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Content Validation of a Home Parenteral Nutrition Patient Reported Outcomes Questionnaire

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CONTENT VALIDATION OF A HOME PARENTERAL NUTRITION PATIENT
REPORTED OUTCOMES QUESTIONNAIRE

BY TRACY-LEE MILLER

A THESIS SUBMITTED IN PARTIAL FULFILLMENT OF THE
REQUIREMENTS FOR THE DEGREE OF MASTER OF SCIENCE IN
NUTRITION AND FOOD SCIENCE

UNIVERSITY OF RHODE ISLAND

2017

MASTER OF SCIENCE THESIS

OF

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2017

Abstract

Background: Currently, there is no known patient reported outcome (PRO) instrument being used in clinical practice for the home parenteral nutrition (HPN) population. To address this gap, the Home Parenteral Nutrition-Patient Reported Outcome Questionnaire (HPN-PROQ) was developed for use during medical appointments or homecare visits. The purpose of this research is to provide evidence that the items and scales of the HPN-PROQ possess content validity, a crucial step in the process of questionnaire development.

Subjects: Qualitative sample included 32 HPN patients and quantitative sample included 13 expert home care clinicians (physicians, dietitian, pharmacists, registered nurses and patient advocates.)

Methods: In Phase I, cognitive interviews (CI) were conducted to evaluate HPN patients' understanding of the instructions, items, and response scales on a draft HPN-PROQ. The draft HPN-PROQ was revised based on results of CIs. In Phase II, a revised draft was sent to expert clinicians to complete the Content Validity Index (CVI). Any item achieving a I-CVI kappa score ≤ 0.783 was removed. The Scale-CVI-Average (S-CVI/AVG) was calculated following a second round of CVI by a reduced expert panel.

Results: The final HPN-PROQ contains thirty-four items with an I-CVI score ≥ 0.783 . The overall S-CVI/AVG score of the HPN-PROQ was 0.961.

Conclusion: This study provides evidence that the HPN-PROQ has acceptable content-validity and after future validation procedures, may be appropriate as a new tool for fostering dialogue between HPN patients and their clinicians.

ACKNOWLEDGEMENTS

First, thank you to the members of my committee. Their unwavering patience with me throughout this process deserves my utmost recognition and gratitude. To my family and friends – thank you for your encouragement and for accepting my frequent absences and enduring the (infrequent) complaining. Lastly, to my partner Jess, without whom none of this would have been possible – thank you for giving me the confidence to do this “crazy thing.” You have never stopped believing in me and your continuous encouragement was invaluable. But, in all seriousness, would you mind terribly if I enroll for six more years?

Working alongside Dr. Winkler has given me the extraordinary opportunity to work with the home parenteral nutrition population which has uncovered an entirely new platform of interest that I look forward to exploring beyond my graduate studies. Dr. Winkler’s mentorship is unmatched – she epitomizes the true meaning and purpose of being a mentor. Dr. Winkler strives to reach her mentees in a meaningful way, acknowledges every learning opportunity as a crucial one, and graciously pushes them to their full potential. Without a doubt, this has been the most inspiring experience I have had while in graduate school.

It would be impossible for me to not acknowledge my grandmother. She was a crusader for special education and embraced the true meaning and purpose of being an educator. She is remembered as a woman who had an unwavering desire to stand up for what she believed was “right” and still inspires me today and every day. My grandmother never missed an opportunity to mentor another viewed many of these relationships as partnerships. She spoke often about how her mentees had inspired her

just as much as she may have inspired them. Because of my grandmother, education holds a special place in my heart and has always been my main motivation in getting a nutrition degree. I too wish to share my knowledge with others and to partner with them in hopes of inspiring their inner interests and talents.

In conclusion, I want to acknowledge what I believe is the greatest purpose of writing a master's thesis – to gain the confidence to actively participate in driving nutrition-knowledge forward. Upon reflection, I feel I have embraced this purpose, and with the support of my mentors, professors, committee members, classmates, family, and friends, I am happy to say I have gained this confidence and look forward to putting it to work.

Preface

This thesis was written to comply with the University of Rhode Island Graduate School Manuscript Thesis Format. This thesis contains one manuscript entitled “Content Validation of a Home Parenteral Nutrition Patient Reported Outcomes Questionnaire”. This manuscript has been written in a form suitable for publication in the journal *Nutrition and Clinical Practice*.

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CONTENT VALIDATION OF A HOME PARENTERAL NUTRITION PATIENT
REPORTED OUTCOMES QUESTIONNAIRE (HPN-PROQ)

By

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Prepared for submission to Nutrition and Clinical Practice

Clinical Relevancy Statement

The Home Parenteral Nutrition-Patient Reported Outcomes Questionnaire (HPN-PROQ) is a novel tool which is designed to foster dialog between HPN patients and providers around quality of life constructs. This study provides support for the content validity of the HPN-PROQ.

Introduction

Background

Home parenteral nutrition (HPN) is a complex therapy involving the intravenous infusion of nutrients and fluids to individuals who have intestinal failure or dysfunction.¹ It is estimated that 33,000 people in the United States required HPN in 2010.² Most frequently, patients receiving HPN have diagnoses of short-bowel syndrome, inflammatory bowel disease, or cancer with bowel obstruction.^{3,4}

Quality of life (QoL) is defined by the Food and Drug Administration (FDA) as a 'general concept that implies an evaluation of the effect of all aspects of life on general well-being'.⁵ Factors that negatively affect the overall QoL of HPN patients are decreased physical, psychological and social function, along with increased occurrences of depression, drug dependency, sleep disturbance, frequent urination, fear of therapy-related complications, and inability to eat.^{1,6-8} The emotional and physical complications associated with HPN and underlying disease require extensive lifestyle adaptation for patients and their families.⁹ Psychosocial factors include; coping with a medical diagnosis, being dependent on technology, coping with the loss of the eating experience, relying on others for care, low self-esteem, interfering with sexual functions, and the financial burden of nutrition support.¹⁰ The emotional and

physical adaptations required by this technology-dependent population emphasizes the necessity of support by a multidisciplinary medical team. This team should have the tools necessary to effectively communicate with their HPN patients as such support is crucial to patient-care and quality of life. One such tool is a Patient Reported Outcome (PRO) questionnaire, which serves to collect information from patients about existing psychosocial challenges as well as a management of their health condition.¹¹

Winkler et al.¹² determined that HPN patients perceived their routine medical appointments as a parenteral nutrition “tune-up”, with sessions focusing primarily on medical or disease aspects of care. Patients self-reported that they desired a more holistic approach to parenteral nutrition management, incorporating physical and emotional support, in addition to medical examination and nutrition assessment.¹² If used in clinical practice, PRO instruments could provide support to patients because feedback is provided to the clinicians with the goal of helping them manage patient care.¹¹ Such instruments can be invaluable in facilitating patient-clinician communication around QoL.¹¹ Although the use of PRO instruments in clinical practice can improve the interactions between patients and their clinicians, the Sustain Registry, a national patient registry for nutrition support, reports that <2% of enrolled HPN patients have had QoL constructs measured or assessed.^{4,11}

There is one validated HPN-specific QoL instrument to assess the HPN population, the Home Parenteral Nutrition Quality of Life Questionnaire.¹³ This instrument has been used to score and assess changes in QoL among HPN patients receiving pharmacological interventions.^{13,14,15} However, the HPN-PROQ was developed with a different purpose in mind than that of the HPN-QoL. Rather than

producing an overall score of the patient's QoL, the HPN-PROQ is an instrument that may enable a HPN patient to easily complete a PRO questionnaire in a clinical setting and prioritize important medical and non-medical issues for discussion with clinicians.

The purpose of this study is to assess the content validity of the HPN-PROQ. Once the instrument has undergone this rigorous content validation process and future studies conduct psychometric testing, and clinical validation, the HPN-PROQ could be applicable for use in the clinical setting with adult HPN patients residing in the United States.

HPN-PROQ Development

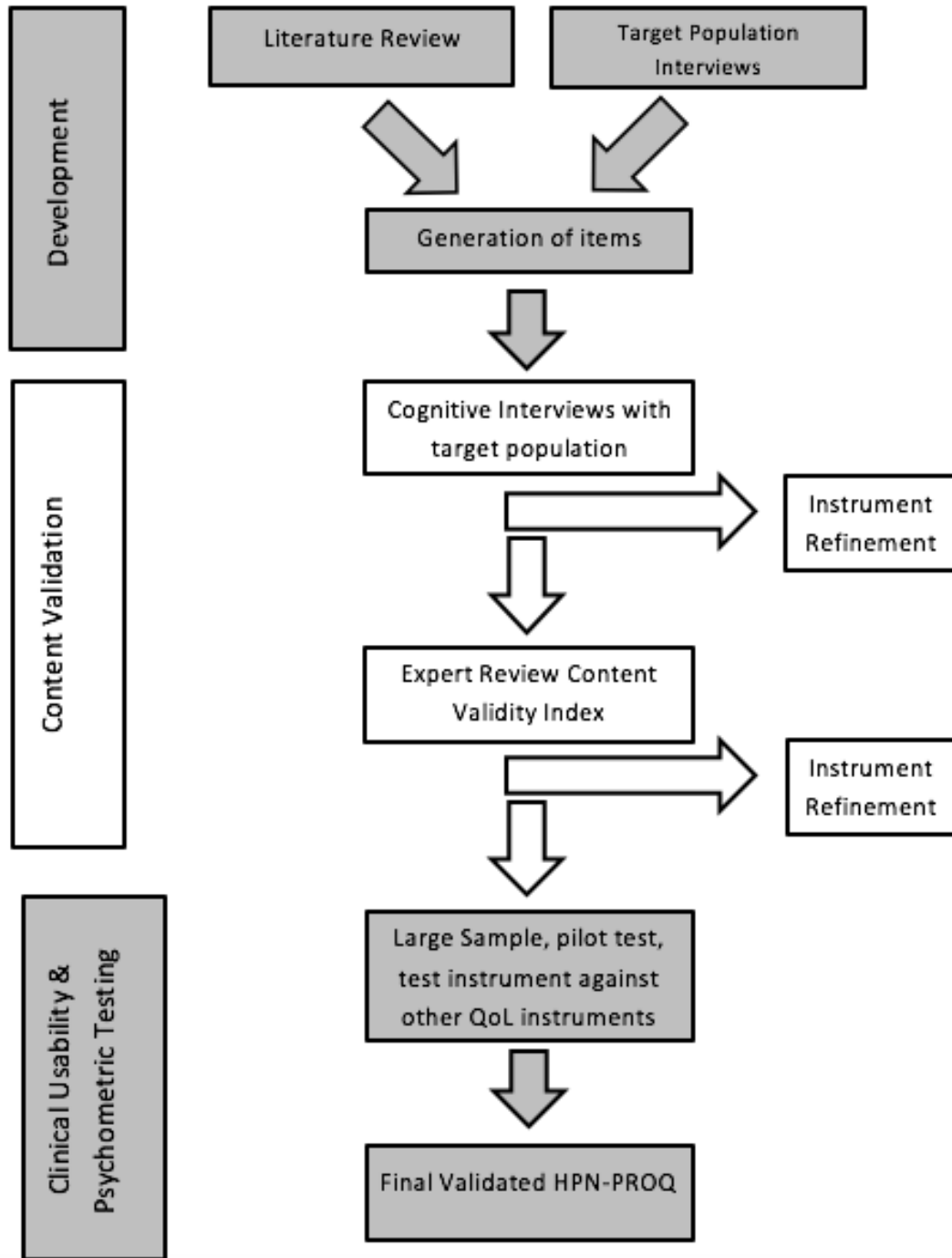
The draft HPN-PROQ was developed after a comprehensive literature review, expert clinician feedback, and qualitative research by Winkler et al.¹, which explored the lived experiences of HPN dependent adults. Qualitative research revealed that GI symptoms (with or without an ostomy), eating and mealtimes, energy level and ability to do activities of daily living, sleep, psychosocial function and coping, and the complexity of technology and training for HPN, all influenced self-perceived QoL of HPN patients.¹

The draft HPN-PROQ included two sections with a total of 54 items. *Section One* asked patients to report how often they experience specific situations during the previous two-week period. A four-point Likert response-scale was chosen for this section: “never”, “2-3 days per week”, “more than half of days”, and “nearly every day”. Constructs included: eating and mealtimes, psychosocial functioning and coping, HPN management, energy level and ability to do activities of daily living, sleep, and GI symptoms (36 items total). Items relating to GI symptoms were

differentiated by anatomy (ostomy or bowel in continuity). *Section Two* included 18 true/false items. A four-point Likert response scale was chosen for this section: “mostly false”, “somewhat false”, “somewhat true”, and “mostly true”. Constructs included: QoL, living with HPN, and HPN equipment-related knowledge.

A crucial step in the development of questionnaires is to provide evidence that the items and scales possess content validity.⁵ When testing the content of a newly developed PRO, there are two primary components of importance.^{16,17} First, what is the intent of the question: what do respondents believe the question is asking? Second is the meaning of specific terms in the instrument: what do specific words and phrases in the instructions, items, and/or response options mean to respondents? Is that meaning consistent with the intent of the researchers?¹⁸ Because PRO instruments assess concepts most relevant and important to a patient, content validity must be established as it is the extent to which an instrument assesses the concepts it proposes to assess.¹⁸

Figure 1 illustrates the process of content validation and where it falls in instrument development and validation. This figure has been adopted from Schildmann et. al.¹⁹



**Steps denoted in white shaded boxes were completed in this study.

Figure 1: Instrument Validation Process Flow

Methods

This study assessed the content validity of the HPN-PROQ using a two phase mixed-method study design; qualitative methods and quantitative methods via the administration of the Content Validity Index (CVI).²⁰ The purpose was to modify this draft based on cognitive interview (CIs) feedback from HPN patients (Phase I) followed by expert review with home care clinicians who completed the CVI (Phase II). (See Table 1) This study protocol was reviewed and approved by the University of Rhode Island’s Institutional Review Board (IRB) prior to the start of recruitment.

Table 1: Content Validation Methods Process Flow			
<i>*Start: draft HPN-PROQ</i>			
Phase	Method	Sample	Result
I	Qualitative Cognitive Interview & analysis of feedback to drive decisions for revision to draft.	HPN Patients	<i>Modified draft HPN-PROQ</i>
II	Quantitative Content Validity Index to determine “excellent” item and scale relevance of modified draft.	HPN Expert Clinicians	<i>Content Valid HPN-PROQ</i>

Sampling

HPN patients

Similar to Chopy et al.²¹, the Oley Foundation, a national, independent, non-profit 501(c)(3) organization serving HPN patients through education, advocacy, and networking, approved the study protocol and, agreed to post and distribute announcements calling for study volunteers. (Recruitment materials can be found in

Appendix E). Eligibility requirements for HPN patients included being 18+ years of age, receiving HPN, speaking English, living in the U.S., having an active email address, and ability to access a computer while simultaneously being on the telephone. Exclusion criteria included being pregnant and those receiving enteral nutrition. Study patients self-selected to participate by contacting the research email address. Each was sent the eligibility screener including seven questions to verify eligibility: “Do you live in the US?”, “What is your age in years?”, “Are you pregnant?”, “Are you receiving home TPN?”, “Do you speak English?”, “Do you have computer access?”, “Can you talk on the telephone and read on the computer at the same time?”. A target number of cognitive interviews (n=30) was chosen by the research team prior to the start of Phase I. Demographic information included medical diagnosis, length of time dependent on HPN, number of infusions per week, number of infusion hours per day, age, sex, race, number of people in household, and highest level of education. Microsoft Office Excel (2017) was used for descriptive statistical analysis and results are reported as mean and frequency.

HPN Experts

For Phase II, a convenience sample of expert HPN clinicians identified through publication (recognized contributions to the literature on the topic of HPN), leadership in the American Society for Parenteral and Enteral Nutrition home care section, and the Oley Foundation were asked to participate. The expert panel included physicians, registered dietitians, pharmacists, registered nurses, and home-care advocates. The goal was to recruit 12 experts as this is an acceptable sample size for completion of the CVI and is comparable to other studies.^{20,22-24} A reduced panel utilized a second round

of the S-CVI/AVG after analysis of full CVI panel results. This sample was also stratified by profession in order include input from commonly included members of a medical team who serve the HPN population.

Data Collection Phase I: Cognitive Interviews

All interviews were audio-recorded on a Sony ICD-PX333 digital voice recorder and notes were taken during interviews to keep an audit trail and enhance the researchers' understanding of the recorded conversations. During semi-structured interviews, a verbal probing cognitive interviewing technique was employed.²⁵ The interviewer used the following probes: verbal probes (“what does the term *xyz* mean to you”); paraphrasing (“please repeat the question I just read to you in your own words.”); recall probe (“how do you remember how often you experienced *xyz* in the past 2 weeks?”); and general probes (“would this be easy or hard to answer? I noticed that you hesitated - tell me what you were thinking”).²⁶ Patient responses to probes served to guide the interviewer to probe more efficiently in future interviews and to collect more streamlined data. After all interviews, patients were asked to share their “overall impression” of the HPN-PROQ (i.e. if they felt the instrument would be useful in starting a conversation with any of their health-care clinicians.)

Recordings from each interview were transcribed verbatim, de-identified, and saved as Microsoft Word (2017) documents. The collaborative research team (CRT) met frequently throughout the qualitative data collection process to discuss potential revisions to the draft HPN-PROQ. In cognitive interviewing, data collection and analysis is an iterative, concurrent, and interrelated process. Patterns and themes were identified in an ongoing manner throughout Phase I.²⁵

A pilot interview was conducted to test the interview template/script and to establish an estimation of the time required to complete the interview. This interview was not recorded and data from this pilot interview are not included in results. Because of the length of the pilot interview (approximately 97 minutes), round-one CIs were split into two sets. See Figure 2. Round-one interviews were conducted to evaluate the overall relevance, comprehensiveness and suitability of items, instructions, and response scales on the draft HPN-PROQ with the purpose of subsequently modifying the questionnaire based on interview feedback. Specifically, *set one* interviews (n=10) evaluated items *Section One* items 1-20 and *set two* interviews (n=10) evaluated items *Section One* items 21-36, and *Section Two*, items 1-18. All round-one interviews tested the 4-point Likert response-scales included in the draft HPN-PROQ.

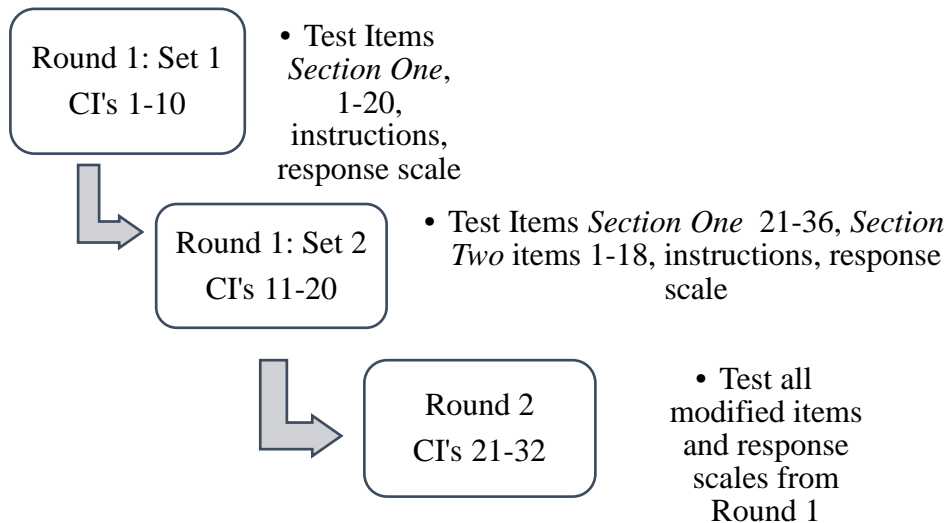


Figure 2: Cognitive Interview Process Flow

Each patient received the draft HPN-PROQ via email 5-10 minutes prior to the interview call. Patients were not asked to complete the draft HPN-PROQ. During interviews, the researcher focused on the interpretation of the items rather than considering how the patient would respond. The method of returning analyzed data to a participant, known as member checking, is often used to validate data collected in one interview by checking with another informant before subsequent interviews are conducted.^{27, 28, 29} After first round interviews and prior to starting round two interviews, a second interview (member check) was conducted with all round one patients (n=20) to review some projected modifications to the draft HPN-PROQ. These patients were contacted via email and asked to participate in a “member check” interview to discuss proposed modifications to the questionnaire.

Following round one interviews and member checking, thematic analysis of interview data was used to inform all necessary revisions to the draft HPN-PROQ. To ensure a robust set of findings, the revisions to the draft HPN-PROQ were tested in round-two interviews. Round two patients (n=12) were sent the modified draft HPN-PROQ and interviews were conducted to assess the clarity, relevance, and interpretation of the revised items and response scales. Patient feedback was again analyzed, and the CRT assessed the need for further revisions. Potential revisions to be included in the final draft were tested via member checking and in three final interviews. (i.e. interviews 29-32)

At the completion of Phase I, the CRT met to finalize all revisions before proceeding to Phase II. Qualitative data are presented and reported as representative quotes from HPN patients.

Data Analysis Phase I: Cognitive Interviews

Interview data were summarized and evaluated by the CRT and ultimately informed revisions to the draft HPN-PROQ. All decisions to change or modify any aspect of the questionnaire during Phase I were based solely on interview data and decisions made by the CRT based on these data.

Transcript contents were organized on an item-by-item basis using Microsoft Excel. By combining itemized patient feedback pertaining to each item, a cross-interview data matrix table was developed to aggregate feedback across interviews and seek patterns that identify key findings. Thematic analysis was used to sort and condense these data into themes, support decisions for revision to the questionnaire, and identify non-problematic items. A “theme” serves to categorize data and represents a level of patterned responses or meanings within the data set.³⁰ Thematic analysis offers a “theoretically-flexible” approach to analyzing qualitative data and serves to organize a rich and detailed, yet complex account of data into meaningful results.³⁰ Throughout this process, members of the CRT met frequently to discuss interview feedback and decide upon potential revisions to the draft HPN-PROQ. Careful consideration was given to vague or ineffective instructions, confusing questions and response options, variable interpretation of terms, general signs of misinterpretation by the patient and potentially reactive or offensive items.

Data Collection Phase II: Content Validity Index

Following the completion of Phase I, a *CVI Worksheet* representing the modified draft HPN-PROQ (see Appendix G) was administered via email to 13 HPN expert clinicians who agreed to participate in the study. Each participant returned the

CVI worksheet to the research email address and data were entered in Microsoft Excel (2017) software for analysis. After determining any necessary deletion of items based on I-CVI criteria of ≥ 0.783 , five experts (one physician, pharmacist, registered dietitian, registered nurse, and home care advocate) were chosen based on order of completion of round one CVI worksheets. (i.e. the first participant in each profession to complete the worksheet and return it to the research email was selected). These experts were sent a modified *CVI Worksheet* which excluded items not meeting the criteria for retention. Four experts returned the worksheet and data were entered in Microsoft Excel (2017) software for analysis. One expert clinician (registered nurse) did not respond to the research email with round 2 responses to the CVI.

Data Analysis Phase II: Content Validity Index

The I-CVI was calculated by having the experts rate the relevance of each item to the HPN population (1=not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant). The I-CVI of each item is defined as the number of experts offering a rating of “3” or “4” on each item, divided by the total number of experts and expresses the proportion of agreement by all experts on the relevancy of each item, as number between zero and one.²² For example, an item rated as “quite” or “highly” relevant by four out of five expert clinicians would have an I-CVI of 0.80.

The I-CVI was then adjusted for chance agreements using a multi-rater kappa statistic proposed by Wynd et al.³¹ The kappa statistic represents the proportion of agreement remaining after chance agreement is removed.³¹ The multi-rater kappa statistic is described as follows.

$$P_c = \left[\frac{n!}{A!(n-A)!} \right] \times .05^n$$

Where P_c is the probability of chance agreement, n is the number of experts, and A is the number of approving with “good relevance”.³¹ K was calculated using the I-CVI and probability of chance agreement as follows:

$$k^* = \frac{ICVI - P_c}{1 - P_c}$$

Each item on the scale was rated as “fair”, “good”, or “excellent” based on the following rating criteria: fair, $K = 0.40-0.59$; good, $K = 0.60-0.74$; excellent, $K > 0.74$. In the content validation of questionnaires, any item receiving a I-CVI kappa statistic ≥ 0.783 is considered to have high relevance and should be retained, and any item receiving a kappa < 0.783 should be removed from the questionnaire.²⁰

The Scale-CVI/AVG (S-CVI/AVG) was calculated using Microsoft Excel (2017) software. The S-CVI/AVG is the average I-CVI scores across all items.³¹

$$SCVI/AVG = \frac{\sum ICVI}{n}$$

Where n = the number of experts, a S-CVI/AVG over ≥ 0.83 is deemed acceptable in the content validation assessment of a newly developed instrument.²⁰ If deletions occur as the result of the I-CVI, the S-CVI/AVG can be repeated with a reduced panel to demonstrate differences in these scores after modification to the questionnaire.³¹

Table 2: Demographic Characteristics of HPN Patients Participating in Cognitive Interviews (N=32)

Female sex, %	71%
White race, %	98%
Marital Status, % married	61%
Caregiver present, %	35%
Highest Level of Education (n)	Doctorate n=2 Masters n=6 Bachelors n=7 Associates=2 High School Diploma n=15
Medical diagnosis relating to need for HPN (n)	Short Bowel Syndrome n= 22 Gastroparesis n=3 Pseudo Obstruction n=4 Intestinal malformation n=1 Severe Food Allergy n=1 Mitochondrial Disease n=1
Number of people living in household, mean +/- SD (range)	2.4 +/-1.5 (1-7 people)
Age (years), mean +/- SD (range)	52 +/-15 (22-73 years)
Years on HPN, mean +/- SD	12.0 +/- 10.5 (1.2-34 years)
HPN infusions per week, mean +/- SD	6.5 +/- 1.1
HPN infusion hours, mean +/- SD	12.0 +/- 3.7

*HPN=Home Parenteral Nutrition

Results

Phase I: Cognitive Interviews

Fifty-five adult HPN patients contacted the research email address indicating their interest in participating. Forty-three HPN patients replied to the screener email and 38 were determined eligible. Thirty-two patients comprised the study sample. Participant's mean age was 52 years (+/- 15 years), 71% female (n=23), and 98% Caucasian (n=31) with a diagnosis of either short bowel syndrome (n=22), gastroparesis (n=3), pseudo obstruction (n=4), intestinal malformation (n=1) severe food allergy (n=1), or mitochondrial disease (n=1). All participants possessed at least a high-school diploma, and 46% (n=15) had achieved a bachelor's degree or beyond (See Table 2).

The mean length of time for round one interviews was 51 (\pm 9) minutes and for round two interviews was 37 (\pm 10) minutes. Four themes were identified during qualitative data analysis.³² (see Appendix F). Based on this analysis, problematic items or response scales were revised or deleted.

Concerns with tone: Patients voiced concerns about the phrases “normal lifestyle”, “controls my life”, and “limits my freedom”. These phrases elicited unfavorable comments, indicating the items’ tone may be overly negative. For example, the item “*I am able to live what I consider a normal lifestyle*” elicited the following comment from one patient who felt the item would be difficult to answer; “*...this one is a little harder to answer... because I think normal is hard to define for everybody...that would need some parameters*”. Another patient provided similar feedback; “*...that’s kind of a hard one, because people have different lifestyles.*” One bluntly stated; “*I don’t live a normal lifestyle.*”

Issues with ambiguity and meaning: Across interviews, some items and phrases were inconsistently interpreted. For example, several patients requested additional clarification around the meaning of the phrase “many times”. Several patients requested that the interviewer quantify what was meant by “many times”. One patient felt the question would be difficult to answer, “*I would wonder about what you mean with ‘many’ times.*” Clarification was needed on several occasions around the concept of being “satisfied or “coping”. For example, “I am satisfied with the amount of sleep I get” was difficult for some patients to conceptualize; “*... someone can be satisfied with no sleep so it’s very individual*”.

Concerns with use of jargon or word choice: Patients voiced concern with the terminology used in some items. Patient feedback assisted in the refinement of these items to reflect more general terminology, or more commonly used terms and phrases in the HPN population. For example, the term “ostomy appliance”; one patient explained that this term is rarely used in their daily language, “*...I have a big issue*

with this. I tell my nurses when they ask me about changing my ostomy appliance that I don't change it more than once a day but I empty it frequently... changing and emptying is two different things so I would change that.". Another patient suggested the word "change" be revised to "empty", "*...change is not appropriate in here...you don't change it, you empty the bag.*". When these changes were tested in subsequent interviews, patients agreed with this feedback, "*I agree, I think I tend to call it a bag.*"

Table 3: Utility of the HPN-PROQ Representative Quotations
"I think these questions are phenomenal. I think they nail it...doctors don't ask that (these questions) ...but this feels so human and full empathy, I really appreciate this kind of questions".
"Yes, I think it (the HPN-PROQ) would benefit and give them (clinicians) an idea on how you're doing on TPN, that broad questions show them how it's affecting everyday of your life and not just how you're doing right now."
"I do (feel the HPN-PROQ would be useful) provided a doctor actually takes the time to kind of divulge in these kinds of things. Most of the time they're like "ok here's your action and what you have to do" and the home nurse will explain it all to you. There's not much (conversation) beyond that, the treatment plan..."
"A lot of times the patients want to talk about how they feel, but the physicians don't."
"They know the medical "in's and out's" in terms of intestine and bowel (issues) but they are clueless to what the TPN patient goes through emotionally and physically".
"Yes it (the HPN-PROQ) would spark a conversation...if you said you have a concern about your diet or diarrhea and they can offer you a dietitian."
"I think it's excellent it gives somebody topics to focus on when you're at the doctor and you have many questions to ask and they you go home and you remember that you forgot to ask some question... so I think it's a great conversation starter to have them (patients) fill it (the HPN-PROQ) out and discuss it during the visit."

HPN-PROQ Utility : Overall, patients provided very positive feedback regarding the use of the HPN-PROQ and were supportive of the development of the instrument. Patients described the draft HPN-PROQ as “useful”, and the items as “beneficial”, “human”, and “empathetic”. Representative quotations supporting this theme can be found in Table 3.

Revision to Response Scales and Instructions: Across round one interviews, patients’ interpretation of middle response options of the four-point Likert Scale varied widely across interviews. For example, patients described the response option “2-3 days per week” as “...three to four days per week.”; “...maybe six times.”; “...I would say four days per week.”. The response option “more than half of days” was described as “...four days per week”, “more than seven days.”; “anywhere between eight to 13 days”. These inconsistencies showed that revision to the response scale was necessary. The response-scales were changed to Visual Analog Scales (VAS) with the stems “Not at all” and “Every day” for *Section One*, and “Definitely false” and “Definitely true” for *Section Two*. The decision to use a VAS was based on review of relevant literature that indicated a VAS would be a suitable response scale for the intended utility of the HPN-PROQ.³³ Revisions to the response scale were tested with all patients from round one interviews via member checking. One hundred percent of round one interviewees (n=20) participated in the member check, and the majority (n=16) agreed with the need to revise the response option and preferred the VAS to the Likert Scales. Patients described the VAS as “better”, “less time consuming”, “a great visual” and “more accurate”. The VAS was included and tested in round two interviews. The instructional set for *Section One* was also revised; “please *indicate*

how often you experienced any of the following situations in the past two weeks” to “please *estimate how often* you experienced any of the following situations in the past two weeks”. This change was also tested via member checking and was found to be appropriate.

Additional Revisions

In addition to the revisions driven by participant feedback and qualitative data analysis, structural changes to the draft HPN-PROQ were made by the CRT. Three items in Section 1 were moved to Section 2 (true/false). “*I feel supported by my family and friends*”, “*I eat and enjoy the foods I want to eat*”, “*I am confident with my ability to perform TPN procedures on my own.*”. These items were tested as true/false items in interviews 29-32. Participants agreed with this revision and felt the questions were better suited for section two of the questionnaire.

Other results of interest in this study are the patient’s interpretation of the item relative to the definition of QoL. Winkler’s definition of QoL for the HPN population, defined as “doing what I want to do when I want to do it”.¹ Participants in our study agreed strongly with this QoL definition “doing what I want to do when I want to do it”. This item was repeated verbatim by many participants and feedback supported this QoL definition in the HPN population. One patient stated “*I think it’s very clear...it pretty much sums it up. I like that statement*”. Another agreed by saying, “*I think good quality of life means being able to do what I want do*”.

Summary

Many items (n=29, 54%) were described as “understandable”, were deemed acceptable, and viewed as comprehensible, acceptable, “clear” and “easy to answer”.

These items were interpreted as intended by the researchers and participants consistently rephrased them verbatim. These items did not require revision and were retained, whereas items or response scales viewed by participants as being problematic were revised or deleted from the instrument (deleted; n=11, 20%, revised; n=14, 25%). The modified draft HPN-PROQ tested in Phase II contained 43 items and included two sections: Section One (24 items) with a VAS response scale (stems “Not at all”; “Every day”). Section Two (18 items) with a VAS response scale (stems “Definitely false”; “Definitely true”).

Phase II: Quantitative CVI

Thirty-three home care clinicians were invited to participate in the expert panel CVI. Thirteen expert reviewers, stratified by profession (physicians n=2, pharmacists n=3, registered dietitians n=3, registered nurses n=2, home care advocates n=3), agreed to complete the CVI with the modified draft HPN-PROQ. The first participant from each profession to complete the I-CVI from round one was selected for round two of the S-CVI/AVG. This sample included one physician, one registered dietitian, one pharmacist, and one homecare advocate.

Individual, adjusted, multi-rater kappa scores were examined for each of the items on the modified draft HPN-PROQ following cognitive interviews. Thirty-four items scored as “excellent”, with an I-CVI score ≥ 0.783 , and nine items were deleted based on a I-CVI score < 0.783 , indicating low relevance to the HPN population.³⁴ See Table 4 for an item by item analysis of the I-CVI.

The S-CVI/AVG score was calculated in two rounds: prior to modification based on I-CVI analysis and again after the removal of the nine items not meeting

criteria for relevance. The S-CVI/AVG score improved from 0.91 in round-one to 0.96 in round two. The final S-CVI/AVG score was > 0.80 , which is considered acceptable for the content validation of newly developed PRO questionnaires.²⁰

Discussion

Patient reported outcome questionnaires serve to increase awareness on both the patients' and clinicians' behalf, as they facilitate discussion around QoL constructs, treatment plans and goals, and patient knowledge of caring for their medical condition and/or treatment.³⁵ There are many factors affecting the QoL of HPN patients, signifying the need for clinicians to have the tools necessary to support their patients not only medically, but also psychosocially. Researchers have concluded that assessment of QoL in this population should be facilitated using a therapy-specific instrument.^{1, 10, 36} Currently, only one validated QoL instrument exists to clinically evaluate the HPN patient, however, use of this instrument has only been published in research studies thus far.^{14, 15} The HPN-PROQ was developed with patient-clinician communication in mind. Once validation procedures such as content validity, clinical relevance testing, and psychometric validation, are completed, the HPN-PROQ could be used to foster communication between the patient and clinician around issues impacting their QoL. The purpose of this study was to demonstrate the content validity of the newly developed HPN-PROQ in a sample of adult HPN patients in the U.S.

Presently, the HPN-PROQ may be more suitable for use in clinical practice in the U.S. than the only other instrument, the Home Parenteral Nutrition Quality of Life (HPN-QOL©) given the in-depth involvement of adult U.S. HPN patients and clinicians in both the generation of items and in the content validation of the

questionnaire. Additionally, the HPN-QOL© has only been validated in European cultures, and therefore may not be applicable for use in the United States.³⁷ Another critical difference between the HPN-QOL© and the HPN-PROQ is that the HPN-QOL© is designed to be a scored instrument, i.e. generates a number that can be compared over time and/or with other populations (normal/well or disease-specific). The HPN-PROQ does not produce a score, but instead allows a subjective approach to the evaluation of issues that may impact QoL. Use of the HPN-PROQ could help patients prioritize specific areas that they may wish to discuss with their clinician. It also allows patients the opportunity to explain their concerns to their clinician in more detail and discuss why they are feeling the way they are feeling.

The VAS response scale makes this questionnaire a more “user-friendly” instrument for both patients and clinicians than a Likert Scale.³³ Use of VAS in the clinical setting with self-administered questionnaires is common.³⁸ Visual Analog Scales are frequently used to evaluate pain, mood, and patient satisfaction, are advantageous in that they are less vulnerable to bias from confounding factors linked to Likert scales (i.e. ambiguity of response descriptors/options), and require less time to complete.³³ Our sample of HPN patients expressed a preference for the VAS and considered the VAS superior to the Likert Scale. They noted that the VAS would be “easier to use”, a “good visual”, and “possibly more accurate”. Because the purpose of the HPN-PROQ is to facilitate discussion rather than produce a final score, the VAS may provide a better “snap shot” than what could be obtained with a Likert scale. The HPN-PROQ de-emphasizes the significance of overall/total scores and may turn attention to factors influencing QoL and lifestyle adaptation with HPN. This could

allow for clinicians to pay attention to individual response patterns to decide what type of care is needed. Because patients may be embarrassed or hesitant to initiate conversations with their clinicians around psychosocial issues, having the HPN-PROQ may facilitate discussions between clinicians and their patients.

Validation of newly developed instruments is a rigorous process which includes the establishment of content validity.¹⁸ The importance of content validity in developing PRO instruments is emphasized by both the US Food and Drug Administration and the European Medicines Agency^{5,39}. The US Food and Drug Administration also highlights the importance of including substantial patient input in PRO development.⁵ We have included a target population of HPN patients and an iterative qualitative research process to confirm content validity.⁵ Although addressing all concerns and suggestions made by every participant was not possible, demonstration that the new PRO instrument is understandable to potential respondents is essential in evaluation of content validity.¹⁸

Cognitive interviewing is commonly employed to improve the content validity of newly developed PRO instruments because they should utilize common terms understood by the target population. In this study, results from cognitive interviews demonstrated that many items were understood by HPN patients in the original form written, were interpreted by HPN patients as intended by the researchers, and were not found to be difficult to recall or challenging to answer. HPN patients provided several suggestions in relation to word-choice and issues with jargon. Cognitive interviewing is an evidence-based technique to assist researchers in providing content validity-evidence by assessing the participants interpretation of items during interviews.⁴⁰ It is

important to recognize that data collected from cognitive interviews are qualitative in nature and are mainly used to assess and improve questionnaire items before the questionnaire is implemented.⁴¹ Cognitive interviewing requires a level of understanding of patient issues alongside the ability to listen, interpret, and accurately report patient comments; none of which are reflected in quantitative research.⁴² Although not frequently reported in the same detailed or robust manner as in this study, many content validation studies use cognitive interviewing in the target population as a means to improve validity.^{13, 14, 42, 43, 44, 46}

We identified item-specific issues with lack of clarity regarding word choice, comprehension, and ambiguity and uncovered potentially problematic items and terms not previously identified in HPN-QOL© validation studies. For example, patients suggested using “central line” to replace “catheter” and “emptying an ostomy bag” instead of “changing the appliance”. This study builds upon the validation of the HPN-QOL© by informing researchers of the value of patient input in questionnaire development and validation.

This study possessed many strengths, one being the combination of qualitative and quantitative methodology. This study possesses rigor in qualitative research which was accomplished by having a sound scientific methodology and protocol, which included semi-structured interview scripts, appropriate analysis of the data, and documentation of findings.⁴² The use of quantitative data in the absence of thorough collection of knowledge, frameworks, and qualitative considerations can potentially produce a clinically ineffective instrument. It also should be recognized that the use of qualitative data alone to substantiate an instrument may be rhetorically convincing, but

scientifically incomplete.¹⁸ Keeping in mind the broader patient-centered philosophy, collaboration with the target population in early development and validation stages can ensure effective handling of sensitive content, and possibly prevent attrition that could result from invasive or offensive content.⁴⁵

Cognitive interview projects are normally small in scope and may involve just 10 participants.^{13, 14, 42, 43, 44, 45} Characteristics of the sample should reflect as closely as possible the patient population to be included in future studies that will incorporate the PRO.⁴⁸ This study conducted two rounds of interviews to provide ample opportunity for problematic items to emerge.³² The target sample for this study was adult patients receiving HPN. The demographics, diagnoses, length of time receiving HPN, and length of infusion schedule compares favorably to similar studies.^{4,21} Demographic data from in our sample is comparable to the Sustain Registry in that short bowel syndrome was the primary indication for HPN adults (28.7%) and the Sustain cohort was predominantly female (59%) and Caucasian (75%).⁴ Our sample was also homogenous (98 % Caucasian, 71% female) and our sample size of 32 was comparable, if not stronger than, other published sample size criteria for content validation via qualitative methods.¹⁸ It was determined during review of transcripts and analysis that data saturation was achieved in our sample (n=32). Data saturation is the point in data collection and analysis when new feedback no longer contributes significant information.³²

Five experts or more are required to have a valid sample for CVI.²⁰ We exceeded this target as well as stratified our sample by profession given the multi-disciplinary team often involved in the care of HPN patients. Our sample included

clinicians with experience managing HPN, two physicians, three pharmacists, three registered dietitians, two registered nurses, and three home care advocates. HPN expert home care clinicians rated most items as having “excellent” relevance, leading to a highly acceptable S-CVI/AVG score. The I-CVI of the items on the HPN-PROQ were analyzed using conservative criteria for retention; only the items accomplishing a kappa I-CVI rating ≥ 0.783 were retained resulting in the deletion of nine items. The final overall S-CVI/AVG was 0.96. This as an acceptable score and is comparable to the results of other content validation studies.^{23, 24, 34, 44}

The results and methodology of this study are consistent with similar content validation studies using the CVI to determine content validity of a newly developed questionnaire. The Osteoporosis Risk Assessment Tool (ORAT), eight experts were selected from nationally known clinicians and researchers holding well-respected reputations in the area of osteoporosis risk prevention and treatment.⁴⁸ This study used an acceptable level of relevance score of 0.58 to determine item relevance and criteria for the deletion or retention of items on a draft questionnaire.⁴⁸ In the development and content validation of an instrument for measuring patient-centered communication, fourteen designated experts completed the CVI using a modified kappa statistic to quantify item relevance.²³ Compared to our study, researchers in this study used a more liberal CVI criteria (>0.70) to determine item retention; resulting in the removal of 4 items from the prototype questionnaire. Similar to this study and by using a slightly smaller sample (n=9), Larsson et al.²⁴ used the CVI in the validation of a muscle endurance questionnaire with an I-CVI criteria of (>0.78) to indicate “excellent” relevance; resulting in the deletion of fourteen items.

Five items in *Section One* of the modified HPN-PROQ were slightly lower than criterion for retention based on the I-CVI. (i.e. they scored at 0.77 vs. 0.78). While this reduces the number of items on the questionnaire and decreases participant burden, elimination of these items may leave out some important constructs of HPN-related quality of life. The CRT thought that these items' topics are sufficiently covered by other items included in the questionnaire that were not eliminated. For example, "I am able to walk up and down the stairs without difficulty" was eliminated but this topic could be sufficiently assessed by "I am able to walk without difficulty". Three items pertaining to patients' experiences with eating (i.e. bloating, pain, cramps as the result of consuming foods) were deleted from the questionnaire due to I-CVI scores. This does not mean to imply that this construct is irrelevant to the HPN patient population, as numerous studies have demonstrated its importance.^{1,3,6,7} It should be noted that these items represent aspects of eating that are physical in nature, rather than psychosocial in nature, and two remaining items assessed eating-related issues, justifying the removal of these items from this QoL instrument. However, in future clinical validation studies, clinicians and patients may find that these physical food-related issues are relevant and therefore should be included in the HPN-PROQ. By design, the CRT felt that the general nature of some items retained on the questionnaire could be useful to cue the physician to ask the patient to describe more specifically what they are struggling with. This fosters the one main purpose of the HPN-PROQ, which is to drive these conversations between the patient and the clinician.

PRO instruments can enhance patient–clinician communication and inform plans of care to better target interventions that will improve patient outcomes.^{50, 51} Evidence from randomized controlled trials suggests that the use of PROs in clinical practice is valuable in improving the discussion and detection of QoL constructs, but has less of an impact on how clinicians manage patient problems or on subsequent patient outcomes.³⁵ Many of the reasons for this may lie in the ways in which PROs fit (or do not fit) into the routine ways in which patients and clinicians communicate with each other, how clinicians make decisions, and how healthcare is organized. Greenhalgh et al.³⁵ suggests future research should seek to identify ways in which PROs can be better incorporated into the routine care of patients by combining qualitative and quantitative methods. Regardless, use of PRO instruments can provide several advantages: as a means to alert the clinician to the patient’s concerns about their QoL, to clarify via discussion the patient’s priorities for care, and to facilitate conversation between patients and clinicians about these issues.⁵⁰ This is especially important as patients and physicians do not always agree on which outcomes of care are most important.⁵¹ For example, patients with multiple sclerosis and possibly those with other chronic diseases are less concerned than their clinicians about physical disability in their illness and are more concerned with issues impacting their QoL.⁵² Studies have also shown that provision of PRO feedback to clinicians results in an increase use of health services and referrals, more timely reporting and management of symptoms, less patient anxiety, fewer preventable emergency room and office visits or calls, greater patient adherence to advice, greater satisfaction with care, more effective self-management, and more efficient use of resources.^{49, 53, 54}

The HPN-PROQ illustrates acceptable quantitative and qualitative indices for content validity, as determined by HPN patients and expert home care clinicians.²⁰ Future quantitative validation of the revised scale and items should be considered alongside a large sample of HPN patients to provide quantitative support for the conceptual framework of the HPN-PROQ, specifically, it will be important to compare results from the HPN-PROQ to the HPN-QOL©. Clinical validation should also be conducted to assess the impact of the HPN-PROQ on treatment decision making. Specifically, future studies should include observations of patient-clinician interaction while using the HPN-PROQ with an assessment of patient and clinician satisfaction and communication. Lastly, all PRO instruments should be translated into different languages, including forward and backward translation methods.¹⁸ Many healthcare settings serve diverse populations with diverse language preference. Translation of the HPN-PROQ into other languages would prevent a relative or friend having to translate the questionnaire to the patient, potentially interfering with validity.

Limitations

There are some limitations in content validity studies that should be noted. Expert feedback is subjective, and may introduce biases to the study, that may exist among the experts. Additionally, there was a demographic limitation in the CI sample which had a high rate of Caucasian females (71%). However, there is no reason to suspect that this would impact our data in a way that would impair the clarity, relevance, and acceptability of the revised components of the HPN-PROQ. Selection bias is likely as participants were self-selected, interested, and willing to participate. Lastly, this study was conducted with adult HPN patients only and therefore, results

are not generalizable to pediatric patients or their parents or caregivers. [most parents or caregivers act as proxy for young children who cannot complete QoL or other questionnaires.] Future studies should incorporate these populations.

Conclusion

To the best of our knowledge, this study adheres to standard procedures in content validation and our data provides evidence that the final version of the HPN-PROQ is a content valid questionnaire with relevant, clear, and refined items and response scales. We are confident that the HPN-PROQ meets the standards set forth by the FDA in terms of content validity, item readability, and understanding for the development of a PRO instrument. Cognitive interviewing, member checking, and calculation of the CVI were utilized to demonstrate the content validity of the HPN-PROQ. The methodology used in this study (i.e. interview scripts, iterative analysis, actions taken to delete or modify an item in response to the cognitive interviews, and member checking) are appropriate to assess content validity.¹⁸ These methods help provide a valid set of items which will in-turn increase the likelihood of reliable responses from HPN patients.¹⁸ Overall, the majority of items included in the original HPN-PROQ were understood by HPN patients and interpreted as intended by the researchers. The questions were described as “clear” and “easy to answer” and represented important areas in the lives of HPN patients.¹

Although the primary intent of the cognitive interviews was to evaluate if HPN patients in our sample understood the items and could offer congruent interpretations, we also further identified the patient need for a HPN therapy specific instrument to support the HPN population in clinical practice. Patients frequently expressed their

gratitude for the work of project and were eager to participate; repeatedly commenting on the relevance of the issues raised in the HPN-PROQ and how effectively communicating with their clinicians about these issues is meaningful to them. This study found that patients perceived the need for an instrument such as the HPN-PROQ which could be used to facilitate communication among HPN patients and their clinicians to assist in the improvement of patient-care.

Table 4: Content Validity Index Data Quantitative Analysis

Item		Number of Experts giving a rating of a “3” or “4”	k
Section 1			
1.	I felt like my health limited the things I want to do in my life.	13	1.00
2.	Being on TPN was difficult to cope with emotionally.	13	1.00
3.	My daily activities were limited by my TPN infusion schedule.	11	0.85
4.*	Carrying my TPN solution limited what I could do.	10	0.77
5.*	I felt physically strong.	10	0.77
6.	I was able to participate in the activities I enjoy.	12	0.92
7.	I was able to walk without difficulty.	11	0.85
8.*	I was able to climb up and down stairs without difficulty.	9	0.69
9.	I was able to rise from a chair or bed without difficulty.	12	0.92
10.*	I was able to pick up an object from the floor without difficulty.	8	0.62
11.*	I needed to nap when I felt tired.	7	0.54
12.	I had enough strength and stamina to do daily chores or work.	12	0.92
13.	The TPN pump disrupted my sleep.	13	1.00
14.	My sleep was disrupted because I had to get up to move my bowels or empty my ostomy bag.	12	0.92
15.	My sleep was disrupted because I had to get up to urinate.	13	1.00
16.	I ate comfortably in social situations and around others.	12	0.92
17.*	Eating caused me to have gas or feel bloated.	10	0.77
18.*	Eating caused me to have pain.	10	0.77

Item	Number of Experts giving a rating of a “3” or “4”	k
19. I had episodes of uncontrollable diarrhea.	12	0.92
20.* I had to move my bowels shortly after I ate food.	10	0.77
21. I had to rearrange my daily plans because of how much diarrhea I had.	12	0.92
22. I had episodes of uncontrollable ostomy leakage.	13	1.00
23. * I had to empty my ostomy bag shortly after I ate food.	9	0.690
24. I had to rearrange my daily plans because of how much ostomy output I had.	13	1.00

Section 2

1. Good quality of life means being able to do what I want to do when I want to do it.	11	0.85
2. I eat and enjoy the foods I want to eat.	11	0.85
3. I am confident in my ability to perform TPN procedures on my own.	13	1.00
4. Having one or more nights or days without TPN is important to me.	13	1.00
5. Having a shorter TPN infusion schedule is important to me.	13	1.00
6. I feel relieved knowing my nutritional needs are being met by TPN therapy.	13	1.00
7. I am fearful of developing complications related to my TPN therapy and/or central line.	12	0.92
8. I understand my need for being on TPN therapy.	13	1.00

Item	Number of Experts giving a rating of a “3” or “4”	k
9. I know and have been trained on how to manage my TPN therapy.	13	1.00
10. I know and have been trained on how to care for my central line.	13	1.00
11. I know and have been trained on how to use my pump.	13	1.00
12. I know and have been trained on the signs and symptoms of a central line infection.	13	1.00
13. I know and have been trained on the signs and symptoms of dehydration.	13	1.00
14. I know and have been trained about my diet and what I should be eating.	13	1.00
15. I know whom to call when I have questions about my TPN therapy.	13	1.00
16. I feel emotionally supported by my family and friends.	12	0.92
17. I feel well supported by my home care specialists.	13	1.00
18. I received information about local or national support groups for TPN therapy.	13	1.00
19. I wish I knew more about my TPN therapy.	12	0.92

NOTE: I-CVI: item-level content validity index, ^{} p_c (probability of a chance occurrence) was computed using the formula: p_c= [N! /A! (N -A)!] ^{*}.5^N where N= number of experts and A= number of panelists who agree that the item is relevant. Number of experts=14, ^{***} k (modified kappa) was computed using the formula: K= (I-CVI- P_C)/(1- P_C). Interpretation criteria for kappa, using guidelines described in Polit et al. ²⁰ an item is considered “excellent” if k >0.780. Any item not meeting this criterion was deleted from the final HPN-PROQ. *Item**

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Appendix A: Literature Review

Introduction

A patient reported outcome (PRO) questionnaire may enhance a clinician's awareness of factors influencing a patient's ability to adapt and cope with receiving long-term parenteral nutrition as their purpose is to collect quality of life (QoL) information.¹⁻³ Currently, there is one validated tool to support the Home Parenteral Nutrition (HPN) population, the Home Parenteral Nutrition Quality of Life Questionnaire (HPN-QoL)©.⁴ However, according to published reports, this tool has only been used in research studies thus far.⁴⁻⁶ For this reason, the Home Parenteral Nutrition Patient Reported Outcome Questionnaire (HPN-PROQ) was developed for patients to self-assess aspects of their lives; aspects they may want to consider discussing with their HPN clinicians. Patient responses on the questionnaire are to be used to facilitate discussion between the HPN patient and clinician regarding patient goals and lifestyle adaptation. The aim of this study was to determine the content validity of the HPN-PROQ through cognitive interviewing with HPN patients and computing the Content Validity Index (CVI) with HPN expert clinicians.

Content validity must be established as part of the development phase of new PRO instruments.⁷ Content validity is defined as the extent to which a new instrument congruently measures aspects of a patient's life; this can include aspects both medical and non-medical in nature.⁷ This literature review will broadly cover indications of HPN and QoL with a more in-depth review of the processes involved in PRO development, the application of cognitive interviewing (CI) and the Content Validity Index (CVI) in content validation, and the use of PRO instruments in clinical practice.

Home Parenteral Nutrition

Parenteral nutrition is a complex therapy involving the intravenous infusion of nutrients and fluids to individuals who have intestinal failure or dysfunction.⁸ Most frequently, these patients carry diagnoses of short-bowel syndrome, inflammatory bowel disease, or cancer with bowel obstruction.^{9,10} Over the last three decades, the expansion of home-health and nutrition support agencies have allowed HPN to become the primary treatment for patients who require long-term parenteral nutrition.¹¹ Home parenteral nutrition should be used exclusively with patients who cannot meet their nutritional requirement by enteral intake, and who are able to receive therapy safely outside the acute care setting.^{12,13}

It is estimated that 33,000 people in the United States required HPN in 2010.¹⁴ The likelihood of being weaned from HPN is significantly reduced after 3 years and 20-30% of patients require permanent treatment.¹⁵ Home-based care provides patients the opportunity to receive complex therapy in a familiar and comfortable environment, with support from family members and trained healthcare professionals.¹⁶ Furthermore, patients benefit from home-based care as it provides improved QoL and comes at a lower cost than inpatient parenteral nutrition.^{16,17}

Quality of Life

Quality of life is defined by the Food and Drug Administration (FDA) as a 'general concept that implies an evaluation of the effect of all aspects of life on general well-being'.¹⁸ Health-related quality of life (HrQoL) is composed of multiple domains that comprehensively measure the patient's experience of symptoms (i.e. functional status, and psychosocial elements) against the patient's expectations and to

quantify the extent to which the burden of disease impacts a patient's quality of life.¹⁹ Due to the complex technology of HPN as well as the underlying intestinal disease, QoL is thought to be poorer in individuals receiving HPN compared to patients with intestinal diseases who do not require nutritional support.¹⁰ Practical daily life restrictions and physical parenteral nutrition-associated complications may negatively affect quality of life (QoL).¹⁷

Roskott et al.¹¹ determined that although HPN patients have a variety of different somatic symptoms, psychosocial problems have the greatest negative impact on QoL. Psychosocial factors include coping with medical diagnosis, being dependent on technology, coping with the loss of the eating experience, relying on others for care, low self-esteem, interfering with sexual functions, and enduring the financial burden of nutrition support.⁸ Home parenteral nutrition patients also experience decreased physical, psychological, and social function along with increased occurrences of depression, drug dependency, sleep disturbance, frequent urination, fear of therapy-related complications, and inability to eat.^{8,16,20} All of these factors may affect the QoL if a HPN patient.

When patients are discharged on HPN, support is available for HPN patients who are adjusting to HPN dependence outside of the clinical setting. Via membership of support and educational organizations, such as the Oley Foundation patients can actively participate in the HPN community, blogs, and research projects, and receive newsletters and educational information. Studies have shown that membership in such an organization is valuable the QoL of HPN patients.^{21,22} The Oley Foundation offers resources such as education, support groups, and workshops to HPN patients, and their

caregivers and families clinicians play a key role in introducing their patients to organizations such as the Oley Foundation.²¹ In addition to helping patients adjust to complexities of HPN therapy nutrition support.²¹ Support in the clinical setting is also important in the management, success, and quality of life of the HPN patient. Roskott et al.¹¹ reported on the importance of offering psychosocial and medical support for fatigue, sleeping disorders, anxiety, depression, and social isolation, to improve QoL. However, research by Winkler et al.²³ demonstrated that HPN patients perceive their routine medical appointments with their clinicians as a parenteral nutrition “tune-up”, and reported that with session focus primarily on medical or disease aspects of care. Patients self-reported they desire a more holistic approach to parenteral nutrition management, incorporating physical and emotional support, in addition to medical examination and nutrition assessment.²³

Clinicians have serious concerns about the QoL of their HPN patients but are in need of guidance assessing the nature and severity of individually experienced problems.²⁴ Baxter et al.²⁴ demonstrated the need for HPN-specific questionnaire to support the HPN population and subsequently developed the Home Parenteral Nutrition Quality of Life questionnaire (HPN-QOL©) for the measurement of QoL in the HPN population. However, the use of this instrument has only been reported in clinical trials and research studies thus far.⁴⁻⁶ Furthermore, findings from the Sustain™ National HPN Registry demonstrate lack of routine assessment of QoL in the management and care of HPN patients in the U.S.⁹

Of difference between the HPN-QOL© and the HPN-PROQ is the HPN-QOL© is a scored instrument, i.e. generates a number that can be compared over time

and/or with other populations (normal/well or disease-specific). The HPN-PROQ does not produce a score, but instead allows a subjective approach to the evaluation of issues that may impact QoL. Use of this tool helps patients prioritize specific areas that they may wish to discuss with their clinicians and allows patients the opportunity to explain their concerns and qualify why they are feeling the way they are feeling to their clinician in more detail. The HPN-PROQ is a necessary and novel instrument which should be used to facilitate communication among HPN patients and their clinicians to assist in the improvement of patient-care and interventions aimed at supporting the HPN population.

Patient Report Outcome Instruments

Overall, research within and outside the HPN population strongly supports the use of PRO's in clinical practice.²⁴ Patient reported outcomes instruments collect information from the patient about a health condition and its management, including QoL constructs.²⁵ Traditional applications of PRO instruments are in clinical research and health services research, although use in clinical practice is increasing.²⁵ Many PRO instruments are self-administered questionnaires. They are given directly to the patient without the intervention of a clinician and without a third party's interpretation; making them more reliable than observer-reported measures because they are not affected by inter-observer variability.¹⁸

In the clinical practice setting, PRO instruments are used as screening tools, monitoring tools, decision aids, and as a method of facilitating communication amongst multi-disciplinary teams.²⁶ The potential use of PRO instruments in clinical practice to improve the interactions between patients and their clinicians is

promising.²⁷ When used in clinical practice, feedback is provided to the clinicians with the goal of helping them manage patient care.²⁷ Detmar et al.² found that incorporating standardized QoL assessments in daily clinical oncology practice facilitated discussions of HR-QoL issues and heighten physicians' awareness of their patients' HR-QoL. Two recent trials measured clinician–patient communication and determined there was an increase in the number of times HR-QoL issues were discussed in the consultation following PRO feedback.^{28,29} These discussions could lead to patients becoming more involved in decisions about their care thereby increasing their self-efficacy to manage their own health.²⁶

Not only have investigators found positive results with the use of standardized PRO instruments in facilitating patient-clinician communication, they also improve clinicians' understanding of patients' problems--particularly those of a psychosocial nature.²⁵ Provision of PRO feedback to clinicians also results in an increase use of health services and referrals, more timely reporting and management of symptoms, less patient anxiety, fewer preventable emergency room and office visits or calls, greater patient adherence to advice, greater satisfaction with care, more effective self-management, and more efficient use of resources.^{30,31,32} Having information on patients' functioning and well-being alongside their laboratory results, imaging studies, and treatment notes, allows clinicians to see a more complete picture of the patient's status.²⁷

Development of New PRO Instruments

This process begins with item generation based upon data from literature review, focus groups, or interviews with patient.¹⁸ It should be noted that PRO

instrument item generation is incomplete without patient involvement, and should incorporate a wide range of patients to represent variations in severity and in populations characteristics such as age and sex.¹⁸ Keeping in mind the broader patient-centered philosophy, collaboration with the target population in early development and validation stages can ensure effective handling of sensitive content, and possibly prevent attrition that could result from invasive or offensive content.³³ The US Food and Drug Administration also highlights the importance of including substantial patient input in PRO development.¹⁸ Choice of data collection method and choice of recall period typically follow item generation and is usually determined according to the intended purpose of the questionnaire.¹⁸ The rationale for choosing these components should be evaluated; showing consideration for a patients ability to accurately recall the information requested, the characteristics of the disease/condition, and the treatment received.¹⁸

Choice of response options should include clear wording, clear distinction between choices, be appropriate for the target population, and come with adequate instructions. Ceiling and floor effects should be kept in mind, and avoided. Response options should also avoid directional bias.¹⁸ Use of VAS in the clinical setting with self-administered questionnaires is common.³⁴ Baxter et al.²⁴ found that QoL questionnaires currently being used in the HPN population can be grouped into three categories; generic and applicable to a rand of diseases of populations; those which are disease specific, and those which are non-validated. Of the three validated tools in this study (Short Form 36, EuroQol EQ5D, and the Sickness Impact Profile), all make use of a VAS.²⁴ Visual Analog Scales are frequently used to evaluate pain, mood, and

patient satisfaction, and are advantageous in that they are less vulnerable to bias from confounding factors linked to Likert scales (i.e. ambiguity of response descriptors/options) and require less time to complete.³⁵ Visual analog response scales makes questionnaires a more “user-friendly” instrument for both patients and clinicians.³⁵ Lastly, in pain assessment, VAS scales are more sensitive and a better measure of magnitude than descriptive scales. The Irritable Bowel Disease Control questionnaire also utilizes a VAS.

Content Validation

Validation of newly developed instruments is a rigorous process which includes the establishment of content validity.⁷ The importance of content validity in developing PRO instruments is emphasized by both the US Food and Drug Administration and the European Medicines Agency^{18,36}. The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Board of Directors approved the formation of the Patient Reported Outcomes Content Validity Good Research Practices Task Force to develop a good research practices report addressing methods for documenting the content validity of newly developed questionnaires⁷.

When testing the content of a newly developed PRO, there are two primary components of importance.^{37,38} First, what is the intent of the question: what do respondents believe the question is asking? Second is the meaning of specific terms in the instrument: what do specific words and phrases in the instructions, items, and/or response options mean to respondents? Is that meaning consistent with the intent of the researchers? Is it relevant to the concept of interest? Does it raise new content important to the concept of interest and/or new content not reflected in the instrument

as it is currently designated? If problems are identified, this will result in the revision of the draft instrument, followed by a new round of cognitive interviewing to test said revisions.³⁸

Cognitive Interviewing

After item generation, reporting evidence of content validity for a new PRO should be address in the processes taken for gathering evidence that persons in the target population understand the instruments structure and content. Patient-reported outcome questionnaires must include concepts and language relevant to patients and be easily understood. To improve content validity specifically, PRO instruments should utilize common terms understood by the target population. The technique of cognitive interviewing (CI) can be used to conduct a systematic, in-depth approach in assessing the validity of a questionnaire's content and instructions. Cognitive interviewing is an evidence-based technique to assist researchers in providing content validity-evidence by assessing the participants interpretation of items during interviews.³⁹ This process is often done as part of preliminary development, in the pretesting phase, prior, and to distribution in the field.^{33,40-44} This method is employed to test the relevance, comprehension, sensitivity, and the acceptability of the items.⁴⁰ Overall, this process and analysis allows researchers to demonstrate that the new PRO instrument is understandable to potential respondents.

Cognitive interviewing can minimize errors arising from respondents' misunderstanding during data collection by assessing clarity of terminology, phrasing and format and is considered most valuable in pretesting complex questions and where questions might be sensitive and intrusive.⁴² Individual interviews are used within the

target population using techniques such as think aloud and /or verbal probing to ascertain exactly how an item is interpreted and how a response is formed.⁷ Semi-structured interviews are recommended method for developing QoL questionnaires where lay people are involved.⁴⁵ Cognitive interviews are audio recorded and transcribed verbatim and results are presentment in summary of essential findings, including representative quotations for each item or concept tested.⁷

Interview data serves to assist researchers in identifying problematic questions that may elicit response error and verify the relevance of item content to the target population.^{41,42} Findings from these interviews are reviewed and interpreted by the researcher, and modification/revisions are incorporated into the instrument.⁴¹ Key findings show whether items or scales on the questionnaire deviate from what is expected by the survey developers, or identify items, response scales, or instructions requiring modification. The revised instrument is often tested in further rounds until data saturation is achieved.⁴¹

Addressing all concerns and suggestions made by every participant is not possible, however demonstration that the new PRO instrument is understandable to potential respondents is essential in evaluation of content validity.⁷ It is important to recognize that data collected from cognitive interviews are qualitative in nature, and are mainly used to assess and improve questionnaire items before the questionnaire is implemented.⁴² Cognitive interviewing requires a level of understanding of patient issues alongside the ability to listen, interpret, and accurately report patient comments; all of which are not reflected in quantitative research.⁴⁶

Cognitive interviews have been used in several areas in health care research to pretest and validate questionnaire and to ensure high response rates and can be highly effective in developing questionnaires.⁴² Generally, small numbers of patients are selected, usually between 5 and fifteen, to complete a round of interviewing.^{6,41,46,47,48,49} Baxter et al.⁴ used a cognitive debriefing questionnaire asking patients eight generic questions to identify general content validity issues with the HPN-QOL©. Patients were asked if they thought any of the questions were irrelevant, or problematic. Researchers collaborated with patients in the development of the Rheumatoid Arthritis fatigue PRO questionnaire by using qualitative interview data to strengthen face and content validity of a draft conceptual framework. In this process, the researchers ensured comprehension of the PRO by the target population.⁴⁹ Schildmann et al.⁵⁰ used cognitive interviewing in the first phase of a validation study of the Integrated Palliative care Outcome Scale, which proved to be valuable to increase content validity of the questionnaire. Additionally, in the development and validation of a new PRO for patients with pressure ulcers, cognitive interviews were used to identify problems with item content (i.e. ambiguous or confusing).⁵¹

It must be noted that cognitive interviews have been criticized for being overly subjective and artificial.⁴² However, rigor in qualitative research can be accomplished by having a “sound scientific methodology” and protocol, which includes semi-structured interview scripts, appropriate analysis of the data and documentation of the findings.⁴⁶

The Content Validity Index

Instrument content validity is often established through qualitative review alongside quantitative analysis of reviewer agreements.⁵² The use of quantitative data in the absence of thorough collection of knowledge, frameworks, and qualitative considerations can lead to a theoretical instrumentation producing scores with unknown meaning. It also should be recognized that the use of qualitative data alone to substantiate an instrument may be rhetorically convincing, but scientifically incomplete.⁷

In reports of instrument development, the most widely reported approach for content validity is the Content Validity Index (CVI).^{53,54} According to Polit et al.⁵⁵, the CVI is the most widely used method of quantifying content validity for multiple item scales among nurse researchers.

The CVI is based on expert ratings of relevance, and is used for quantifying content validity for scales.⁵⁵ A CVI value can be computed for each item on a scale (I-CVI) as well as for the overall scale content validity average (S-CVI/AVG).⁵⁵ The I-CVI is calculated by having experts in the field of interest rate the relevance of each item to its own subdomain.⁵⁶ A 4-point ordinal scale is used and expert panel members are asked to rate the item's relevance to the construct of interest (i.e. 1: not relevant, 2: somewhat relevant, 3: quite relevant, and 4: highly relevant). The number of those judging the item as relevant (rating of 3 or 4), are divided by the number of experts on the panel.⁵⁷ Although the CVI is used to determine content validity, this index does not consider the chance agreement. Wynd et al.⁵² proposed using both the multi-rater kappa statistic alongside the CVI to account for chance agreements.

Calculating the S-CVI/AVG is done by first computing the I-CVI for each item on the scale and then by calculating the average I-CVI across items.⁵⁵

In the development and content validation of an instrument measuring patient-centered communication, fourteen designated experts completed the CVI using a modified kappa statistic to quantify item relevance.⁵⁸ In this study, the researchers used a CVI criteria of .70 for item retention; resulting in the removal of 4 items from their prototype questionnaire as the result of this method. In a smaller sample (n=9), Larsson et al.⁵⁹ used the CVI in the validation of muscle endurance questionnaire using a I-CVI score of $\geq .78$ to indicate “excellent” relevance; resulting in the deletion of fourteen items. To determine the content validity of The Osteoporosis Risk Assessment Tool (ORAT), eight experts were selected from nationally known clinicians and researchers holding well-respected reputations in the area of osteoporosis risk prevention and treatment.⁶⁰ This study used an acceptable level of relevance score of .58 to determine item relevance and criteria for the deletion or retention of items on a draft questionnaire.⁶⁰ Overall, the CVI is valuable to researchers because of its simplicity and its ability to provide information about each item, which then can be used for modification or deletion of instrument items.^{55,57}

Once content validity is established and is ready for pilot testing, respondent burden should be assessed for undue physical, emotional, or cognitive strain. The time to complete the questionnaire should be adequate and efficient.¹⁸

Psychometric Validation

As a final stage in instrument development, PRO measurement properties should be assessed for reliability (test-re-test), validity, ability to detect change, and

the interpretability (e.g. minimum important difference).¹⁸ Any indication for modification to the instrument following these steps should be addressed.¹⁸

Translation of PROMs into other languages should also be completed in the development process of all PRO questionnaires. This involves establishing conceptual and semantic equivalence and should include forward and backward translation methods, plus an assessment of the translated questionnaire's measurement properties.⁶¹ However, most PROMs are not available in a variety of different languages because of the costly nature of such a project.⁶¹ This is problematic in healthcare settings because diverse cultures and language preferences are prevalent. Having a relative or friend to translate the questionnaire for the patient is not acceptable, as maintaining the correct meaning in the exchange cannot be guaranteed.⁶¹

PRO's in Clinical Practice

The use of PRO measures might seem quite straightforward; however, a number of pitfalls await clinicians with limited expertise. Defining the different applications of PRO instruments in clinical practice is difficult because of its complex nature and the heterogeneous methodology across PRO studies. These studies differ in what type of PRO they use, how the information is fed back, and whom it is fed back to.²⁶ However, it is known that PRO instruments can enhance patient–clinician communication and inform plans of care to better target interventions that will improve patient outcomes.^{30, 31} Evidence supporting positive associations between physician communication behaviors and positive patient outcomes is strong. Such

outcomes include: patient ability to recall information, increase in patient understanding, and patient adherence to therapy.

There is also consensus on what constitutes “best practice” for physician communication in medical encounters (i.e. fostering the relationship, gathering information, providing information, making decisions, responding to emotions, and enabling disease-and treatment-related behavior).⁶² This is especially important as patients and doctors do not always agree on which outcomes of care are most significant. For example, patients with multiple sclerosis, and possibly those with other chronic diseases, reported being less concerned than their clinicians about physical disability and are more concerned with issues impacting their QoL.⁶³

According to Dawsons et al.⁶¹, there are very few published examples of the application of PRO’s in the context of clinical practice and quality assurance, and little evidence of the impact of using PRO’s in routine practice is lacking. Because there are a number of relevant questionnaires to choose from, clinicians can be challenged with determining the appropriate questionnaire for their intended purpose. Alternatively, some questionnaires may seem entirely inappropriate and may contain items that are irrelevant to the target population. For this reason, the development of a treatment and disease specific PRO instruments is an important in fostering a increase in the use of PRO’s in clinical practice.

Evidence from randomized controlled trials suggests that the use of PROs in clinical practice is valuable in improving the discussion and detection of QoL constructs, but has less of an impact on how clinicians manage patient problems or on subsequent patient outcomes.²⁶ Many of the reasons for this may lie in the ways in

which PROs fit (or do not fit) into the routine ways in which patients and clinicians communicate with each other, how clinicians make decisions, and how healthcare is organized. Greenhalgh et al.²⁶ suggests future research should seek to identify ways in which PROs can be better incorporated into the routine care of patients by combining qualitative and quantitative methods.

Regardless, use PRO instruments can provide several advantages; as a means to alert the clinician to the patient's concerns about their QoL, to clarify via discussion the patient's priorities for care, and to facilitate conversation between patients and clinicians about these issues.³ These positive outcomes and processes in patient care could lead to increased patient satisfaction.⁶⁴ Use of PRO's in clinical practice could also increase patient satisfaction by promoting patient-centered care. Domains used to assess patient satisfaction with care includes "communication and relationships", and PRO instruments serve to foster improved communication between the patient and the clinician.⁶⁵ In conclusion, this literature review supports the development of a PRO questionnaire for the HPN population could have a positive impact on patient-clinician communication, patient care and satisfaction, and overall quality of life.⁴⁸

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Appendix B: Draft HPN-PROQ

**Home Parenteral Nutrition Patient Reported Outcomes Questionnaire
(HPN-PRO-Q)**

Patient Instructions:

This questionnaire is intended to help you identify areas of concern or problems with your home TPN over the last 2 weeks that may affect your quality of life and/or your ability to do the things you would like to do. These patient-reported outcomes (PRO) may be used to prioritize what you would like to discuss with your physician, health care professional, or members of your home parenteral nutrition management team as well as set goals for your care.

Healthcare Professional Instructions: The responses on this questionnaire are intended to facilitate discussion between patient and practitioner regarding patient goals related to home TPN and lifestyle adaptation.

TPN = total parenteral nutrition

During the past 2 weeks, how often have you experienced any of the following situations?		Not at all	Two to three days per week	More than half of days	Nearly every day
1	I eat and enjoy the foods I want to eat.				
2	I can participate comfortably in social situations where food is served.				
3	Eating causes me to have gas or feel bloated.				
4	Eating causes me to have pain.				
5	I am able to live what I consider a normal lifestyle.				
6	I feel emotionally supported by my family and friends.				
7	I feel like my medical condition controls my life.				
8	Being on TPN is difficult to cope with.				
9	My TPN schedule limits my freedom to participate in daily activities.				
10	Carrying my TPN solution limits what I can do.				
11	I am confident with my ability to perform TPN procedures on my own.				
12	I feel physically strong.				
13	I am able to take care of myself.				

14	I am able to participate in the activities I enjoy.				
15	I am able to walk without difficulty.				
16	I am able to climb up and down stairs without difficulty.				
17	I am able to rise from a chair or bed without difficulty.				
18	I am able to pick up an object from the floor without difficulty.				
19	I need to nap when I feel tired.				
20	I have enough strength and stamina to do daily chores or work.				
21	I am satisfied with the amount I sleep at night.				
22	The TPN pump disrupts my sleep.				
23	My sleep is disrupted because I have to get up to move my bowels or change my ostomy appliance.				
24	My sleep is disrupted because I have to get up to urinate.				

***Please answer these questions if you **DO NOT** have an end-jejunostomy or ileostomy **BUT DO HAVE** bowel in continuity. ***

During the past 2 weeks, how often have you experienced any of the following situations?		Not at all	Two to three days per week	More than half of days	Nearly every day
25	I move my bowels many times during the day.				
26	I move my bowels many times during the night.				
27	I have to move my bowels urgently.				
28	I have episodes of uncontrollable diarrhea.				
29	I have to move my bowels as soon as I eat food.				
30	I plan my daily activities around how much diarrhea I have.				

***Please answer these questions if you **DO HAVE** an end-jejunostomy or ileostomy.

During the past 2 weeks, how often have you experienced any of the following situations?		Not at all	Two to three days per week	More than half of days	Nearly every day
31	I empty my ostomy appliance many times during the day.				
32	I empty my ostomy appliance many times during the night.				
33	I have to empty my ostomy appliance urgently.				
34	I have episodes of uncontrollable ostomy leakage.				
35	I have to empty my ostomy appliance as soon as I eat food.				
36	I plan my daily activities around how much ostomy output I have.				

How TRUE or FALSE is <u>each</u> of the following statements for you?		Definitely True	Mostly True	Mostly False	Definitely False
1	Good quality of life means being able to do what I want to do when I want to do it.				
2	Having one or more nights without TPN is important to me.				
3	Having a shorter TPN infusion schedule is important to me.				
4	I feel relieved knowing my nutritional needs are being met by TPN.				
5	I do not need to eat because I receive TPN.				
6	I am fearful of developing complications related to my catheter.				
7	I am fearful of developing complications related to TPN.				
8	I understand the need for being on TPN.				
9	I am informed and well trained about managing my TPN.				

10	I am informed and well trained about the care of my catheter.				
11	I am informed and well trained about using my pump.				
12	I am informed and well trained about signs and symptoms of infection.				
13	I am informed and well trained about signs and symptoms of dehydration.				
14	I understand my diet and what I should be eating.				
15	I know whom to call when I have questions about my TPN.				
16	I feel well supported by my home care specialists.				
17	I received information about local or national support groups for TPN.				
18	I wish I knew more about my TPN.				

Appendix C: Final HPN-PROQ

HPN-PROQ

Home Parenteral Nutrition Patient Reported Outcomes Questionnaire

Patient Instructions:

This questionnaire is intended to help you identify areas of concern or problems with your home TPN over the last 2 weeks that may affect your quality of life and/or your ability to do the things you would like to do. These patient-reported outcomes (PRO) may be used to prioritize what you would like to discuss with your physician, health care professional, or members of your home parenteral nutrition management team as well as set goals for your care.

Healthcare Professional Instructions: The responses on this questionnaire are intended to facilitate discussion between patient and practitioner regarding patient goals related to home TPN and lifestyle adaptation.

“TPN” = total parenteral nutrition solution/formula.

“TPN therapy” = procedures/equipment/devices necessary to administer the TPN solution/formula

HPN Consumers: Please place a “X” on the dotted line where it most clearly indicates the frequency of occurrence for each of the given situations over the past two weeks.

During the past 2 weeks , please estimate how often you experienced any of the following situations.	
1. I felt like my health limited the things I want to do in my life.	
Not at all ----- -----	Every day
2. Being on TPN was difficult to cope with emotionally.	
Not at all ----- -----	Every day

- Please continue to the next page -

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

3.	My daily activities were limited by my TPN infusion schedule.	Not at all ----- -----	Every day
4.	I was able to participate in the activities I enjoy.	Not at all ----- -----	Every day
5.	I was able to walk without difficulty.	Not at all ----- -----	Every day
6.	I was able to rise from a chair or bed without difficulty.	Not at all ----- -----	Every day
7.	I had enough strength and stamina to do daily chores or work.	Not at all ----- -----	Every day
8.	The TPN pump disrupted my sleep.	Not at all ----- -----	Every day
9.	My sleep was disrupted because I had to get up to move my bowels or empty my ostomy bag.	Not at all ----- -----	Every day
10.	My sleep was disrupted because I had to get up to urinate.	Not at all ----- -----	Every day
11.	I ate comfortably in social situations and around others.	Not at all ----- -----	Every day

- Please continue to the next page -

*** Answer questions 12 & 13 if you do **NOT** have an end-jejunostomy or ileostomy **but do have** bowel in continuity. ***

12. I had episodes of uncontrollable diarrhea.

Not at all -----|----- Every day

13. I had to rearrange my daily plans because of how much diarrhea I had.

Not at all -----|----- Every day

*** Answer questions 14-16 if you **HAVE** an end-jejunostomy or ileostomy. ***

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

14. I had episodes of uncontrollable ostomy leakage.

Not at all -----|----- Every day

15. I had to empty my ostomy bag shortly after I ate food.

Not at all -----|----- Every day

16. I had to rearrange my daily plans because of how much ostomy output I had.

Not at all -----|----- Every day

- Please continue to the next page -

How **TRUE** or **FALSE** are the following statements to you?

1.	Good quality of life means being able to do what I want to do when I want to do it. Definitely false ----- ----- Definitely true
2.	I eat and enjoy the foods I want to eat. Definitely false ----- ----- Definitely true
3.	I am confident in my ability to perform TPN procedures on my own. Definitely false ----- ----- Definitely true
4.	Having one or more nights or days without TPN is important to me. Definitely false ----- ----- Definitely true
5.	Having a shorter TPN infusion schedule is important to me. Definitely false ----- ----- Definitely true
6.	I feel relieved knowing my nutritional needs are being met by TPN therapy. Definitely false ----- ----- Definitely true
7.	I am fearful of developing complications related to my TPN therapy and/or central line. Definitely false ----- ----- Definitely true
8.	I understand my need for being on TPN therapy. Definitely false ----- ----- Definitely true
9.	I know and have been trained on how to manage my TPN therapy. Definitely false ----- ----- Definitely true

- Please continue to the next page -

How **TRUE** or **FALSE** are the following statements to you?

10. I know and have been trained on how to care for my central line. Definitely false ----- ----- Definitely true
11. I know and have been trained on how to use my pump. Definitely false ----- ----- Definitely true
12. I know and have been trained on the signs and symptoms of a central line infection. Definitely false ----- ----- Definitely true
13. I know and have been trained on the signs and symptoms of dehydration. Definitely false ----- ----- Definitely true
14. I know and have been trained about my diet and what I should be eating. Definitely false ----- ----- Definitely true
15. I know whom to call when I have questions about my TPN therapy. Definitely false ----- ----- Definitely true
16. I feel emotionally supported by my family and friends. Definitely false ----- ----- Definitely true
17. I feel well supported by my home care specialists. Definitely false ----- ----- Definitely true
18. I received information about local or national support groups for TPN therapy. Definitely false ----- ----- Definitely true

- Please continue to the next page -

How **TRUE or FALSE** are the following statements to you?

19. I wish I knew more about my TPN therapy.

Definitely false -----|----- Definitely true

Thank you for completing the
Home Parenteral Nutrition Patient Reported Outcomes Questionnaire

Appendix D: Approval Letters

THE

UNIVERSITY

OF RHODE ISLAND

DIVISION OF RESEARCH

AND ECONOMIC

DEVELOPMENT

OFFICE OF RESEARCH INTEGRITY

70 Lower College Road, Suite 002, Kingston, RI 02881 USA

p: 401.874.4328 f: 401.874.4814 web.uri.edu/researchcondev/office-of-research-integrity

FWA: 00003132

IRB: 00000599

DATE: October 21, 2016

TO: Geoffrey Greene

FROM: University of Rhode Island IRB

STUDY TITLE: Content Validation of a Home Parenteral Nutrition Patient Reported Outcomes Questionnaire

IRB REFERENCE #: 906446-3

LOCAL REFERENCE #: HU1617-011

SUBMISSION TYPE: Amendment/Modification

ACTION: APPROVED

EFFECTIVE DATE: October 21, 2016

EXPIRATION DATE: September 20, 2017

REVIEW TYPE: Expedited Review

REVIEW CATEGORY: Expedited review category # 7

The above referenced human subjects research project has been APPROVED by the University of Rhode Island Institutional Review Board (URI IRB). This submission has received Expedited Review based on the applicable federal regulation 45 CFR 46 and 21 CFR 50 & 56. All research must be conducted in accordance with this approved submission.

INFORMED CONSENT

The URI IRB requires the use of IRB STAMPED consent/assent documents only. Stamped documents are located on IRBNet under Board Documents. Federal regulations require each patient receive a copy of the signed consent document.

MODIFICATIONS AND AMENDMENTS

Changes to the protocol or its related stamped consent/assent documents must be approved by the URI IRB before implementation.

RECORDKEEPING

Federal regulations require all research records must be retained for a minimum of five years after the project ends.

PROTOCOL EXPIRATION

Based on the risks, this project requires Continuing Review by this office by September 20, 2017. Please use the CONTINUING REVIEW FORM for this procedure.

REPORTING

Unanticipated problems involving risk to subjects or others, adverse events, and other problems must be reported to the IRB using the Appendix S - Event Reporting form. Additionally, all FDA and sponsor reporting requirements must be followed.

URI IRB RESEARCH POLICIES

All individuals engaged in human subjects research are responsible for the compliance with all applicable URI IRB policies (<http://web.uri.edu/researchcondev/office-of-research-integrity/human-subjectsprotections/general-guidance/>). The Principal Investigator of the study is ultimately responsible for assuring all study team members review and adhere to applicable policies for the conduct of human subjects research.

If you have any general questions, please contact us by email at researchintegrity@etal.uri.edu. For study related questions, please contact us via project mail through IRBNet. Please include your study title and reference number in all correspondence with this office. -- Generated on IRBNet
Matthew J. Delmonico, PhD, MPH IRB Chair

Appendix E: Recruitment Materials

Flyer for Oley Foundation Website/Newsletter/Email

Volunteers Wanted for Research Study To participate in the development of a new questionnaire created to serve the Home Parenteral Nutrition (HPN) Population.

This is a URI research study, the principle investigator is Dr. Geoffrey Greene. The purpose of this study is to assess the content validity of the Home Parenteral Nutrition Patient Reported Outcome Questionnaire (HPN-PRO-Q). This questionnaire is intended to be used in clinical practice by patients to self-assess factors that influence quality of life or adaptation to HPN. We intend to evaluate a questionnaire about HPN and quality of life that may be used in the future to start a conversation about your quality of life with your doctor or HPN management team.

You will be asked to participate in a interview via telephone so that we may assess your individual understanding and comprehension of the questions included on the HPN-PRO-Q. The interviewer will be located in be in a private office located at the University of Rhode Island Kingston, RI- Fogerty Hall, office 103. The interview should take about one hour or longer, depending on how much you want to speak about each item on the questionnaire. Our conversation will be kept completely confidential and your responses will remain confidential. There is no direct benefit to you. It is hoped that the information from the interview will lead to a better understanding of the relevance, comprehension, and appropriateness of each question in the HPN-PRO-Q.

This research has been approved by the University of Rhode Island (URI) Institutional Review Board (IRB).

To be eligible you must:

- Receive home parenteral nutrition.
- Be willing to speak about your experiences living with home parenteral nutrition.
- Be over 18 years-old.
- Live in the United States
- Have computer access, an active email address, access to the internet, and a telephone you can access while simultaneously using your computer.
- Be English speaking.

Confidentiality of all information will be maintained. This study will take place from June-November 2016.

Appendix E: Recruitment Materials

For more information or to indicate your interest in participating in the study, email Tracy Miller at HPN-PRO@etal.uri.edu. Please include your name, telephone number with area code, email address, and best time to reach you.

Thank you for considering to participate in this research study!

The University of Rhode Island

Department of: Department of Nutrition and Food Sciences

Content Validity of Home Parenteral Nutrition Patient Reported Outcome
Questionnaire

Appendix E: Recruitment Materials

Expert Panel I-CVI, S-CVI Recruitment Letter/Email

Volunteers Wanted for Research Study To participate in the development of a new questionnaire created to serve the Home Parenteral Nutrition Population

We are looking for the following persons:

- **Home parenteral nutrition clinicians, physicians, nurses**
- **Homecare advocates**
- **Registered dietitians**

This is a URI research study; the principle investigator is Dr. Geoffrey Greene. The purpose of this study is to assess the content validity of the Home Parenteral Nutrition Patient Reported Outcome Questionnaire (HPN-PRO-Q). This questionnaire is intended to be used in clinical practice by patients to self-assess factors that influence quality of life or adaptation to HPN. This assessment is meant to facilitate a conversation between health-care providers, the patient, and other members of the home nutrition care team. *This research is being conducted in collaboration with Marion Winkler, PhD, RD, LDN, CNSC.*

We are looking for experts in the field of HPN. **If you are a HPN clinician, physician, homecare advocate, nurses, and/or a dietitian** you are eligible to participate in this study. We are looking for your feedback on the HPN-PRO-Q, as it is valuable in the development of this instrument.

We will be asking you to complete the Content Validity Index (CVI). The item-level Content Validity Index (I-CVI) is calculated by having experts in the field of interest rate the relevance of each item to its own subdomain. The item-level Content Validity Index (I-CVI) is calculated by having the experts rate the relevance of each item to its own subdomain. (1=not relevant, 2=somewhat relevant, 3=quite relevant, 4=highly relevant.)

If you agree to participate, you will be sent a CVI-Worksheet via email. Upon completion of the worksheet, you will be asked to save your work as a PDF and return it to the research email address.

This process should take approximately 20 minutes. Pending your availability, you may be asked to complete an additional round of the I-CVI after revisions to the instrument are made. This process should take an approximately and additional 20 minutes.

Confidentiality of all all information will be maintained. This research has been approved by the University of Rhode Island's (URI) Institutional Review Board (IRB).

Appendix E: Recruitment Materials

There is no direct benefit to you for participating in the study. It is hoped that the information you provide will lead to a better understanding of the relevance of the items included on the HPN-PRO-Q.

For more information or to indicate your interest in participating in the study, email Tracy Miller at HPN-PRO@etal.uri.edu. Please include your name, telephone number with area code, email address, and best time to reach you.

Thank you for considering to participate in this research study.

Appendix E: Recruitment Materials

HPN Patient-Cognitive Interview Screener Email

Dear Mr. or Ms. _____,

Thank you for your interest in this study. This is a URI research study, the principle investigator is Dr. Geoffrey Greene. The purpose of this study is to assess the content validity of the Home Parenteral Nutrition Patient Reported Outcome Questionnaire (HPN-PRO-Q). This questionnaire is intended to be used in clinical practice by patients to self-assess factors that influence quality of life or adaptation to HPN. There is no direct benefit to you. It is hoped that the information from the interview will lead to a better understanding of the relevance, comprehension, and appropriateness of each question in the HPN-PRO-Q.

This research has been approved by the University of Rhode Island (URI) Institutional Review Board (IRB).

In order to determine if you are eligible to participate, please answer the following questions and return by email within the next 3 days. If you have any questions, please contact the research team @ HPN-PRO@etal.uri.edu.

Criteria for Participation

Do you live in the US?

What is your age in years?

Are you pregnant?

Are you receiving home TPN?

Do you speak English?

Do you have computer access?

Can you talk on the telephone and read on the computer at the same time?

You will be asked to participate in a 60-90 minute interview via telephone so that we may assess your individual understanding and comprehension of the questions included on the HPN-PRO-Q. The interviewer will be located in a private office located at the University of Rhode Island Kingston, RI- Fogerty Hall, office 103.

Please send responses to HPN-PRO@etal.uri.edu

You will be hearing from me by [Date]

Thank you and I am looking forward to working with you!

Sincerely,

Tracy-Lee Miller,

Graduate Student in Food Science and Nutrition

Appendix F: Oral Consent Script and Interview Guide

Introduction

Hello,

My name is Tracy. I am a graduate student at the University of Rhode Island. Thank you for participating in this study. The purpose of this study is to evaluate a questionnaire about HPN and quality of life that may be used in the future to start a conversation about your quality of life with your doctor or HPN management team.

This questionnaire is called the Home Parenteral Nutrition Patient Reported Outcomes Questionnaire (HPN-PRO-Q) for short. I appreciate the time you've set aside to speak with me about your experiences on home parenteral nutrition and living with nutrition support.

Before we begin, I want to review a few things with you.

Your participation in this interview is completely voluntary; you may choose not to participate.

If there are any questions you do not wish to answer, just let me know and we can skip it.

You can stop the interview at any time.

The interview should take about one hour or longer, depending on how much you want to speak about each item on the questionnaire. Our conversation will be kept completely confidential and your responses will remain anonymous.

I am in a private office and will be using a speakerphone. No one else will be in the room with me.

If you agree, our conversation will be tape-recorded in order to document your exact words. The tapes will be destroyed at the end of this project. The transcripts will be numbered and will not contain your name or any identifying information.

There is no risk to you by answering these questions. There is no direct benefit to you. It is hoped that the information from the interview will lead to a better understanding of the relevance, comprehension, and appropriateness of each question in the HPN-PRO-Q.

Your comments will be combined with other study patients when the results are analyzed. Nothing you tell me will be presented or published in a way that someone could identify you.

Appendix F: Oral Consent Script and Interview Guide

Do you have any questions about the information we discussed?

I will be turning the tape recorder on now. Do I have permission to tape this conversation?

--This interview should take about 1 hour. Please let me know if you need to take a break, would like to end the interview, or prefer to skip a question.

The first couple of questions are about your TPN.

What is your diagnosis relating to your need for home TPN?

How long have you been receiving home parenteral nutrition?

What is your number of home TPN infusion days/hours per week?

Now, I am going to read you 30 statements and ask you what the statement means to you. I may ask you to repeat the statement in your own words. I may ask you what a specific term or word means to you. All of the statements will ask you to recall how often you experienced the symptom or feeling in the past 2 weeks. I may ask you how you remember that you felt that way.

The first questions I am going to ask you are about how often something or an event happens to you in a 2-week period.

In a 2 week time frame, what does the response "not at all" mean to you?

In a 2 week time frame, what does the response "2-3 days per week " mean to you?

In a 2 week time frame, what does the response "" more than half the day mean to you?

In a 2-week time frame, what does the response "nearly every day" mean to you?

The next few questions are about eating. Tell me what you are thinking when I read the statement to you:

I eat and enjoy the foods I want to eat.

Please repeat the statement I just read to you in your own words.

Would this be easy or hard to answer?

What does "eat" mean to you?

What does "enjoy foods" mean to you?

Would you be able to remember how many times you enjoyed eating food in the past 2 weeks?

Appendix F: Oral Consent Script and Interview Guide

How do you remember how often you experienced enjoying the foods you want to eat in the past 2 weeks?

I can participate comfortably in social situations where food is served.

Please repeat the statement I just read to you in your own words.

Would this be easy or hard to answer?

What does "social situation" mean to you?

What does "around others" mean to you?

Would you be able to remember how many times you comfortably ate in social situations or around others in the past 2 weeks?

How do you remember how often you experienced you comfortably ate in social situations or around others in the past 2 weeks?

Eating causes me to have gas or feel bloated?

Please repeat the statement I just read to you in your own words.

Would this be easy or hard to answer?

What does "gas" mean to you?

What does "bloated" mean to you?

Would you be able to remember how many times eating caused gas or made you bloated in the past 2 weeks?

How do you remember how often you experienced gas or felt bloated in the past 2 weeks?

Eating causes me to have pain?

Please repeat the statement I just read to you in your own words.

Would this be easy or hard to answer?

What does "pain" mean to you?

Would you be able to remember how many times eating caused pain in the past 2 weeks?

How do you remember how often you experienced had pain while eating in the past 2 weeks?

The next few questions are about your lifestyle. Tell me what you are thinking when I read the statement to you:

I am able to live what I consider a normal lifestyle.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does the term "normal lifestyle" mean to you?

Would you be able to answer how often in the last 2 weeks you were able to live a normal lifestyle?

Appendix F: Oral Consent Script and Interview Guide

I feel emotionally supported by my family and friends.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Who are you referring to when I ask about feeling emotionally supported by “family”?

Who are you referring to when I ask about “friends” emotionally supporting you?

I feel like my medical condition controls my life.

Please repeat this statement in your own words?

Would this be easy or hard to answer?

What does the term "medical condition" mean to you?

What does the concept "control your life" mean to you?

Would you be able to remember how many times you felt controlled by your medical condition in the past two weeks?

The next few questions are about your TPN or [patients name for nutrition therapy].

Tell me what you are thinking when I read the statement to you:

Being on TPN [or patient’s name for nutrition therapy] is difficult to cope with.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does the term "cope" mean to you?

Would you be able to remember how many times in the past 2 weeks TPN was difficult to cope with?

My TPN schedule limits my freedom to participate in daily activities?

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “TPN schedule” mean to you?

What does “limit my freedom” mean to you?

What does “daily activities” mean to you?

Would you be able to remember how many times your TPN schedule limited your daily activities in the past 2 weeks?

Carrying the TPN solution limits what I can do.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does the term “TPN solution” mean to you?

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What does “limits” mean to you?

Would you be able to remember how many times carrying your TPN solution limited what you wanted to do in the past 2 weeks?

I am confident with my ability to perform TPN procedures on my own?

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does it mean to you to be "confident"?

What does "perform TPN procedures" mean to you?

What TPN procedures do you perform by yourself?

Would you be able to remember how many times you performed TPN procedures by yourself in the past 2 weeks?

The next questions are about your energy level and strength. Tell me what you are thinking when I read the statement to you:

I feel physically strong.

Please repeat this statement in your own words.

Would this be easy or hard to answer

What does it mean to you to be "physically strong"?

Would you be able to remember how many times you felt physically strong in the past 2 weeks?

I am able to take care of myself.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does "able to take care of yourself" mean to you?

Would you be able to remember how many times you were able to take care of yourself in the past 2 weeks?

I am able to participate in the activities I enjoy.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What “activities” would you be referring to if you were answering this question?

Would you be able to remember how many times you were able to enjoy the activities you listed above in the past 2 weeks?

I am able to walk without difficulty.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “without difficulty” mean to you?

Would you be able to remember how many times you were able to walk

Appendix F: Oral Consent Script and Interview Guide

without difficulty in the past 2 weeks?

I am able to climb up and down stairs without difficulty.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Do you have stairs you need to climb in your home?

What does “without difficulty” mean to you?

Would you be able to remember how many times you climbed the stairs without difficulty in the past 2 weeks?

I am able to rise from a chair or bed without difficulty.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “rise without difficulty” mean to you?

Would you be able to remember how many times in you got out of bed or chair without difficulty the past 2 weeks?

I am able to pick up an object from the floor without difficulty.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does the term “object” mean to you?

What does “without difficulty” mean to you?

Would you be able to remember how many times you were able to pick up a object from the floor in the past 2 weeks?

I need to nap when I feel tired.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “nap” mean to you?

What does “feel tired” mean to you?

Would you be able to remember how many times you napped in the past 2 weeks?

I have enough strength and stamina to do daily chores or work.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “enough” mean to you?

What does “strength” mean to you?

What does “stamina” mean to you?

What do “daily” chores mean to you?

Do you work? What do you do for work?

Would you be able to remember how many times you had enough stamina to do daily chores or work in the past 2 weeks?

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The next few questions are about sleeping. Tell me what you are thinking when I read the statement to you:

I am satisfied with the amount I sleep at night.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “satisfied” mean to you?

How many hours do you sleep?

Would you be able to remember how many times you were satisfied with the amount of time you slept in the past 2 weeks?

The TPN pump disrupts my sleep.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “disrupts” mean to you?

In what way does your TPN pump disrupt your sleep?

Would you be able to remember how many times the pump disrupted your sleep in the past 2 weeks?

My sleep is disrupted because I have to get up to move my bowels or change my ostomy appliance.

Please repeat this statement in your own words,

Would this be easy or hard to answer?

What does “disrupted” mean to you?

Would you be able to remember how many times your sleep was disrupted because of needing to move your bowels or empty your ostomy appliance in the past 2 weeks?

My sleep is disrupted because I have to get up to urinate.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “urinate” mean to you?

What does “disrupted sleep” mean to you?

Would you be able to remember how many times your sleep was disrupted to get up and urinate in the past 2 weeks?

Before I ask you the next question, please tell me if you have an ostomy or if you go to the bathroom to move your bowels on the toilet?

If YES,

I move my bowels many times during the day.

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Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “move my bowels” mean to you?

What does “many times a day” mean to you?

Would you be able to remember how many days you had to move your bowels many times a day in the past 2 weeks?

I move my bowels many times during the night.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “many times during the night” mean to you?

Would you be able to remember how many nights you had to move your bowels throughout the night in the past 2 weeks?

I have to move my bowels urgently.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “urgently” mean to you?

Would you be able to remember how many days you had to move your bowels urgently in the past 2 weeks?

I have episodes of uncontrollable diarrhea.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “uncontrollable diarrhea” mean to you?

Would you be able to remember how many episodes of uncontrollable diarrhea you had in the past 2 weeks?

I have to move my bowels as soon as I eat food.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “as soon as you eat” mean to you?

Would you be able to remember how times you had to move your bowels as soon as you ate in the past 2 weeks?

I plan my daily activities around how much diarrhea I have.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “daily activities” mean to you?

What does it mean to “plan around” your daily activities?

Would you be able to remember how many days you had plan your daily activities around how much diarrhea you have?

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If NO,

I empty my ostomy appliance many times during the day.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “many times” mean to you?

What does “empty my ostomy appliance” mean to you?

Would you be able to remember how many days you have to empty your ostomy appliance many times a day in the past 2 weeks?

I empty my ostomy appliance many times during the night.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “many times during the night” mean to you?

Would you be able to remember how many nights you had to empty your ostomy appliance many times in the past 2 weeks?

I have to empty my ostomy appliance urgently.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “urgently” mean to you?

Would you be able to remember how many times you had to urgently empty your ostomy appliance in the past 2 weeks?

I have episodes of uncontrollable ostomy leakage

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “uncontrollable leakage” mean to you?

Would you be able to remember how many days you had uncontrollable ostomy leakage in the past 2 weeks?

I have to empty my ostomy appliance as soon as I eat food.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “as soon as you eat” mean to you?

Would you be able to remember how many times you had to empty your ostomy appliance as soon as you ate food in the past 2 weeks?

I plan my daily activities around how much ostomy output I have.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “daily activities” mean to you?

What does “ostomy output” mean to you?

Would you be able to remember how many days you had to plan your daily

Appendix F: Oral Consent Script and Interview Guide

activities around how much ostomy output you have move in the past 2 weeks?

True/False

Good quality of life means being able to do what I want to do when I want to do it.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Having one or more nights without TPN is important to me.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Having a shorter TPN infusion schedule is important to me.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

I feel relieved knowing my nutritional needs are being met by TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does the term “nutritional needs” mean to you?

What does it mean to “have your nutritional needs met”?

I do not need to eat because I receive TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “do not need to eat” mean to you?

I am fearful of developing complications related to my catheter.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “complications related to my catheter” mean to you?

What does “fearful” mean to you?

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I understand the need for being on TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “need for being on TPN” mean to you?

I am informed and well trained about managing my TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer

What does “informed” mean to you?

What does “well-trained” mean to you?

What does “managing my TPN” mean to you?

I am informed and well trained about the care of my catheter.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

In this instance, what does “informed” mean to you?

What does “well-trained” mean to you?

I am informed and well trained about using my pump.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

In this instance, what does “informed” mean to you?

What does “well-trained to take care of my catheter” mean to you?

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I am informed and well trained about signs and symptoms of infection.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “signs and symptoms of infection” mean to you?

In this instance, what does “informed” mean to you?

What does “using my pump” mean to you?

I am informed and well trained about signs and symptoms of dehydration.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “signs and symptoms of dehydration” mean to you?

In this instance, what does “informed” mean to you?

What does “well-trained” mean to you?

I understand my diet and what I should be eating.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “diet” mean to you?

What does “should be eating” mean to you?

What does it mean to “understand”?

I know whom to call when I have questions about my TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Who do you call when you have questions about your TPN?

Would you call that person if you had questions about your TPN?

Appendix F: Oral Consent Script and Interview Guide

What does it mean to have “questions about my TPN”?

I feel well supported by my home care specialists.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “home care specialists” mean to you?

Do you have a “home care specialist?”

What does the concept of feeling well supported mean to you?

I received information about local or national support groups for TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

Appendix G: Oral Consent Script and Interview Guide

What does “support group” mean to you?

Do you utilize local or national support groups?

If yes, which support group do you utilize?

I wish I knew more about my TPN.

Please repeat this statement in your own words.

Would this be easy or hard to answer?

What does “know more” mean to you?

Do you know how to learn more about your TPN?

Now, a few more questions are about you:

What is your age in years?

Are you male or female?

What is your highest level of education?
How many people live in your household?
Are you married, single, or divorced?
Do you have a caregiver to help with TPN procedures, and if yes, who?
What is your race?
What is your ethnicity?

Finally, I would like to get your personal impression on the HPN-PROQ. Do you think this may be useful during a visit the doctor, clinician, or other health-care professional who helps you manage your TPN?

Thank you for participating in this study. If is okay with you, may I contact you at a future date to clarify some of the feedback you provided me with today?

Appendix G: Content Validity Index Cover Letter & Workbook

HPN-PROQ

Thank you for agreeing to participate in this study. Research by Winkler et al. (2010) determined that patients in the Home Parenteral Nutrition (HPN) population perceived their routine medical appointments as a parenteral nutrition “tune-up,” with sessions focusing primarily on disease aspects of care. In addition to medical examination and nutrition assessment, HPN patients desired a more holistic approach to parenteral nutrition management incorporating both physical and emotional support.

Patient reported outcomes comprise information from patients about health conditions and management, making them a valuable tool to identify concerns and in facilitating communication around patients’ health-related quality of life. The Home Parenteral Nutrition Patient Reported Outcome Questionnaire (HPN-PROQ) is meant to be completed by adult home parenteral nutrition patients.

This is a University of Rhode Island research study; the principal investigator is Dr. Geoffrey Greene. **The completion of this worksheet represents your informed consent and agreement to participate in this study.** Your responses will remain confidential and results will not be published in a way that may identify you.

Attached to this cover letter is the Content Validity Index Worksheet. Instructions are included within the document. At your earliest convenience, please complete the worksheet, **save as a PDF**, and return it to HPNpatientoutcomes@etal.uri.edu by 2/10/17. If you have any questions, please contact me via email.

-This research is being conducted in collaboration with Marion Winkler, PhD, RD, LDN,

CNSC-

HPN-PROQ

Expert Review: Content Validity Index

Directions: Attached is the HPN-PROQ. Please rate each item on the *Home Parenteral Nutrition Patient Reported Outcome Questionnaire* (HPN-PRO-Q) based on its relevance to the HPN population. ** Please **CHECK THE BOX** next to the number that corresponds to your answer.

1="Not Relevant", 2="Somewhat Relevant", 3="Quite Relevant", or 4="Highly Relevant".

SEE EXAMPLES 1 & 2 EXPERT REVIEWERS: Please **CHECK THE BOX** next to the number that corresponds to your answer. **PLEASE MAKE SURE YOU ONLY CHOOSE ONE BOX PER QUESTION.**

During the past 2 weeks , please estimate how often you have experienced any of the following situations.			
1. I felt like my health limited the things I want to do in my life.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input checked="" type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
2. Being on TPN was difficult to cope with emotionally.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input checked="" type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page -

**Home Parenteral Nutrition Patient Reported Outcomes Questionnaire
CVI WORKSHEET**

Patient Instructions:

This questionnaire is intended to help you identify areas of concern or problems with your home TPN over the last 2 weeks that may affect your quality of life and/or your ability to do the things you would like to do. These patient-reported outcomes (PRO) may be used to prioritize what you would like to discuss with your physician, health care professional, or members of your home parenteral nutrition management team as well as set goals for your care.

Healthcare Professional Instructions: The responses on this questionnaire are intended to facilitate discussion between patient and practitioner regarding patient goals related to home TPN and lifestyle adaptation.

“TPN” = total parenteral nutrition solution/formula.

“TPN therapy” = procedures/equipment/devices necessary to administer the TPN solution/formula

HPN Consumers: Please place a “X” on the dotted line where it most clearly indicates the frequency of occurrence for each of the given situations over the past two weeks.

EXPERT REVIEWERS: Please **CHECK THE BOX** next to the number that corresponds to your answer. **PLEASE MAKE SURE YOU ONLY CHOOSE ONE BOX PER QUESTION.**

During the past 2 weeks , please estimate how often you experienced any of the following situations.			
1. I felt like my health limited the things I want to do in my life. Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
2. Being on TPN was difficult to cope with emotionally. Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page -

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

3. My daily activities were limited by my TPN infusion schedule.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
4. Carrying my TPN solution limited what I could do.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
5. I felt physically strong.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
6. I was able to participate in the activities I enjoy.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
7. I was able to walk without difficulty.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page -

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

8. I was able to climb up and down stairs without difficulty.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
9. I was able to rise from a chair or bed without difficulty.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
10. I was able to pick up an object from the floor without difficulty.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
11. I needed to nap when I felt tired.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
12. I had enough strength and stamina to do daily chores or work.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page -

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

<p>13. The TPN pump disrupted my sleep.</p> <p>Not at all ----- ----- Every day</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>14. My sleep was disrupted because I had to get up to move my bowels or empty my ostomy bag.</p> <p>Not at all ----- ----- Every day</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>15. My sleep was disrupted because I had to get up to urinate.</p> <p>Not at all ----- ----- Every day</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>16. I ate comfortably in social situations and around others.</p> <p>Not at all ----- ----- Every day</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>17. Eating caused me to have gas or feel bloated.</p> <p>Not at all ----- ----- Every day</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>

- Please continue to the next page -

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

18. Eating caused me to have pain.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

***Answer questions 19-21 if you do **NOT** have an end-jejunostomy or ileostomy **but do have** bowel in continuity. ***

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

19. I had episodes of uncontrollable diarrhea.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

20. I had to move my bowels shortly after I ate food.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

21. I had to rearrange my daily plans because of how much diarrhea I had.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

***Answer questions 22-24 if you **HAVE** an end-jejunostomy or ileostomy. ***

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

22. I had episodes of uncontrollable ostomy leakage.			
Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

During the **past 2 weeks**, please **estimate** how often you experienced any of the following situations.

23. I had to empty my ostomy bag shortly after I ate food. Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
24. I had to rearrange my daily plans because of how much ostomy output I had. Not at all ----- ----- Every day			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page for True/False section-

How **TRUE** or **FALSE** are the following statements to you?

1. Good quality of life means being able to do what I want to do when I want to do it.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
2. I eat and enjoy the foods I want to eat.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
3. I am confident in my ability to perform TPN procedures on my own.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
4. Having one or more nights or days without TPN is important to me.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
5. Having a shorter TPN infusion schedule is important to me.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>
6. I feel relieved knowing my nutritional needs are being met by TPN therapy.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

- Please continue to the next page -

How **TRUE or FALSE** are the following statements to you?

7.	I am fearful of developing complications related to my TPN therapy and/or central line.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
8.	I understand my need for being on TPN therapy.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
9.	I know and have been trained on how to manage my TPN therapy.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
10.	I know and have been trained on how to care for my central line.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
11.	I know and have been trained on how to use my pump.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>
12.	I know and have been trained on the signs and symptoms of a central line infection.		
	Definitely false ----- ----- Definitely true		
Not Relevant	Somewhat Relevant	Quite Relevant	Highly Relevant
1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>	4 <input type="checkbox"/>

- Please continue to the next page -

How **TRUE** or **FALSE** are the following statements to you?

<p>13. I know and have been trained on the signs and symptoms of dehydration.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>14. I know and have been trained about my diet and what I should be eating.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>15. I know whom to call when I have questions about my TPN therapy.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>16. I feel emotionally supported by my family and friends.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>17. I feel well supported by my home care specialists.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>
<p>18. I received information about local or national support groups for TPN therapy.</p> <p>Definitely false ----- ----- Definitely true</p>			
<p>Not Relevant 1 <input type="checkbox"/></p>	<p>Somewhat Relevant 2 <input type="checkbox"/></p>	<p>Quite Relevant 3 <input type="checkbox"/></p>	<p>Highly Relevant 4 <input type="checkbox"/></p>

- Please continue to the next page -

How **TRUE or FALSE** are the following statements to you?

19. I wish I knew more about my TPN therapy.			
Definitely false ----- ----- Definitely true			
Not Relevant 1 <input type="checkbox"/>	Somewhat Relevant 2 <input type="checkbox"/>	Quite Relevant 3 <input type="checkbox"/>	Highly Relevant 4 <input type="checkbox"/>

Thank you for completing the
Home Parenteral Nutrition Patient Reported Outcomes Questionnaire
Content Validity Index Worksheet

Please **SAVE AS a PDF** and email to HPNpatientoutcomes@etal.uri.edu

CONTENT VALIDATION OF A HOME PARENTERAL NUTRITION PATIENT
REPORTED OUTCOMES QUESTIONNAIRE

Appendix F: Phase I Themes and Representative Quotations			
Concerns with tone			
Item Tested	Representative Quotations	CRT Decision	Implication/Interpretation
<p>“I am able to live what I consider a normal lifestyle.”</p>	<p>"I think normal is hard to define for everybody.</p> <p>“Normal is relative”</p> <p>“I think this question is too generalized. each of us has his own normal.”</p> <p>“I don’t like the word normal because there’s nothing normal with someone on TPN”.</p>	<p>Eliminate Item</p>	<p>Address concerns with the overall tone of the item and the patient’s most salient concern.</p>
<p>“I feel like my medical condition controls my life”</p>	<p>"When I say medical condition, I don’t think it’s just referring to TPN. Mostly (because) I still I have other issues."</p> <p>“We all have things that come up, but I think we are a little more hypersensitive”</p> <p>“...dictates your day to day (not controls)".</p>	<p>Revise Item</p> <p>“I felt like my health limited the things I want to do in my life.”</p>	<p>Increased acceptability of the item, tailored to patient feedback</p>

<p>“My TPN schedule limits my freedom to participate in daily activities”.</p>	<p>“...to limit my freedom to me makes me think like you can't. I think it's a more strict of a term”.</p> <p>“these are two entirely different schedules that you have to focus on because TPN schedule might be being home making the deliveries, getting tools, so that schedule is completely different than how many hours you're infusing.</p>	<p>Revise Item</p> <p>“My daily activities were limited by my TPN infusion schedule.” Add “infusion” to all items referring to TPN schedule.</p>	<p>Increased acceptability of the item, increased clarity, tailored to patient feedback</p>
<p>Issues with ambiguity and meaning</p>			
<p>“Being on TPN is difficult to cope with”.</p>	<p>“...it's a lot more difficult than to cope...I think if you put emotionally there would describe it more specifically.”</p>	<p>Revise Item</p> <p>“Being on TPN was difficult to cope with emotionally”.</p>	<p>Increased acceptability of the item, increased clarity, tailored to patient feedback</p>
<p>“I have to empty my ostomy appliance urgently”</p>	<p>“What do you mean, urgently?”</p> <p>“...do you mean within five minutes...or longer?”</p>	<p>Eliminate Item</p>	<p>Addressed unnecessary confusion related to intended purpose of the item, purpose covered in other items</p>

<p>“I move my bowels many times during the day” and “I empty my ostomy appliance many times during the day/night”</p>	<p>“I would wonder about what you mean with “many”? Many to me I don’t think as my frequency as many but my friend with normal bowels they would say like “what... you go many times”.</p>	<p>Eliminate Item</p>	<p>Addressed unnecessary confusion related to intended purpose of the item, intent covered in other items.</p>
<p>“I am satisfied with the amount I sleep at night”</p>	<p>“I think it would be difficult to answer just because the fact the it varies so much that, someone can be satisfied with no sleep so it’s very individual”</p>	<p>Eliminate Item</p>	<p>Addressed unnecessary confusion related to intended purpose of the item, purpose covered in other items</p>
<p>“I am able to take care of myself”.</p>	<p>“That’s ambiguous to me... I am able to take care of my hygiene, in that sense I am able to take care of myself. I can brush my teeth...but I can’t live on my own.</p>	<p>Eliminate Item</p>	<p>Addressed unnecessary confusion related to intended purpose of the item, purpose covered in other items</p>
<p>Concerns with use of jargon or word choice</p>			
<p>“My sleep is disrupted because I have to get up to move my bowels or change my ostomy appliance.”</p>	<p>“Change is not appropriate in here... you don’t change it, you empty the bag.”</p>	<p>Revise Item “My sleep was disrupted because I had to get up to move my bowels or empty my ostomy bag”</p>	<p>Increased acceptability of the item.</p>
<p>“I am fearful of developing complications related to my</p>	<p>“Central line would cover everything.” “...most of the</p>	<p>Revise Item “I am fearful of</p>	<p>Increased acceptability of the item.</p>

<p>catheter” and “I am informed and well trained about how to care for my catheter”</p>	<p>people say central line and I don’t know if everyone knows about a catheter”</p> <p>“if you changed catheter to central line would be clear”</p>	<p>developing complications related to my central line” and “I am informed and well trained about how to care for my central line”</p>	
<p>“I am informed and well-trained to...”</p>	<p>“The question here for me is the well-trained part...obviously, my situation is different but it wouldn’t be specifically trained doing that, so that’s where I’m informed but not trained”</p> <p>“Well-trained doesn’t seem like something I would use, maybe knowledgeable?”</p> <p>“Informed would be I understand why I have TPN, I know what it is, what it’s doing for me, and I have been taught or trained how to manage.”</p>	<p>Revise Item I understand and have been trained to....”</p>	<p>Eliminated unnecessary confusion related to intended purpose of the item.</p>