Development and Psychometric Properties of the Thai Health-Related Quality of Life Instrument for Dialysis Patients

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Abstract: This study sought to develop and assess the psychometric properties of the Thai Health-Related Quality of Life Instrument for Dialysis Patients (THAI-HRQOL-D). The conceptual definition and content domains of the instrument were developed through semi-structured interviews and a comprehensive literature review. Ferrans' Quality of Life conceptual framework was used to guide the research. Face validity of the instrument was determined via ten dialysis patients. Content validity was assessed via a panel of seven experts, and the initial psychometric properties and identification of inappropriate items were determined by 40 dialysis patients.

Data for final psychometric assessment of the instrument were collected from 420 Thai dialysis patients, who attended one of three dialysis centers in Bangkok or a dialysis center in Samutsakorn province, Thailand. The construct validity of the tool was determined through exploratory and confirmatory factor analysis.

The results revealed seven factors explained 54.86% of the variance. These factors, consisting of 37 items, including: health and functioning; psychological well-being; socioeconomics and family; living with dialysis; spirituality; living with symptoms; and, cognition. The measurement model was found to have a relatively goodness of fit with the data (χ^2=892.53; df = 603 ($p<.001$); χ^2/df =1.48; RMSEA= 0.048; GFI = 0.820; and, CFI= 0.904). Cronbach's alpha coefficients for each of the subscales ranged from 0.557 to 0.889 and the total scale's Cronbach's alpha was 0.842. In addition, a 0.63 correlation was found between the THAI-HRQOL-D and the Thai Health Status Assessment Instrument providing evidence of the instrument's convergent validity. Concurrent validity was found between the THAI-HRQOL-D and two concurrent measures (serum albumin levels and hospitalizations of dialysis patients). Thus, it was determined the newly developed instrument demonstrated adequate reliability and validity for assessing health-related quality of life among Thai dialysis patients.

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Background

Chronic kidney disease (i.e. the slow loss of kidney function whereby the body is unable to adequately remove waste and excess water) is a long-term condition that has become more prevalent, worldwide, with Thailand being no exception.[1, 2] In order to increase the survival of individuals afflicted with the disease, there is an increased need for renal

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replacement therapies (RRT). RRTs do not cure chronic kidney disease; however, they are regarded as life-extending procedures. These therapies include: hemodialysis; peritoneal dialysis; hemofiltration; and, renal transplantation.[3] Hemodialysis is a method for extracorporeal removal of waste products (i.e. creatinine and urea) and fluid from the blood, while peritoneal dialysis involves use of the peritoneum, in the abdomen, for the waste and fluid removal process.[2] Hemofiltration is similar to hemodialysis, but is governed by convection rather than diffusion, and does not involve use of a dialysate.[2] It is used almost exclusively in an intensive care setting. Lastly, renal transplantation is the transplant of a kidney, into a recipient, from either a deceased or living donor.[2]

This study, however, dealt exclusively with patients undergoing hemodialysis or peritoneal dialysis as a result of chronic kidney disease. Hemodialysis uses a membrane (dialyzer) to filter wastes and remove extra fluid from the blood via vascular access (i.e. arteriovenous [AV] fistula, AV graft or venous catheter) and is performed at a health care center.[3] In order to remove wastes and extra fluid, hemodialysis patients are required to follow a strict schedule of dialysis that occurs two to three times a week and lasts three or more hours each time. The most frequent complication of the procedure is intradialytic hypotension (symptoms: dizziness, fainting, muscle cramps and nausea) that occurs when fluid is removed too rapidly.[2] Living with hemodialysis involves limitation of food and fluid, activity restriction, pain and discomfort, fears and feelings of uncertainty about the future, and disruption in job performance.[2, 4] By comparison, peritoneal dialysis, which can be carried out at home, or in the workplace, uses the lining of the abdominal cavity (peritoneal membrane) and a solution (dialysate) to remove wastes and extra fluid from the body, via peritoneal access (i.e.Tenckhoff catheter).[3] Peritoneal dialysis patients are taught to carry out the procedure that is conducted on a regular schedule of 4 to 5 times a day and involves the support of a peritoneal dialysis health care team or a personal care giver. Since they are being dialyzed a number of times every day, patients involved in peritoneal dialysis do not need to follow a strict diet or limitations in fluid intake. Peritoneal dialysis is appropriate for patients who have severely compromised cardiac function that will not tolerate fluctuations in blood volume.[2] The most frequent complications of peritoneal dialysis include peritonitis, exit site infection and catheter malfunction (symptoms: fever, abdominal pain, nausea and vomiting).[2] Patients undergoing peritoneal dialysis face the burdens of activity/travel limitations, loss of body image and time consumption in carrying out the dialysis procedure.[4, 5]

The prevalence rate of RRT, in 2009, included 27,056 cases of hemodialysis, 5,133 cases of peritoneal dialysis, and 2,923 cases of renal transplantation.[6, 7] No data were available regarding the prevalence of hemofiltration. An individual needing RRT requires continual care that can become very costly.

The impact of chronic renal disease and its related treatment affects an individual's physical, psychological and social well-being.[5, 8] Thus, the health-related quality of life (HRQOL) experienced by persons afflicted with chronic renal disease should be of concern to providers who are involved in their clinical care.

Acknowledgement of HRQOL is important as health care providers consider the management and plan of care of an individual based upon his/her illness.[9, 10] Recognizing and noting disease-specific HRQOL allows health care providers to focus on the assessment of specific information related to an individual's illness. Thus, utilization of disease-specific HRQOL instruments allows for more sensitivity in the assessment of characteristics of a given population.[11]

In Thailand, there currently are no published disease-specific instruments available for measuring HRQOL in patients with chronic kidney disease. Although there are various HRQOL instruments used

with this patient group, most are generic measures that are relevant to western cultures, but not necessarily sensitive to the Thai culture.[12, 13] Thus, there is need for a HRQOL instrument that is sensitive to both the context of the Thai culture and health-related needs of patients undergoing dialysis, as a result of chronic kidney disease. Therefore, the purpose of this study was to develop and test the psychometric properties of the "Thai Health-Related Quality of Life Instrument for Dialysis Patients" (THAI-HRQOL-D).

Conceptual Framework

Quality of life (QOL) is a broad and difficult construct to define and measure. Thus, identifying a framework that could systematically guide the development of an instrument measuring QOL was imperative.[14] Ferrans' "Conceptual Model of Quality of Life"[15] was selected as the framework for guiding the development of the instrument produced by this study. Ferrans defines QOL as "a person's sense of well-being that stems from satisfaction or dissatisfaction with the areas of life that are important to him/her"[16; p.15] In addition, she identifies four dimensions for QOL: health and functioning; social and economics; psychological/spiritual; and, family.[15] The health and functioning dimension has fourteen elements: usefulness to others; physical independence; ability to meet family responsibilities; general health; ability for travel; leisure time activities, control over own life; sex life; potential for a happy old age/retirement; potential for a long life; pain; energy (fatigue); stress or worries; and, health care. The social and economics dimension consists of eight elements: standard of living; financial independence; home (house, apartment); neighborhood; job/unemployment; friends; emotional support; and, education. Seven elements make up the psychological/spiritual dimension: satisfaction with life; satisfaction with self; happiness in general; achievement of personal goals; peace of mind; personal appearance; and, faith in God. Finally, the family dimension has four elements: family happiness; children; relationship with spouse; and, family health.

Method

Design: This instrumentation study consisted of two phases: 1) instrument development; and, 2) testing the instrument's psychometric properties.

Ethical Considerations: Prior to implementation, study protocol approval was obtained from the Institutional Review Board of the primary investigator's (PI) academic institution and the dialysis centers used to access potential subjects. All participants were provided information regarding: study aims and procedures; safeguards for anonymity and confidentiality; and, the right to withdraw without repercussions. All individuals agreeing to take part in the study were asked to sign a consent form.

Setting and Sample: Due to the inadequate distribution of dialysis services in Thailand,[7] a total of four dialysis centers (three in Bangkok and one in Samutsakorn province) served as study sites. These centers were used because of either the number of hemodialysis, or hemodialysis and peritoneal dialysis patients they treated. During the development phase of the study, two of the three dialysis centers, located in Bangkok, were used. During the psychometric testing phase of the study, all four dialysis centers were used.

The sample, throughout the study, was purposively selected. Inclusion criteria were being a Thai who was: on either hemodialysis (HD) or peritoneal dialysis (PD) for chronic kidney disease; 18 years of age or older; able to communicate in Thai; receiving dialysis treatment for more than three months (the recommended duration for experiencing life with dialysis treatment);[4] and, either Buddhist, Muslim or Christian. Due to the influence of religious beliefs on one's QOL[17] and the proportion of Thais practicing one of three major world religions, during a portion of the development phase (semi-structured interviews and face validity

examination), the sample purposively included Muslims (10%), Christians (10%) and Buddhists (80%). An equal number of HD and PD patients were used throughout the various stages of the two phases of the study.

During the development phase of the instrument, a total of 35 HD patients and 35 PD patients were used (10 for each group for interviewing; 5 for each group for face validity examination; and, 20 for each group for pilot testing). For the psychometric testing phase of the instrument, 210 HD patients and 210 PD patients were used. The sample size for the study's psychometric testing phase was based upon either five or ten subjects, per instrument item, depending upon the objectives of the specific analysis being conducted.[18-20]

The 35 subjects taking part in the various stages of the development phase of the instrument had the following demographic characteristics. The twenty subjects involved in the interviewing process: were equally divided by gender for both the HD group (5 males and 5 females) and the PD group (5 males and 5 females); had a mean age of 50.0 years (range = 25 to 81 years); were receiving dialysis for a median of 26 months (range = 4 to 252 months); were Buddhist (n = 16; 80%), Muslim (n = 2; 10%) or Christian (n = 2; 10%); were single (n = 7; 35%), married (n = 11; 55%) and widowed/ divorced/ separated (n = 2; 10%); and, worked either full or part-time (n = 11; 55%). The five HD patients and five PD patients, involved in examining face validity of the instrument: had a mean age of 48.4 years (range = 22 to 71 years); were receiving dialysis for a median of 32 months (range = 6 to 98 months); were Buddhist (n = 8; 80%), Muslim (n = 1; 10%) or Christian (n = 1; 10%); were single (n = 4; 40%), married (n = 5; 50%) or widowed (n = 1; 10%); and, worked either full or part-time (n = 6, 60%). The 40 patients (22 males and 18 females), involved in pilot testing the instrument: had a mean age of 49 years (range = 20 to 76 years); had received dialysis for a median of 45 months (range = 12 to 170 months); were Buddhist (n = 34; 85%); were single (n = 15; 37.5%), married (n = 22; 55%) or widowed (n = 3; 7.5%); and, worked either full or part-time (n = 21; 52.5%).

The 420 subjects taking part in the psychometric testing phase of the study, primarily: were from a clinic in Bangkok (n = 353; 84%); were female (n = 227; 54%); were married (n = 285; 67.9%); were unemployed (n = 236; 56.2%); were Buddhist (n = 392; 93.3%); had a mean age of 52.3 years (range = 17 to 84 years); had received dialysis for a median of 24 months (range = 3 to 257 months); had a primary school education (n = 230; 54.8%), secondary school education (n = 151; 35.9%) or held a bachelor's or higher university degree (n = 39; 9.3%); had been hospitalized in the past year (n = 142; 33.8%); had received the erythropoietin hormone supplement (n = 399; 95%); and, had co-morbidities (n = 386; 92%), such as hypertension (n = 380; 90.5%), diabetes mellitus (n = 154; 36.7%) and dyslipidemia (n = 156; 37.1%).

Procedure and Data Analysis: The study consisted of two phases. Phase I, development of the THAI-HRQOL-D, involved five steps (definition and content domain construction; item generation; determination of the scaling format; item review and face validity examination; and, pilot testing), while Phase II consisted solely of testing the psychometric properties of the THAI-HRQOL-D developed during Phase I.

Phase I: Step1 - Definition and Content Domain Construction. The definition and content domains of HRQOL, within the contexts of dialysis and the Thai culture, was determined as a result of a thorough review of both the literature and existing HRQOL instruments (between 1981 and 2010), as well as semi-structured interviews with patients experiencing either HD or PD. The literature review revealed that although diverse definitions of HRQOL exist, the various definitions tend to address five major areas: having happiness/ satisfaction; living a normal life; achieving personal

goals; maintaining physical and/or mental capacities; and, having a social life.[21] Other descriptions of HRQOL found were: "good health or good life",[22, 23] and "being healthy or being happy."[24]

Review of the literature also revealed a variety of both generic and disease-specific instruments addressing HRQOL. The generic instruments commonly used with individuals undergoing renal disease included the: Sickness Impact Profile (SIP);[25] Nottingham Health Profile (NHP);[26] Medical Outcomes Study Short Form-36 (SF-36);[27] World Health Organization Quality of Life Questionnaire (WHOQOL);[28] and, European QOL Assessment/ EuroQoL (EQ-5D).[29] The renal disease-specific HRQOL instruments were found to include the: Quality of Life Index-Dialysis Version (QLI);[30] Kidney Disease Quality of Life (KDQOL);[31] CHOICE Health Experience Questionnaire (CHEQ);[8,] and, Chinese Dialysis Quality of Life (CDQOL).[23] In order to be aware of HRQOL instruments that address illness unrelated to diseases or treatments of the kidney, such instruments as the Functional Assessment of Cancer (FACT-G)[32] and the European Organization for Research and Treatment of Cancer Quality of life (EORTC)[33] also were reviewed. It was interesting to note that among the existing HRQOL instruments the following dimensions tended to be present: physical health; psychological/ mental/ spiritual health; socioeconomic status; and, somatic/disease and treatment related symptoms.

Semi-structured interviews, via use of an interview guide, were conducted on 10 HD and 10 PD patients. The interview guide consisted of 12 questions that focused on patients' perspectives regarding: the meaning of QOL and its components; the impact of chronic kidney disease and dialysis; living with dialysis; and, indicators for having a good QOL. Examples of questions were: "What does quality of life mean to you?"; "How do you describe 'good' quality of life?"; "How do you describe the components of quality of life?"; and, "How does having chronic kidney disease and dealing with its related treatments affect your life?" All interviews were conducted by the PI, took approximately 45 to 60 minutes to complete, and were tape recorded and conducted in the dialysis units where patients were receiving care. Demographic characteristics were obtained via a demographic questionnaire, while health-related information were obtained from the patients' medical records. In addition, field notes were written to describe information that might be relevant to the content of the interview (i.e. environmental surroundings and non-verbal communications). The interviews and field notes were assessed via content analysis, by the PI and another member of the research team, resulting in the emergence of themes and categories that assisted in determining the definition of the HRQOL and its domains. The outcome of the literature review, review of existing HRQOL instruments and interviews suggested the following definition and domains for an HRQOL instrument for use with dialysis patients (i.e. THAI-HRQOL-D): "Personal perceptions of life satisfaction in important dimensions, which include health and functioning, psychological/spiritual well-being, socioeconomics, family, and living with dialysis."

Phase I: Step 2-Item Generation. The second step of Phase I involved generation of an item pool for each of the identified dimensions of HRQOL. Item generation was carried out based upon the information gained during step one of Phase I. The first draft of the THAI-HRQOL-D consisted of 55 items that were divided into two parts. Part I had five dimensions with 39 items: health and functioning (11 items); psychological/spiritual well-being (9 items); socioeconomics (8 items); family (6 items); and, living with dialysis (5 items). Part II contained 16 items requesting the frequency and impact of 16 common renal disease symptoms. The rationale for Part II of the instrument was based upon the fact that the effects of symptoms, on daily living, have been found to be strong indicators for HRQOL.[5, 11]

Phase I: Step 3-Determination of the Scaling Format. Step 3 of Phase I involved determining the scaling format for the THAI-HRQOL-D. Since the instrument was designed to assess the level of satisfaction with life (Part I), and frequency and impact of 16 renal disease symptoms (Part II), a five-point Likert-like scale (1 = not at all; 2 = a little bit; 3 = somewhat; 4 = quite a bit; and, 5 = very much) was developed. The score for Part I of the instrument was determined by summing responses across all 39 items, generating a possible score range of 39 to 195. The score for Part II was determined by summing across all 16 items for both frequency and impact, and then dividing by 2 to obtain a mean frequency-impact score. The possible range for a score for Part II was 16 to 80. The scores for both Part I and Part II of the THAI-HRQOL-D instrument were added together to obtain a total score, which could range from 55 to 275. A high score suggested a high level of HRQOL.

Phase I: Step 4-Item Review and Face Validity Examination. Review of the items and examination of the THAI-HRQOL-D instrument's face validity made up step 4 of Phase I. A panel of seven experts in HRQOL concept and measurement development, and dialysis patient care took part in this process. The panel members were asked to assess each item for relevance, clarity and language appropriateness. Based upon the panel's suggestions, a second draft of the instrument was developed, which involved the addition of two items to Part I (one item, addressing helpfulness for others, was added to the health and functioning domain, and one item, addressing standard of living, was added to the social and economics domain) making a total of 41 items. Part II of the instrument involved no changes. The item-level CVI (content validity index), generated by the expert panel, was found to range from 0.571 to 1.00, while the scale-level CVI (an average proportion) was 0.949.

The second draft of the THAI-HRQOL-D instrument and a demographic data questionnaire, that requested information about each subject's gender, age, length of dialysis, religion, marital status and current employment, were verbally administered, by the PI, to five HD and five PD patients. These 10 patients were used for the purpose of determining the instrument's face validity. Each verbal administration took approximately 30 to 45 minutes to complete. The patients reflected on problems regarding clarity of wording and the appropriateness of questions. Based upon their input, a third draft of the instrument was developed. Revisions to the instrument involved addition of an item (i.e. on mental status related to sexual health) to Part I, making a total of 42 items. Part II of the instrument remained unchanged.

Phase I: Step5- Pilot Testing. The final step in Phase I involved pilot testing the third draft of the THAI-HRQOL-D for the purpose of assessing its initial psychometric properties and identifying inappropriate items. This step involved administration, by the PI, of the THAI-HRQOL-D, along with a demographic data questionnaire to a convenience sample of 20 HD and 20 PD patients. The questionnaires took an average of 25 minutes to complete. The findings showed Cronbach's alpha for the total scale was 0.82, while the range of Cronbach's alpha for each item ranged from 0.78 to 0.82. Almost all items (n = 47; 81%) had corrected item-total correlations between 0.30 and 0.80. As a result of the pilot test, all instrument items were retained for further psychometric testing.

Phase II: Testing of Psychometric Properties. The focus of Phase II was final testing of the psychometric properties (construct, convergent and concurrent validity, and internal consistency reliability) of version three of the THAI-HRQOL-D. The revised THAI-HRQOL-D and a revised demographic questionnaire, that requested information about each subject's gender, age, education level, length of dialysis, religion, marital status, current employment, hospitalization, receipt of erythropoietin hormone supplement and presence of co-morbidities, was administered, by the PI, to 210 HD patients and 210

PD patients being seen in one of the dialysis units used as a study site. The subjects completed both questionnaires in about 20 minutes.

Information from the demographic questionnaire and the scores for the THAI-HRQOL-D were assessed using descriptive statistics. Construct validity was determined via principal component analysis (PCA) for exploratory factor analysis and structural equation modeling for confirmatory factory analysis. The PCA with orthogonal varimax rotation was conducted to extract the factors for Part I of the instrument. The criteria used to select the number of factors were: an eigenvalue of more than one; characteristics of the screen plot of the eigenvalues; at least three items substantially loading on a factor; a variance of 50%-60% being explained; and, meaningful interpretability.[34, 35] Finally, the independent t-test and Chi-Square test (Pearson Chi-Square and Fisher's Exact test) were used, based on the type of data and the assumptions of each statistical test, to determine if there were characteristic differences between subjects used for the exploratory factor analysis and those used for the confirmatory factor analysis.

Due to the number of symptoms and redundancy of items in Part II of the THAI-HRQOL-D, the clinical impact method and symptom clustering were performed to select the most relevant symptoms reflecting HRQOL in dialysis patients. Clinical impact scores (a clinical metric strategy for item reduction) were based on the participants' rating of frequency and impact of each symptom. The mean frequency-impact scores of each symptom were calculated as the clinical impact score.[36, 37] Symptoms with the highest mean scores and representing each symptom cluster were identified as important symptoms to be included in the final version of the THAI-HRQOL-D.

Convergent validity was assessed via Pearson's correlation between the THAI-HRQOL-D instrument and the Thai Health Status Assessment Instrument (9-Thai).[12] The 9-Thai, a generic health status measure (4 items of physical status, 3 items of mental health and 2 items of global health status) was developed and used as part of the 2003 Thai National Health and Welfare Survey.[38] Prior use of the 9-Thai, with the general population and patients on renal replacement therapy, demonstrated evidence of good instrument validity and reliability.[12, 38]

Multivariate regression analysis was carried out with adjusted confounding variables (age, gender, education, dialysis modality, duration of dialysis, hospitalization and co-morbidity) for assessing concurrent validity through the relationships between HRQOL and concurrent clinical measures (i.e. hematocrit level and serum albumin level) obtained from patients' medical records. Moreover, the independent t-test and Mann Whitney U-test were conducted to determine differences within the THAI-HRQOL-D (overall HRQOL and each domain score) between dialysis patients with and without a history of hospitalization in the last year. The instrument's internal consistency reliability was assessed by Cronbach's alpha coefficient for each of the subscales and the overall scale.

Results

The findings from the exploratory factor analysis suggested the presence of six factors, along with the elimination of nine of the 42 items because of low communality, a factor loading of less than 0.35, item loading on more than one factor, or no contribution to factor interpretability.[34] Although one item (feelings of depression, stress or anxiety) demonstrated a slightly low factor loading (0.348), it was retained due to its strong theoretical support for assessing QOL.[5, 11] The remaining 33 items in the scale were re-analyzed in a second factor analysis together with six important symptoms having the highest clinical impact scores (i.e. 2.09 to 2.87). The symptom cluster method also revealed the same six symptoms (fatigue/lack of energy [2.87]; thirst [2.47]; shortness of breath [2.46]; anorexia [2.42]; muscle

or bone pain [2.30]; and, dizziness or fainting [2.09]). The mean scores of the response in frequency and impact of these six symptoms, in each subject, were used to formulate the extracted factors in this step. The findings revealed seven extracted factors: health and functioning; psychological well-being; socioeconomics and family; living with dialysis; spirituality; living with symptoms; and, cognition. Four symptoms (anorexia, muscle or bone pain, shortness of breath, and dizziness or fainting) strongly loaded on the Factor 6. Additionally, item 8 (ability to sleep and rest), which initially loaded on Factor 1, also loaded on Factor 6. The symptoms, fatigue/lack of energy and thirst, loaded on both Factor 1 and Factor 4. As a result, they were eliminated due to the fact they reflected the same meaning, respectively, as item 2 (having enough energy to do activities) in Factor 1and item 15 (difficulty in water restriction) in Factor 4.The final results being the presence of 37 items in the THAI-HRQOL-D

A third factor analysis was conducted, using the 37 remaining items, and revealed the same seven extracted factors that accounted for 54.86% of the total variance (see **Table 1**). Part I of the instrument consisted of 32 items (Factors: 1, 2, 3, 4, 5 and 7) and Part II consisted of 5 items (Factor 6).

Table 1 Exploratory factor analysis of the THAI-HRQOL-D (n = 420)

Items	Statements	Factor loadings	Communalities (h^2)
Factor 1: Health and Functioning (10 items) with Eigen value = 5.601, percent of variance = 15.137			
7	How much are you satisfied with your duty and responsibility in the family?	.772	.631
3	How much are you able to help yourself in doing activities of daily living (i.e., eating a meal, going to the restroom, taking a shower, or getting dressed)?	.759	.641
6	How much are you satisfied with your capability to work, do housework or study?	.752	.629
2	How much power/energy do you have to do your activities of daily living?	.727	.605
4	How much are you able to engage in recreation, hobbies, or any activity you like (i.e., watching TV, listening to music, reading books, playing sports or relaxing)?	.689	.546
38	How much do you feel that you are dependent on your family, since being ill?	.647	.499
5	How much are you able to adapt your lifestyle and manage your activities of daily living?	.644	.554
23	How much are you satisfied with your ability to control and prevent complications and disease severity?	.575	.463
1	How much are you satisfied with your general health?	.530	.474
13	How much do you feel that illness and dialysis are limitations in traveling by yourself or traveling long distances (i.e., going to other provinces, visiting family members or taking a trip)?	.356	.385
Factor 2: Psychological Well-being (7 items) with Eigen value = 3.442, percent of variance = 9.303			
39	How much do you worry or feel uncertainty about you future?	.678	.573
40	How much do you feel illness is the barrier to expected goal achievements and life accomplishments?	.640	.574
17	How much do figure, body image, skin color change, and the presence of a wound/dialysis catheter or vessel/AV shunt cause you to worry?	.604	.531
22	How much does the hope to have a renal transplant affect your feelings/ happiness in life?	.601	.421
12	How much does your sexual health affect your mental status?	.573	.376
18	How often do you feel worried/stressed or depressed with your illness?	.518	.589
27	How much does your disease/ illness affect your ability to control your emotions?	.507	.384

Table 1 Exploratory factor analysis of the THAI-HRQOL-D (n = 420) (Continued)

Items	Statements	Factor loadings	Communalities (h^2)
Factor 3: Socioeconomics and Family (5 items) with Eigen value = 3.136, percent of variance = 8.477			
32	Compared to other families in the community, how much are you satisfied with your social status, finances and family's living conditions?	.793	.727
33	How sufficient is your budget for daily living expenses and medical treatments?	.760	.668
34	How much are you satisfied with your family's care and attention?	.754	.638
37	How much are you satisfied with your housing and surroundings?	.686	.543
28	How much are you satisfied with your relationships with spouse/ family members and doing family activities together?	.671	.566
Factor 4: Living with Dialysis (4 items) with Eigen value = 2.325, percent of variance = 6.285			
14	How much difficulty do you have in changing your dietary behavior following dialysis?	.897	.871
15	How much difficulty do you have in changing your behavior of drinking water following dialysis?	.891	.857
9	How much does your wound/peritoneal drain or vessel/AV shunt affect your activities of daily living?	.396	.430
10	How much do treatment activities (i.e. caring and changing peritoneal dialysate, hemodialysis, and meeting with doctors) cause a burden on your time each day?	.356	.385
Factor 5: Spirituality (3 items) with Eigen value = 1.991, percent of variance = 5.382			
20	How much inspiration do you have after engaging in religious activities (i.e. going to temple/church/mosque, praying and making merit)?	.897	.831
21	How much do you accept your illness according to the following phrase: "Illness is common for life or is the consequence of past actions (Buddhism); or illness is the fate determined by God or the repayment for sin (Christianity or Islam)"?	.879	.794
19	How much are you able to prepare for and accept your illness ("thumjai")?	.401	.504
Factor 6: Living with Symptoms (5 items) with Eigen value = 1.958, percent of variance = 5.292			
s6	How much does muscle/bone pain bother your daily living?	.630	.434
s2	How much does dizziness/fainting bother your daily living?	.542	.414
s3	How much does shortness of breath bother your daily living?	.542	.421
s8	How much does anorexia bother your daily living?	.502	.367
8	How much are you able to sleep and rest as needed?	.354	.302
Factor 7: Cognition (3 items) with Eigen value = 1.846, percent of variance = 4.989			
25	How often do you forget things or forget to do intended work?	.662	.562
24	How often do you feel distracted from doing activities?	.654	.613
26	How confident do you feel about thinking and making decisions about do things by yourself?	.472	.497

Note: S = symptom

Second order, confirmatory factor analysis (CFA) was carried out to confirm the factor structure of HRQOL. Structural equation modeling, with maximum likelihood estimation (MLE), was performed to verify the hypothesized structure through use of a data set from 210 (minimum recommended sample size was 200)[20] of the 420 original subjects used in Phase II of the study. The 210 subjects: ranged in age from 18 and 82 years (mean = 52.71); had been receiving dialysis between 3 to 257 months (median = 24); primarily were females (54.3%); predominately were Buddhist (91.9%); had a history of being hospitalized (65.7%); and, had hypertension (91.9%) and/or diabetes mellitus (36.2%). When these demographic characteristics were compared to the demographic characteristics of the original 420 subjects, no significant differences were noted.

As shown in **Table 2,** results of the CFA revealed the measurement model provided an acceptable, but not perfect fit. The factor loadings ranged from 0.49 to 0.87, and the construct reliabilities (square multiple correlations of each dimension: R^2) performed an acceptable level of reliability ($R^2 \geq .25$) for a newly developed instrument.[18] These findings suggested all seven dimensions and 37 items were contributing to the measurement of HRQOL.

Table 2 Model fit assessment of the THAI-HRQOL-D (Second-order CFA)

	Fit indices					
	χ^2 = 892.53 *df* = 603 ($p < .001$)	χ^2/df	GFI	CFI	RMSEA	PNFI
		1.48	.82	.90	.04	.81
Acceptable values for model fit		≤ 2	≥ .90	≥ .90	≤ .08	≥ .90

Note: CFA = Confirmatory Factor Analysis; GFI = Goodness of Fit Index; CFI = Comparative Fit Index; RMSEA = Root Mean-Square-Error of Approximation; PNFI = Parsimonious Normed Fit Index

Pearson's correlation coefficient between the THAI-HRQOL-D and the 9-THAI revealed good convergent validity ($r = .63$, $p < .01$).[34, 35] Multivariate regression analysis, with adjusted confounding variables (age, gender, education, dialysis modality, duration of dialysis, hospitalization, and co-morbidity) for assessing concurrent validity through the relationships among HRQOL and concurrent clinical measures, revealed the albumin level was positively correlated with the THAI-HRQOL-D. Moreover, results of the independent t-test and Mann Whitney U-test, to determine if there were differences in the results of the THAI-HRQOL-D (overall HRQOL and each dimension score) between dialysis patients with and without a history of hospitalization over the past year, found dialysis patients who had been hospitalized had lower HRQOL than those who had not been hospitalized. Such a finding supported the concurrent validity of the THAI-HRQOL-D.

Internal consistency reliability assessments, with Cronbach's alpha coefficient for each of the subscales and the overall scale, are presented in **Table 3.** An alpha coefficient of at least 0.7 indicates sufficient reliability for a new instrument.[35] The dimension, living with symptoms, had a slightly lower alpha coefficient (0.557) than the other six dimensions. No doubt this was because the four symptoms listed in this dimension could not be expected to be correlated with each other or to occur together (different symptom clusters). The corrected item-to-total correlations ranged from 0.300 to 0.644 and, thereby, demonstrated an acceptable range for supporting the presence of the THAI-HRQOL-D's internal consistency.[34, 35]

Table 3 Cronbach's alpha coefficients of the THAI-HRQOL-D

Scale/Sub-scales	Number of Items	Cronbach's Alpha Coefficients
THAI-HRQOL-D instrument	37	.842
Health and functioning	10	.889
Psychological well-being	7	.749
Socioeconomics and family	5	.813
Living with dialysis	4	.727
Spirituality	3	.721
Living with symptoms	5	.557
Cognition	3	.714

Discussion

The THAI-HRQOL-D, a new specific HRQOL instrument for Thai dialysis patients, was developed through qualitative and quantitative approaches during instrument formation and validation. Construction of the conceptual definition of HRQOL and the content domains of the instrument, within the context of the Thai culture, were performed based on semi-structured interviews and a comprehensive review of the literature. These approaches provided a meaningful definition and helped to capture the culturally relevant themes and contents for the THAI-HRQOL-D items.[19, 39] Instrument items were reviewed by content experts for content validity and the resulting refined draft of the instrument were reviewed, for face validity, by dialysis patients. These approaches contributed to: inclusion of appropriate items and dimensions in the THAI-HRQOL-D; assuring good reliability and validity of the instrument; and, easy administration of the instrument, via self-report or interview.[19]

Five dimensions emerged from the semi-structured interviews including: health and functioning; psychological/spiritual well-being; socioeconomics; family; and, living with dialysis. Consistent with a content analysis of QOL among Thai HD patients,[24] the concept was composed of health and functioning, psychology, socioeconomics, family, healthcare provider, and the law of Karma. In this study, "health care provider" was manifested within the dimension of "socioeconomics," while the "law of Karma," in terms of accepting illness and one's life condition, was within the dimension of "psychological/spiritual well-being". The THAI-HRQOL-D's definition of health, similar to the one proposed by the World Health Organization,[28] reflected a multidimensional perspective that included socioeconomics, social support and cultural beliefs.[40, 41]

The clinical impact scores were found to be useful in terms of identification of the most relevant symptoms, for this population, for inclusion as an instrument item. The final version of the THAI-HRQOL-D consisted of 37 items within seven dimensions: health and functioning; psychological well-being; socioeconomics and family; living with dialysis; spirituality; living with symptoms; and, cognition. The majority of these dimensions were related to those proposed in Ferrans' model.[21] The health and functioning domain, in the initial structure of the instrument, was found to require a division into three dimensions: "health and functioning"; "living with symptoms"; and, "cognition." This finding is consistent

with prior studies on HRQOL instruments.[8, 28, 33] Since the THAI-HRQOL-D was specifically designed for assessing HRQOL in dialysis patients, it was appropriate to count "living with dialysis" and "living with symptoms" as separate dimensions.[11, 42] Living with dialysis and symptoms could reflect the degree of which the patients were concerned about their dialysis treatment and symptom experiences and might signal a change in their QOL. The "psychological and spiritual well-being" dimension separately loaded as "psychological well-being" and "spirituality". This was found to be unique for this study, but was congruent with a previous study of QOL in Thai HD patients[24] that suggested belief systems play an essential role in personal values of QOL. Spirituality (i.e. "believing in the Law of Karma"), in this study, was found to have the same meaning as "understanding and accepting illness" in other religious beliefs, as well as found to differ from the dimension of "psychological well-being." The two dimensions, "socioeconomics" and "family," from the initial structure of the instrument, were found to load onto one dimension, "socioeconomics and family." Such a finding suggests various aspects of the family (relationships, social status, economics and support) are interrelated. The fact the initial instrument dimensions, "socioeconomics" and "family," became one dimension (i.e. "socioeconomics and family") is different from findings of prior studies on HRQOL instruments.[8, 23] This could be attributed to the fact that prior instruments did not focus specifically on family relationships or support.

The psychometric data suggested the THAI-HRQOL-D had sufficient reliability and validity for a new instrument. Cronbach's alpha coefficient of the scale was 0.842 and the subscales were more than 0.700. The "living with symptoms" dimension had a slightly lower alpha coefficient (0.557) than the other six dimensions. No doubt this was because the nature of each symptom was different and the symptoms could not be expected to be correlated with each other or to occur together (different symptom clusters).

Correlation between the THAI-HRQOL-D and the 9-THAI provided support for convergent validity (r = 0.63). The significant relationships found between the THAI-HRQOL-D and a concurrent clinical measure (albumin level) and hospitalization supported concurrent validity of the instrument. This finding was congruent with those of prior studies of patient with chronic kidney disease.[12, 42]

In conclusion, development and testing of the THAI-HRQOL-D resulted in an explanation of variables contributing to HRQOL for patients undergoing dialysis. In addition, the instrument was found to be a valid and reliability means of measuring HRQOL among Thai dialysis patients.

Limitations and Future Research

Although this study found the THAI-HRQOL-D to be an appropriate means of measurement of HRQOL among Thai dialysis patients, there are limitations in this study that need to be taken into consideration. First, only four dialysis centers were used in this study and the centers were primarily located within hospitals in the greater Bangkok area. Thus, future studies need to test the instrument on patients receiving dialysis in non-hospital related dialysis centers (i.e. private dialysis centers) and in other regions of Thailand. Second, the THAI-HRQOL-D had numerous items that consisted of rather long questions and it did not request the level of one's HRQOL. Future studies, therefore, need to develop a shorter version of the instrument that also examines the respondent's level of HRQOL. Lastly, due to a non-perfect fit of the measurement model, as reflected in the confirmatory factor analysis, a competing model, along with a larger sample size, needs to be considered in future studies.

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การพัฒนาและคุณสมบัติการวัดทางจิตวิทยาของเครื่องมือประเมินคุณภาพชีวิตด้านสุขภาพในผู้ป่วย Dialysis

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บทคัดย่อ: การศึกษานี้มีวัตถุประสงค์เพื่อพัฒนาและทดสอบคุณสมบัติการวัดทางจิตวิทยาของเครื่องมือประเมินคุณภาพชีวิตด้านสุขภาพในผู้ป่วย dialysis (THAI-HRQOL-D)โดยความหมายและองค์ประกอบของคุณภาพชีวิตด้านสุขภาพในการศึกษาครั้งนี้ได้พัฒนามาจาก การวิเคราะห์เนื้อหาจากการสัมภาษณ์เชิงโครงสร้างและการทบทวนวรรณกรรมที่เกี่ยวข้อง โดยมีกรอบทฤษฎีในการศึกษาคือกรอบแนวคิดคุณภาพชีวิตของ Ferrans เครื่องมือนี้ผ่านการตรวจสอบความตรงเชิงเนื้อหาจากผู้เชี่ยวชาญจำนวน 7 คน ทดสอบความยากง่ายและความเข้าใจข้อคำถามในผู้ป่วย dialysis จำนวน 10 คน และทดสอบคุณสมบัติการวัดเบื้องต้น และความเหมาะสมของข้อคำถามในผู้ป่วย dialysis จำนวน 40 คน

ทดสอบคุณสมบัติของเครื่องมือในผู้ป่วย dialysis จำนวน 420 คน ที่ได้รับบริการบำบัดทดแทนไตในเขตกรุงเทพมหานครจำนวนสองศูนย์ รวมทั้งหน่วยไตเทียมมูลนิธิโรคไตแห่งประเทศไทย ณ โรงพยาบาลสงฆ์ และอีกหนึ่งศูนย์บริการบำบัดทดแทนไตในจังหวัดสมุทรสาคร โดยทดสอบความตรงเชิงโครงสร้างด้วยการวิเคราะห์องค์ประกอบเชิงสำรวจ และการวิเคราะห์องค์ประกอบเชิงยืนยัน

ผลการวิเคราะห์พบว่าแบบประเมินคุณภาพชีวิตด้านสุขภาพประกอบด้วย 7 องค์ประกอบ 37 ข้อคำถาม ซึ่งสามารถอธิบายความแปรปรวนได้ทั้งหมด 54.86% ประกอบด้วย 1) สุขภาพและการทำหน้าที่ของร่างกาย 2) ความผาสุกทางจิตใจ 3) เศรษฐกิจ-สังคม และครอบครัว 4) การดำรงชีวิตอยู่กับการฟอกไต 5) จิตวิญญาณ 6) การดำรงชีวิตอยู่กับอาการแสดง และ 7) การรู้คิด โมเดลการประเมินคุณภาพชีวิตด้านสุขภาพมีความสอดคล้องกับข้อมูลเชิงประจักษ์อยู่ในเกณฑ์ดี (χ^2=892.53, *df* = 603 (p<.001), χ^2/df =1.48, RMSEA=.048, GFI =.820, CFI=.904) เครื่องมือนี้มีค่าความเที่ยงชนิดสอดคล้องภายใน (Cronbach's alpha coefficients) ของแต่ละองค์ประกอบ .557 ถึง .889 และของเครื่องมือทั้งฉบับ .842 นอกจากนี้ยังมีคุณสมบัติของความตรงเชิงเหมือน โดยสัมประสิทธิ์สหสัมพันธ์ระหว่าง คุณภาพชีวิตด้านสุขภาพของ THAI-HRQOL-D และ Thai Health Status Assessment Instrument เท่ากับ .63 และมีคุณสมบัติความตรงเชิงสัมพันธ์กับเกณฑ์ ระหว่าง คุณภาพชีวิตด้านสุขภาพของ THAI-HRQOL-D กับเกณฑ์ประเมิน 2 เกณฑ์คือ ระดับอัลบูมินในเลือด และประวัติการเข้ารับการรักษาในโรงพยาบาลของผู้ป่วย dialysis ดังนั้นเครื่องมือที่พัฒนาใหม่นี้มีความตรงและความเที่ยงในการประเมินคุณภาพชีวิตด้านสุขภาพในผู้ป่วยไทยที่ได้รับการรักษาด้วยวิธี dialysis

Pacific Rim Int J Nurs Res 2012 ; 16(2) 154-168

คำสำคัญ: คุณภาพชีวิตด้านสุขภาพ การพัฒนาเครื่องมือวัด คุณสมบัติการวัดทางจิตวิทยา ผู้ป่วย dialysis

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