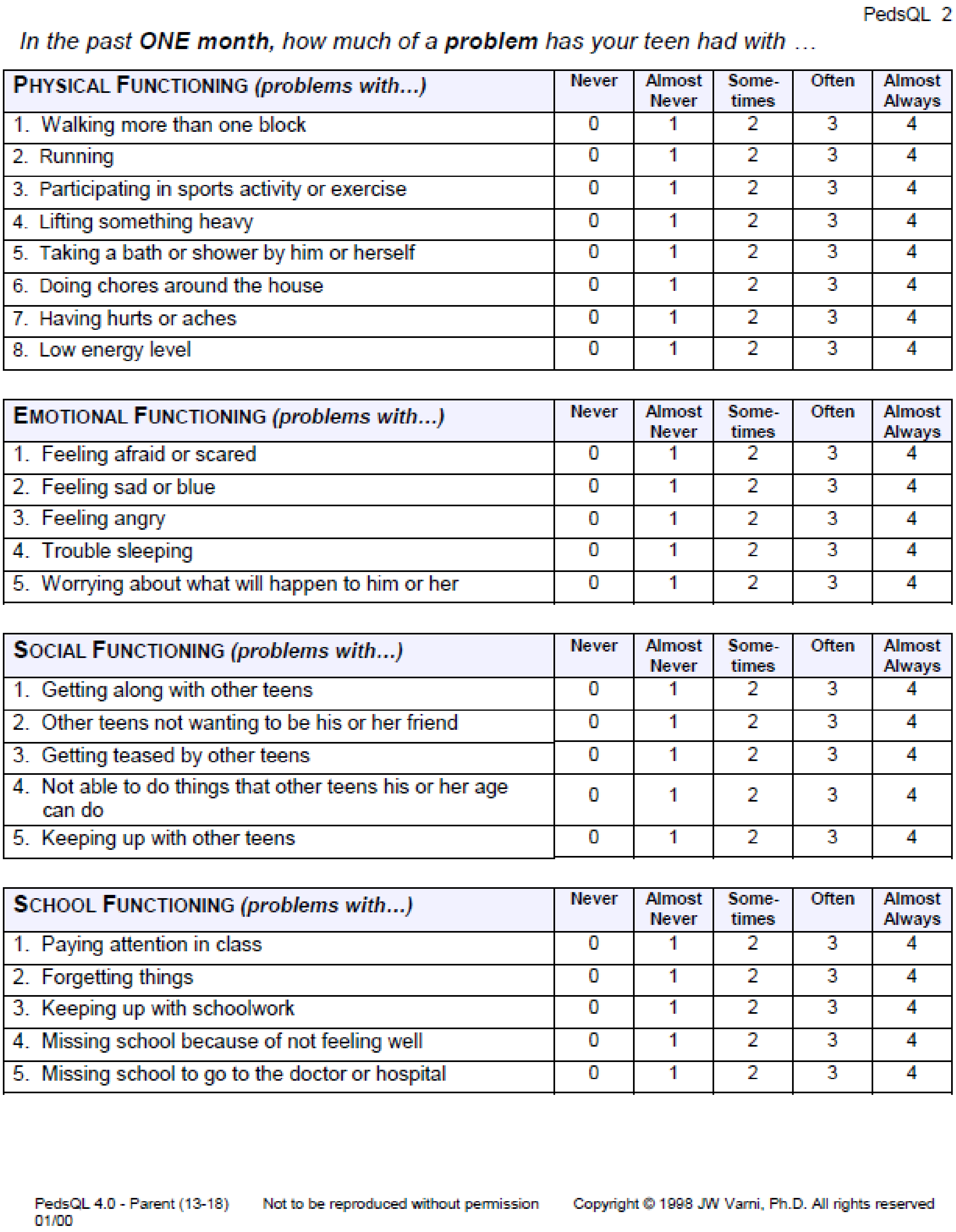

PedsQL 2

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

PHYSICAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Walking more than one block	0	1	2	3	4
2. Running	0	1	2	3	4
3. Participating in sports activity or exercise	0	1	2	3	4
4. Lifting something heavy	0	1	2	3	4
5. Taking a bath or shower by him or herself	0	1	2	3	4
6. Doing chores around the house	0	1	2	3	4
7. Having hurts or aches	0	1	2	3	4
8. Low energy level	0	1	2	3	4

EMOTIONAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Feeling afraid or scared	0	1	2	3	4
2. Feeling sad or blue	0	1	2	3	4
3. Feeling angry	0	1	2	3	4
4. Trouble sleeping	0	1	2	3	4
5. Worrying about what will happen to him or her	0	1	2	3	4

SOCIAL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Getting along with other teens	0	1	2	3	4
2. Other teens not wanting to be his or her friend	0	1	2	3	4
3. Getting teased by other teens	0	1	2	3	4
4. Not able to do things that other teens his or her age can do	0	1	2	3	4
5. Keeping up with other teens	0	1	2	3	4

SCHOOL FUNCTIONING *(problems with…)*	Never	Almost Never	Some-times	Often	Almost Always
1. Paying attention in class	0	1	2	3	4
2. Forgetting things	0	1	2	3	4
3. Keeping up with schoolwork	0	1	2	3	4
4. Missing school because of not feeling well	0	1	2	3	4
5. Missing school to go to the doctor or hospital	0	1	2	3	4

PedsQL 4.0 - Parent (13-18)
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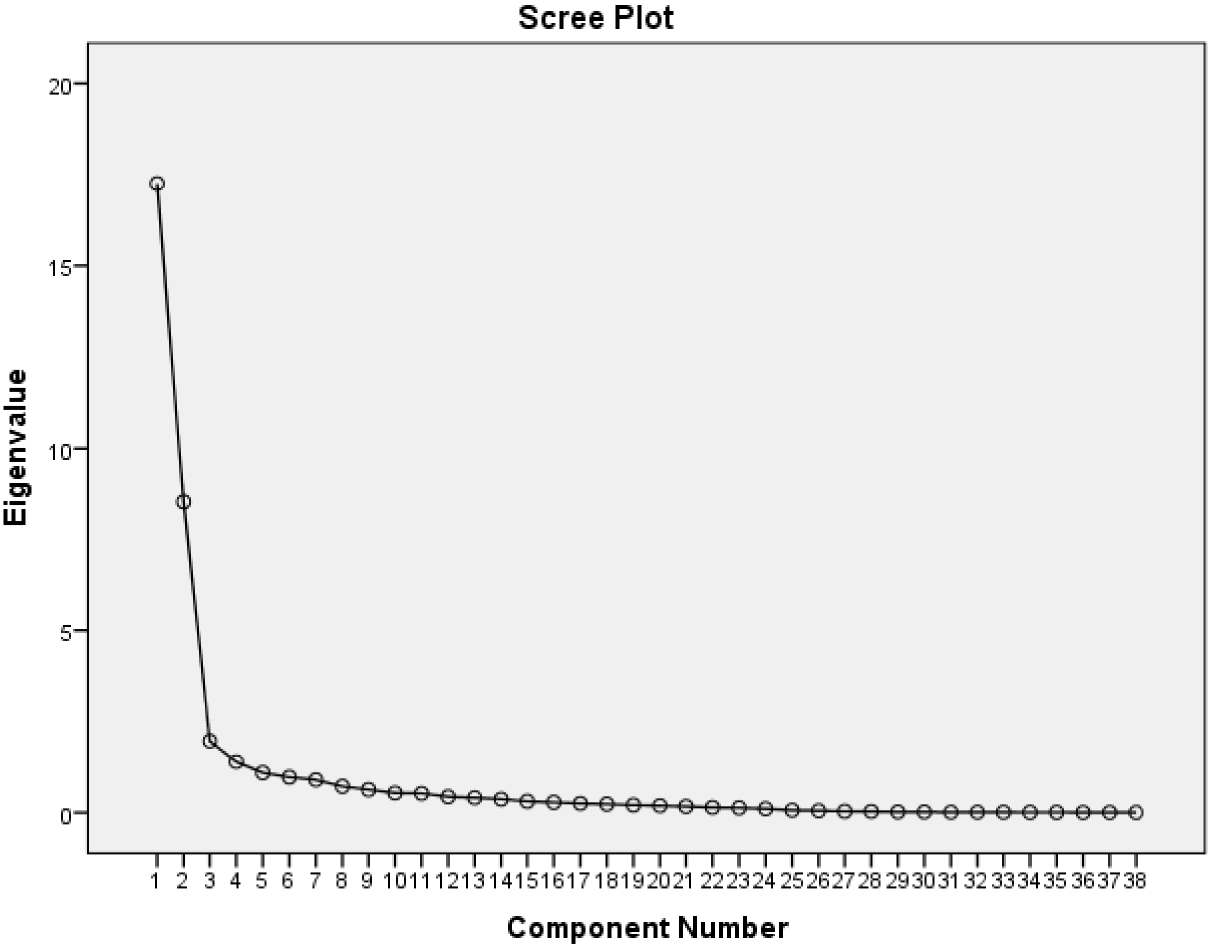

Figure 1. Scree plot. Lists number of components appropriate for PedsQL™ Food Allergy Module.

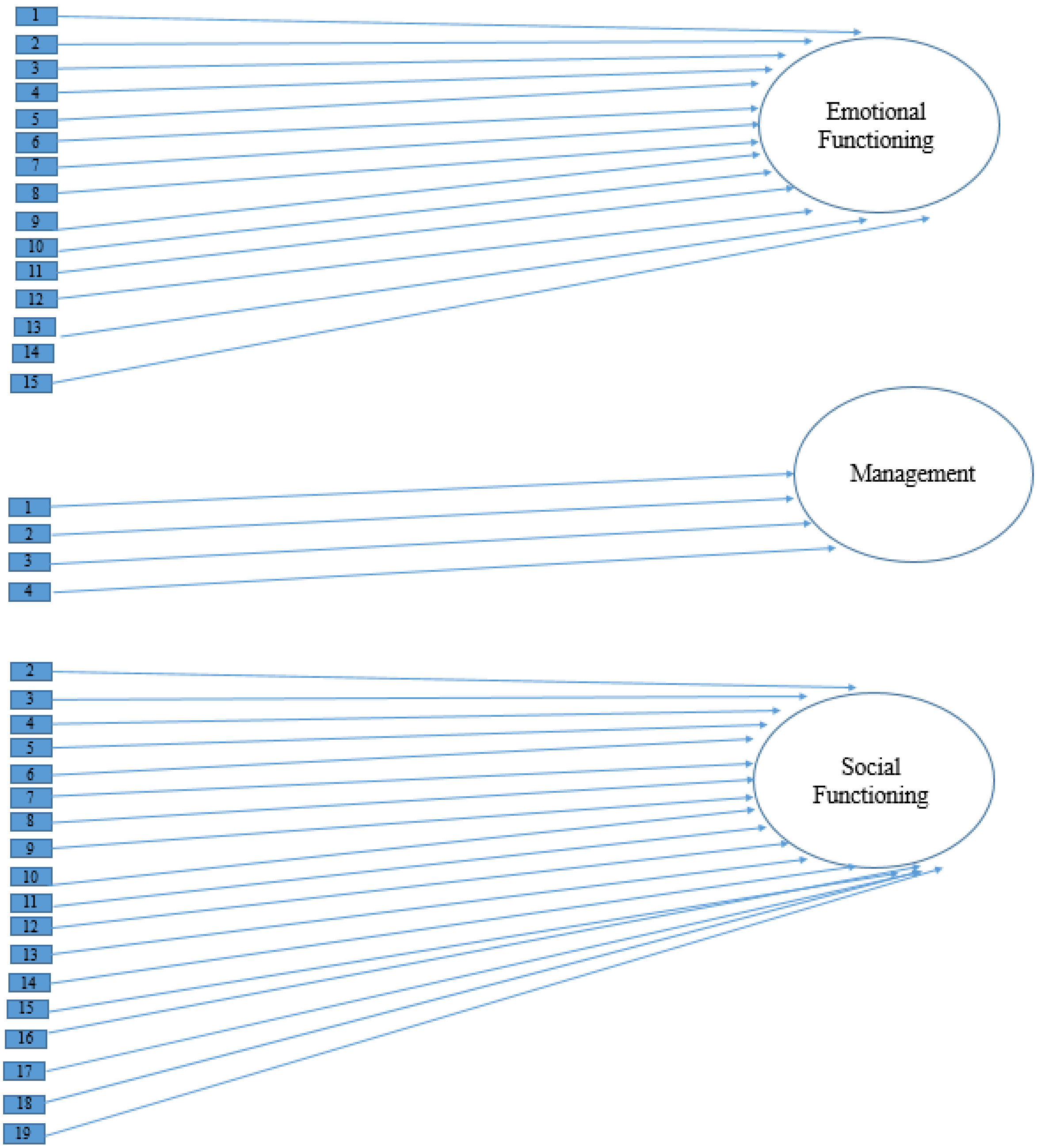

Figure 2. PedsQL™ Food Allergy Module- Parent Report 3 Component Model, with item 1 of Social Functioning Scale removed.