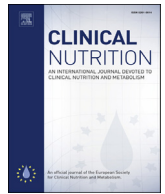




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Original article

Development and validation of the Parenteral Nutrition Impact Questionnaire (PNIQ), a patient-centric outcome measure for Home Parenteral Nutrition

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SUMMARY

Background & aims: Patients with Type 3 Intestinal Failure (IF) who need Home Parenteral Nutrition (HPN) face several clinical, psychological and social problems.

The study was designed to produce and test the first patient-centric measure for HPN ('PNIQ: Parenteral Nutrition Impact Questionnaire'). The new measure focused on the extent to which patients were able to fulfil their human needs.

Methods: Questionnaire content was derived from the analysis of transcripts of interviews conducted with UK HPN patients. Cognitive debriefing interviews (CDIs) were performed to ensure patients found the draft scale clear, relevant and accessible. Finally, a test–retest postal validation survey was conducted to reduce the number of items in the scale and to ensure that; it was unidimensional, reproducible and had construct validity.

Results: The 30 interview transcripts were analysed to identify issues related to a wide range of needs. Fifteen CDIs showed that patients found the draft scale easy to complete and highly relevant. The postal survey included 233 patients on HPN recruited through two IF units. Items were rejected if they did not fit the Rasch model, had too similar content to other items or displayed differential item functioning related to age, gender or underlying mechanism of IF. A 20-item unidimensional scale was identified with high internal consistency (0.91) and test–retest reliability (0.92). Scores on PNIQ correlated moderately highly with social isolation, emotional reactions and energy level and were related to perceived interference on life of HPN. The underlying cause of IF did not influence the way the scale worked.

Conclusions: The PNIQ is a scientifically rigorous, unidimensional outcome measure that provides a complete assessment of the effect of HPN on everyday life. It will prove useful for measuring patient value in clinical practice and for determining outcome in clinical trials, audit, economic evaluations and outcomes-based reimbursement.

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Abbreviations: CDI, Cognitive Debriefing Interviews; DIF, Differential Item Functioning; IF, Intestinal Failure; HPN, Home Parenteral Nutrition; HPN-QoL, Home Parenteral Nutrition-Quality of Life questionnaire; HRQL, Health-Related Quality of Life; IQR, Interquartile range; NHP, Nottingham Health Profile; OBC, Outcome Based Commissioning; OBR, Outcome based Reimbursement; PROM, Patient-Reported Outcome Measure; PSI, Person Separation Index; QoL, Quality of Life; RUMM, Rasch Unidimensional Measurement Model; SBS-QoL, Short Bowel Syndrome Quality of Life questionnaire; SF-36, Short-Form 36; PNIQ, Parenteral Nutrition Impact Questionnaire.

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1. Introduction

Home Parenteral Nutrition (HPN) is essential for patients with Intestinal Failure (IF) (Type 3). Such patients are unable to absorb the macronutrients and/or water and electrolytes that they need and require intravenous supplementation [1]. Although a potentially life-saving treatment for people with IF, HPN imposes restrictions on an individual's life [2]. Administering HPN is an invasive and time-consuming procedure requiring in-depth

training on the aseptic technique for patient and/or caregiver. Due to the nature of the treatment and its associated complications [3,4] HPN affects the quality of life (QoL) of patients [5].

Previous research in this field has focused on the measurement of health-related quality of life (HRQL) [6,7]. HRQL differs from QoL as it is concerned with the impairments and functional limitations that are of interest to health professionals, yet may not be of specific concern to the patients themselves [8]. Furthermore, HRQL is only designed to assess clinical outcomes directly influenced by health services. Non-clinical variables such as educational level, the availability of caregivers, or financial resources are specifically excluded from HRQL assessment, despite their potential influence on QoL.

Health services are moving away from a fee for service model to outcomes based commissioning (OBC) and reimbursement (OBR). Consequently, payers are becoming more interested in the concept of patient value [9]. Such an approach requires the availability of a patient-centric measure of value. Changes in patient value can then be related to the cost of the intervention. While QoL clearly provides an estimation of patient value, HRQL does not. To obtain a holistic picture of the impact of a condition and prescribed interventions on a patient (patient value), it is essential to determine QoL [8].

Baxter et al. [3] found that the Medical Outcomes Study-based measures (SF-36) [10] was the most widely used instrument for assessing HRQL in people receiving HPN. These authors developed another HRQL measure – the Home Parenteral Nutrition Quality of Life questionnaire (HPN-QoL) [11]. More recently, the SBS-QoL has been developed, specific for people with short bowel syndrome [12]. The SF-36, HPN-QoL and SBS-QoL all assess HRQL. Furthermore, all three measures applied Classical Test Theory in their development which has been largely replaced by Item Response Theory (IRT) in instrument development. The application of IRT, and particularly Rasch analysis, greatly improves the precision of measurement [13].

To date, no measure has been developed that assesses the patient value of HPN. The most widely implemented method of evaluating patient value is the needs-based model [14]. This argues that disease and its treatment influence an individual's ability to fulfil his or her human needs. QoL is considered poor when few human needs are satisfied. Over 20 disease-specific measures are available that adopted the needs-based model. Several of these are widely used in international studies of clinical [15] and non-clinical [16] interventions. The article describes the development of the PNIQ (Parenteral Nutrition Impact Questionnaire), a patient-centric measure for people on HPN that adopted the needs-based model.

2. Materials and methods

2.1. Ethics

Ethics approval for the study was granted by National Research Ethics Committee North West (11/NW/0171).

2.2. Patients

Patients were recruited from the IF Units at Salford Royal NHS Foundation Trust and St Mark's NHS Foundation Trust. Participants were identified from a database held by the clinical team at each hospital. A separate sample of people was recruited for each stage of the study. Participants gave written informed consent prior to inclusion in the study.

Participants were eligible for the study if they were aged over 18, had a confirmed Type 3 IF diagnosis, provided written informed consent and could answer the questionnaire independently.

Patients were excluded if they had a major co-morbidity considered likely to influence their responses on the questionnaire, were unable to provide informed consent or were judged by the clinical team to be incapable of participation.

2.3. Generation of questionnaire content

PNIQ items were generated from semi-structured, qualitative interviews conducted by experienced researchers. Interviewees were asked to describe how their lives had been affected by HPN. Interviews were conducted in patients' own homes or in special interview rooms at Salford Royal NHS Foundation Trust. With the agreement of the interviewees, the interviews were audio-recorded and, later, transcribed. Thematic content analysis was employed to generate potential items for the questionnaire [17]. Items selected informed on ways in which need fulfilment was impaired by HPN. Potential items were discarded if they were duplicates, idiosyncratic, ambiguous or poorly worded. The resulting draft questionnaire deliberately included some item redundancy to ensure that the best wording was used in the final questionnaire.

2.4. Assessment of face and content validity

The relevance, acceptability and comprehensiveness of the draft PNIQ was tested by means of cognitive debriefing interviews. An interviewer observed and noted any problems experienced by patients while they completed the PNIQ. These problems were then discussed followed by specific questions about the acceptability, relevance and comprehensiveness of the questionnaire.

2.5. Postal validation survey

The postal survey had three main functions; to identify the final version of the questionnaire (item reduction), to determine its scaling properties (unidimensionality) and to establish its classical psychometric properties (reproducibility and construct validity). The survey pack consisted of the PNIQ, a demographic questionnaire and the Nottingham Health Profile (NHP; [18]). The NHP was used as the comparator measure as it was deemed more suitable than other generic HRQL measures that focus more on physical impairments and functioning. It has six sections; emotional reactions, social isolation, energy level, sleep, pain and physical mobility.

The same survey pack (excluding the NHP) was sent to a subset of respondents two weeks after they had returned the first completed package, to assess reproducibility.

2.6. Scale reduction

Rasch analysis [19] (one-parameter logistic item response theory) was applied to the PNIQ data collected in the first postal survey to determine unidimensionality, using the RUMM 2020 programme [20]. The scale misfits the Rasch model if a χ^2 p-value of <0.05 (after Bonferroni corrections) is observed. Person Separation Index (PSI) is an indication of internal reliability, with 0.70 the minimum acceptable value. Item redundancy is defined as local dependence on another item and/or the item having the same value as another item in the scale. Rasch requires items to be invariant across groups. This is tested by examining differential item functioning (DIF). In the present study DIF by gender, age group (below or above median), duration of HPN (below or above median), underlying disease (Crohn's versus other) and primary mechanism (short-bowel versus other) were examined. Crohn's disease and short bowel were chosen as they were the most common underlying disease and primary mechanism respectively in our sample, to see if

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