



Precision and sensitivity of the short-form pediatric enuresis module to assess quality of life (PEMQOL)

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KEYWORDS

PEMQOL; Quality of life; Outcomes; Pediatric enuresis; Measurement **Abstract** *Purpose*: To evaluate a derived short-form version of the Pediatric Enuresis Module to assess Quality of Life (PEMQOL) Child and Family Impact Scales, a survey intended for use in clinical practice and research as a means of continuous monitoring of the impacts of enuresis on the child and family.

Materials and methods: The full-length PEMQOL was completed by parents in two clinical trials (n=143 and n=397, respectively) and for children receiving care at five specialty clinics (n=208). The short-form scales were derived using regression and factor analysis. Multitrait scaling analysis was used to evaluate item internal consistency and discriminant validity. Reliability was estimated using Cronbach's alpha. Clinical validity was computed by comparing the proportion of variance explained by the short-form scales relative to their respective full-length versions. Differences in scores were examined by: (1) less wetting episodes, (2) number of pads used and (3) changes over time.

Results and conclusions: The Child and Family Scales were reduced from 14 to 7 items and 17 to 9 items, respectively. Eighty six percent (median) of items in the Child Scale and 100% in the Family Scale met item level scaling criteria. Median alpha coefficients across seven sub-samples were 0.72 and 0.76, respectively. Relative validity estimates for the Family Scale ranged from 2.66 to 0.87. Findings for the Child Scale were lower and ranged from 0.78 to 0.54.

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Introduction

While diurnal and/or nocturnal enuresis may not pose a significant physical health risk for the 5–7 million afflicted children, there are considerable social and emotional consequences for them and their families [1–7]. Routine assessment of the emotional well-being of the child has been recommended, since effective treatment depends on the child and family's commitment [8]. The Pediatric Enuresis Module to assess Quality of Life (PEMQOL) [9] was designed to address the need for a comprehensive questionnaire that could be used in research and with further development be integrated into routine care as part of a comprehensive care plan for patients and their families.

Materials and methods

Brief description of the PEMQOL

The PEMQOL is a parent-reported instrument; a full-length research version was developed based on a review of the literature, and interviews and discussions with an expert panel of pediatric urologists [9]. Two multi-item, Likert-type rating scales [10], Impact on the child's well-being (Child Scale) and Impact on the Family's emotional and social well-being (Family Scale), were developed and tested. Items are reversed (if appropriate) so that a higher score is better and a mean score is calculated to derive an overall scale score as is the standard for ordered categorical or Likerttype scales [11]. For ease of interpretation, the raw scale scores are converted to a 0-100 continuum using a standard mathematical formula [9,11-14].

Initial results for the full version were promising but from the outset of its development we anticipated that the length (Child Scale 14 items and Family scale 17 items) might not be feasible for ongoing use in the busy clinical setting. The question remained, would it be possible to achieve equally sound scientific findings with fewer items? Thus, the goal of the present study was to (1) derive a short, more practical version of the two core scales, (2) evaluate their structural framework, and (3) assess the tradeoffs in precision between the full-length and the short-form versions of the scales [12,13]. Table 1 provides the item content for the full-length version (31 items) and the resulting 16item short-form version. Response options for both scales have five levels each: 'A lot', 'Quite a bit', 'Some', 'A little bit', 'Not at all'.

Data collection

The full-length PEMQOL was fielded in two clinical trials and a community-based sample. Data from these studies were used to derive and evaluate the short-form. Trial One was an open label safety and efficacy study across 29 study sites in the United States and Canada. Trial Two was a randomized double-blind efficacy and safety study conducted in 49 study sites in Europe, Asia and the United States. The PEMQOL was rigorously translated using published international criteria.

Children aged 5–10 years, with symptoms of urge incontinence suggestive of detrusor overactivity (*1 diurnal incontinence episode/24 h *5 of 7 days) were recruited for participation in Trial One. In Trial Two, enrollment criteria also required that eligible children have *6 voids/24 h at baseline.

The community-based study has been described in detail elsewhere [9]. Briefly, a cross-sectional study design was used to collect data between June 2001 and June 2002 from parents of patients aged 5 years and older presenting for a scheduled visit at one of five academic pediatric specialty clinics across the US. Type of treatment was open-ended and human subject's approval/exemption was received.

Statistical analyses

Analytic samples

Table 2 provides a summary of the study samples. One hundred and forty-three patients with a mean age of 8 years (SD=1.71) were enrolled in Trial One. Three hundred and sixty-nine patients with a mean age of 7 years (SD=1.53) were enrolled in Trial Two. Two hundred and eight patients with a mean age of 9 years (SD=2.63) were enrolled in the community samples. Detailed clinical and other socioeconomic data were not available for purposes of deriving and evaluating the shortform scales. Datasets were analyzed separately.

Item reduction

A multi-staged approach was employed to reduce the Child Scale to seven items (50% reduction) and the Family Scale to nine items (47% reduction). The three methods used were factor analysis (principal components varimax), stepwise regression, and multitrait item-scaling analysis, a confirmatory factor analytic method known as the Revised Multitrait/Multi-item Analysis Program (MAP-R) which allows for smaller sample sizes [14,15]. All items were used in each method and the items that had the most consistent results across all three methods were selected for the short-form.

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