Dialysis Modality and Health-Related Quality of Life of Persons with End Stage Renal Disease

by

Luxana Reynaga-Ornelas

A Dissertation Presented in Partial Fulfillment
of the Requirements for the Degree
Doctor of Philosophy

Approved November 2011 by the
Graduate Supervisory Committee:

Carol M. Baldwin, Chair
Stuart F. Quan
Kimberly Arcoleo

ARIZONA STATE UNIVERSITY

December 2011

ABSTRACT

Health-related quality of life (HR-QOL) is a significant treatment outcome for persons with end-stage renal disease (ESRD); however, little is known about the HR-QOL of Mexican patients with ESRD. This pilot study describes relationships between demographics, sleep disorders, spirituality, mood, folk practices and dialysis modality on the HR-QOL of patients with ESRD residing in Guanajuato, Mexico.

Mexican patients receiving continuous ambulatory peritoneal dialysis (CAPD), automated peritoneal dialysis (APD) and hemodialysis (HD) provided information on demographics, clinical health data including body mass index (BMI), and folk health practices. Measures included the Short Form (SF)-36 HR-QOL survey, Sleep Habits Questionnaire, Latin Spirituality Perspective Scale and Hospital Anxiety and Depression Scale. Data were analyzed using SAS software (V9.1). Significance level for this pilot study was set at $p<0.10$. The Quality-Adjusted Life Year method was utilized to examine cost effectiveness for each dialysis modality.

Demographics and clinical data showed participants (*N*=121) to be 59 (*SD*=13) years, predominantly men (55.4%), married (66.9%), Catholic (92.6%), and not currently working (78.3%). The majority were diabetic (72%) and slightly overweight (BMI *M=26.1; SD=5.1*). The CAPD group (*n=39*) demonstrated significantly lower HR-QOL scores compared to the APD (*n=42*) and HD (*n=40*) groups. Patients on HD reported higher rates and greater numbers of sleep disorders, including insomnia symptoms, non-restorative and insufficient sleep,

and daytime somnolence compared to patients on CAPD and APD. Patients on CAPD reported more anxiety and depression compared to patients on HD and APD. Overall linear regression for HR-QOL found dialysis type, sleep disorders and income to be significant predictors and the model accounted for 31% of the variance. Cost analysis indicated APD as the preferred treatment because it is less costly and results in the best HR-QOL compared to the other treatment modalities.

Findings provide the first SF-36 norms for Mexicans with ESRD. Sleep disorders and dialysis type greatly impinge on the HR-QOL of these patients, particularly their mental health. APD was identified as the preferred treatment based on low cost and improved HR-QOL. Results can inform clinical care and health policy for Mexican patients with ESRD.

DEDICATION

To my wonderful family: my husband Luis Gerardo who was always understanding, loving and patient, my dear son Gerardo Javier and my precious daughters Ilse Paloma, Luxana and Julieta Amelie who are the joy of my life; to my parents Lupita and Javier, who showed me the value of science, art, love and the pursuit of academic excellence; and to my dearest and loving sisters Upis and Maye, who helped and have given me their fullest support. I also wish to dedicate this work to my friends, who have been always there throughout the process.

ACKNOWLEDGMENTS

I would like to acknowledge and thank my committee members, particularly to Dr. Carol M. Baldwin, for her generosity with her expertise and precious time. She provided the best guidance as a researcher and as a person. She was committed to my studies giving reflecting and encouraging advice throughout the entire program. Special thanks to Dr. Stuart Quan for sharing his vast expertise as a sleep researcher and clinician and Dr. Kim Arcoleo, who wisely conducted me through the statistical analysis, always giving kind advice and strong support.

I want to recognize Dr. Bernadette M. Melnyk for sharing the spirit of scientific inquiry and the inspiration to dream, discover and deliver. Thanks to Arizona State University, the Bardewyck Scholarship and the College of Nursing and Health Innovation for their continued assistance and support, especially to Levi Colton and Christina Peete.

A special recognition to the University of Guanajuato for supporting my scholarly pursuits through the PROMEP scholarship and, in particular to my mentor, teacher and friend, Cipriana Caudillo Cisneros, Dean of the Department of Nursing and Obstetrics for her unconditional support. Finally, I would like to acknowledge the nurses from the clinics that I visited: Eva, Yolanda, Martha, the social worker, Ofelia, the respective authorities from the ISSSTE at Irapuato, Guanajuato, Celaya and Leon cities for their availability and openness to support this project and, especially to the patients, who made this study possible.

TABLE OF CONTENTS

APPENDIX Page

LIST OF TABLES

Table Page

LIST OF FIGURES

LIST OF ABBREVIATIONS

APD = Automated Peritoneal Dialysis

BP = Blood Pressure

BMI = Body Mass Index

CAM = Complementary and Alternative Medicine

CHF = Congestive Heart Failure

CAPD = Continuous Ambulatory Peritoneal Dialysis

DIMS = Difficulty Initiating and Maintaining Sleep

ESRD = End-Stage Renal Disease

ESS = Epworth Sleepiness Scale

EDS = Excessive Daytime Sleepiness

HR-QOL = Health-Related Quality of Life

HD = Hemodialysis

HADS = Hospital Anxiety and Depression Scale

ICER = Incremental Cost-Effectiveness Ratio

IMSS = Instituto Mexicano del Seguro Social

ISSSTE = Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado

NREM = Non-Rapid Eye Movement (dream) sleep

N1 = Stage 1 (lightest stage) of non-rapid eye movement sleep

N2 = Stage 2 of non-rapid eye movement sleep

OSA = Obstructive Sleep Apnea

PLMD = Periodic Limb Movement Disorder

PEMEX = Petróleos Mexicanos

QALY = Quality Adjusted Life Year

QOL = Quality of Life

RT = Renal Transplantation

RLS = Restless Legs Syndrome

SP = Seguro Popular (Mexican health coverage for uninsured)

SF-36 = Short Form-36

SDB = Sleep Disordered Breathing

SHQ = Sleep Habits Questionnaire

SHHS = Sleep Heart Health Study

SES = Socioeconomic Status

SD = Standard Deviation

US = United States

WHO = World Health Organization

Chapter 1

INTRODUCTION

Overview

The increased prevalence of chronic diseases around the world has been well documented (Collins, Gilbertson, Snyder, Chen & Foley, 2010; Saran, Hedgeman, Huseini, Stack & Shahinian, 2010). The World Health Organization (WHO) has predicted the prevalence of type 2 diabetes to reach 366 million persons globally by 2030 (WHO, 2004). Type 2 diabetes is the leading cause of end-stage renal disease (ESRD) (Cusumano, García-García & González Bedat, 2009; Mendez-Durán, Méndez-Bueno, Tapia-Yáñez, Muñoz-Montes & Aguilar-Sánchez, 2010; Paniagua, Ramos, Fabian, Lagunas & Amato, 2007). In Mexico, the prevalence of type 2 diabetes is 14.4% (Instituto Nacional de Salud Pública, 2011); it is predicted that 18% of the adult population in Mexico will have type 2 diabetes by 2025 (Atkins & Zimmet, 2009). In 2007, the Mexican Kidney Foundation estimated that approximately 100,000 patients have ESRD. Of the Mexican patients receiving dialysis treatment, 80% were on Continued Ambulatory Peritoneal Dialysis (CAPD), 19% were on Hemodialysis (HD) and 1% was on Automated Peritoneal Dialysis (APD) (Fundación Mexicana del Riñón, 2007; Nissenson, 1994).

In the past, the intent of medical care for persons with ESRD was to improve survival. In recent years, however, the major treatment goal has been to improve their health-related quality of life (HR-QOL) (Harris, Lamping, Brown & Constantinovici, 2002). Thus, health services researchers have reported the need

to measure HR-QOL as a significant outcome for evaluating treatment of persons with ESRD (Anderson & Burckhardt, 1999). Patients' perceptions about their own wellness are also being recognized as an indicator to evaluate health care outcomes (Bakewell, Higgins, & Edmunds, 2002; Lii, Tsay, & Wang, 2007; Morsch, Goncalves, & Barros, 2006; Ware & Sherbourne, 1992;). Various HR-QOL models have been published in order to achieve a better understanding that allows for evidence-based psychosocial interventions (Cummings, 2005; Ferrans, Zerwick, Wilbur & Larson, 2005; Haas, 1999; Joyce, Hickey, McGee & O'Boyle, 2003; Rapkin & Schwartz, 2004; Schwartzmann, 2003; Souza & Chen, 2002; Taillefer, Dupuis, Roberge & Le May, 2003; Ventegodt, Merrick & Andersen, 2003; Wilson & Cleary, 1995).

Goals, Specific Aims and Hypotheses

Short-term goal. Perform a descriptive, cross-sectional study to examine associations between dialysis modality, demographic variables, sleep disorders, spiritual perspective, anxiety, depression, and folk practices on the HR-QOL of persons with ESRD residing in Guanajuato, Mexico.

Long-term goal. Utilize findings from this descriptive study to develop targeted interventions for sleep disorders that may impact the HR-QOL of persons with ESRD on 3 types of dialysis thereby reducing future health care costs by improving sleep.

Aim 1. To characterize the demographics, socioeconomic status (SES), health histories, prevalence rates and types of sleep disorders, folk practices used,

spiritual perspective, anxiety, depression, and HR-QOL scores of Mexicans with ESRD for each of 3 types of dialysis.

Aim 1 is descriptive in nature, therefore; no hypotheses are specified.

Aim 2. To analyze HR-QOL outcomes of Mexicans with ESRD on 3 modalities of dialysis controlling for demographics, SES, sleep disorder types, spiritual perspectives.

Research Question 1. Do HR-QOL, sleep disorders, spiritual perspective, anxiety, depression, and use of folk practices differ by dialysis modality?

Hypothesis 1. HRQOL, sleep disorders, spirituality, anxiety, depression, and use of folk practices will differ by dialysis modality.

Aim 3. To examine associations between cost effectiveness and dialysis modalities among Mexicans with ESRD.

Aim 3 is descriptive in nature, therefore; no hypotheses are specified.

Chapter 2

BACKGROUND LITERATURE

End-Stage Renal Disease (ESRD)

End-stage renal disease has been globally recognized as a complicated disease. In 2008, the number of patients with the disease was projected to increase to more than 2 million by 2010 (Pecoits-Filho et al., 2008), but in 2009 it had already been calculated to be 2.5 million. Current studies have predicted the prevalence to be 5.5 million patients by 2030 (Meichelboeck, 2011).

In the United States (US), the adjusted incidence rate of ESRD in 2006 reached 360 per million population (USRDS, 2008). After a 2.1% decline in 2007, it fell 1.1% in 2008, to 350.8 per million (USRDS, 2010). The prevalence rate for ESRD, adjusted for age, gender, and race rose 2.3% between 2005 and 2006 to reach 1,626 per million population (USRDS, 2008). In 2007 and 2008, the adjusted rate of prevalent cases of ESRD rose 1.9% to 1,699 per million population. This rate is nearly 20% higher than in 2000. The annual rate of increase has remained between 1.9% and 2.3% since 2003 (USRDS, 2010).

The increase in the incidence and prevalence of ESRD has resulted in significantly greater costs of care. Total US Medicare spending in 2008 was reported to be nearly $453.9 billion. The costs for ESRD rose to $26.8 billion — 5.9% of the entire Medicare budget, including Part D, and 6.6 % of the budget excluding Part D. This level has not changed over the past four years. The stability of costs is a result of comparable growth in both the Medicare and ESRD programs, which has kept proportional costs constant (USRDS, 2010).

Because renal transplant (RT) opportunities are relatively limited, hemodialysis (HD) is the initial treatment of choice for the majority of patients with ESRD in the US. Approximately 94% of incident patients begin treatment with HD, amounting to 101,033 patients in 2008 (USRDS, 2010). Ninety-two percent of prevalent patients on dialysis are prescribed this mode of therapy (347,150 patients as of 2008 [USRDS, 2010]).

In Latin America, the prevalence and incidence of ESRD is variable, but the growth trend is similar to the US. As the distribution of patients by therapy and the sources of funding for dialysis therapy are determined by the local health care financial systems, they often vary widely from country to country. In 2006, Mexico reported the prevalence and incidence rates of ESRD of 510.4 and 345.9 per million population, respectively. The lack of a formal national registry system in Mexico, however, could result in underestimation of these rates (Cusumano, et al., 2009). In 2005, the prevalence rate for creatinine clearance less than 15 mL/min (considered as renal failure) was 1,142 per million population just in the Mexican state of Michoacan (Amato et al., 2005). Furthermore, in 2007 the Mexican Kidney Foundation reported 100,000 persons diagnosed with ESRD in Mexico (Fundación Mexicana del Riñón, 2007). These numbers are similar to the ESRD prevalence rates in developed countries. The presence of malnutrition, diabetes, reduced access to high quality health care and a minimal 6% of the national gross product spent on health care in a developing country such as Mexico, are several factors that can influence clinical and HR-QOL outcomes (Cueto-Manzano & Rojas-Campos, 2007).

Mexican Health Care

Health System. Figure 1 illustrates the organizational structure of the health insurance system in Mexico**.** The private sector in Mexico only covers 3% of the entire population, usually wealthy, private insurance or medical tourism (Whyte, 2009). The public sector is the primary provider of health services for 55 million salaried workers in the formal sector, also called the social security institutions. The services are paid by the employee (according to their salary), the government, and the employer. The Mexican Institute of Social Security (IMSS) is the second largest provider with 44.5 million people. The Insurance and Social Service Institute for State Workers (ISSSTE) covers 10.6 million workers, followed by Petróleos Mexicanos (PEMEX) with 700,000 insured petroleum workers, then the Secretariat of National Defense (SEDENA) that covers 600,000 military and their dependents (Pan American Health Organization, 2007).

Informal workers, rural populations, and the unemployed account for 45 million people and are expected to be covered by the Seguro Popular (SP), a recent strategy that the Mexican Health Ministry has implemented to achieve universal coverage in Mexico. It is expected to change the entire health system structure (García-García, Reniorte-López & Márquez-Magaña, 2010) (See Figure 2).

ESRD Treatment. Treatment for ESRD has physiological, psychological, socio-economic, and spiritual implications for the individual, family, and community (Schatell & Witten, 2008). The number of patients receiving renal replacement in Mexico increased at an annual rate of 10% from 2001 to 2005

(Cueto-Manzano, et al., 2007). The most common treatment for ESRD in Mexico is continuous ambulatory peritoneal dialysis (CAPD), which is a manual therapy done at home 4 times a day using a double bag device to introduce and exchange the fluid through the abdomen. Another dialysis modality, the automated peritoneal dialysis (APD), was introduced in 1998 and has increasingly been implemented using a machine to assist delivery and drainage of dialysate to the peritoneal cavity during the night in the patient's home. The third modality, hemodialysis (HD), is performed in specialized centers or units next to the hospitals where the patients attend their programmed sessions 2-3 times per week, 3-4 hours in length, day or night. In 2007, the Mexican Kidney Foundation estimated that approximately 100,000 patients have ESRD. Of the Mexican patients receiving dialysis treatment, 80% were on CAPD, 19% were on HD and 1% was on APD (Fundación Mexicana del Riñón, 2007). Although RT is the optimal intervention, there was only a 10% annual growth for this option from 2001 to 2005 (Cueto-Manzano, et al., 2007).

Cost Coverage for Dialysis. Seventy-five percent of the patients on PD are treated in the IMSS, 13% in the ISSSTE, 7% in what now would be SP, and 5% in private settings. Sixty-eight percent of the patients on HD are treated in the IMSS, 8% in the ISSSTE, 3% SP, and 21% in private settings. García-García et al. (2010) have reported differences between uninsured and insured patients related to access to a renal replacement therapy. They found an incidence rate of 99 versus 327 patients per million population and a prevalence rate of 166 versus 939 patients per million population. The type and quality of care offered at the

different social security institutions is limited due to government economic constraints. The annual costs of treating ESRD estimated by Prieto, Bhattacharyya, Divino & Paniagua (2007) are $24,032 USD/patient and $15,724 USD/patient for HD and PD, respectively. These costs included drugs, supplies, hospitalization, treatment-related infections, infrastructure and physician and nurse fees as direct treatment-related costs and the indirect costs related to work loss and patient transportation.

The risk of death has been reported to be higher for patients on PD than for HD patients after 1 year (Jaar et al, 2005; McDonald, Marshall, Johnson & Polkinhorne, 2009) depending on age, time in dialysis, and presence of comorbidities (McDonald, 2009). Small differences were observed in the quality-adjusted life year (QALY) score that compared PD versus HD on an ESRD population in the Netherlands; the long-term survival hazard radio favored PD (Eryavuz et al, 2008; Korevaar et al, 2003).

There are medical and non-medical factors that influence the selection of the optimal renal replacement therapy for the patient with ESRD. The few possibilities of RT limit the options available to be HD or PD (CAPD/APD). Paniagua and colleagues (2007) indicated that only 35% of patients participated in modality selection. Generally, patients do not have the opportunity to choose the type of treatment because there may only be one modality available in the dialysis unit, or a relative or the physician made the decision for the patient. Few patients sign an informed consent, or have a clear understanding of treatment prior to having the catheter installed. Hence, in addition to multiple medications, dietary

restrictions, and comorbid conditions, these patients now confront a new and unknown situation with dialysis.

According to Cueto-Manzano (2007), non-medical factors seem to be more significant than medical factors when prescribing a treatment to an ESRD patient in Mexico. Similar to other countries studied, patient characteristics like autonomy, scheduling, and maintaining their current lifestyle are major factors in patients' decisions about dialysis modality (Johansen, 2011). Nephrologists' recommendations, as recently observed in the Philippines, can also be based on overall cost, renal residual function preservation, patient preference, and availability of dialysis support staff (Cruz et al., 2011).

Some security institutions in Mexico have a policy of using CAPD as the first line of treatment, and HD as a second option when PD fails. This should not be taken as a competition between therapies, but as suggested by Chaudhary, Sangha & Khanna (2011), as complementary therapies given the long-term goals for the patient. Thus, some of the compelling and constraining factors include financial, infrastructure, and human resources.

End-stage renal disease and HR-QOL

The intent of medical care in ESRD cannot be solely to improve survival. The effects of health, illness, impairment, and treatment on HR-QOL must be considered. It is measured by assessing physical, mental/cognitive, and social functioning, as well as cultural, emotional, spiritual, political, or societal attributes (Unruh, Weisbord & Kimmel, 2005). In chronic illnesses, however, it is difficult to say what it is health-related or non-health-related, as almost all areas of life are

affected by health (Ferrans, et al., 2005). Persons living daily with ESRD and its treatment have their own "perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns" (World Health Organization, 1995). Generally, persons with ESRD have reported poorer HR-QOL compared to the general population (Morales-Jaimes, Salazar-Martínez, Flores-Villegas, Bochicchio-Riccardelli & López-Caudana, 2007; Reina-Neyra, Cirera-Segura & Martin-Espejo, 2008; Rocco, Mercieri & Yavuzer, 2006; Rodríguez-Vidal et al. 2005; Varela, Vázquez, Bolaños & Alonso, 2011). Older patients perceived their HR-QOL to be poorer than young patients with ESRD in some dimensions (Grincenkov, et al., 2011; Kusumoto, Marques, Hass & Rodrigues, 2008; Reina-Neyra, 2008; Sandoval-Jurado, Ceballos-Martínez, Navarrete-Novello, González-Hernández & Hernández-Collin, 2007; Wehbe, Salazar, Vaccaro, Wehbe & Guerrero, 2004). In some studies, women reported worse physical and/or mental health (Kusek et al., 2002; Santos, Daher, Silva, Liborio & Kerr, 2009) or worse overall HR-QOL (Gil-Cunqueiro et al, 2003; Wehbe et al, 2004), while men reported poorer physical health in other studies (Bakewell et al., 2002; Sandoval-Jurado et al., 2007).

The major impact of ESRD on the physical domain of HR-QOL is consistently cited (Esquivel-Molina et al, 2009; Shrestha, Ghotekar, Sharma, Shangwa & Karki, 2008). Morsch et al. (2006) found that the ESRD Severity Index was strongly related to physical functioning. In their follow-up mortality study, persons with ESRD who had subsequently died reported worse perception

of their physical functioning than those who survived. Lii et al. (2007) showed statistically significant improvement in the physical component of HR-QOL indices following a psychosocial intervention.

With respect to emotional HR-QOL, Fowler and Bass (2006) reported a strong relationship between poorer HR-QOL and the degree to which emotions were provoked by having ESRD. Rodríguez-Vidal et al. (2005) reported that 45% of their subjects recognized emotional problems in daily life, with role emotional and vitality as the most affected domains. Other factors that were related to HR-QOL and mental health included depression (Cruz, Fleck, & Polanczyk, 2010; Esquivel-Molina et al., 2009; Lii et al, 2007; Morales-Jaimes et al., 2007; Varela et al., 2011; Vázquez et al., 2004), emotional defensiveness (Kaltsouda et al, 2011), poor functional independence (Rocco et al., 2006), anxiety (Varela et al., 2011;Vázquez, 2004), stress, affect and cognitive appraisal (Chan et al., 2011).

Relevant to the adequacy of dialysis, Martin and Thompson (2000) identified a single significant negative correlation between role physical and dialysis efficacy (Kt/V) whereas Paniagua, Amato, Vonesh, Guo, & Mujais (2005) reported no evidence of a long term benefit in HR-QOL on CAPD patients by increasing peritoneal small solute clearances. In their longitudinal study, Wu et al. (2004) found that SF-36 scores improved for HD patients at the end of one year, particularly vitality. This study also described significant independent predictors of higher physical health scores for patients on HD, including male sex, high serum albumin, less severe cardiac and pulmonary disease. On the other

hand, higher serum albumin, dialysis adequacy, and social support were significant predictors of better mental health scores for persons on HD.

Spiritual beliefs are related to HR-QOL and may act as coping mechanisms for patients with ESRD (Finkelstein, West, Gobin, Finkelstein & Wuerth, 2007; Kimmel, Emont, Newmann, Danko & Moss, 2003; Patel, Shah, Peterson & Kimmel, 2002). Patients in Taiwan on long-term HD who did not have strong spiritual beliefs showed worse HR-QOL scores (Tze-Wah et al., 2009), whereas spiritual distress and low existential well-being were associated with poor HR-QOL in Canada (Davison & Jhangri, 2010). Women reported higher religious, existential, and spiritual well-being, suggesting a gender difference for patients living with ESRD (Tanyi & Werner, 2003; Tanyi & Werner, 2008). Spinale and colleagues (2008) found an association between spirituality and survival in HD patients who participated in religious activities; the authors indicated that this association was most likely due to the increased perception of social support. Taken together, patients with ESRD appear to have unmet spiritual and supportive care needs that require a better understanding by health care professionals to guide interventions aimed at improving HR-QOL (Davison & Jhangri, 2010a).

Health-related Quality of Life and Dialysis Modality

Several extant studies have examined dialysis modality type on HR-QOL. Higher (better) scores for HR-QOL have been noted for PD compared to HD treatment for ESRD (Brown et al, 2010; Caballero-Morales, 2006; Frimat et al, 2006; Fructuoso, Castro, Oliveira, Prata,& Morgado, 2011; Ginieri-Coccossis,

Theofilou, Synodinou, Tomaras & Soldatos, 2008; Harris, 2002; Juergensen, Wuerth, Finkelstein, Juergensen & Finkelstein, 2006; Kutner, 2005; Mittal, 2001; Shrestha et al., 2008; Wu, 2004; Wu et al., 2001). Kutner et al. (2005) reported higher scores in PD patients for effects of kidney disease, staff encouragement, and satisfaction with care scales. In addition, Harris et al. (2002) reported less annual mortality and hospitalization rates among PD patients and another study reported the overall intention-to-treat mortality risk after dialysis initiation was 8% lower in PD versus HD matched patients (Weinhandl et al., 2010). Alternatively, a recent Canadian study showed no significant difference between HD and PD incidence rate ratios, rates of infection-related hospitalizations, risk of access loss, modality change or death following hospitalization for infection (Williams, Quinn, Callery, Kiss & Oliver, 2010).

Travel and fewer dietary restrictions, recreation, and dialysis access were improved with PD, which differed significantly with HD (Wu, 2001; Wu, 2004). Shrestha et al. (2008) reported better HR-QOL in PD compared to HD patients, especially in mental health, whereas three studies found higher depression scores for HD compared to CAPD patients, particularly for patients with extensive years of treatment (García and Calvanese, 2008; Ginieri-Coccossis et al., 2008; Kalender, Ozdemir, Dervisoglu & Oademir, 2007; Panagopoulou, Hardalias, Berati & Fourtounas, 2009). Brown (2010) found treatment modality to be an independent predictor of illness intrusion, particularly among patients on HD (higher comorbidity score) compared with PD in a cross-sectional multi-center study. In a US cross-sectional survey study (N=656), PD patients were more

likely to give excellent ratings of dialysis care than HD patients (Rubin et al., 2004).

In general, results for HR-QOL are not consistent when comparing PD with HD. A study conducted by Wu and colleagues (2004), demonstrated that PD was financially preferred whereas HD was preferable for sleep and overall HR-QOL after 1 year of treatment. Based on individual preferences, HR-QOL may be scored better or worse. In Spain, for instance, patients reported better HR-QOL scores on the physical function, general health and vitality dimensions for APD versus CAPD, with the best scores for women in the general health dimension (Reina-Neyra, 2008). When PD, APD and HD modalities were compared, the best HR-QOL scores were noted for APD, due to patient satisfaction with treatment and significantly more time for work, family or social activities (Bro et al., 1999; Caballero-Morales, 2006; De Wit, Krediet, & De Charro, 2001).

End-stage Renal Disease and Sleep

The prevalence of sleep disorders in persons with ESRD is higher compared to the general population and negatively influences HR-QOL (Alvarez-Ude et al., 1999; Cengić, Resić, Spasovski, Avdić & Alajbegović, 2010; Cohen, Patel, Peterson & Kimmel, 2007; Gusbeth-Tatomir, Boisteanu, Seica, Buga & Covic, 2007; Kimmel & Patel, 2006; Mei-Fen et al., 2007). Sleep disorders among patients with ESRD include difficulty falling asleep, nightmares, excessive daytime sleepiness (EDS), restless leg syndrome (RLS), sleep apnea syndrome, insomnia, chronic fatigue and difficulty finding a comfortable sleeping position (Cengić et al., 2010; Mucsi et al., 2004; Unruh et al., 2008; Yngman-Uhlin &

Edéll-Gustafsson, 2006). Factors associated with sleep disturbances were comorbid conditions, marital status, gender (Alvarez-Ude, 1999) and cognitive function (Kutner, Zhang, Huang & Bliwise, 2007). In Bosnia Herzegovina, authors reported snoring, pain, daytime napping, and pruritus as frequent causes of sleep disorders. In this study, poor sleepers showed higher serum phosphate and parathyroid hormone, and significantly lower hemoglobin (Cengić et al., 2010). The severity of the sleep disorder has been reported to be higher for patients receiving HD compared to PD (Eghbali, Shahqolian, Nazari & Babaee, 2008), although a high rate of poor sleep quality was found in both therapies in a Turkish study (Eryavuz et al., 2008).

The characteristics of some sleep disturbances in patients with ESRD may differ from the rest of the population. In obstructive sleep apnea (OSA), patients with ESRD are less likely to report snoring, witnessed apnea during sleep, unrefreshing sleep and morning headaches compared to normal renal function patients. Beecroft, Pierratos & Hanly (2009) have also reported that presentation of OSA's symptoms differ in ESRD patients from the general population. The sleep time of patients with ESRD is poorer with a reported 4.4 to 6 hours of sleep fragmented by high frequency of arousals, sleep efficiency from 66% to 85%, an increase in N1 (Stage 1 lightest stage of sleep) and N2 sleep (second stage of sleep characterized by sleep spindles and low-voltage activity) with concomitant reductions in N3 slow wave sleep and rapid eye movement (REM) sleep (Hanly, 2008). Based on associations between short sleep duration with hypertension and type 2 diabetes (Gottieb et al., 2005, 2006), patients with ESRD could be at

greater risk for cardiovascular disease and mortality. A decline in sleep quality during the first year on dialysis has been associated with shorter survival (Unruh et al., 2006). Recently, it has been reported that poor sleepers receiving HD treatment scored worse in the physical and mental domains of HR-QOL; the mental component scale is a predictor for poor sleep quality (Guney et al., 2010).

Costs-effectiveness in renal replacement therapies

Along with the assessment of efficacy and effectiveness of a treatment and given the economic burden that chronic disease care represents for health care systems, in recent years health researchers have studied the costs (resource uses) and the consequences (outcomes) of alternative strategies of treatment (Virgili, Koleva, Garattini, Banzi & Gensini, 2010). These economic evaluations are highly important in such cases as renal replacement therapies when the simple calculation of survival and morbidity rates are no longer sufficient. Recently, the evaluation of the impact of the treatment on the patients' daily life, i.e., QOL, is the targeted outcome. The quality-adjusted life year (QALY) has been developed to include QOL and survival, i.e., 'length and quality' of life (Wong, Howard & Craig, 2010). The QALY method allows the comparison of cost-utility estimates of different interventions for the purposes of public health decision making (Virgili, 2010).

In order to calculate the QALY, researchers have to know the health state of the population. Utility measures in healthcare commonly used are EQ-5D and SF-6D, which have been developed from the EUROQOL and SF-36 instruments respectively, and have been called utility assessments or preference-based

assessments (Feeny, Wu & Eng, 2004; Hornbrook et al., 2011; Liem et al., 2008). The use of EQ-5D and SF-6D have shown moderate to strong correlations with one another and have been considered valid for application in economic health analysis (Goncalves-Campolina, 2010). The Health Utilities Index Mark 3 (HUI3) is another instrument used by researchers (Davison, Jhangri & Fenny, 2009).

Liem and colleagues (2008) summarized the literature on health utilities in HD, PD and RT and compared utilities between these patients groups. They obtained 27 different articles which reported the use of the visual analog scale (VAS), time trade-off (TTO), standard gamble (SG), EuroQol (EQ-5D), and health utilities index (HUI). They concluded that RT patients tended to have a higher utility than dialysis patients. No statistically significant differences in utility were found among HD and PD patients.

On the other hand, in Greece, a nationally representative sample of patients receiving renal replacement therapies was studied to estimate QALYs using the SF-6D. Results showed lifelong QALYs of 4.37 (HD), 3.94 (PD) and 16.11 (RT). The cost per QALY differed by treatment modality; HD (€60,353) compared to PD (€54,504) and 1st year RT (€45,523) (Kontodimopooulos & Niakas, 2007).

In Mexico, the annual costs of treating ESRD estimated by Prieto et al., (2007) were $24,032 USD/patient and $15,724 USD/patient for HD and PD, respectively. These costs included drugs, supplies, hospitalization, treatment-related infections, infrastructure and physician and nurse fees as direct treatment-related costs and the indirect costs related to work loss and patient transportation.

No QALY estimations for ESRD in Mexico were found in a search of the literature.

Folk, complementary, and alternative medicine (CAM)

Although there is no strong evidence to indicate CAM use among patients with ESRD (Burrowes &Van Houten, 2005; Wojcikowski, Johnson & Gobe, 2006) and data regarding efficacy and safety in patients with chronic disease are scarce, a few studies indicate that some patients with ESRD are utilizing supplements, herbs and other therapies given their popularity (Markell, 2005). In general, 18% of dialysis patients reported using some form of CAM and 63% reported a willingness to use CAM in a Cincinnati, Ohio survey of 153 patients (Duncan et al, 2006). A German study reported 57% of dialysis patients and 49% of transplant patients were regular CAM consumers (Nowack et al, 2009). In Mexico, there is a wide range of nonconventional medical practices transmitted over centuries by indigenous people (folk practices), or as a result of the acquisition of another culture's knowledge (alternative) that have been used before, during or after the practice of conventional medicine (complementary) (Secretaría de salud, 2007).

Folk medicine practices are still primarily chosen by the general Mexican population. One of them, the 'herbolaria' and two alternative therapies, acupuncture and homeopathy, have been recognized in the health system and their utilization has already been legislated (Secretaría de Salud, 2010). It has been suggested that when the people have access to conventional Western medicine, they no longer use folk and CAM practices (Van Gameren, 2010).

Summary

In summary, ESRD is a chronic disease with a high global prevalence. Until RT is established in the health system as the first priority for treatment, other options should be the ones with the best clinical outcomes, lowest cost and the best opportunity for enhanced HR-QOL as perceived by the persons who have experienced the disease. There is extensive evidence of the impact of dialysis treatment on HR-QOL (physical, emotional, mental, spiritual dimensions) and its relationship to patient characteristics (age, gender, comorbidity, and marital status), treatment modality, other treatment-related factors and quality of care. A majority of these studies, however, have been done in developed countries with differing systems of health delivery, health care quality, dialysis therapy, cultural and SES factors. Few studies have been done with Latino or Mexican populations; therefore, findings from these prior studies are not fully generalizable. Furthermore, the results cannot be easily extrapolated to support local or national programs to improve the quality of care, design innovative interventions, promote the awareness of health providers, or change policy in Mexico. If health care innovations are going to be promoted, it is necessary to determine how dialysis modality and other relevant factors are associated with HR-QOL of Mexican persons with ESRD.

Theoretical Underpinnings

The dependent variable of interest for this study is HR-QOL. Several nurse theorists have conceptualized QOL. Leninger, Peplau, Parse, King & Rogers have generally focused on the subjective perception and intangible nature

of the concept as the perception of one's lived experience (Plummer & Molzhan, 2009; Reed & Shearer, 2009). These approaches are representative of the changing worldviews of health from mechanistic-reductionistic to unitary-transformative paradigm in nursing in the US (Bernick, 2004).

In Mexico, there has been an effort to integrate alternative modalities of care (Secretaría de Salud, 2007-2012). Nevertheless, in a curative model, conventional medical practices are still relevant and cultural beliefs could discourage the application of postmodern nursing theories in the clinical arena. In addition, language translation of conceptual theoretical components represents a real challenge.

In order to avoid the classical disconnection between theory and practice, some concepts from Jean Watson's Theory of Human Caring are applied to the phenomenon of HR-QOL in persons with ESRD in Mexico. It is believed that Watson's theory can provide the framework for nursing care intervention for future studies, be understandable to administrators and raise the consciousness that will urge the change of paradigm needed to transform health care from the 'control disease, prolong life and alleviate pain' vision to the humanistic 'caring for' values, quality of life and death perspective (Symonds, Berzon, Marquis, Rummans et al, 2002; Watson, 1981). Hence, Watson's (2006) theoretical framework will lay the groundwork for the reintegration of the caring-healing modalities and nursing arts to ensure attention to quality of life, inner healing experiences, subjective meaning, and caring practices that will affect patient

outcomes and system successes alike. Quality of life and other related features of persons with ESRD are consonant with this theoretical model.

In agreement with Watson (1999), attending the person as a total being is more than cure and physical treatment of diseases, especially for a person with a chronic condition and end-of-life challenges. The caring-healing focus "draws attention to the unique human qualities that are embedded in each individual and upholds the ethical and moral value of care that informs the praxis of caring within the nursing discipline" (Bernick, 2004). Findings from this study will provide the basis for understanding the Mexican ESRD patient's perception of his/her HR-QOL, and will offer practice reflections (Watson, 2006, p.50), including :

• Human caring is not a commodity to be bought and sold; and

• Caring and economics are not mutuality exclusive, and can co-exist to achieve cost-benefits and cost-effectiveness.

Potential theory-based nursing interventions would utilize several of the "carative" factors proposed by Watson (1988) to help nurses with their human activity, including 'sensitivity to self and to others,' 'expressing positive and negative feelings,' 'creative problem-solving,' 'caring processes,' 'human needs assistance' and 'supportive, protective, and/or corrective mental, physical, societal, and spiritual environment.' Laying the groundwork for the reintegration of the caring-healing modalities and nursing arts to ensure attention to QOL, inner healing experiences, subjective meaning, and caring practices will combine to promote positive patient outcomes and system successes alike (Watson, 2006).

Chapter 3

RESEARCH DESIGN AND METHODS

Design

Because few previous data were found regarding the HR-QOL of Mexican patients with ESRD, this is a descriptive, exploratory, cross-sectional study. This pilot project was designed to provide information for future quasi-experimental and experimental studies examining the effects of an evidence-based, theory-based nursing intervention to improve the HR-QOL and sleep disorders among persons with ESRD in Guanajuato, Mexico.

Sampling Method

As described above, there are three kinds of healthcare institutions in Mexico. To eliminate bias, patients were selected from one type of insurance (ISSSTE), and they were proportionately selected by clusters. A convenience sample included 30 patients from each geographic location of dialysis treatment units in Guanajuato State (the cities of Celaya, Irapuato, Guanajuato and Leon); ten patients were selected per each dialysis modality (Continuous Ambulatory Peritoneal Dialysis [CAPD], Automated Peritoneal Dialysis [APD], and Hemodialysis [HD]).

Persons with dialysis treatment in each unit were invited to participate in the study either during their monthly meetings or in the waiting room for their specialist appointment. They received general information about the project, and if they were interested in participating, they were asked to give their contact data to researchers, and make an appointment. Most of the time, the patient agreed to

be interviewed at that moment. The total number of potential participants to be recruited was 125. The study was approved by the University of Guanajuato Ethics Committee and the Arizona State University Institutional Review Board.

Participants

During the appointment with the research team member, the participant was asked to provide written informed consent and to complete an individual interview/survey about their health, health and folk practices, sleep, HR-QOL, spirituality, anxiety, and depression. They were also asked to give consent for chart review (Appendix A).

Inclusion criteria: Patients who were 18 years old or older, attending the ISSSTE and receiving dialysis treatment for ≥6 months were eligible. The minimum 6 months of dialysis criteria ensured that all patients had completed the initial process of adaptation. Participants had to be Spanish-speaking volunteers capable of providing written informed consent and with no hospitalizations during the past three months of the interview. These criteria ensured that HR-QOL would be directly attributed to daily living with ESRD treatment, rather than complications from an acute illness or current hospitalizations. Participants were enrolled in the study without regard to gender, ethnicity, or educational achievement.

Exclusion criteria: Patients with cognitive or other mental health deficits that would preclude them from completing survey questionnaires were excluded from the study.

Setting

The interview was held in a private room in the dialysis unit of the clinic, or at the patient's home depending on each patient's preference. The first part of the interview consisted of questions regarding demographics and medical history. The interview also asked questions about complementary traditional and alternative medicine practices, sleep disturbances, HR-QOL, spiritual perspective, depression and anxiety (Appendix B1 English and B2 Spanish).

Procedure

Recruitment and Enrollment. Figure 3 illustrates the study flow chart. The Medical Director of each clinic was asked to give the authorization to the research team to visit each clinic. Only one director returned written acceptance (Appendix C). Once the visit to the clinic was accepted by the administration, information about the project was given to the dialysis nurse manager related to the purpose of the study, the inclusion/exclusion criteria and the risks of the study for the potential participants. Interested potential participants were screened to confirm that they met the inclusion criteria and, if so, the researcher provided and explained the informed consent document. The participant or the companion was asked to provide contact information and schedule the interview with the research team. The majority of the time, the patient agreed to be interviewed, either before or after the medical appointment.

Informed Consent. The principal researcher explained the purpose of the study, risks and benefits, and the time needed to participate in the interview. Patients were informed that participation was completely voluntary and that non-

participation would not affect their healthcare. They were asked to sign an informed consent only after they were fully informed and able to indicate their understanding of the study. Participants were asked to provide written consent for the release of information from medical records (Appendix A).

Data Collection. Research assistants included one nursing student and one licensed nurse. They were trained regarding the project aims, interviewing techniques, and use of the instruments one month prior to the start of the data collection. They were provided with all the materials needed for the interviews, and financial support for travel and food expenses. The principal investigator also carried out interviews.

The interviewers obtained information regarding age, gender, marital status, SES, educational level, number of hospitalizations, time since first treatment, and CAM/folk use. Participants also completed the Spanish translated and validated Sleep Heart Health Study (SHHS) Sleep Habits Questionnaire (SHQ), the Spanish version of the 36-item Medical Outcomes Study (MOS) short form (SF-36) HR-QOL measure, the Latino Spirituality Perspective Scale, and the Hospital Anxiety and Depression Scale (HADS). Height and weight were obtained to determine body mass index (BMI). Recent glucose, albumin, creatinine, urea, and hematocrit/hemoglobin blood levels were extracted from the patient's medical record within the past three months. Additional clinical data collected to calculate the financial cost were ESRD etiology, hospitalizations within the past year, type of catheter, dialysis dose, number of anti-hypertensive drugs, use of erythropoietin, number of HD sessions per week and last home visit

by the dialysis team. In order to determine quality adjusted life years (QALYs), type and time of dialysis were collected and examined with respect to SF-6D utility index scores.

Measurement Tools

Sleep Heart Health Study Sleep Habits Questionnaire. See Table 1 for the full listing of measures used in this study. The SHQ instrument typically has been used with patients with unidentified sleep disorders. The questionnaire addresses ten aspects of sleep disorders: 1) Snoring, which is ascertained by the question "Have you ever snored (now or at any time in the past)?" with possible responses "yes," "no," or "don't know." Participants answering "yes" were asked, "How often do you snore now?" with possible responses including "rarely--less than one night a week," "sometimes--1 or 2 nights a week," "frequently--3 to 5 nights a week," "always or almost always--6 or 7 nights a week," or "don't know;" 2) Breathing pauses (apnea) were ascertained by the questions, "Are there times when you stop breathing during sleep?" and "Has anyone ever told you that you stop breathing during sleep?" with possible responses "yes," "no," or "don't know;" 3) Witnessed apneas were assessed with participant response to a question as to how often there is someone else nearby while they are sleeping, with possible responses of "never," "sometimes," and "always;" 4) Daytime sleepiness from two somnolence statements, "Feel excessively (overly) sleepy during the day," and "Feel unrested during the day, no matter how many hours of sleep you had;" 5) Insufficient sleep with the question "Not getting enough sleep;" 6) Insomnia symptoms with the statements "Trouble falling asleep," "Wake up

during the night and have difficulty resuming sleep," and "Wake up too early in the morning and be unable to resume sleep;" 7) Nightmares, 8) Restless legs syndrome (RLS) using questions regarding leg sensations, time of day, alleviation of symptoms, family history; and 9) Self-reported weekday and weekend sleep duration. Sleep symptoms questions were rated on a 5-point Likert-type scale from 'Never' to 'Almost Always.'

The SHQ examined by Kump and colleagues (1994) was shown to have validity for characterizing symptom distributions in an epidemiological study of sleep. Sleep habits, sleepiness and daytime performance from 465 participants were analyzed with factor analysis, logistic regression, and receiver-operator characteristics (ROC) with area under the curve (AUC) estimates. Subscales demonstrated excellent internal consistency (Cronbach's alpha: 0.91 to 0.98). Analysis identified five factors: 1) functional impact of sleepiness, 2) self-reported breathing disturbances; 3) witnessed apnea, 4) insomnia symptoms, and 5) driving impairment. Logistic regression demonstrated that OSA-associated apnea could best be predicted by three questions about snoring intensity, witnessed apnea, and falling asleep while driving (ROC AUC: 0.78). Adding the variables gender and BMI improved predictive ability by 10% (ROC AUC: 0.87) (Kump et al., 1994). The questionnaire has been used in a variety of investigations since that time as well as with over 6400 subjects in the SHHS and is generally accepted as an appropriate means of characterizing sleep health (Baldwin et al., 2010, 2001; Baldwin, Kapur, Holberg, Rosen & Nieto, 2004; Gottlieb et al., 2005;

Gottlieb et al., 2006; Newman et al., 2001; Nieto et al., 2000; O'Connor et al., 2002; Resnick, Redline, Shahar, Gilpin et al., 2003; Winkelman et al., 2008).

The Spanish version of the SHQ was cross-language validated by Baldwin and colleagues (Baldwin et al., 2008; Baldwin et al., 2009); translations and back-translations were performed and the English and Spanish SHQs were completed by bilingual participants one week apart in randomized fashion. The sample was 52% women and 92% Hispanic, primarily of Mexican heritage. Mean age was 39 years (*SD*=12) and mean education was 15 years (*SD*=3). Psychometrics for the English version of the SHQ showed a Cronbach's alpha of 0.82 for the 12-item sleep symptoms (e.g., daytime sleepiness, insufficient sleep and leg jerks) and 0.71 for the 3-item insomnia symptoms (have trouble falling sleep, staying asleep, wake up too early in the morning and unable to return to sleep). For the Spanish version, the Cronbach's alpha was 0.85 for 12-item sleep symptoms and 0.81 for 3-item insomnia symptoms. Spearman-Brown correlations were > 0.90 for all sleep categories, suggesting strong agreement between language versions.

Correlation and agreement between the Spanish and English versions of the 3-item insomnia symptoms category was also analyzed by Baldwin and colleagues (2009) in the cross-language validation study. Total and category scores for the insomnia symptoms were compared across Spanish and English versions for subgroups defined by order of assessment, gender, age, education, language facility, acculturation, or health condition. English and Spanish versions were highly correlated with *r* values ranging from 0.83 to 0.94. Classification

congruence for insomnia symptoms was also good with Φ and κ ranging from 0.63 to 0.79.

Epworth Sleepiness Scale. The Epworth Sleepiness Scale (ESS) is a validated self-completion tool that asks subjects to rate the likelihood of falling asleep in several common situations (Johns, 1991). The ESS was assessed by the question, "What is the chance that you would doze off or fall asleep" followed by a list of eight common situations including "riding as a passenger in a car," "watching TV," and others. For each situation, possible responses include four ordinal categories ranging from 0 (*no chance*) to 3 (*high chance*). Scores range from 0 to 24 with a score of >10 suggesting EDS (Gottlieb et al., 2005). The Epworth was included with the SHQ in the Spanish translation and validation study. Cronbach's alphas for the English and Spanish versions were 0.83 and 0.81 respectively. Spearman-Brown correlations were >0.90 for both language versions (Baldwin et al., 2008, 2009).

CAM practices instrument. The 2007 National Health Interview Survey (NHIS) Questionnaire survey of adult health, complementary and alternative medicine (CAM) was adapted for this study. This questionnaire was part of a multi-purpose health survey conducted by the National Center for Health Statistics (NCHS, 2007), Centers for Disease Control and Prevention, and is the principal source of information on health of the civilian, non-institutionalized household population of the United States. The Adult CAM Supplement was designed to collect information from adults on their use of 18 non-conventional health care practices, including acupuncture, ayurveda, biofeedback, chelation

therapy, chiropractic or osteopathic manipulation, energy healing therapy, hypnosis, massage, naturopathy, traditional healers, movement therapies, herbal and non-vitamin supplements, vitamins and minerals, homeopathy, special diets, yoga/tai chi/qi-gong, relaxation techniques, and prayer for health reasons. Questions were asked about use, frequency, and cost of the eighteen different practices, conditions for which the modality was used, for which health conditions, treatment received and whether they told their primary care providers about their CAM use. In addition to these modalities, Mexican folk practices for self-treatment of ESRD, including herbal remedies, use of a *sobador* or *curandero*, or other non-Western medicine practice not listed on the NCHS survey were included to assess for traditional Mexican culture care.

Latino Spiritual Perspective Scale (LSPS). This questionnaire assesses spiritual beliefs, feelings, and practices among Latino populations. Reliability testing showed a Cronbach's alpha range of 0.88-0.93 in US English speaking samples of adults, and 0.93 for the Spanish version in a sample of bilingual adults (Campesino & Schwartz, 2006; Campesino, Belyea & Schwartz, 2009). Eight items from the spirituality scale validated by Campesino and colleagues (2009) were used to examine spirituality of the Mexican participants with ESRD. The statements were rated by the patient on a Likert-type scale from 6 (*strongly agree*) to 1 (*strongly disagree*). Two additional questions were ranked on a 5-point scale from 0 (*not or no*) to 4 (*extremely*) to determine the degree to which participants conceptualized themselves as spiritual persons and the degree to which their spirituality or religion helped to endure their chronic disease. A third question had

the participants indicate the frequency with which they performed spiritual or religious activities, including prayer, meditation or attending religious activities on a scale of 0 (*never*) to 3 (*daily*).

Hospital Anxiety and Depression Scale (HADS). The HADS was developed by Zigmond and Snaith (1983) for use with physically ill patients. Numerous studies worldwide have reported clinically meaningful results with several aspects of disease and QOL (Herrmann, 1997). The depression scale consists of 7 items (e.g., loss of interest, feeling slowed down) scored from 0 to 3 with a range of 0 (*low*) to 21 (*high*) probability of depression. The anxiety scale consists of questions relevant to worry, tension and fear and is scored in the same manner as the depression scale. The authors suggested that a score above 8 on an individual (depression or anxiety) scale should be regarded as a possible case and a score above 10 as a probable case of depression or anxiety. Tyrer and Methuen referred to the HADS as the third most commonly used self-report screening instrument; the citation rate per year has been reported to be 1,333 (Brennan, Worral-Davies, McMillan, Gilbody & House, 2010).

According with Brennan and colleagues (2010) this instrument has been shown to be a useful screening tool for identifying emotional distress in non-psychiatric patients. They conducted a meta-analysis and found that for major depressive disorders, a cut point of ≥ 8 gave a sensitivity of 0.82 (95% CI, 0.73–0.89) and a specificity of 0.74 (95% CI, 0.60–0.84) and a cut point of ≥ 11 gave a sensitivity of 0.56 (95% CI, 0.40–0.71) and a specificity of 0.92 (95% CI, 0.79–0.97). The HADS has been published by Granada Learning Assessment Limited,

part of the Granada Learning Group, and a license to use it was properly purchased (Appendix E).

Medical Outcomes Survey (MOS) Short Form SF-36 (Spanish version). The MOS SF-36 measures variations in health care practices and outcomes in a self-administered survey that assesses eight health dimensions. Scores for each subscale range from 0–100, with higher scores representing better quality of life (Ware et al., 1992). Subscales measure the following eight general health concepts: physical activities (PF), role physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), mental health (MH) and role emotional (RE) (McHorney, Ware and Raczec, 1993; McHorney, Ware, Rachel Lu & Sherbourne, 1994). Some of the scales (PF, GH, VT, and MH) are heterogeneous in terms of item content. The median item-scale correlation (corrected for overlap) for each of the eight scales was very high, ranging from a low of 0.63 (GH) to a high of 0.79 (MH). When testing for internal consistency, the 0.40 standard was achieved 97% of the time. Internal-consistency reliability coefficients for each of the scales exceeded the minimum reliability standard of 0.50 to 0.70 recommended for group comparisons. The SF-36 survey also includes a single-item measure of health transition, which is not used to score any of the eight multi-item scales (McHorney, 1994). The SF-36 questionnaire is a widely-used measure of health status and health-related quality of life (HR-QOL) with a substantial body of evidence supporting its reliability and validity in a variety of patient populations (Baldwin et al., 2001, 2010; Bennett & Riegel,

2003; Kung & Lu, 2008; Laureau, Breslin & Meek, 1996; Stewart, Hays & Ware, 1988; Ware, Snow, Kosinski & Gandek, 1993).

Short Form-6 D scores. The SF-6D is a preference-based health state classification developed from the SF-36. All participants who complete the SF-36 can be assigned an SF-6D score (Brazier, Roberts & Deverill, 2002). The SF-6D is a continuous measure, scored on a 0 (*death*) to 1 (*optimal health*) scale. Cost effectiveness and impact studies using the SF-6D have examined health state utilities and diabetes prevention, and predictors of SF-6D scores of persons with colorectal cancer (Ackermann et al., 2009; Hornbrook et al., 2011).

Cost assessment. Cost by type of ESRD treatment for CAPD and APD was obtained from the Sub-direction of Regulation and Hospital Attention of the Medical Direction of the ISSSTE online report for contracted services from 2010 to 2011 (Delgado-Serrano, 2011). The cost for each dialysis type included tubing, solution, mini-cap for line closing (four mini-caps per day), APD machine maintenance, home delivery, first-time catheter and connector and new transfer line every six months. Both CAPD and APD were done at home. The cost for CAPD and APD does not include taxes, catheter insertion costs, physician or nursing fees, monthly visits to the nephrology clinic or patient/primary caregiver training, transportation, home visits, or medication.

The cost for HD was obtained from the online publication of the contract that the ISSSTE made for the HD services for 2010 to 2012 (Contraloría Ciudadana para la Rendición de Cuentas, A.C., 2010). Cost for HD included all of the solution, lines, machinery, water treatment for the dialysis machines required

for each session. The cost for HD did not include taxes, cost for vascular access, tri-weekly transportation to and from the clinic, clinic costs, nephrology visits, nursing care, patient/primary caregiver education or medications. Each modality cost was calculated based on average number of treatments relevant to the modality type. Costs for each dialysis modality were estimated for one year.

Ethics and Human Subjects

This research was consistent with the Mexican "*Ley General de Salud*," which regulates the Mexican health system. This research was approved as fulfilling the ethical guidelines as outlined in the Human Subjects section titled "*Investigación para la Salud*," and the study was found to be of minimal risk for participants. This study was approved minimal risk to the participants. Following the Helsinki Code, participants signed a consent form, and were assured that their participation was completely voluntary and could be terminated at anytime without compromising their medical care. The University of Guanajuato approved the protocol by the university ethics committee (see Appendix D-1). The study was protocol was approved by the Arizona State University Institutional Review Board (Protocol Number 1104006292) (See Appendix D-2).

Chapter 4

DATA ANALYSIS AND RESULTS

Data Analysis

Descriptive analyses were performed for all variables. Continuous variables are reported as means and standard deviations and categorical variables by percentages. A chi-square test was used to assess the association of demographic characteristics with dialysis modality. Comparisons between HR-QOL scores and the treatment groups were performed by analysis of variance (ANOVA). Multiple linear regression analysis was performed controlling for demographics, income (SES), sleep disorders, spirituality, and CAM variables. The significance level of $p<0.10$ was adopted because this is a pilot study with three groups and a small sample size. SAS software (V9.1) was used for data analysis.

The cost analysis utilized the quality-adjusted life year (QALY) method to investigate the cost-effectiveness of each dialysis modality group. The QALY was computed as the number of years on dialysis/hemodialysis time SF-6D score. A ratio of the difference in cost to the difference in effectiveness (QALY) was computed for each of the three therapies which yielded the incremental cost-effectiveness ratio (ICER).

Population

The study population was recruited from the four ISSSTE clinical hospitals in Guanajuato State (Celaya, Irapuato, Guanajuato and Leon cities). There were 125 patients at the beginning of the study, two patients never started

the study because they were less than 18 years old, one patient interrupted the interview and was hospitalized after a medical appointment, and one patient did not finish the interview and was eliminated. One-hundred and twenty-one patients fulfilled the inclusion criteria and all agreed to voluntarily participate and provided written informed consent. Table 2 shows city of origin and dialysis modality of the population included in the study.

Aim 1. To characterize the demographics, socioeconomic status (SES), health histories, prevalence rates and types of sleep disorders, folk practices used, spiritual perspective, anxiety, depression, and HR-QOL scores of Mexicans with ESRD for each of 3 types of dialysis.

Overall, ESRD patients had an average age of 59 (*SD*=13) years, were predominantly men (55.4%), married (66.9 %), Catholic (92.6%), and not currently working (78.3%). Overall, 57% of participants reported a yearly income of less than $4,823 USD. The average number of people in living in the household was 4; interestingly, 48.8 % and 54.1% of all participants reported have never smoked or consumed alcohol, respectively.

The distribution for dialysis type was CAPD (*n*=39), APD (*n*=42), and HD (*n*=40). Demographic characteristics for each dialysis modality group are compared in Table 3. Patients on APD compared to CAPD and HD were younger (53 years versus 64 and 61 years respectively, p=0.0001), had more education (11 years versus 8 and 9 years respectively, p =0.06), more likely to be employed (33% versus 5% and 8% respectively, p=0.002), and had incomes in the $4K to $6K range (21% versus 10% each, p=0.05). Notably, however, the patients on

APD also showed extremes in income. For example, 24% of the APD group reported no annual income compared to the CAPD and HD groups (18% and 10% respectively, p=0.05), while both the APD (26%) and CAPD (26%) groups reported incomes in the >$8K range compared to the HD group (15%, p=0.05). The APD patients were significantly more likely to report a past history of alcohol intake (63%) compared to the CAPD and HD groups (31% and 41% respectively, p=0.04). None of the groups reported current alcohol use. The treatment groups did not differ significantly with respect to gender, marital status, smoking, religion, medical insurance, years of education, or number of people in the household.

The majority of the subjects were diabetic (72%) and slightly overweight (BMI: M=26.1, SD=5.1). Participants took an average of 6 medications daily including erythropoietin (90%) and reported a mean systolic blood pressure (SBP) of 144 (SD=27) and mean diastolic blood pressure (DBP) of 80 (SD=17). Thirty-three percent reported taking more than two different antihypertensive medications. In general, the study population reported at least three comorbidities, including diabetes and ESRD. Forty-seven percent have not been hospitalized during the prior 12 months and 25% had been hospitalized for less than three days. Laboratory data registries were as follows, mean hemoglobin=11.2 (SD=3 g/dl), mean albumin=3.5 (SD=0.7 g/dl), mean urea=96.4 (SD=39 mg/dl), mean creatinine= 9 (SD=4.3 mg/dl), mean BUN=49 (SD=18 mg/dl), and mean glucose=123 (SD=53 mg/dl).

CAPD patients tended to be older (*M*=64.2, *SD*=8.9, *p*=0.000), not working (92.1%, *p*=0.002), had higher BMI (*M*=27.7, *SD*=5.6, *p*=0.06), SBP (*M*=147.7, *SD*=31.7) and glucose levels (*M*=129.1, *SD*=5.4) and reported taking more medications (*M*=6.8, *SD*=2.6). APD patients tended to be younger (*M*=53.1, *SD*=13.4, *p*=0.000), married (66.7%), working (33%, *p*=0.002), more educated (*M*=11.4 years, *SD*=6.4, *p*=0.06), had a higher annual income (26.2%, *p*=0.05), had an elevated DBP (*M*=84.9, *SD*=14.1), higher creatinine (*M*=11.8, *SD*=4.3, *p*=0.00) and urea levels (*M*=102, *SD*=39.3) and fewer hospitalizations in the past year (78.6%, 0-1 times). HD patients had higher albumin levels (*M*=3.9, *SD*=0.5, *p*=0.002), took fewer antihypertensive medications (35.9%), had lower BMI (*M*=24.8, *SD*=5.4, *p*=0.06) and more use of erythropoietin (100%, *p*=0.06). Both PD (CAPD and APD included) and HD patients had a mean time in the therapy of 26 months. The remaining clinical characteristics are presented in Tables 4 and 5.

Sleep Disorders. An overview of sleep disorders by dialysis type are provided in Table 6. Notably, all patients reported at least one sleep symptom in the past year. Patients on APD (21%) were significantly less likely to report un-refreshing (non-restorative) sleep compared to the CAPD (41%) and HD (43%, *p*=0.08) groups. Insomnia was most frequently reported for patients receiving HD. Interestingly, HD patients reported higher rates of non-restorative (un-refreshing) sleep (43%), insufficient sleep (30%) and tiredness during the day (23%) on the SHQ compared to the patients on other therapies. Alternatively, APD patients reported higher rates of snoring (26%, *p*=0.07) and witnessed apneas (14%, *p*=0.04). CAPD (26%) and HD (25%) patients reported higher rates of EDS on

the Epworth scale compared to APD (13%) patients. The CAPD patients also reported higher rates of RLS (23%) compared to patients on HD (18%) and APD (17%), but had lower rates of insufficient sleep (26%) than APD (28%) and HD (30%) patients. Patients receiving APD were less likely to report EDS on the Epworth (12%), feeling excessively tired during the day on the SHQ (19%), RLS (17%) and insomnia (31%) compared to patients on CAPD and HD. These differences, however, were not statistically significant between groups for sleep variables other than un-refreshing sleep, snoring and witnessed apnea.

Anxiety and Depression. The assessment of anxiety and depression based on the HADS showed scores within normal levels in the study population for anxiety (*M*=5.4*, SD*=5.2) and depression (*M*=5.5*, SD*=4.8) (see Table 7). Mean scores for anxiety were lowest (less anxiety) for HD (*M*=3.8*, SD*=3.9), higher for APD (*M*=5.1*, SD*=5.2) and highest for CAPD (*M*=7.3*, SD*=6.0*, p*=0.03) patients. Scores for the CAPD patients suggest borderline anxiety. As well, mean scores for depression were lowest for HD (*M*=3.8*, SD*=2.9), then APD (*M*=6.2*, SD*=5.2) and CAPD (*M*=6.5*, SD*=5.6*, p*=0.05) patients.

Prevalence of abnormal anxiety across the three groups is 18.7% with the highest rates of abnormal anxiety among CAPD (24%), then APD (22%), then HD (10%) patients. The rates within the borderline range for anxiety are similar with CAPD patients reporting highest levels of anxiety and HD patients reporting lowest levels. Alternatively, HD patients show greater representation in the normal range (87%), then APD (72%) and the lowest percentage among the CAPD (62%) patients. Overall, the rates for anxiety within each of the levels by

group is significant (p=0.06). The prevalence of abnormal depression levels is 11% with CAPD and APD groups showing equivalent rates (17% and 16% respectively). Interestingly, APD patients show the highest prevalence for borderline depression (19%) compared to CAPD and HD patients (each 10%). Rates within the normal range are highest for HD (90%), then CAPD (72%), then APD (66%) patients. On the whole, rates for depression within each of the levels by modality are significant (p=0.045).

CAM use. Overall, twenty-five patients (21%) stated that they had used some form of CAM. The proportion of lifetime CAM use was similar across all dialysis modalities. Eighteen of 121 patients (15%) indicated that they used CAM during the past 12 months, again with very similar proportions across all dialysis modalities. Seventy-three percent of the sample reported that ESRD led to CAM use and 77% reported that CAM was effective. The most frequently reported types of CAM were homeopathy (4%), herbal preparations (3%), acupuncture (2%), massage (2%) and vitamins (2%). When questioned about self-medication (allopathic, CAM, or folk), 15% of the participants confirmed the use of medications for headache (55%), flu (16.7%), and debilitation (11%).

Spirituality. Participants, in general, agreed with the spiritual beliefs and practices stated in the LSPS (M=5.5, SD=0.7). The CAPD patients showed a tendency to report "*strongly agree*" (M=5.7, SD=0.05) to the LSPS spirituality questions, although no significant differences were observed between groups for any items. Approximately 47% of participants considered themselves to be spiritual persons, while 48% reported frequent use of or participant in

spiritual/religious practices, and 72% indicated that these practices were used to help cope with their disease (Table 8). The HD group was most likely to consider themselves to be spiritual (61%) compared to CAPD (54%), then APD patients (30%, p=0.06). The CAPD patients were more likely to report the use of spiritual/religious practices (62%), then HD (52%), then APD (33%) patients. Use of these practices to help endure their disease was highest among HD (83%), then CAPD (73%), then APD (63%) patients. The findings for spiritual/practices, or their use for disease were not significant at the p<0.10 level.

HR-QOL. Table 9 and Figure 5 present the comparison of the eight SF-36 domains and the Physical and Mental Component Summary (PCS and MCS) scores for the three dialysis modality groups. The patients on HD reported significantly better HR-QOL on the Vitality (p<0.05) and Social Functioning (p<0.01) scales compared to the patients on CAPD and APD; however, the CAPD patients reported the poorest quality of life on these two scales compared to the other two groups. The APD and HD patients reported significantly better Physical Functioning and Role Physical HR-QOL compared to the CAPD patients (each p <0.10). There were no significant differences between groups for Bodily Pain, General Health, Role Emotional and the Mental Health domains. The patients on HD and APD reported significantly better mental health on the MCS compared to patients on CAPD (p=0.07); however, there were no significant differences between groups for physical health on the PCS. The SF-6D score, derived from the SF-36, indicates the level of health and wellness on a 0 (*dead*) to 1 (*best health*) scale. The SF-6D score, a measure of health utility, is used in cost analysis

and complement the HR-QOL findings. The CAPD group showed significantly poorer SF-6D health utility (0.59) compared to the HD and APD patients (0.68 and 0.69 respectively, $p<0.01$).

Table 10 displays the SF-36 and MCS and PCS scores for comparison between the patients with ESRD in this study, the Mexican General Population Norms (Durán-Arenas, Gallegos-Carrillo, Salinas-Escudero, & Martínez-Salgado, 2004) the US General Population Norms and US Norms for Persons with Hypertension, Type 2 Diabetes and Congestive Heart Failure (CHF) (Ware, Kosinski, & Keller, 1994; Ware, Snow, Kosinski, & Gandek, 1997). Norms for hypertension and diabetes are included given their relationships with ESRD, and CHF is included as it is akin to HR-QOL debilitation noted among persons with ESRD. Notably, the SF-36 scores for the Mexican patients with ESRD are lower (suggesting poorer HR-QOL) for the eight scale and composite scores compared to the Mexican general population norms (Duran-Arenas et al., 2004) and similar to the US norms for persons with CHF (Ware et al., 1994, 1997). There are no extant SF-36 or PCS and MCS norms for persons with ESRD in Mexico or in the United States.

Aim 2. To analyze HR-QOL outcomes of Mexicans with ESRD on 3 modalities of dialysis controlling for demographics, SES, sleep disorder types, spiritual perspectives, and folk practices used.

The overall model accounted for 31% of the variance in HR-QOL which was highly significant (F=3.36, p=.002). After controlling for demographics (age, sex, and comorbidities), SES (income as proxy), sleep disorders, spirituality, and

CAM use, there were statistically significant differences in HR-QOL by dialysis type (Table 11). Income, sleep disorders, and comorbidities were significant predictors of HR-QOL. The CAPD group demonstrated significantly lower HR-QOL scores (M=.56, SE=.03) compared to the APD group (M=.68, SE=.03, p=.009) and the HD group (M=.64, SE=.03, p=.08).

The same model was repeated with the PCS (Table 12) and MCS (Table 13) scores as dependent variables. The PCS model was not statistically significant and no differences in PCS scores were observed by dialysis group. The MCS model (Table 13) accounted for 34% of the variance (F=4.02, p=.0004). Sleep disorders (p<0.001) and income (p<0.05) were the only significant covariates and there were statistically significant differences in MCS scores by dialysis group (F=4.87, p=0.01). Similar to what was observed for HR-QOL, the CAPD group demonstrated significantly lower MCS scores (M=42.99, SE=2.49) compared to the APD group (M=52.20, SE=2.32, p=0.01 and the HD group (M=51.35, SE=2.58, p=0.02).

Aim 3. To examine associations between cost effectiveness and dialysis modalities among Mexicans with ESRD.

Total hospital costs for each dialysis type were obtained. The QALY was computed as the number of years on dialysis/hemodialysis x SF6-D score (SF-6D scores are presented in Table 9). The incremental cost-effectiveness ratio (ICER) is calculated as a cost/QALY. The results of these analyses (Table 14) demonstrate that based solely on hospital costs, APD is the preferred dialysis type. Although CAPD was the least costly alternative, it was the least effective,

thus it was inferior to APD and HD. Comparing the ICER for APD and CAPD, only $239 needs to be spent for APD to gain an additional QALY. Examination of the ICER for HD versus CAPD revealed that HD is the preferred strategy because the cost/QALY is only $759. The analysis compared the two preferred strategies. APD was superior to HD because it was less costly and more effective.

Chapter 5

DISCUSSION

Traditionally, medical professionals focused on extending survival rates for persons with ESRD. In the past two decades, HR-QOL has become an important treatment goal and outcome measure for patients with ESRD (Anderson & Burckhardt, 1999; Harris, et al., 2002). To date, however, there are few studies that have provided HR-QOL norms or guidelines for patients being treated for ESRD in Mexico. This study extends the literature in several ways: 1) Findings provide SF-36 and PCS and MCS scores as a basis for norms for Mexican patients with ESRD on three distinct types of dialysis (APD, CAPD and HD); 2) The HR-QOL norms provide the basis on which treatment outcomes can be evaluated; 3) Sleep disorders have been identified as significantly associated critical factors that contribute to poorer mental HR-QOL of Mexican patients with ESRD; and 4) cost comparisons of the two leading dialysis types indicated that APD was superior to HD due to reduced cost and improved outcomes, which can inform health policy and treatment for Mexican patients with ESRD. Furthermore, comparisons of norms for the Mexican General Population, the US General Population, the Mexican patients with ESRD, and US patient with hypertension, type 2 diabetes and CHF are also available (Table 10) are presented for bi-national evaluation.

HR-QOL and Dialysis Modality. In Mexico, estimates suggest that there are approximately 100,000 patients with ESRD of which 80% are on CAPD (least expensive and poorest HR-QOL in this study), 19% are on HD (most expensive with HR-QOL comparable to APD in this study), and 1% are on APD (HR-QOL

comparable to HD in this study at reduced cost) (Fundación Mexicana del Riñón, 2007). The present research is one of the few studies that compared patients' perceptions of HR-QOL among dialysis modalities (CAPD, APD and HD) in addition to other lifestyle factors that may be influenced by a history of ESRD and ultimately further compromise HR-QOL. Caballero-Morales & colleagues (2006) reported better HR-QOL in most of the SF-36 domains for APD versus CAPD and HD patients; notably, their HD patients reported the poorest HR-QOL, while the HR-QOL of the HD and APD patients in this study were comparable. Differences among patients on HD in this study could be explained by factors that include advanced training of medical and nursing personal in HD units, greater participation of nephrologists in medical management, and the extensive availability of HD as a treatment option contributing to APD and CAPD as less likely treatment options.

Interestingly, in prior international studies, no significant differences were reported between PD and HD patients' overall HR-QOL (Mau, 2008; Morales-Jaimes, 2008; Peng, 2010; Wasserfallen, 2004). However, some authors have reported significantly higher scores in SF-36 domains, including Physical and Social Function, Bodily Pain, Vitality, Role Emotional and the MCS among PD compared to HD patients (Brown, 2010, Caballero.Morales, 2006, Frimat, 2006; Fructuoso, 2011; Ginieri-Coccossis, 2008; Harris, 2002; Juergensen, 2006, Kalender, 2007; Kutner, 2005, Liem, 2007; Mittal, 2001; Peng, 2010; Shrestha, 2008; Wu, 2004). A longitudinal study has also reported higher HR-QOL scores for PD patients versus HD patients after more than 4 years of treatment (Ginieri-

Coccossis, 2008). Some, but not all studies have reported patients on APD to have higher HR-QOL scores compared to CAPD patients; APD patients also had lower peritonitis rates and more time for work, family or social activities; nevertheless, other authors found no significant differences between both therapies (Balasubramanian, 2010; Bro, 1999; Guney, 2010; Rabindranath, 2007). These factors should be examined in future HR-QOL and cost-analysis studies of patients with ESRD on various modes of dialysis to determine whether the cost effectiveness and improved HR-QOL for APD are consistent.

Many of the HR-QOL findings are consistent with prior literature regarding the impact of ESRD on the physical, social and emotional dimensions of HR-QOL (Esquivel Molina, 2009; Lii, 2007, Morsch, 2006; Shrestha, 2008). What is not captured in norm-based HR-QOL studies, however, are patients' qualitative perceptions of their life quality and well-being. Notably, during data collection, several participants displayed what Albrecht and Devlieger (1999) refer to as a 'disability paradox;' in which some patients have a perception of personal health that is discordant with their objective health status and disability. For example, a diabetic patient on HD treatment was interviewed sitting in a wheelchair due to his left leg being amputated. He lived in a poor neighborhood with his wife, daughter, and grandchildren on limited retirement pension and was having financial problems, yet he perceived his general health as 'excellent.' Alternatively, a young patient on APD treatment was denying her disease, appeared physically healthy and was independent, yet reported to be "living like in hell." Given the limited renal replacement options offered by the Mexican

health system, further qualitative or mixed-method (quantitative and qualitative) studies regarding the experiences of living with ESRD on CAPD, APD or HD are warranted in the growing Mexican ESRD patient population.

In Mexico, social health institutions have had a policy of PD as the first line of treatment and HD as a second option when PD was not successful, which could lead to surmising that patients on PD are healthier, more likely to be working, more able to travel, have fewer dietary restrictions, reduced financial burden and less dependence on the health system. Realistically, however, it means that patients on PD require more self-care, adherence to treatment, life-style changes, a better understanding of their own medical management, strong health-team guidance, on-going patient and care-giver training and family support. Giving the fact that the CAPD group showed higher values in BMI, systolic blood pressure, BUN and glucose levels, number of medications taken and lower albumin level, the health team should establish clinical guidelines for a successful outcome-oriented PD unit that would include regular patient support, an interdisciplinary health team focused on improved quality of care, programmed home visits by the health team, and tracking of medical and nursing records. The characteristics of dialysis centers showed clinically relevant differences in a study by Mazairac and colleagues (2011); therefore, further assessment is needed to determine associations between quality of care delivery and HR-QOL outcomes, particularly for patients on CAPD. It is notable that APD patients in this study are younger than CAPD patients and half of the patients on APD continue to work. These factors may contribute to patients on APD experiencing greater ‘self

efficacy.' The discrepancies between CAPD and APD patients may be due attitudes toward the treatment modality, age, quality of care, availability of medical and pharmaceutical resources, lifestyle, health beliefs, and other factors. Future investigations are required to determine relationship between these factors and HR-QOL outcomes.

Higher scores (better HR-QOL) among ESRD patients on HD, particularly the social domains could reflect the greater attention they receive attending the HD clinic several times a week for 3 to 4 hours each visit. These clinic visits also allow for continuous care, biochemical and clinical control and, importantly, social support they receive from other HD patients and the HD team. In this study, for example, all the participants in the HD group received erythropoietin which has been considered to improve the HR-QOL (Unruh, 2005; Weisbord, 2008). Other authors have reported associations between social support on perceived HR-QOL (Gallegos-Carrillo et al., 2009; Spinale et al., 2008; Wu, 2004). Future studies that examine HR-QOL, social support and other biomedical factors provided ESRD patients on HD in Mexico are warranted.

Sleep Disorders and ESRD. Perl and colleagues (2006) have suggested that sleep disorders could act as markers of inadequate dialysis in ESRD patients and the severity of the sleep disorder has been reported to be higher for HD compared to PD patients (Eghbali, et al., 2008). Findings from this study indicate that the HD group showed higher rates of insomnia symptoms, excessive tiredness, un-refreshing (non-restorative) and insufficient sleep. It is common for

patients with ESRD to sleep during their daytime HD session, thus contributing to difficult or disturbed nighttime sleep, a finding also observed among patients in this study.

While Tang and colleagues (2009) found that sleep apnea was less prevalent among APD compared to CAPD patients, the present study noted higher rates of witnessed apnea among APD (14.3%) compared to CAPD (10.3%) patients. Reasons for these discrepancies are unknown and further studies are required, particularly objective studies that use overnight polysomnography. Higher rates for RLS (23%) in tandem with daytime sleepiness (26%) among patients on CAPD are consistent with other studies (Al-Jahdali, et al., 2009; Almeida-Araujo, et al., 2010; Mucsi, 2005). Restless legs syndrome was also found to be associated with elevated rates of depression among a sample of US military veterans (Baldwin, Bell & Quan, 2005). Disrupted sleep from leg movements and/or depression could be major contributors to daytime somnolence in these patients.

Spirituality. Quality of life (QOL) and well-being studies frequently include spirituality as a QOL construct. Mexican patients with ESRD in this study are predominantly Catholic. Of note, the CAPD group, who showed the poorest HR-QOL, was frequently more likely to utilize spiritual/religious practices. These findings are consistent with other studies (Davison et al., 2010; Tze-Wah et al., 2009) and could reflect a logic in which they turn to the divine for hope and comfort when they are not experiencing physical improvement. The patients on

CAPD also showed higher scores on the LSPS (p=0.06) compared to the APD and HD groups. Consistent with prior studies, the use of spiritual/religious beliefs and practices reportedly helped the patients with ESRD to endure their disease as well as provide methods of coping (Finkelstein, et al., 2007; Kimmel, et al., 2003; Patel, et al., 2002).

Depression and Anxiety. Depression has been demonstrated to be an independent factor associated with poor HR-QOL (Cruz et al., 2010). Rates for depression in prior studies of patients with ESRD have ranged from 25% to 65% (Bilgic, et al., 2007; Drayer et al, 2006; Weisbord, et al., 2005); the overall rate for depression in the present study was 11%. Reasons for these differences are not known. One might speculate that the high rates of *familism* (connection with family; thereby, high family support) in the Mexican culture might account for the lower rates in this population. Further studies are needed to determine if culture plays a role in mood in the presence of debilitating illness. To date, this appears to be the first study to examine anxiety among Mexican patients with ESRD on three types of dialysis. Notably, the patients on CAPD in this study reported the poorest HR-QOL and showed higher depression and anxiety scores, albeit not significantly so, compared to the other two dialysis groups. This finding does not match Kalender and colleagues (2007), who found the higher proportion of depressive patients in the HD compared to the CAPD group. The patients on CAPD were also more likely to report RLS, which has been correlated with higher depression and anxiety rates in a population based study (Sevim et al., 2004). It is suggested that future studies of sleep disorders by dialysis type include

standardized depression and anxiety measures, family histories of these mood disorders along with assessment for RLS (patient and family) to determine associations between these variables.

Utility & Cost Analysis. This is the first study to examine the cost-effectiveness of three dialysis modalities (CAPD, APD and HD). Findings from this study support APD as it is less costly and most efficient. One other study done in Mexico estimated costs, but did not include HR-QOL for dialysis; the per-patient cost of HD was 35% higher than PD (Prieto, et al., 2007). Liem and colleagues (2008) examined health utility (akin to SF-6D scores) for HD, PD and renal therapy (RT) and found no significant differences in utility; however, QALY and cost analysis was not included in the study. A cost analysis study that compared health utility and lifelong QALY of HD, PD and RT was consistent with findings from this study; findings indicated that after RT, PD was the second most cost-effective therapy (Kontodimopooulos & Niakas, 2007).

Some differences in findings relevant to cost findings in this study could be related to what was included and available for analysis. Cost for this study was based on public purchase information estimated by year and by patient. The cost for CAPD and APD did not include taxes, catheter insertion costs, physician or nursing fees, monthly visits to the nephrology clinic or patient/primary caregiver training, transportation, home visits, or medication. The cost for HD did not include taxes, cost for vascular access, tri-weekly transportation to and from the clinic, clinic costs, nephrology visits, nursing care, patient/primary caregiver

education or medications. Each modality cost was calculated based on average number of treatments relevant to the modality type. Future studies of cost effectiveness analysis should include these and other related direct and indirect costs for each modality type for more exact accounts. Given the high costs for clinic visits and trained personnel, however, HD will remain the most costly financially.

Clinical Implications. There are a number of important clinical implications to be derived from this study. First, SF-36 and PCS and MCS norms are available for Mexican patients with ESRD which can be used as benchmarks for HR-QOL outcomes studies, including between modality types. Sleep disorders, in particular, and income accounted for 34% of the variance in the mental health model. Training in the assessment of and interventions for sleep disorders, particularly for advanced practice nurses can be implemented to promote healthful sleep that can contribute to improvements in mental HR-QOL. A majority of the sleep symptoms can be addressed through nurse/patient teaching, cognitive-behavioral approaches, sleep hygiene and other non-pharmacologic interventions. Nephrologists and physicians who practice sleep medicine in Mexico should be apprised of the propensity for witnessed apnea and snoring rates of patients with ESRD, particularly patients on APD to determine if there are treatment-related contributions to these rates and treat accordingly (e.g., weight loss, continuous positive airway pressure breathing). Prior associations noted between RLS and mood suggest that treatment of mood disorders of dialysis patients might lessen RLS symptoms. Other clinical implications include

assessing the best treatment option for the given ESRD patient, whether APD, HD or CAPD. Based on findings from this study, APD would be the recommended intervention that provides effective cost with best HR-QOL outcomes. The cost analysis from this study also lends basis to informing health policy for patients with ESRD and their treatment.

Limitations of the Study. As with any study, there are limitations as well. These include, small sample size, costs solely from bids that do not include all durables relevant to providing care for HD, APD and CAPD patients, potential for participants to want to please the interviewer, which might have influenced responses, and data collected from one state in central Mexico, which hinders generalizability of findings. The cross-sectional study design cannot infer cause and effect relationships between variables. The pilot nature of this study and the generous *p*-value of 0.10 is also a limitation. Future studies will need to recruit larger samples of participants within each of the modality types to determine consistency of findings with a more stringent level of significance that accounts for multiple variables (i.e., Bonferroni correction).

Summary. Despite any limitations, this study has provided a first-ever glimpse of SF-36 norms for Mexican patients with ESRD. Norms for this disorder have yet to be established for patients with ESRD from other countries. As well, findings have identified sleep disorders experienced by patients within dialysis modalities, and these sleep disorders impinge greatly on the mental health of ESRD patients. Identification of the sleep disorder types alone can inform medical

and nursing curriculum in Mexico for assessing and treating sleep disorders that can lead to improved HR-QOL. Importantly, the SF-6D scores derived from the SF-36 in tandem with QALY data have provided insight into the most efficacious form of dialysis delivery that is cost effective and supports improved HR-QOL, the APD modality.

REFERENCES

Ackermann, R. T., Edelstein, S. L., Venkat-Narayan, K. M., Zhang P., Engelgau, M. M., Herman, W.H., & Marrero, D.G. (2009). Changes in health state utilities with changes in body mass in the Diabetes Prevention Program. *Obesity, 17*, 2176-2181. doi: 10.1038/oby.2009.114

Albrecht, G.L., Devlieger, P. J. (1999). The disability paradox: High quality of life against all odds. *Social Science & Medicine*; *48,* 977-988.

Al-Jahdali, H. H., Khogeer, H. A., Al-Qadhi, W. A., Baharoon, S., Tamim, H., Al-Hejaili, F. F., Al-Ghamdi, S. M., & Al-Sayyari, A. A. (2010). *Journal of Circadian Rhythms, 8*, 1-7. Retrieved from http://www.jcircadianrhythms.com/content/8/1/7

Almeida-Araujo, S.M.H, Mireles-Sales de Bruin, V., Nepomuceno, L.A., Lelio-Maximo, M., De Francesco-Daher, E., Correia-Ferrer, D.P., & Carvalhedo-de Bruin, P.F. (2010). Restless legs syndrome in end-stage renal disease: Clinical characteristics and associated comorbidities. *Sleep Medicine, 11*(8), 785-790.

Alvarez-Ude, F., Alamo, C., Fernández-Reyes, M. J., Bravo B., Vicente E., Ferrer, M., Alonso, J., & Badia, X. (1999). Alteraciones del sueño y salud percibida en pacientes en hemodiálisis crónica. *Nefrología*, *19*(2), 168-176.

Amato, D., Alvarez-Aguilar, C., Castañeda-Limones, R., Rodríguez, E., Avila-Díaz, M., Arreola, F.,…Paniagua, R. (2005). Prevalence of chronic kidney disease in an urban Mexican population. *Kidney International*, *68*(97), S11-S17.

Anderson, K. L., & Burckhardt, C. S. (1999). Conceptualization and measurement of quality of life as an outcome variable for health care intervention and research. *Journal of Advanced Nursing*, *29*(2), 298-306.

Atkins, R. C., & Zimmet, P. (2009). Diabetic Kidney disease: Act now or pay later? "World Kidney Day" March 11th 2010. *Archivos de Cardiología de México*, *80*(1), 44-47. Retrieved from www.elsevier.com.mx

Bakewell, A. B., Higgins, R. M., & Edmunds, M. E. (2002). Quality of Life in peritoneal dialysis patients: Decline over time and association with clinical outcomes. *Kidney International*, *61*, 239-248.

Balasubramanian, G., McKitty, K., & Fan, S. L. S. (2010). Comparing automated peritoneal dialysis with continuous ambulatory peritoneal dialysis: survival and quality of life differences? *Nephrology Dialysis Transplantation*, *25*(5), 1702-1708. doi: 10.1093/ndt/gfq607

Baldwin, C. M., Bell, I. R. & Quan, S. F. (2005). RLS is associated with depression and elevated leptin in military veterans. *Sleep*, *28*, A269.

Baldwin, C. M., Ervin, A., Mays, M. Z., Robbins, J., Shafazand, S., Walsleben, J., & Weaver, T. (2010). Sleep disturbances, quality of life and ethnicity: The Sleep Heart Health Study. *Journal of Clinical Sleep Medicine*, *6*, 176-183.

Baldwin, C. M., Griffith, K. A., Nieto, F. J., O'Connor, G. T., Walsleben, J. A., & Redline, S. (2001). The association of sleep-disordered breathing and sleep symptoms with quality of life in the Sleep Heart Health Study. *Sleep, 24,* 96-105.

Baldwin, C. M. Kapur, V. K., Holberg, C. J., Rosen, C., & Nieto, F. J. (2004). Associations between gender and measures of daytime somnolence in the Sleep Heart Health Study. *Sleep, 27,* 305-311.

Baldwin, C. M., Mays M. Z., Márquez-Gamiño S., Caudillo-Cisneros, C., & Quan, S. F. (2008). English/Spanish cross validation of a sleep measure [Abstract]. *Sleep*, *31*, A337.

Baldwin, C. M., Mays, M. Z., Marquez-Gamino, S., Caudillo-Cisneros, C., Reynaga-Ornelas, L., & Quan, S. F. (2009). Correlation versus agreement of the Spanish and English versions of the SHHS Sleep Habits Questionnaire insomnia subscale [Abstract]. *Sleep*, *32*, A375.

Beecroft, J. M., Pierratos, A., & Hanly, P. J. (2009). Clinical presentation of obstructive sleep apnea in patients with end-stage renal disease. *Journal of Clinical Sleep Medicine*, *5*(2), 115-121.

Bennett, J. A., & Riegel, B. (2003). United States Spanish Short-Form-36 Health Survey: Scaling assumptions and reliability in elderly community-dwelling Mexican Americans. *Nursing Research*, *52*, 262-269.

Bernick, L. (2004). Caring for older adults: Practice guided by Watson's Caring-Healing Model. *Nursing Science Quarterly*, *17*, 128-134. doi: 10.1177/0894318404263374

Bilgic, A., Akgul, A., Sezer, S., Arat, Z., Ozdemir, F. N., & Haberal, M. (2007). Nutritional status and depression, sleep disorder, and quality of life in hemodialysis patients. *Journal of Renal Nutrition*, *17*(6), 381-388. doi: 10.1053/j.jrn.2007.08.008.

Brazier J., Roberts J., & Deverill M. (2002). The estimation of a preference-based measure of health from the SF-36. *Journal of Health Economics, 21*, 271-292.

Brennan, C., Worral-Davies, A., McMillan, D., Gilbody, S., & House, A. (2010). The Hospital Anxiety and Depression Scale: A diagnostic meta-analysis of case-finding ability. *Journal of Psychosomatic Research, 69*, 371-378.

Bro, S., Bjorner, J. B., Tofte-Jensen, P., Klem S., Almtoft, B., Danielsen, H.,…Feldt-Rasmussen, B. (1999). A prospective randomized multicenter study comparing APD and CAPD treatment. *Peritoneal Dialysis International*, *19*, 526-533. Retrieved from www.pdiconnect.com

Brown, E. A., Johansson, L., Farrington, K., Gallagher H., Sensky, T., Gordon, F.,..Hickson, M. (2010). Broadening options for long-term dialysis in de elderly (BOLDE): Differences in quality of life on peritoneal dialysis compared to haemodialysis for older patients. *Nephrology Dialysis Transplantation*, *1*, 9. doi: 10.1093/ndt/gfq212

Burrowes, J. D., & Van Houten, G. (2005). Use of alternative medicine by patients with stage 5 chronic kidney disease. *Advances in Chronic Kidney Disease*, *12*(3), 312-325. doi: 10.1053/j.ackd.2005.04.001

Caballero-Morales, S., Trujillo-Garcia, J. U., Welsh-Orozco, U., Hernandez-Cruz, S. T., & Martinez-Torres, J. (2006). Quality of life in patients with hemodialysis, and ambulatory and automated continuous peritoneal dialysis. *Archivos en Medicina Familiar, 8*(3), 163-168.

Campesino, M., Belyea, M., & Schwartz, G. (2009). Spirituality and cultural identification among Latino and non-Latino college students. *Hispanic Health Care International*, *7*(2), 72. doi: 10.1891/1540-4153.7.2.72

Campesino, M., & Schwartz, G. (2006). Spirituality among Latinas/os implications of culture in conceptualization and measurement. *Advanced Nursing Practice*, *29*(1), 69-81.

Cengić, B., Resić, H., Spasovski, G., Avdić E., & Alajbegović, A. (2010). Quality of sleep in patients undergoing hemodialysis. *International Urology Nephrology*. doi: 10.1007/s11255-010-9881-x

Chan, R., Brooks, R., Steel, Z., Heung, T., Erlich, J., Chow, J., & Suranyi, M. (2011). *Quality of Life Research*, [Epub ahead of print]. doi: 10.1007/s11136-011-9973-9

Chaudhary, K., Sangha, H., & Khanna, R. (2011). Peritoneal Dialysis First: Rationale. *Clinical Journal of the American Society of Nephrology*, *6,*447-456. doi: 10.2215/CJN.07920910

Cohen, S. D., Patel, S. S., Khetpal, P., Peterson, R. A., & Kimmel, P. L. (2007). Pain, sleep disturbance, and quality of life in patients with chronic kidney disease. *Clinical Journal of the American Society of Nephrology*, *2*, 919-925. doi: 10.2215/CJN.00820207

Collins, A. J., Gilbertson, D. T., Snyder, J. J., Chen S., & Foley, R. N. (2010). Chronic kidney disease awareness, screening and prevention: Rationale for

the design of a public education program. *Nephrology*, *15*, 37-42. doi: 10.1111/j.1440-1797.2010.01312.x

Contraloría Ciudadana para la Rendición de Cuentas, A. C. (2010). Testimonio de la participación como testigo social en la Licitación Pública Nacional No. 00637173-002-10 para la contratación del servicio integral de hemodiálisis del 2010 al 2012. Retrieved from http://www.contraloriaciudadana.org.mx/atestiguamientos_federales/documentos/TESTIMONIO_HEMODIALISIS.pdf

Cruz, D.N., Troidle, L., Danguilan, R., Padilla, B., Frando, L., Sebastian, E., & Finkelstein, F. (2011). Factors influencing dialysis modality for end-stage renal disease in developing countries: A survey of Filipino nephrologists. *Blood Purification, 32*(2), 117-123. doi: 10.1159/000324396

Cruz, L.N., Fleck, M.P., & Polanczyk, C. A. (2010). Depression as a determinant of quality of life in patients with chronic disease: data from Brazil. *Society of Psychiatry Psychiatric Epidemiology, 45*(10):953-61.

Cueto-Manzano, A. M., & Rojas-Campos, E. (2007). PD in the developing world. Status of renal replacement therapy and peritoneal dialysis in Mexico. *Peritoneal Dialysis International*, *27*, 142-148. Retrieved from www.PDIConnect.com

Cummins, R. A. (2005). Moving from the quality of life concept to a theory. *Journal of Intellectual Disability Research*, *49*(10), 699-706.

Cusumano, A., García-García G., & González Bedat, C. (2009). The Latin American dialysis and transplant registry: Report 2006. *Ethnicity & Disease*, *19*, (S1) 3-6.

De Wit, G. A., Merkus, M. P., Krediet, R. T, & De Charro, F. T. (2001). A comparison of quality of life of patients on automated and continuous ambulatory peritoneal dialysis. *Peritoneal Dialysis International*, *21*(3), 306-312.

Davison S. N., & Jhangri, G. S. (2010). Existential and religious dimensions of spirituality and their relationship with health-related quality of life in chronic kidney disease. *Clinical Journal of the American Society of Nephrology* (epress). doi: 10.2215/CJN.01890310

Davison, S. N., & Jhangri, G. S. (2010a). Existential and supportive care needs among patients with chronic kidney disease. *Journal of Pain and Symptom Management*, (in press). doi: 10.1016/j.jpainsymman.2010.03.015

Davison, S. N., Jhangri, G. S., & Fenny, D. H. (2009). Comparing the health utilities Index Mark 3 (HUI3) with the Short Form-36 preference-based SF-

6D in chronic kidney disease. *Value in Health*, *12*(2), 340-345. doi: 10.1111/j.1524-4733.2008.00433.x

Delgado-Serrano, J. (2011). Procedimiento de licitación nacional mixta No. LA-019GYN005-N9-2011. Testimonio, 1-8. Retrieved from http://www.issste.gob.mx/www/prebases/documents/dadm_servdialisisperi_25abral25jul_2011.pdf

Drayer, R. A., Piraino, B., Reynolds III, C. F., Houck, P. R., Mazumdar, S., Bernardini, J., Shear, M. K. & Rollman, B. L. (2006). Characteristics of depression in hemodialysis patients: Symptoms, quality of life and mortality risk. *General Hospital Psychiatry*, *28*, 306-312. Retrieved from www.sciencedirect.com

Duncan, H. J., Pittman, S., Govil, A., Sorn, L., Bissler, G., Schultz, T., & Roy-Chaudhury, P. (2007). Alternative medicine use in dialysis patients: Potential for good and bad! *Nephron Clinical Practice*, *105*, c108-c113. doi: 10.1159/000097986

Durán-Arenas, L., Gallegos-Carrillo, K., Salinas-Escudero, G., & Martínez-Salgado, H. (2004). Hacia una base normativa mexicana en la medición de calidad de vida relacionada con la salud, mediante el Formato Corto 36. *Salud Pública de México*, *46*, 306-315.

Eghbali, M., Shahqolian, N., Nazari, F., & Babaee, S. (2008). Comparing problems of patients with chronic renal failure undergoing hemodialysis and peritoneal dialysis referring to medical university's hospitals. *Iranian Journal of Nursing and Midwifery Research*, *14*(1), 1-5.

Eryavuz, N., Yuksel, S., Acarturk, G., Uslan I., Demir, S., Demir, M., & Sezer, M. T. (2008). Comparison of sleep quality between hemodialysis and peritoneal dialysis patients. *International Urology and Nephrology*, *40*, 785-791. doi: 10.1007/s11255-008-9359-2

Esquivel-Molina, C. G., Prieto-Fierro, J. G., López-Robledo, J., Ortega-Carrasco R., Martínez-Mendoza, J. A., & Velasco-Rodríguez, V. M. (2009). Calidad de vida y depresión en pacientes con insuficiencia renal crónica terminal en hemodiálisis. *Medicina Interna de México*, *25*(6), 443-449.

Feeny, D., Wu, L. & Eng, K. (2004). Comparing Short Form 6D, Standard Gamble, and Health Utilities Index Mark 2 and Mark 3 utility scores: Results from total hip arthroplasty patients. *Quality of Life Research, 13*, 1659-1670.

Ferrans, C. E., Zerwic, J. J., Wilbur, J. E., & Larson, J. L. (2005). Conceptual model of health-related quality of life. *Journal of Nursing Scholarship, 37*(4), 336-342.

Finkelstein, F. O., West, W., Gobin, J., Finkelstein, S. H., & Wuerth, D. (2007). Spirituality, quality of life and the dialysis patient. *Nephrology Dialysis Transplantation*, *22*, 2432-2434. doi: 10.1093/ntd/gfm215

Fowler, C., & Bass, L. S. (2006). Ilness representations in patients with chronic kidney disease on maintenance hemodialysis. *Nephrology Nursing Journal*, 33(2), 173-187.

Frenk, J., Sepúlveda, J., Gómez-Dantés, O., & Knaul, F. (2003). Evidence-based health policy: Three generations of reform in Mexico. *The Lancet*, *362*, 1667-71.

Frimat, L., Durand, P. Y., Loos-Ayav, C., Villar E., Panescu, V., Briancon, S., & Kessler, M. (2006). Impact of first dialysis modality on outcome of patients contraindicated for kidney transplant. *Peritoneal Dialysis International, 26*, 231-239. Retrieved from www.PDIConnect.com

Fructuoso, M., Castro, R., Oliveira, L., Prata, C., & Morgado, T. (2011). Quality of life in chronic kidney disease. *Nefrología, 31*(1), 91-96. doi: 10.3265/Nefrologia.pre2010.Jul.10483.

Fundación Mexicana del Riñón. (2007). *Fundación Mexicana del Riñón*, 2007. Retrieved from http://www.fundrenal.org.mx/

Gallegos-Carrillo, K., Mudgal, J., Sánchez-García, S., Wagner, F.A., Gallo, J.J., Salmerón, J., & García-Peña, C. (2009). Social networks and health-related quality of life: A population based study among older adults. *Salud Pública de México*, *51*, 6-13.

García-García, G., Reniorte-López, K., & Márquez-Magaña, I. (2010). Disparities in renal care in Jalisco, Mexico. *Seminars in Nephrology*, *30*(1), 3-7. doi: 10.1016/j.semnephrol.2009.10.001

García, H., & Calvanese, N. (2008). Calidad de vida percibida, depresión y ansiedad en pacientes con tratamiento sustitutivo de la función renal. *Psicología y Salud*, *18*(1), 5-15.

Gil-Cunqueiro, J. M., García-Cortés, M. J., Foronda, J., Borrego, J. F., Sánchez-Perales, M.C.,…Pérez-Bañasco, V. (2003). Calidad de vida relacionada con la salud en pacientes ancianos en hemodiálisis. *Nefrología*, *23*(6), 528-537. ISSN 0211-6995

Ginieri-Coccossis, M., Theofilou, P., Synodinou, C., Tomaras V., & Soldatos, C. (2008). Quality of life, mental health and health beliefs in haemodialysis and peritoneal dialysis patients: Investigating differences in early and later years of current treatment. *BMC Nephrology*, *9*, 14. doi: 10.1186/1471-2369-9-14

Goncalves-Campolina, A. , Bruscato-Bortoluzzo, A., Bosi-Ferraz, M., & Mesquita-Ciconelli, R. (2010). The SF-6D Brazil Questionnaire: Generation models and applications in health economics. *Rev Assoc Med Bras*, *56*(4), 409-414.

Gottlieb, D. J., Punjabi, N. M., Newman, A. B., Resnick, H. E., Redline, S., Baldwin, C. M., & Nieto, J. (2005). Association of sleep time with diabetes mellitus and impaired glucose tolerance. *Archives of Internal Medicine*, *165*, 863-868.

Gottlieb, D. J., Redline, S., Nieto, J., Baldwin C. M., Newman, A. B., Resnick, H. E., & Punjabi, N. M. (2006). Association of usual sleep duration with hypertension: The Sleep Heart Health Study. *Sleep*, *29*(8), 1009-1014.

Grincenkov, F. R., Fernandes, N., Chaoubah, A., Bastos, K., Qureshi, A. R., Pécoits-Filho, R., Divino Filho, J. C., & Bastos, M. G. (2011). Factors associated with the quality of life of incident patients on PD in Brazil (BRAZPD). *Journal of Brazilian Nephrology, 33*(1):38-44.

Guney, I., Atalay, H., Solak, Y., Altintepe L., Toy, H., Tonbul, H. Z., & Turk, S. (2010). Predictors of sleep quality in hemodialysis patients. *The International Journal of Artificial Organs*, *33*(3), 154-160. ISSN 0391-3988

Gusbeth-Tatomir, P., Boisteanu, D., Seica, A., Buga, C., & Covic, A. (2007). Sleep disorders: A systematic review of an emerging major clinical issue in renal patients. *International Urology and Nephrology*, *39*, 1217-1226. doi: 10.1007/s11255-007-9262-2

Hass, B. K. (1999). Clarification and integration of similar quality of life concepts. *Journal of Nursing Scholarship*, *31*(3), 215-220.

Hanly, P. (2008). Sleep disorders and end-stage renal disease. *Current Opinion on Pulmonar Medicine*, *14*, 543-550. doi: 10.1097/MCP.0b013e328310f96

Harris, S. A. C., Lamping, D. L., Brown, E. A., & Constantinovici, N. (2002). Clinical outcomes and quality of life in elderly patients on peritoneal dialysis versus hemodialysis. *Peritoneal Dialysis International, 22*, 463-470.

Herrmann, C. (1997). International experiences with the Hospital Anxiety and Depression Scale - a review of validation data and clinical results. *Journal of Psychosomatic Research, 42* (1), 17-41.

Hornbrook, M. C., Wendel, C. S., Coons, S. J., Grant, M., Herrinton, L. J., Mohler M. J., Baldwin C. M., McMullen C. K., Green, S. B., Altschuler A., Rawl, S. M., & Krouse R. S. (2011). Complications among colorectal cancer survivors: SF-6D preference-weighted quality of life scores. *Medical Care, 49*(3), 321-326. doi: 10.1097/MLR.0b013e31820194c8

Instituto Nacional de Salud Pública. (2011). Corrigen al alza datos sobre diabetes; la padecen 14.4%. *La Jornada.* Retrieved from http://www.insp.mx/noticias/nutricion-y-salud/1782-revision-de-la-ensanut-2006-144-la-prevalencia-de-diabetes.html

Jaar, B. G., Coresh, J., Plantinga, L. C., Fink, N. E., Klag, M. J., Levey, A. S.,…Powe, N. R. (2005). Comparing the risk for death with peritoneal dialysis and hemodialysis in a national cohort of patients with chronic kidney disease. *Annals of Internal Medicine*, *143*, 174-183. Retrieved from www.annals.org

Johansen, K. L. (2011). Choice of dialysis modality in United States. *Archives of Internal Medicine*, *171*(2), 107-109.

Johns, M. W. (1991). A new method for measuring daytime sleepiness: The Epworth Sleepiness Scale. *Sleep, 14,* 540-545.

Joyce, C. R. B., Hickey, A., McGee, H. M., & O'Boyle, C. A. (2003). A theory-based method for the evaluation of individual quality of life: The SEIQoL. *Quality of Life Research*, *12*, 275-280.

Juergensen, E., Wuerth, D., Finkelstein, S. H., Juergensen, P., H., Bekui, A., & Finkelstein, F. O. (2006). Hemodialysis and peritoneal dialysis: Patients' assessment of their satisfaction with therapy and the impact of the therapy on their lives. *Clinical Journal of the American Society of Nephrology*, *1*, 1191-1196. doi: 10.2215/CJN.01220406

Kalender, B., Ozdemir, A. C., Dervisoglu, E., & Ozdemir, O. (2007). Quality of life in chronic kidney disease: Effects of treatment modality, depression, malnutrition and inflammation. *Journal of Clinical Practice*, *61*(4), 569-576. doi: 10.1111/j.1742-1241.2006.01251.x

Kaltsouda, A., Skapinakis, P., Damigos, D., Ikonomou, M., Kalaitzidis, R., Mavreas, V., & Siamopoulos, K.C. (2011). Defensive coping and health-related quality of life in chronic kidney disease: A cross-sectional study. *BMC Nephrology*, *12*(1), 28.

Kimmel P. L., Emont S. L., Newmann J. M., Danko H., & Moss A. H. (2003). ESRD patient quality of life: Symptoms, spiritual beliefs, psychosocial factors and ethnicity. *American Journal of Kidney Diseases*, *42*(4), 713-721. doi: 10.1053/S0272-6386(03)00907-7

Kontodimopooulos, N., & Niakas, D. (2007). An estimate of lifelong costs and QALYs in renal replacement therapy based in patients's life expectancy. *Health Policy*, *86*(1), 85-96. doi: 10.1016/j.healthpol.2007.10.002

Korevaar, J. C., Feith, G. W., Dekker, F. W., Van Manen, J. G., Boeschoten E. W., Bossuyt, M. M., & Krediet, R. T. (2003). Effect of starting with

hemodialysis compared with peritoneal dialysis in patients new on dialysis treatment: A randomized controlled trial. *Kidney International*, *64*, 222-228.

Kung, W. W., & Lu, P. C. (2008). How symptom manifestations affect help seeking for mental health problems among Chinese Americans. *Journal of Nervous and Mental Disease, 196*, 46-54.

Kump, K., Whalen, C., Tishler, P. V., Browner, I., Ferrette, V., Strohl, K. P., Rosenberg, C., & Redline, S. (1994). Assessment of the validity and utility of a sleep-symptom questionnaire. *American Journal of Respiratory and Critical Care Medicine, 150,* 735-741.

Kusek, J. W., Greene, P., Wang, S. R., West, D., Jamerson, K., Agodoa, L. Y., Faulkner, M., & Level, B. (2002). Cross-sectional study of quality of life in African Americans with chronic renal insufficiency: The African American Study of Kidney Disease and Hypertension Trial. *American Journal of Kidney Diseases*, *39* (3).

Kusumoto, L., Marques, S., Haas, V. J., & Rodrigues, R. (2008). Adults and elderly on hemodialysis evaluation of health related quality of life. World Congress of Nephrology Nursing, São Paulo, 2007. *Acta Paulista De Enfermagem*, *21*, 152-159.

Kutner, N. G., Zhang, R., Barnhart, H., & Collins, A. J. (2005). Health status and quality of life reported by incident patients after 1 year on hemodialysis or peritoneal dialysis. *Nephrology Dialysis Transplantation*, *20*(10), 2159-2167. doi: 10.1093/ndt/gfh973

Kutner, N. G., Zhang, R., Huang, Y., & Bliwise, D. L. (2007). Association of sleep difficulty with kidney disease quality of life cognitive function score reported by patients who recently started dialysis. *Clinical Journal of the American Society of Nephrology*, *2*, 284-289. doi: 10.2215/CJN.030000906

Lareau, S. C., Breslin, E. I., & Meek, P. M. (1996). Functional status instruments: outcome measure in the evaluation of patients with chronic obstructive pulmonary disease. *Heart Lung, 25*, 212-224.

Liem, Y. S., Bosch, J. L., & Hunink, M. (2008). Preference-based quality of life of patients on renal replacement therapy: A systematic review and meta-analysis. *Value in Health*, *11*(4), 773-741. doi: 10.1111/j.1524-4733.2007.00308.x

Lii, Y. C., Tsay, S. L., & Wang, T. J. (2007). Group intervention to improve quality of life in haemodialysis patients. *Journal of Nursing and Healthcare of Chronic Illness in association with Journal of Clinical Nursing*, *16*(11c), 268–275.

Markell, M. (2005). Potential benefits of complementary medicine modalities in patients with chronic kidney disease. *Advances in Chronic Kidney Disease*, *12*(3), 292-299. doi: 10.1053/j.ackd.2005.03.004

Martin, C. R., & Thompson, D. R. (2000). Prediction of quality of life in patients with end-stage renal disease. *British Journal of Health Psychology*, 5, 41-55.

McDonald, S. P., Marshall, M. R., Johnson, D. W., & Polkinghorne, K. R. (2009). Relationship between dialysis modality and mortality. *Journal of the American Society of Nephrology*, *20*(1), 155-163. doi: 10.1681/ASN.2007111188

McHorney, C. A., Ware, J. E., & Raczec, A. E. (1993). The MOS 36-item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. *Medical Care*, *31*(3), 247-263.

McHorney, C. A., Ware, J. E., Rachel Lu, J. F., & Sherbourne, C. D. (1994). The MOS 36-item short-form health survey (SF-36): III. Tests of data quality, scaling assumptions and reliability across diverse patient groups. *Medical Care*, *32*(1), 40-66.

Mehrota, R., Chiu, Y., Kalantar, K., & Vonesh E. (2009). The outcomes of continuous ambulatory and automated peritoneal dialysis are similar. *Kidney International*, *76*, 97-107. doi: 10.1038/ki2009.94

Meichelboeck, W. (2011). *End stage renal disease (ESRD) epidemiology – Where are we going?* Paper presented at the Seventh International Congress of the Vascular Access Society, Istanbul (Turkey). Retreived from http://www.vascularaccesssociety.com/images/stories/PDF/meichelboeck%20wolfgang_esrd-epidemiology%20-20where%20are%20we%20going_vas%20congress_istanbul_tr_may%202011_web.pdf

Mei-Fen, P., Shing-Ping H., Shao-Yu, Y., Tai-I, H., Chun-Fu, L., & Yu-Sen, P. (2007). Sleep disturbance in chronic hemodialysis patients: The impact of depression and anemia. *Renal Failure*, *29*, 673-677. doi: 10.1080/08860220701459642

Méndez-Durán, A., Méndez-Bueno, J. F., Tapia-Yáñez, T., Muñoz-Montes, A., & Aguilar-Sánchez, L. (2010). Epidemiología de la insuficiencia renal crónica en México. *Diálisis y Trasplante*, *31*(1), 7-11. Retrieved from www.elsevier.es/dialisis

Mittal, S. M., Ahern, L., Flaster, E., Mittal, V. S., Maesaka, J. K., & Fishbane, S. (2001). Self-assessed quality of life in peritoneal dialysis patients. *American Journal of Nephrology*, *21*, 215-220.

Morsch, C. M., Goncalves, L. F., & Barros, E. (2006). Health-related quality of life among haemodialysis patients–relationship with clinical indicators, morbidity and mortality. *Journal of Clinical Nursing 15*, 498-504.

Morales-Jaimes, R., Salazar-Martínez, E., Flores-Villegas, F. J., Bochicchio-Riccardelli, T., & López-Caudana, A. E. (2007). Calidad de vida relacionada con la salud en los pacientes con tratamiento sustitutivo renal: El papel de la depresión. *Gaceta Médica Mexicana*, *144*(2), 91-98.

Mucsi, I., Molnar, M. Z., Rethelyi, J., Vamos, E., Csepanyi, G., Tompa, G.,…Novak, M. (2004). Sleep disorders and intrusiveness in patients on chronic dialysis. *Nephrology Dialysis and Transplantation*, *19*, 1815-1822. doi: 10.1093/ndt/gfhl30

National Center for Health Statistics. (2008). Data *File Documentation, National Health Interview Survey, 2007* (machine readable data file and documentation). National Center for Health Statistics, Centers for Disease Control and Prevention, Hyattsville, Maryland.

Newman, A. B., Nieto, F. J., Guidry, U., Lind, B. K., Redline, S., Pickering, T. G., & Quan, S. F. (2001). Relation of sleep-disordered breathing to cardiovascular disease risk factors in the Sleep Heart Health Study. *American Journal of Epidemiology, 154,* 50-59.

Nieto, F. J., Young, T. B., Lind, B. K., Shahar, E., Samet, J. M., Redline, S.,… Pickering, T. G. (2000). Association of sleep-disordered breathing, sleep apnea, and hypertension in a large community-based study. *Journal of the American Medical Association, 283,* 1829-1836.

Nissenson, A. R. (1994). Measuring, managing, and improving quality in the end-stage renal disease treatment setting: Peritoneal dialysis. *American Journal of Kidney Disease*, *24*(2), 368-75.

Nowack, R., Ballé, C., Birnkammer, F., Koch, W., Sessler, R., & Brick, R. (2009). Complementary and alternative medications consumed by renal patients in Southern Germany. *Journal of Renal Nutrition*, *19*(3), 211-219. doi: 10.1053/j.jrn.2008.08.008

O'Connor, G. T., Lind, B. K., Lee, E. T., Nieto, F. J., Redline, S., Samet, J. M., & Foster, G. L. (2002). Variation in symptoms of sleep-disordered breathing with race and ethnicity: The Sleep Heart Health Study. *Sleep, 26,* 74-79.

Pan American Health Organization. (2007). *Health in the Americas*. México. Retrieved from http://www.paho.org/hia/vol1regionaling.html

Panagopoulou, A., Hardalias, A., Berati, S., & Fourtounas, C. (2009). Psychosocial issues and quality of life in patients on renal replacement

therapy. *Saudi Journal of Kidney Diseases and Transplantation*, *20*(2), 212-218. Retrieved from www.sjkdt.org

Paniagua, R., Amato, D., Vonesh, E., Guo, A., & Mujais, S. (2005). Health-related quality of life predicts outcomes but is not affected by peritoneal clearance: The Ademex trial. *Kidney International*, *67*, 1093-1104.

Paniagua, R., Ramos, A., Fabian, R., Lagunas, J., & Amato, D. (2007). Peritoneal dialysis in America. Chronic kidney disease and dialysis in Mexico. *Peritoneal Dialysis International*, *27*, 405-409. Retrieved from www.pdiconnect.com

Patel, S. S., Shah, V. S., Peterson, R. A., & Kimmel, P. L. (2002). Psychosocial variables, quality of life, and religious beliefs in ESRD patients treated with hemodialysis. *American Journal of Kidney Diseases*, *40*(5), 1013-1022. doi: 0272-6386/02/4005-0017

Pecoits-Filho, R., Campos, C., Cerdas-Calderón, M., Fortes, P., Jarpa, C., Just, P.,... De Arteaga, J. (2008). Policies and health care financing issues for dialysis in Latin America: Extracts from the roundtable discussion on the economics of dialysis and chronic kidney disease. *Peritoneal Dialysis International*, *29*(52), S222-226. Retrieved from PDIConnect.com

Perl, J., Unruh, M. L., & Chan, C. T. (2006). Sleep disorders in end-stage renal disease: 'Markers of inadequate dialysis?' *Kidney International, 70*, 1687-1693.

Plummer, M., & Molzhan, A. E. (2009). Quality of life in contemporary nursing theory: A concept analysis. *Nursing Sciences Quarterly*, *22*, 134-140. doi: 10-1177/0894318409332807

Prieto, I., Bhattacharyya, S. K., Divino J.C., & Paniagua R. (2007). Cost of treating ESRD patients with various dialysis therapies in Mexico. *IHEA 2007 6th World Congress: Explorations in Health Economics Paper*. Available at SSRN: http://ssrn.com.ezproxy1.lib.asu.edu/abstract=992072

Rabindranath, K. S., Adams, J., Aly, T. Z., Daly, C., Vale, L., & MacLeod, A. M. (2007). Automated vs. continuous ambulatory peritoneal dialysis: A systematic review of randomized controlled trials. *Nephrology Dialysis and Transplantation*, 1-8 doi: 10.1093/ndt/gfm515

Rapkin, B. D., & Schwartz, C. E. (2004). Toward a theoretical model of quality-of-life appraisal: Implications of findings from studies of response shift. *Health and Quality of life Outcomes*, *2*, 14. Retrieved from www.hqlo.com/content/2/1/14

Reed, P. G., & Shearer, N. B. C. (2009). *Perspectives on nursing theory* (5th ed.). Philadelphia: Lippincott Williams, & Wilkins.

Reina-Neyra, M., Cirera-Segura, F., & Martin-Espejo, J. L. (2008). Salud percibida por los pacientes en DPCA y DPA. *Revista de la Sociedad Española de Enfermería Nefrológica*, *11*(2), 102-109.

Resnick, H. E., Redline, S., Shahar, E., Gilpin, A., Newman, A., Walter, R., …Punjabi, N. M. (2003). Diabetes and sleep disturbances: Findings from the Sleep Heart Health Study. *Diabetes Care, 26,* 702-709.

Rocco, D. G., Mercieri, A., & Yavuzer, G. (2006). Multidimensional health-status assessment of chronic hemodialysis patients: The impact on quality of life. *Europa Medicophysica*, *42* (2), 113-119.

Rodriguez-Vidal, M., Castro-Salas, M., & Merino-Escobar, J. M. (2005). Calidad de vida en pacientes renales hemodializados. *Ciencia y Enfermería*, *11*(2), 47-57. ISSN 0717-2079

Rubin, H. R., Fink, N. E., Plantinga, L. C., Sadler J. H., Kliger A. S., & Powe, N. R. (2004). Patient ratings of dialysis care with peritoneal dialysis vs. hemodialysis. *Journal of the American Medical Association*, *291*(6), 697-703. Retrieved from www.jama.com

Sandoval-Jurado, L., Ceballos-Martínez, Z. I., Navarrete-Novelo, C., González-Hernández, F., & Hernández-Colín, V. (2007). Calidad de vida en pacientes con diálisis peritoneal continua ambulatoria. *Revista Médica del Instituto Mexicano del Seguro Social*, *45*(2), 105-109.

Santos, P. R., Daher, E. F., Silva, G. B., Liborio, A. B., & Kerr, L.R. (2009). Quality of life assessment among haemodialysis patients in a single centre: A 2-year follow-up. *Quality of Life Research*, *18*, 541-546. doi: 10.1007/s11136-009-9474-2

Saran, R., Hedgeman, E., Huseini, M., Stack, A., & Shahinian, V. (2010). Surveillance of chronic kidney disease around the world: Tracking and reining in a global problem. *Advances in Chronic Kidney Disease*, *17*(3), 271-181. doi: 10.1053/j.ackd.2010.03.001

Schatell, D., & Witten, B. (2008). Measuring dialysis patients' health-related quality of life with the KDQOL-36. ©2008 *Medical Education Institute, Inc*. Retrieved from http://www.lifeoptions.org/kdqol/pdfs/kdqol-36_pros_v1.2.pdf

Schwartzmann, L. (2003). Calidad de vida relacionada con la salud: Aspectos conceptuales. *Ciencia y Enfermería*, *9*(2), 9-21. ISSN 0717-2079

Secretaría de Salud. (2010). *Marco legal de la medicina tradicional y las medicinas complementarias*. Dirección de Medicina Tradicional y Desarrollo Intercultural. Subsecretaría de Innovación y Calidad. México.

Retrieved from http://www.dgplades.salud.gob.mx/interior/dmtdi_marco.html

Secretaría de Salud. (2007). *Medicina tradicional y sistemas complementarios de atención a la salud*. Plan de acción específico 2007-2012. México. Retrieved from http://www.dgplades.salud.gob.mx/interior/biblioteca.html

Sevim, S., Dogu, O., Kaleagasi, H., Aral, M., Metin, O., & Camdeviren, H. (2004). Correlation of anxiety and depression symptoms in patients with restless legs syndrome: A population based survey. *Journal of Neurology, Neurosurgery and Psychiatry, 75*, 226-230.

Shrestha, S., Ghotekar, L. R., Sharma, S. K., Shangwa, P. M., & Karki, P. (2008). Assessment of quality of life in patients of end stage renal disease on different modalities of treatment. *Journal of Nepal Medical Association*, *47*(169), 1-6. Retrieved in www.jnma.com.np

Souza, K. H., & Chen, F. F. (2002). A theoretical approach to measuring quality of life. *Journal of Nursing Measurement*, *10*(1), 47-58.

Spinale, J., Cohen, S. D., Khetpal, P., Peterson, R. A., Clougherty, B., Puchalski, C. M., Patel, S. S., & Kimmel, P. L. (2008). Spirituality, social support, and survival in hemodialysis patients. *Clinical Journal of the American Society of Nephrology*, *3*(6), 1620-1627. doi: 10.2215/CJN.01790408

Stewart, A. L., Hays, R. D., & Ware, J. E. (1988). The MOS short-form general health survey: Reliability and validity in a patient population. *Medical Care, 26,* 724-735.

Symonds, T., Berzon, R., Marquis, P., & Rummans, T. A. (2002). The clinical significance of quality-of-life-results: Practical considerations for specific audiences. *Mayo Clinic Procedures*, *77*, 572-583.

Taillefer, M. C., Dupuis, G., Roberge, M. A. & Le May, S. (2003). Health-related quality of life models: Systematic review of the literature. *Social Indicators Research, 64*, 293-323.

Tanyi, R. A., & Werner, J. S. (2003). Adjustment, spirituality, and health in women on hemodialysis. *Clinical Nursing Research*, *12*, 229-245. doi: 10.1177/1054773803253163

Tanyi, R. A., & Werner, J. S. (2008).Spirituality in African American and Caucasian women with end-stage renal disease on hemodialysis treatment. *Health Care for Women International*, *28* (2), 141-154. doi: 10.1080/0739933060112846

Tze-Wah, K., Pau-Chung, Ch., Chia-Jung, H., Hong-Wei, Ch., Lap-Yuen, T., Ing-Fang, Y.,…Wan-Yu, Ch. (2009). Correlations between spiritual beliefs and

health-related quality of life of chronic hemodialysis patients in Taiwan. *Artificial Organs*, *33*(7), 576- 579. doi: 10.1111/j.1525-1594.2009.00739.x

Unruh, M. L., Weisbord, S. D., & Kimmel, P. L. (2005). Health-related quality of life in nephrology research and clinical practice. *Seminars in Dialysis*, *18*(2), 82-90.

Unruh, M. L., Buysse, D. J., Dew, M. A., Evans I. V., Wu, A. W., Fink, N. E., …Meyer, K. B. (2006). Sleep quality and its correlates in the first year of dialysis. *Clinical Journal of the American Society of Nephrology*, *1*, 802-810. doi:10.2215/CJN.00710206

Unruh, M. L., Sanders, M. H., Redline, S., Piraino B. M., Umans, J. G., Cami, H., & Newman, A. B. (2008). Subjective and objective sleep quality in patients on conventional thrice-weekly hemodialysis: Comparison with matched controls from the Sleep Heart Health Study. *American Journal of Kidney Disease*, *52*, 305-313. doi: 10.1053/j.jakd.2008.04.019

U.S. Renal Data System, USRDS. (2008) *Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. www.usrds.org

U.S. Renal Data System, USRDS. (2010) *Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD. www.usrds.org

Van Gameren, E. (2010). Health insurance and use of alternative medicine in Mexico. *Health Policy*, (in press) doi: 10.1016/j.healthpol.2010.04.006

Varela, L., Vázquez, M.I., Bolaños, L., & Alonso, R. (2011). Psychological predictors for health-related quality of life in patients on peritoneal dialysis. *Nefrologia*, *31*(1), 97-106. doi: 10.3265/Nefrologia.pre2010.Jun.10279.

Ventegodt, S., Merrick J., & Andersen, N. J. (2003). Quality of life theory I. The IQOL Theory: an integrative theory of the global quality of life concept. *The Scientific World Journal*, *3*, 1030-1040.

Virgili, G., Koleva, D., Garattini, L., Banzi, R., & Gensini, G. F. (2010). Utilities and QALYs in health economic evaluations: glossary and introduction. *Internal & Emergency Medicine*, *5*, 349-352. doi: 10.1007/s11739-010-0420-7

Watson J. (1981). The lost art of nursing. *Nursing Forum*, *20*(3), 244-249.

Watson, J. (2006). Caring Theory as ethical guide to administrative and clinical practices. *Nursing Administration Quarterly, 30*(1), 48-55.

Ware, J. E., & Sherbourne, C. D. (1992). The MOS 36-item short-form health survey (SF-36). *Medical Care, 20*(6), 473-483. Retrieved from www.jstor.org/stable/3765916

Ware, J. E., Snow, K. K., Kosinski, M., & Gandek, B. (1993). *SF-36 Health Survey: Manual and Interpretation Guide*. Boston, MA: The Health Institute New England Medical Center.

Ware, J. E., Kosinski, M., & Keller, S. D. (1994). *SF-36 Physical & Mental Health Summary Scales: A User's Manual*. Boston, MA: Health Assessment Lab, New England Medical Center.

Ware, J. E., Snow, K. K., Kosinski, M., & Gandek, B. (1997). *SF-36 Health Survey Manual and Interpretation Guide*. Boston, MA: The Health Institute, New England Medical Center.

Wehbe, J., Salazar, J., Vaccaro, Y., Wehbe, I, & Guerrero, R. (2004). Diálisis y calidad de vida. Unidades de diálisis del hospital "Julio Criollo Rivas", Policlínica "Santa Ana" y Centro "Hemotil". Ciudad Bolívar, Estado Bolívar; Junio-Julio 2002. *Archivos Venezolanos de Psiquiatría y Neurología*, *50*(102), 27-32.

Weinhandl, E. D., Foley, R.N., Gilbertson, D. T., Ameson, T. J., Snyder, J. J., & Collins, A. J. (2010). Propensity-matched mortality comparison of incident hemodialysis and peritoneal dialysis patients. *Journal of the American Society of Nephrology*, *21*, 499-506. doi: 10.1681/ASN.2009060635

Weisbord, S. D., Fried, L. F., Arnold, R. M., Fine, M. J., Levenson, D. J., Peterson, R. A., & Switzer, G. E. (2005). Prevalence, severity and importance of physical and emotional symptoms in chronic hemodialysis patients. *Journal of the American Society of Nephrology*, 16, 2487-2494.

Whyte, S. (2009). How Mexico's health system works. *International Health Care*. CBS News. Retrieved from http://www.cbc.ca/health/story/2009/05/04/f-health-mexico-health-system.html

Williams, V. R., Quinn, R., Callery, S., Kiss, A., & Oliver, M. J. (2011). The impact of treatment modality on infection-related hospitalization rates in peritoneal dialysis and hemodialysis patients. *Peritoneal Dialysis International*, *31*. (epub ahead of print). doi: 10.3747/pdi.2009.00224

Wilson, I. B., & Cleary, P. D. (1995). Linking clinical variables with health-related quality of life. A conceptual model of patients' outcomes. *Journal of the American Medical Association*, *273*(1), 59-65.

Winkelman, J. W., Redline, S., Baldwin, C. M., Resnick, H. E., Newman, A. B., & Gottlieb, D. J. (2009). Polysomnographic and health-related quality of

life correlates of restless legs syndrome in The Sleep Heart Health Study. *Sleep, 32*, 772-778. PMCID: PMC2690565

Wojcikowski, K., Johnson D. W., & Gobe, G. (2006). Herbs or natural substances as complementary therapies for chronic kidney disease: Ideas for future studies. *Journal of Laboratory and Clinical Medicine*, *147*(4), 160-166. doi: 10.1016/j.lab.2005.11.011.

Wong, G., Howard, K., & Craig, J. C. (2010). Economic evaluation in clinical nephrology: Part 1. An introduction to conducting an economic evaluation in clinical practice. *Nephrology*, *15*, 434-440.

World Health Organization. (1995). The World Health Organization quality of life assessment (WHOQOL): Position paper from the World Health Organization. *Social Science & Medicine*, *41*(10), 1403-1409.

World Health Organization. (2004). *Diabetes action now: An initiative of the World Health Organization and the International Diabetes Federation*. ISBN 92 4 159151 X. Retrieved from http://www.who.int/diabetes/actionnow/en/DANbooklet.pdf

Wu, W. A., Fink N. E., Marsh-Manzi, J. V. R., Meyer, K. B., Finkelstein, F. O., Chapman, M. M., & Powe, N. R. (2004). Changes in quality of life during hemodialysis and peritoneal dialysis treatment: Generic and disease specific measures. *Journal of the American Society of Nephrology, 15*, 743–753. doi:10.1097/01.ASN.0000113315.81448.CA

Wu, A.W., Fink, N. E., Cagney, K. A., Bass, E. B., Rubin, H. R., Meyer, K. B., Sadler, J. H., & Power, N. R. (2001). Developing a health-related quality of life measure for end-stage renal disease: The CHOICE health experience questionnaire. *American Journal of Kidney Diseases*, *37*(1), 11-21.

Yngman-Uhlin P., & Edéll-Gustafsson, U. (2006). Self-reported subjective sleep quality and fatigue in patients with peritoneal dialysis treatment at home. *International Journal of Nursing Practice*, *12*, 143-152. doi: 10.1111/j. 1440-172X.2006.00566.x

Zhang, Ai-Hua, Bargman, J. M., Lok, C. E., Porter, E., Mendez, M., Oreopoulos, D. G., & Chan, C.T. (2010). Dialysis modality choices among chronic kidney disease patients: identifying the gaps to support patients on home-based therapies. *International Urology and Nephrology.* doi: 10.1007/s11255-010-9793-9

Zigmond, A.S., & Snaith, R.,P. (1983). The Hospital Anxiety and Depression Scale. *Acta Psychiatrica Scandinavia, 67*, 361-370.

Table 1.

Instruments Used in the Study

Construct	*Enroll-ment*	*Inter-view*	*Medical records*	*Instrument name*	Variable for analysis
Modality of Dialysis. Independent Variable	X			Observer data form	Groups: Continuous Ambulatory Peritoneal Dialysis [CAPD], Automated Peritoneal Dialysis [APD], and Hemodialysis [HD])
Social Roles		X		Demographics data form	Age, gender, marital status, work status, SES, education level, religion, social and family support.
Clinical background			X	Clinical and biomarkers data form	Primary cause of ESRD (Diabetes, glomerulonephritis, hypertension/ischemic, polycystic kidney disease, transplant failure, other, unknown). Number of hospitalizations, time since treatment, peritonitis, type of catheter, dialysis dose, number of anti-hypertensive drugs, use of erythropoietin, number of HD sessions per week, last home visit by the dialysis team; Urea, creatinine, hematocrit, BUN.
Anxiety & Depression		X		HADS	Scores for 7 anxiety & 7 depression items.
Sleep Disorders		X		Sleep Habits & Epworth	Subjective scores for snoring, apnea, insomnia/other sleep symptoms, RLS, EDS.
CAM practices		X		CAM practices form	Scores on use, relation with dialysis, and evaluation of helpfulness.
Spirituality		X		LSPS	Subscale score.
PCS		X		SF-36	Scales/Physical Health.
MCS		X		SF-36	Scales/Mental Health.
Costs					Averages from ISSSTE contracts

Table 2

City of Origin and Dialysis Modality of the Study Participants

Guanajuato State ISSSTE City	CAPD (*n*=39)	APD (*n*=42)	HD (*n*=40)	Total (*N*=121)
Celaya	12	12	10	32
Irapuato	10	5	10	25
Guanajuato	7	15	10	34
León	10	10	10	30

Note: ISSSTE (Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado); APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 3

Socio-demographic Characteristics of Study Participants by Dialysis Modality

Characteristics	Treatment Modality								
	CAPD (*n*=39)		APD (*n*=42)		HD (*n*=40)		*p* value	TOTAL (*N*=121)	
	n	%	*n*	%	*n*	%		N	%
Gender									
Female	22	56.4	14	33.3	18	45.0	0.11	54	44.6
Male	17	43.6	28	66.7	22	55.0		67	55.4
Marital Status									
Widowed	8	20.5	5	11.9	8	20.0	0.77	21	17.4
Single	4	10.3	4	9.5	5	12.5		13	10.7
Divorced	3	7.7	1	2.4	2	5.0		6	5.0
Married	24	61.5	32	76.2	25	62.5		81	66.9
Smoking									
Never	17	43.6	19	45.2	23	57.5	0.17	59	48.7
Current	1	2.6	4	9.5	0	0		5	4.1
Past	21	53.9	19	45.2	17	42.5		57	47.1
Alcohol*									
Never	18	69.2	12	37.5	16	59.3	0.04	46	54.1
Current	0	0	0	0	0	0		0	0
Past	8	30.8	20	62.5	11	40.7		39	45.9
Medical Insurance									
ISSSTE	35	89.7	42	100	37	92.5	0.11	114	94.2
ISSSTE/IMSS	2	5.1	0		3	7.5		5	4.1
ISSSTE/SP	2	5.1	0		0	0		2	1.7
Income(per year									
None	7	17.6	10	23.8	4	10.0	0.05	21	17.4
< $1,608	5	12.8	0	0	8	20.0		13	10.7
$1,608-3,215	7	17.9	5	11.9	6	15.0		18	14.9
$3,216-4,823	4	10.3	3	7.1	10	25.0		17	14.1
$4,824-6,431	4	10.3	9	21.4	4	10.0		17	14.1
$6,432-8,040	2	5.1	4	9.5	2	5.0		8	6.6
> $8,040	10	25.6	11	26.2	6	15.0		27	22.3
Religion									
Catholic	35	89.7	39	92.9	38	95.0	0.59	112	92.6
Christian	1	2.6	2	4.8	2	5.0		5	4.1
Jehovah's Witnesses	2	5.1	1	2.4	0	0		3	2.5
Other	1	2.6	0	0	0	0		1	0.8
Working*									
Yes	2	5.3	14	33.3	3	7.5	0.002	19	15.8
No	35	92.1	26	61.9	33	82.5		94	78.3
Occasional	1	2.6	2	4.7	4	10.0		7	5.8
	M	*SD*	*M*	*SD*	*M*	*SD*	*p value*	*M*	*SD*
Education (years)*	8.2	7.4	11.4	6.4	8.7	5.9	0.06	9.5	6.7
People in housing	4	1.8	4.0	1.5	3.67	1.3	0.53	3.9	1.5
Age*	64.2	8.9	53.1	13.4	60.8	14.7	0.00	59.3	13.4

Note:*p < 0.1. APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 4

Clinical Characteristics of Study Participants by Dialysis Modality-continuous Variables

Characteristics	Treatment Modality								
	CAPD		APD		HD		*p* value	TOTAL	
	n	*M(SD)*	*n*	*M(SD)*	*n*	*M(SD)*		*N*	*M(SD)*
BMI	32	27.7(5.6)	38	26.0(4.0)	34	24.8(5.4)	0.06	104	26.1(5.1)
Systolic BP	25	147.7(31.7)	27	140.1(17.4)	29	144.7(31.2)	0.60	81	144.1(27.44)
Diastolic BP	25	78.9(16.6)	27	84.9(14.1)	29	75.4(18.9)	0.11	81	79.7(17.0)
Comorbidities	29	3.1(0.9)	32	3.2(1.2)	30	2.7(1.2)	0.19	91	3.0(1.1)
Hb	26	10.8(2.1)	27	11.5(2.9)	28	11.3(3.9)	0.72	81	11.2(3.0)
Albumin	22	3.2(0.7)	26	3.5(0.6)	15	3.9(0.5)	0.002	63	3.5(0.7)
Creatinine	27	8.3(3.2)	31	11.8(4.3)	29	6.7(3.7)	0.000	87	9.0(4.3)
Urea	28	91.7(35.3)	31	102.0(39.3)	29	94.9(42.0)	0.58	88	96.4(38.8)
BUN	5	61.0(9.5)	7	53.5(15.2)	28	45.3(19.3)	1.95	40	48.7(18.3)
Glucose	25	129.1(56.4)	30	115.7(55.1)	27	125.4(49.2)	0.47	82	123.0(53.3)
# Medications	29	6.8(2.6)	31	6.6(3.1)	29	5.9(2.0)	0.96	89	6.4(2.5)
Time in HD[b]	-	-	-	-	37	26.4(19.8)	--	37	25.1(19.3)
Time in PD[b]	36	15.3(12.7)	41	37.4(22.1)			--	79	26.4(21.5)

Note: [b]Months on the dialysis treatment modality.
*p < 0.1
BMI (Body Mass Index); BP (Blood Pressure); Hb (Hemoglobin); BUN (Blood Urine Nitrogen); APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 5

Clinical History of Study Participants by Dialysis Modality-categorical Variables

	CAPD		APD		HD			TOTAL	
	n	%	*n*	%	*n*	%	*p* value	*N*	%
Etiology*									
Diabetes	31	79.5	32	76.2	24	60.0	0.16	87	72.0
Hypertension	6	15.4	5	11.9	6	15.0		17	14.0
Other	2	5.1	5	11.9	10	25.0		17	14.0
# Hospitalizations in past year									
0	17	43.6	21	50.0	19	47.5	0.49	57	47.1
1	12	30.8	12	28.6	8	20.0		32	26.4
2	3	7.7	6	14.3	9	22.5		18	14.9
3	3	7.7	1	2.4	2	5.0		6	5.0
4	2	5.1	0	0	0	0		2	1.7
>5	2	5.1	2	4.8	2	5.0		6	5.0
Days in past year									
Never	17	43.6	21	50.0	19	47.5	0.82	57	47.1
< 3	10	25.6	10	23.8	10	25.0		30	24.8
4-10	7	17.9	8	19.0	8	20.0		23	19.0
11-15	3	7.7	1	2.4	0	0		4	3.3
15-30	2	5.1	2	4.8	2	5.0		6	5.0
>30	0	0	0	0	1	2.5		1	0.8
#									
0	10	25.6	7	16.7	14	35.9	0.37	31	25.8
1	16	41.0	18	42.9	15	38.5		49	40.8
2-3	10	25.6	11	26.2	9	23.1		30	25.0
4 +	3	7.7	6	14.3	1	2.6		10	8.3
Erythropoietin									
Yes	34	87.2	35	83.3	40	100	0.06	109	90.1
No	5	12.8	7	16.7	0	0		11	9.0

Note:*p < 0.1

APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 6

Prevalence of Self-reported Sleep Disorders by Dialysis Type

Sleep Disorders	Total (*N*=121)	CAPD (*n*=39)	APD (*n*=42)	HD (*n*=40)	*p*-value
	n (%)	*n* (%)	*n* (%)	*n* (%)	
Obstructive sleep apnea	3 (2.7)	1 (2.8)	2 (5.1)	0	0.41
Witnessed apnea*	12 (10.0)	4 (10.3)	6 (14.3)	2 (5.1)	.038
Snoring*	23 (21.1)	7 (19.4)	10 (25.6)	6 (17.6)	.067
Insomnia	45 (37.2)	13 (33.3)	13 (30.9)	19 (47.5)	0.25
Excessive Tiredness	25 (20.7)	8 (20.5)	8 (19.0)	9 (22.5)	0.93
Unrefreshing sleep*	42 (34.7)	16 (41.0)	9 (21.4)	17 (42.5)	0.08
Insufficient sleep	34 (28.1)	10 (25.6)	12 (28.6)	12 (30.0)	0.90
Restless legs syndrome	23 (19.0)	9 (23.1)	7 (16.7)	7 (17.5)	0.73
EDS (Epworth >10)	25 (19.0)	10 (25.6)	5 (11.9)	10 (25.0)	0.22
	M (SD)	*M (SD)*	*M (SD)*	*M (SD)*	*M (SD)*
No. sleep symptoms past year	1.0 (1.5)	0.9 (1.2)	1.2 (1.8)	0.9 (1.5)	0.53

Note:*p < 0.1

SHQ (Sleep Habits Questionnaire); APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 7

Means and Standard Deviations for HADS by Dialysis Modality and Prevalence of Normal, Borderline and Abnormal Anxiety and Depression Rates by Dialysis Modality

HADS	CAPD *M (SD)*	APD *M (SD)*	HD *M (SD)*	*p*-	TOTAL *M (SD)*
Total Anxiety Score*	7.3 (6.0)	5.1 (5.2)	3.8 (3.9)	0.03	5.4 (5.3)
Total Depression Score*	6.5 (5.6)	6.2 (5.2)	3.8 (2.9)	0.05	5.5 (4.8)
	n(%)	*n(%)*	*n(%)*		*n(%)*
Anxiety*				0.060	
Normal (0-7)	18 (62.1)	23 (71.9)	26 (86.7)		67 (73.6)
Borderline (8-10)	4 (13.8)	2 (6.3)	1 (3.3)		7 (4.5)
Abnormal (11-21)	7 (24.1)	7 (21.9)	3 (10.0)		17 (18.7)
Depression*				0.045	
Normal (0-7)	21 (72.4)	21 (65.6)	27 (90.0)		69 (75.8)
Borderline (8-10)	3 (10.3)	6 (18.8)	3 (10.0)		12 (13.2)
Abnormal (11-21)	5 (17.2)	5 (15.6)	0		10 (11.0)

Note:*p < 0.1
HADS (Hospital Anxiety and Depression Scale); APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 8

Self-reported Spirituality and Spiritual Practices by Treatment Modality

Spirituality	TOTAL (*N*=79) *n* (%)	CAPD (*n*=26) *n* (%)	APD (*n*=30) *n* (%)	HD (*n*=23) *n* (%)	*p*-value
Consider yourself a spiritual person*	37 (46.8)	14 (53.8)	9 (30.0)	14 (60.9)	.06
Frequent spiritual/religious practices	38 (48.1)	16 (61.5)	10 (33.3)	12 (52.2)	.10
Help to endure your disease	57 (72.1)	19 (73.1)	19 (63.3)	19 (82.6)	.29
	M (SD)	M (SD)	M (SD)	M (SD)	
Latino Spiritual Perspective Scale*	5.5 (0.7)	5.7 (0.5)	5.3 (0.7)	5.6 (0.8)	.06

Note:*p < 0.1
APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD Hemodialysis).

Table 9

Mean Scores and Standard Deviations for SF-36 Domains, Physical and Mental Composite Scores and SF-6D Scores by Dialysis Modality

SF-36 domain	CAPD Mean (SD)	APD Mean (SD)	HD Mean (SD)	*p* value	Total Mean
Physical Function*	30.38 (29.3)	43.69 (28.9)	43.50(29.20)	0.072	39.34(29.1)
Role Physical*	17.95 (42.6)	35.12 (42.2)	37.50 (42.7)	0.089	30.37(42.5)
Bodily Pain	61.79 (36.4)	71.90 (36.0)	60.44 (36.5)	0.300	64.85(36.3)
General Health	42.31 (24.5)	44.52 (24.1)	53.12 (24.5)	0.118	46.65(24.4)
Vitality*	43.72 (29.0)	53.81 (28.7)	61.25 (29.0)	0.029	53.02(28.9)
Social Functioning*	58.01 (32.6)	70.53 (32.3)	81.56 (32.7)	0.007	70.14(32.5)
Role Emotional	59.83 (42.9)	70.63 (42.4)	76.25 (43.0)	0.229	69.01(42.8)
Mental Health	65.23 (24.5)	72.00 (24.2)	72.80 (24.5)	0.323	70.08(24.4)
PCS	30.13 (11.4)	34.65 (9.8)	34.02 (12.5)	0.156	32.98(11.3)
MCS*	48.10 (15.6)	51.59 (13.4)	55.05 (9.8)	0.067	51.61(13.3)
SF-6D Score*	0.59 (0.1)	0.69 (0.1)	0.68 (0.2)	0.009	0.65 (0.2)

Note:*p < 0.1
PCS (Physical Composite Score); MCS (Mental Composite Score); SD (Standard Deviation); APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 10

Comparison of SF-36, PCS and MCS Scores for Mexicans with ESRD, Mexican General Population Norms, US General Population Norms and US Norms for Persons with Hypertension, Type 2 Diabetes and Congestive Heart Failure

SF-36 domains	Mexican ESRD Patients (N=121)	Mexican General Population Norms* (N=5,961)	US General Population Norms** (N=2,474)	US Norms Hypertension** (N=2,089)	US Norms Type 2 Diabetes** (N=541)	US Norms CHF** (N=216)
	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)	M(SD)
Physical Function	39.3(29.1)	89.6(23.2)	84.1(23.3)	73.4(26.4)	87.7(28.7)	47.5(31.0)
Role Physical	30.4(42.5)	88.7(30.9)	80.9(34.0)	62.0(39.4)	56.8(41.7)	34.4(39.7)
Bodily Pain	64.9(36.3)	85.5(23.2)	75.1(23.7)	72.3(24.4)	68.5(26.5)	61.7(31.0)
General Health	46.7(24.4)	52.2(15.4)	72.0(20.3)	63.3(19.7)	56.1(21.1)	47.1(24.2)
Vitality	53.0(28.9)	70.7(15.4)	60.9(21.0)	58.3(21.4)	55.7(21.6)	44.3(24.4)
Social Functioning	70.1(32.5)	75.1(15.4)	83.8(22.7)	86.7(20.7)	82.0(25.0)	71.3(33.1)
Role Emotional	69.0(42.8)	88.9(23.2)	81.3(33.0)	76.7(35.7)	75.6(36.6)	63.7(43.0)
Mental Health	70.1(24.4)	72.1(15.4)	74.7(18.1)	77.9(17.4)	76.7(18.3)	74.7(21.3)
PCS	33.0(11.3)	79.0(15.4)	50.0(10.0)	44.6(11.3)	39.3(11.3)	31.0(10.6)
MCS	51.6(13.3)	76.7(15.4)	50.0(10.0)	49.2(10.6)	47.9(11.4)	45.7(12.5)

Note:*Duran-Arenas & Cols (2004); **Ware et al. (1994, 1997)
PCS (Physical Composite Score); MCS (Mental Composite Score); M (Mean); SD (Standard Deviation); CHF (Congestive Heart Failure); ESRD (End-Stage Renal Disease); US (United States)

Table 11

*HR-QOL (PCS and MCS) Subgroup Differences by Dialysis Modality**

			Dialysis Modality†		
	F-value	*p*-value**	(1) CAPD *n*=39	(2) APD *n*=42	(3) HD *n*=40
			LSMean (SE)	LSMean (SE)	LSMean (SE)
HR-QOL**	3.36	.002	.56 (.03)[a,b]	.68 (.03)[a]	.64 (.03)[b]
Dialysis type**	3.76	.03			
Sleep disorders**	12.76	.0007			
Comorbidities	2.87	.10			
Spirituality	1.40	.24			
CAM use	1.85	.18			
Sex	0	.95			
Age	0.05	.82			
Income**	4.61	.04			

Note:* Controlling for age, sex, income, co-morbidities, sleep disorders, spirituality, CAM (Complementary and Alternative Medicine) use.
**Statistically significant findings.
†Contrast of 3 level categorical variables at $p<.05$: *a*=1 vs. 2; *b*=1 vs. 3; *c*=2 vs. 3.
HR-QOL (Health-Related Quality of Life); PCS (Physical Composite Scale); MCS (Mental Composite Scale). APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 12

*Physical Composite Summary (PCS) Subgroup Differences by Dialysis Modality**

			Dialysis Modality†		
	F-value	*p*-value**	(1) CAPD *n*=39	(2) APD *n*=42	(3) HD *n*=40
			LSMean (SE)	LSMean (SE)	LSMean (SE)
SF-36 Physical Component Scale (PCS)	1.21	.30	31.39 (2.45)	33.73 (2.28)	34.82 (2.53)
Dialysis type	0.48	.62			
Sleep disorders	1.59	.21			
Comorbidities	2.57	.11			
Spirituality	1.38	.24			
CAM use	0.41	.53			
Sex	1.94	.17			
Age	0	.96			
Income	0.91	.34			

Note:* Controlling for age, sex, income, co-morbidities, sleep disorders, spirituality, CAM (Complementary and Alternative Medicine) use.
**Statistically significant findings.
†Contrast of 3 level categorical variables at $p<.05$: *a*=1 vs. 2; *b*=1 vs. 3; *c*=2 vs. 3.
APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 13

*Mental Composite Summary (MCS) Subgroup Differences by Dialysis Modality**

			Dialysis Modality†		
	F-value	*p*-value**	(1) CAPD *N*=39	(2) APD *N*=42	(3) HD *N*=40
			LSMean (SE)	LSMean (SE)	LSMean (SE)
SF-36 Mental Component Scale (MCS)**	4.02	.0004	42.99 (2.49) [a,b]	52.02 (2.32) [a]	51.35 (2.56) [b]
Dialysis type**	3.98	.02			
Sleep disorders**	19.6	<.0001			
Comorbidities	0				
Spirituality	2.51	.12			
CAM use	0.02	.90			
Sex	0.86	.36			
Age	1.76	.19			
Income**	0	.95			
	4.48	.04			

Note:* Controlling for age, sex, income, co-morbidities, sleep disorders, spirituality, CAM (Complementary and Alternative Medicine) use.
**Statistically significant findings.
†Contrast of 3 level categorical variables at $p<.05$: *a*=1 vs. 2; *b*=1 vs. 3; *c*=2 vs. 3.
APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis).

Table 14

Cost Analysis of the Different Dialysis Modalities of the Study

	Cost	Effectiveness (QALY)	Incremental Cost	Incremental Effectiveness (QALY)	ICER (IC/IE)
CAPD	$286	0.71			
APD	$606	2.05			
HD	$825	1.44			
APD vs. CAPD			$320	1.34	$238.80/QALY
HD vs. CAPD			$539	0.71	$759.15/QALY
HD vs. APD			$219	-0.61	APD DOMINATED

Note:APD (Automated Peritoneal Dialysis); CAPD (Continuous Ambulatory Peritoneal Dialysis); HD (Hemodialysis). QALY (quality-adjusted life year), ICER (Incremental Cost-Effectiveness Ratio); IE (Incremental effectiveness); IC (Incremental Cost).

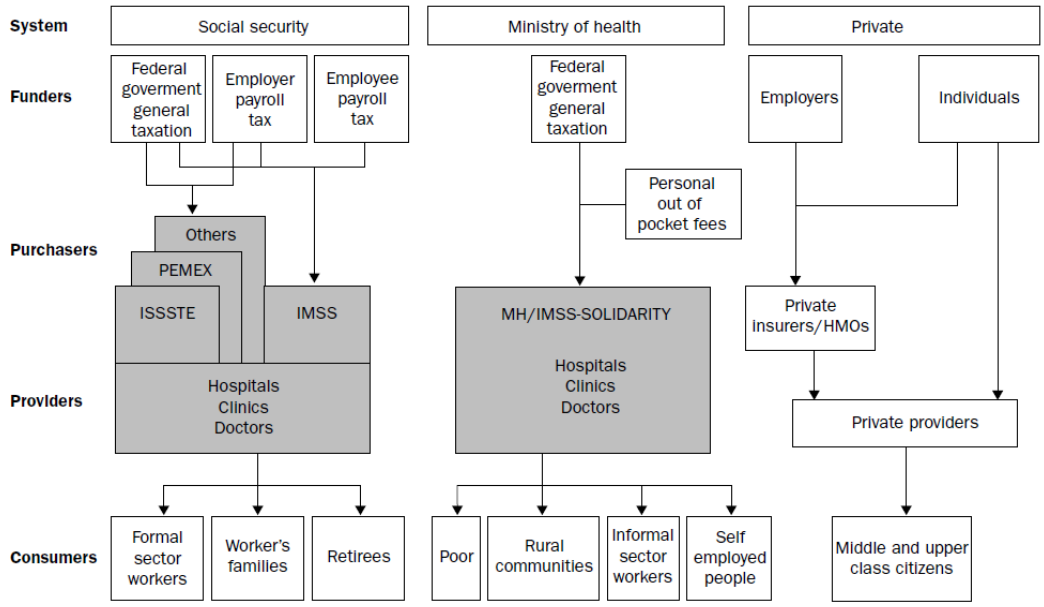


Figure 1. Mexican Health System (Frenk, Sepúlveda, Gómez-Dantés, & Knaul, 2003).

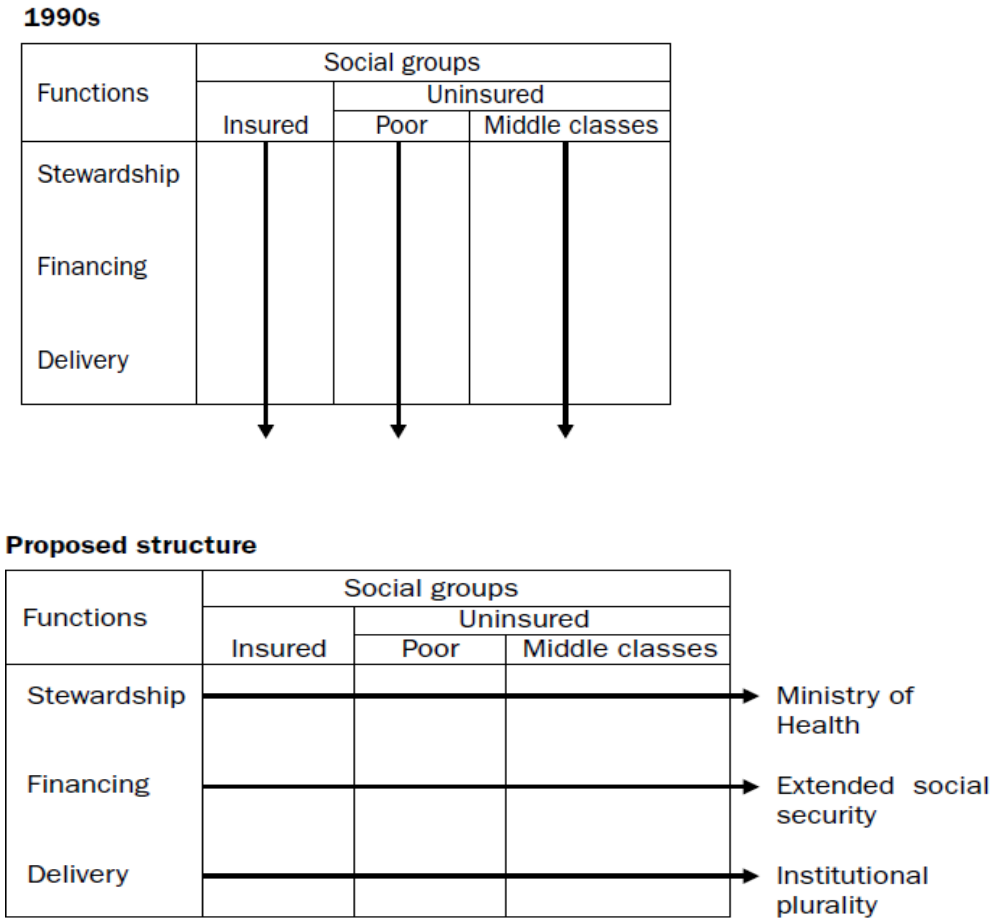


Figure 2. Mexican Health System structural change (Frenk et al, 2003).

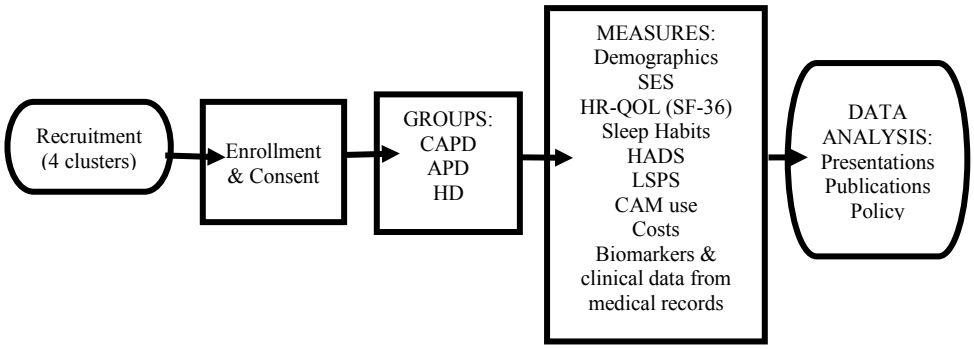
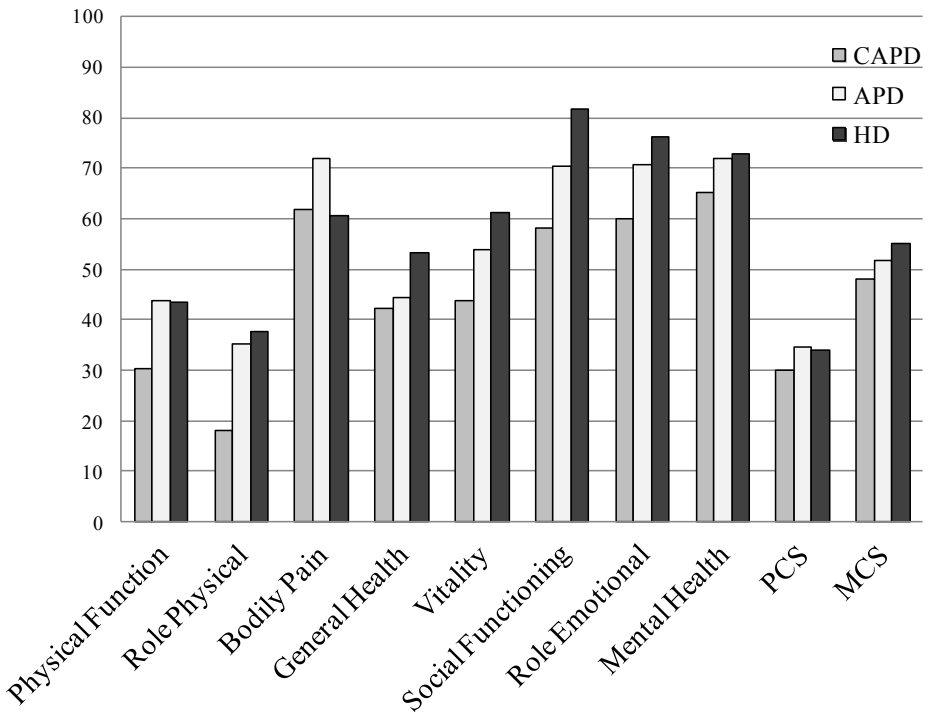


Figure 3. Study participants flow.



Note:CAPD (Continuous Ambulatory Peritoneal Dialysis); APD (Automated Peritoneal Dialysis); HD (Hemodialysis).
*Higher scores indicate better HRQOL

*Figure 4.*Mean values for SF-36 domains by treatment modality.*

APPENDIX A

INFORMED CONSENT

CONSENTIMIENTO INFORMADO PARA LOS PARTICIPANTES

Este documento de consentimiento informado se dirige a hombres y mujeres que son atendidos en las clínicas del ISSSTE del Estado de Guanajuato y que se les invita a participar en la investigación: Modalidad de Diálisis y Calidad de Vida en Personas con Insuficiencia Renal Crónica en Etapa Avanzada.

Primera Parte: Información General

Mi nombre es Luxana Reynaga, soy profesor e investigador de la Universidad de Guanajuato y formo parte de un grupo de investigadores en Salud Integral. Estamos investigando sobre la Insuficiencia Renal Crónica y el impacto de esta enfermedad en su calidad de vida.

La siguiente información le ayudará a decidir si acepta nuestra invitación y participar en el estudio, no tiene que decidirse hoy, puede hablar con alguien con quien se sienta cómodo sobre la investigación. Si hay alguna palabra que no comprenda o tiene preguntas más tarde, puede preguntarme a mí o a los miembros del equipo en cualquier momento.

Sabemos que las personas con insuficiencia renal crónica necesitan de la diálisis como tratamiento para su enfermedad. Existen como cien mil pacientes en México que tienen un tratamiento de diálisis pero no sabemos si este tratamiento ha tenido algún impacto en su calidad de vida desde el punto de vista de la misma persona que se está dializando. La razón por la que hacemos este estudio es averiguar cómo perciben estos pacientes su propia calidad de vida.

Para participar requiere de contestar una serie de preguntas sobre calidad de vida, hábitos de sueño, depresión, espiritualidad y uso de medicina alternativa así como proporcionar información demográfica y antecedentes de su salud.

El tiempo que le tomará responder a las preguntas será de aproximadamente 35 minutos. Su participación en el estudio es voluntaria. Si usted elige no participar o retirarse del estudio, lo cual puede hacer en cualquier momento, no afectará en absoluto su atención médica. Puede elegir no participar. Los resultados de este estudio pueden ser publicados, pero su nombre ni cualquier otra información que lo pudiera identificar serán utilizados. En este estudio su participación será anónima.

Segunda parte: Formulario del Consentimiento Informado

He sido invitado a participar en la investigación sobre el impacto del tratamiento de diálisis en mi calidad de vida. He leído la información proporcionada o me ha sido leída. He tenido la oportunidad de hacer preguntas sobre ella y se me ha contestado satisfactoriamente.

Consiento voluntariamente participar en esta investigación como participante y entiendo que tengo derecho a retirarme de la investigación en cualquier momento sin que me afecte en ninguna manera mi cuidado médico.

Nombre del participante_____

Firma del participante_____

Fecha_____
(dia/mes/año)

En caso de que el participante sea analfabeto:

He sido testigo de la lectura exacta del documento de consentimiento para el potencial participante y el individuo ha tenido la oportunidad de hacer preguntas. Confirmo que el individuo ha dado consentimiento libremente.

Nombre del testigo_____

Huella dactilar del participante

Fecha_____
(dia/mes/año)

He leído con exactitud o he sido testigo de la lectura exacta del documento de consentimiento informado para el potencial participante y el individuo ha tenido la oportunidad de hacer preguntas. Confirmo que el individuo ha dado consentimiento libremente.

Nombre del investigador_____

Firma del Investigador_____

Fecha_____
(dia/mes/año)

APPENDIX B

1. ENGLISH INSTRUMENT

Demographic Information

<u>Instruction</u>: Answer the following questions filling the empty spaces or the circles at the answers. Your information will be completely confidential.

1 Which is the date of today? Month____ Day ____ Year _____

2. Which is your stature? _____ cm

3. Which is your weight? _____ kg

4. ¿Which is your sex?
- ○ 1 Male
- ○ 0 Female

5. How old are you? _____ (*Number of years)*

6. Your birthday is Month ____ Day ____ Year _____

7. Blood Pressure _____Taken (date)_____

7. Where was you born (city, state, & country)? _____

8. Where have you lived most of your adult life (city, state, & country)? _____

9. How many years of school have you completed? _____ (Number of years)

10. What level of school have you completed?
- ○ 0 Never attended to school
- ○ 1 Less tan 6 years (primary school)
- ○ 2 6 to 8 years (secondary school)
- ○ 3 9 to 11 years (preparatory schoool)
- ○ 4 Preparatory
- ○ 5 Associated graduated or equivalent
- ○ 6 Undergraduate or equivalent
- ○ 7 Masters or equivalent
- ○ 8 Doctorate or equivalent

11. Marital Status:
- ○ 4 Married/living with partner
- ○ 3 Separated/Divorced
- ○ 2 Single
- ○ 1 Widow

12. Counting yourself, how many people live in your house or department? Please include adults, babies, children that live with you.
Number of people: _____

13. Have you ever smoked?
- ○ 0 Never smoked
- ○ 1 I somoke
- ○ 2 Before I smoked but no longer

14. What type of medical insurance do you have? (Choose all that applies)

None…. ……..…..…. 1 _____
IMSS…….…..…. 2 _____
ISSSTE……... 3 _____
Private insurance (ej. Prudencial)……..….. 4 _____
PEMEX……. 5 _____
SEDENA……. 6 _____
Popular Insurance…….. 7 _____

15. Which was your total income last month (considera ll the entrances as Money from the government for children, unemployment, disability or social security). Remember that all the answers are confidential.

Please mark with an X your answer for the following information ($54.47):

None…… …… 1 _____

Less tan 1 Minimum Salary (SM)($1661.335)…… 2 _____
Between 1SM and less than 2SM
($1661.335- 3322.67)……..…… 3 _____
Between 2SM and less than 3SM
($3322.67-4984.005)…….…..…… 4 _____
Between 3SM and less than 4SM
($4984.005-6645.34)…….…..…… 5 _____
Between 4SM and less than 5SM
($6645.34-8306.675)…….…..…… 6 _____
5SM or more
($8306.675-more)……..…..…….. 7 _____

16. Which religión do you practice?

Catholic	1_____
Cristian	2_____
Jehova Witnesses	3_____
Jewish	4_____
Buddhist	5_____
Other_____	6_____

17. How many people are in your family?
In what position are you?

18. ¿What do you do for a living?
Do you continue working Yes_____1
No____2
Not as before ____3

19. How many times in a month do you come to this clinic due to your treatment?_____

20. How much Money do you spend in average whenever you come to this clinic?_____

21. Do you lose your day of work, or your companion, whenever you/she comes?

Medical Background

1. Which is the disease that caused your renal insufficiency?

Diabetes Mellitus 1___
Hypertension 2___
Poliquistic kidneys 3___
Glomerulonefritis 4___
Other _____ 5___
Don't know 6___

2. Which has been your dialysis treatment for the last six monts?

Continuous ambulatory peritoneal dialysis (CAPD) 1____
Automated peritoneal dialysis (APD) 2____
Hemodialysis (HD) 3____

3. If you have peritoneal dialysis,

How many changes you do by day?

One or two _____1
3 to 4 _____2
5 to 6 _____3
Not applicable_____4 (APD)

How do you apply the treatment generally?

No. Of bags ____2000ml____1
5000ml____2

Concentration 1.5%___
2.5%___
4.25%___

What type of catheter do you have?

Tenckhoff ____1
Pig tail ____2
Swan neck ____3
Other ____4
Don't know ____5

When was the catheter installed?

Less than 1 year ____1
1 year to 2 years ____2
De 3 a 5 años ____3
Más de 5 años ____4

When did you have your transfer line changed?

Less than 6 months ___1
More tan 6 months ___2

4. If you have hemodialysis,

1. Which shift are you scheduled?_____
   Mañana____1
   Tarde ____2
   Noche ____3
   Variable____4

2. How much time do you wait before going to treatment?_____

3. How much time are you connected to the hemodialysis machine?_____

More than 4 hours ____1
Between 3 & 4 hrs. ____2
Less than 3 hrs. ____3

4. How many times per week do you have your treatment?

One _____1
Two _____2
Three _____3
Four _____4
Five or more_____5

5. How many times where you hospitalized this last year?

One _____1
Two _____2
Three _____3
Four _____4
Five or more _____5

6. How long where you hospitalized the last time?

Three days or less _____1
4 to 10 days _____2
11 to 15 days _____3
15 to 30 days _____4
More than 1 month _____5

7. Which was the cause for hospitalization?_____

5. If you take antihypertensives, how many do you take?

1_____
2_____
3_____
4_____

6. When was the most recent home visit you had from the health team?

Less than 1 month _____1
More than 1 month _____2
More than three months _____3
More than six months _____4

7. Who visited you?

Physician _____1
Nurse _____2
Social worker _____3
Other_____ _____4

8. When did you have your last medical consultation (nephrologyst)?

Less than one month _____1
More than one month _____2
More than three months _____3
More than six months _____4

9. Do you have a personal caregiver? Yes_____1
No____2

10. What is your relationship with the caregiver?

Family(son or daughter) _____1
Family (husband/wife) _____2
Family (parents) _____3
Family (brother/sister) _____4
Family(other_____) _____5
Not family _____6

11. Who performs the Dialysis treatment?

Family(son or daughter) _____1
Family (husband/wife) _____2
Family (parents) _____3
Family (brother/sister) _____4
Family(other_____) _____5
Not family _____6

12. Did you/they receive training? Yes_____1
No____2

13. Where was the training received? _____

14. How many months ago?

Less than three months _____1
Three to 6 months _____2
6 months to 1 year _____3
More than 1 year _____4
More than 3 years _____5

15. What kind of insulin do you use?

NPH _____1
Slow action _____2
Fast action _____3
Don't use _____4

16. How do you use insulin?

Intraperitoneal _____1
Subcutaneus _____2

17. Do you use erytropoyetin regularily?

Yes_____1
No ____2

18. When was the last time you use it?_____

19. Recent lab data: 19.1 Hemoglobin_____. 19.2 Albumin_____.
19.3 Creatinin_____.19.4 Urea_____. 19.5 BUN_____.

Use of Complementary Alternative Medicine

1. **Have you use a therapy or folk medicine like the following?**

Acupuncture	_____1	
Ayurveda	_____2	
Biofeedback	_____3	
Chelation therapy	_____4	
Chiropractic	_____5	Comments_____
Energy healing therapy	_____6	_____
Hypnosis	_____7	_____
Massages	_____8	
Naturopathy	_____9	
Curandero	_____10	
Movement therapies	_____11	
Herbs	_____12	
No-vitamin supplements	_____13	
Vitamins y minerals	_____14	
Homeopathy	_____15	
Special Diets	_____16	
Yoga/tai chi/qi gong	_____17	
RelaxationTechniques	_____18	
Prayers	_____19	
Brujeria (barrido)	_____20	
Otros _____	_____21	

2. **Which of them have you used within the last 12 months?**

3. **How many times have you visited the therapy provider?**

Just once	____1
Les than 5 times	____2
5 to 15 times	____3
More than 15 times	____4

4. **For what condition did you consulted this people?** _____
   related to CKD _____1
   No.related to CKD_____2

5. **Did you receive and take a treatment prescribed by this people?**
   Yes_____1
   No_____2
   Specify_____

6. **Do you consider the treatment received to be effective?**
   Yes_____1
   No____2
   ¿why?_____
   _____

7. **Have you ever self-medicated?**
   Yes_____1
   No____2
   ¿why?_____

SF36

Today's Date:_____

Name: Last:_____ First: _____ Date of Birth: _____

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Please answer these questions by "check-marking" your choice. Please select only one choice for each item.

1- In general, would you say your health is:

□ 1. Excellent □ 2. Very good □ 3. Good □ 4. Fair □ 5. Poor

2- Compared to ONE YEAR AGO, how would you rate your health in general NOW?

□ 1. MUCH BETTER than one year ago.

□ 2. Somewhat BETTER now than one year ago.

□ 3. About the SAME as one year ago.

□ 4. Somewhat WORSE now than one year ago.

□ 5. MUCH WORSE now than one year ago.

3- The following items are about activities you might do during a typical day.

Does your health now limit you in these activities? If so, how much?

Activities	**1. Yes, Limited A Lot**	**2. Yes, Limited A Little**	**3. No, Not Limited At All**
a) **Vigorous activities,** such as running, lifting heavy objects, participating in strenuous sports?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
b) **Moderate activities,** such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
c) Lifting or carrying groceries?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
d) Climbing **several flights** of stairs?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
e) Climbing **one** flight of stairs?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
f) Bending, kneeing or stooping?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
g) Walking **more than a mile**?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
h) Walking **several** blocks?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
i) Walking **one** block?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all
j) Bathing or dressing yourself?	□ 1. Yes, limited a lot	□ 2. Yes, limited a little	□ 3. No, not limited at all

4- During the **past 4 weeks**, have you had any of the following problems with your work or other regular activities *as a result of your physical health*?

	Yes	No
a) Cut down on the **amount of time** you spent on work or other activities?	□ 1. yes	□ 2. No
b) **Accomplished less** than you would like?	□ 1. yes	□ 2. No
c) Were limited in the **kind** of work or other activities?	□ 1. yes	□ 2. No
d) Had **difficulty** performing the work or other activities (for example it took extra effort)?	□ 1. yes	□ 2. No

5. During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	Yes	No
a) Cut down on the **amount of time** you spent on work or other activities?	□ 1. yes	□ 2. No
b) **Accomplished less** than you would like?	□ 1. yes	□ 2. No
c) Didn't do work or other activities as **carefully** as usual?	□ 1. yes	□ 2. No

6. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

□ 1. Not at all □ 2. Slightly □ 3. Moderately □ 4. Quite a bit □ 5. Extremely

7. How much **bodily pain** have you had during the **past 4 weeks**?

□ 1. None □ 2. Very mild □ 3. Mild □ 4. Moderate □ 5. Severe □ 6. Very severe

8. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

□ 1. Not at all □ 2. A little bit □ 3. Moderately □ 4. Quite a bit □ 5. Extremely

9. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question , please give the one answer that comes closest to the way you have been feeling. How much of the time during the **past 4 weeks…**

	1. All of the time	2. Most of the time	3. A good bit of the time	4. Some of the time	5. A little of the time	6. None of the time
a) Did you feel full of pep?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
b) Have you been a very nervous person?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
c) Have you felt so down in the dumps that nothing could cheer you up?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
d) Have you felt calm and peaceful?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
e) Did you have a lot of energy?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
f) Have you felt downhearted and blue?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
g) Do you feel worn out?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
h) Have you been a happy person?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time
i) Did you feel tired?	□ 1. All of the time	□ 2. Most of the time	□ 3. A good bit of the time	□ 4. Some of the time	□ 5. A little of the time	□ 6. None of the time

10. During the **past 4 weeks**, how much of the time has your **physical health** or **emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

□ 1. All of the time

□ 2. Most of the time.

□ 3. Some of the time

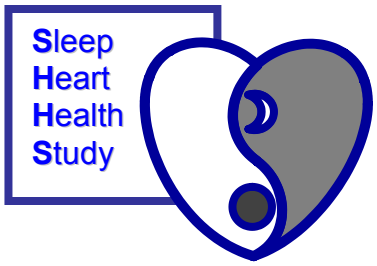
□ 4. A little of the time.

□ 5. None of the time.

11. How TRUE or FALSE is **each** of the following statements for you?

	1. Definitely true	2. Mostly true	3. Don't know	4. Mostly false	5. Definitely false
a) I seem to get sick a little easier than other people?	□ 1. Definitely true	□ 2. Mostly true	□ 3. Don't know	□ 4. Mostly false	□ 5. Definitely false
b) I am as healthy as anybody I know?	□ 1. Definitely true	□ 2. Mostly true	□ 3. Don't know	□ 4. Mostly false	□ 5. Definitely false
c) I expect my health to get worse?	□ 1. Definitely true	□ 2. Mostly true	□ 3. Don't know	□ 4. Mostly false	□ 5. Definitely false
d) My health is excellent?	□ 1. Definitely true	□ 2. Mostly true	□ 3. Don't know	□ 4. Mostly false	□ 5. Definitely false

Thank you!



SLEEP HABITS QUESTIONNAIRE (E-SHQ-r)

Most people sleep at night, but some people work at night and sleep in the day. Your main sleep period is the time of day or night when you usually sleep the longest. Think about your main sleep period when you answer questions on this survey.

Instructions: Fill in the circle in front of the answer that is correct for you on Question 1.

1. When is your main sleep period?
   - ○ 0 Night
   - ○ 1 Day
   - ○ 2 Sometimes in the day and sometimes at night

Instructions: Write a number in the blank to answer Questions 2, 3, and 4.

2. How many minutes does it usually take you to fall asleep at your main sleep period?

_____ _____ *(Number of minutes)*

3. How many hours of sleep do you usually get during your main sleep period on weekdays or days you work?

_____ _____ *(Number of hours)*

4. How many hours of sleep do you usually get during your main sleep period on weekends or days you do not work?

____ _____ *(Number of hours)*

Instructions: Fill in the circle in front of the answer that is correct for you on Question 5.

5. Do you try to make time in your schedule for a nap?
   - ○ 0 Rarely
   - ○ 1 Sometimes
   - ○ 2 Often
   - ○ 3 Almost everyday

Instructions: Write a number in the blank to answer Question 6.

6. Whenever you do nap, how long do you sleep? _____ *(minutes)*

Please continue on the next page

7. Whenever you do nap, what are your reasons for taking a nap in the afternoon?

A. ○ 1 Yes ○ 0 No I do not get enough sleep at night.

B. ○ 1 Yes ○ 0 No I nap due to illness or for medical reasons.

C. ○ 1 Yes ○ 0 No I nap because it makes me feel refreshed in general.

D. ○ 1 Yes ○ 0 No Other reason(s). Please explain: _____

_____

Instructions: Questions 8, 9, and 10 are about the quality of your sleep during a typical main sleep period. Fill in the circle in front of the answer that is correct for you.

8. In general, how would you rate the quality of your sleep?

○ 1 Light (I awaken too easily)
○ 2 Somewhat light (I awaken easily)
○ 3 Moderate (I sometimes awaken, but not easily)
○ 4 Somewhat deep (I sleep well)
○ 5 Deep (I sleep very well)

9. In general, how would you rate the quality of your sleep time?

○ 1 Short (I feel like I just went to sleep even if I slept for 8 hours)
○ 2 Somewhat short (I feel like I slept for 2 hours even if I slept for 8 hours)
○ 3 Moderate (I feel like I slept for 4 hours even if I slept for 8 hours)
○ 4 Somewhat long (I feel like I slept for 6 hours even if I slept for 8 hours)
○ 5 Long (I feel like I slept for a full 8 hours or more even if I slept for 8 hours)

10. In general, how would you rate the quality of your sleep?

○ 1 Restless (I toss and turn during a lot and my sleep is not restful)
○ 2 Somewhat restless (I toss and turn a little and my sleep is not restful)
○ 3 Moderate (I toss and turn and my sleep is a little restful)
○ 4 Somewhat restful (I do not toss and turn very much and get restful sleep)
○ 5 Restful (I do not toss and turn and get restful sleep)

Please continue on the next page

Instructions: Questions in the table below are about how often you have sleep problems. Circle the number that best describes how often you have the problem.

	11. How often do you…?	**Never**	**Rarely** (1 day a month)	**Sometimes** (2 – 4 days a month)	**Often** (1 – 3 days a week)	**Almost Always** (4 or more days a week)
A	Have trouble falling asleep	0	1	2	3	4
B	Wake up during the night and have difficulty getting back to sleep	0	1	2	3	4
C	Wake up too early in the morning and are unable to get back to sleep	0	1	2	3	4
D	Feel unrested during the day, no matter how many hours of sleep you had	0	1	2	3	4
E	Feel excessively (overly) sleepy during the day	0	1	2	3	4
F	Not get enough sleep	0	1	2	3	4
G	Take sleeping pills or other medication to help you sleep	0	1	2	3	4
H	Have nasal stuffiness, obstruction, or discharge at night	0	1	2	3	4
I	Have leg jerks when you sleep	0	1	2	3	4
J	Have leg cramps when you sleep	0	1	2	3	4
K	Have nightmares or bad dreams	0	1	2	3	4

Please continue on the next page

Instructions: Questions in the table below are about how often something wakes you up during your main sleep period. Circle the number that best describes how often you have the problem.

	12. How often do you wake up because of…?	**Never**	**Rarely** (1 day a month)	**Sometimes** (2 – 4 days a month)	**Often** (1 – 3 days a week)	**Almost Always** (4 or more days a week)
A	Coughing or wheezing	0	1	2	3	4
B	Stuffy nose	0	1	2	3	4
C	Sinusitis	0	1	2	3	4
D	Burping/belching	0	1	2	3	4
E	Chest pain or tightness	0	1	2	3	4
F	Shortness of breath	0	1	2	3	4
G	Sweats or hot flashes	0	1	2	3	4
H	Noise in your surroundings	0	1	2	3	4
I	Pain in joints, muscles, or back	0	1	2	3	4
J	Heartburn or indigestion	0	1	2	3	4
K	Eating a spicy meal	0	1	2	3	4
L	Leg cramps	0	1	2	3	4
M	Leg jerks	0	1	2	3	4
N	Need to go to the bathroom	0	1	2	3	4

Please continue on the next page

Instructions: Questions 13 through 17 are about snoring and breathing when you sleep. When you answer these questions, think about what you know about yourself and what others have told you about yourself.

Fill in the circle in front of the answer that is correct for you.

13. Have you ever snored (now or at any time in the past)?
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

14. For how many years have you been snoring?

_____ *(Number of years)*

○ 999 I don't know

15. How often do you snore?
- ○ 0 Never
- ○ 1 Rarely (less than 1 night a week)
- ○ 2 Sometimes (1 or 2 nights a week)
- ○ 3 Often (3 to 5 nights a week)
- ○ 4 Almost always (6 or 7 nights a week)
- ○ 9 I don't know

16. How loud is your snoring?
- ○ 0 I never snore
- ○ 1 Only slightly louder than heavy breathing
- ○ 2 About as loud as mumbling or talking
- ○ 3 Louder than talking
- ○ 4 Extremely loud – can be heard through a closed door
- ○ 9 I don't know

17. Do you ever stop breathing during your sleep?
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

18. Has anyone ever told you that they saw you stop breathing during your sleep?
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

19. Have you ever been told by a health care provider that you have sleep apnea (a condition in which breathing stops briefly during sleep)?
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

Please continue on the next page

Instructions: The following questions are about uncomfortable feelings or sensations that people sometimes get in their legs. Fill in the circle in front of the answer that is correct for you.

20. In the past year, while SITTING OR LYING DOWN, have you had any of the following symptoms?

A. An urge to move your legs
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

B. Unpleasant or uncomfortable feelings in your legs
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

21. How often do you get these symptoms? (Check the one best answer):
- ○ 0 Never
- ○ 1 Less than once a month
- ○ 2 About once a month
- ○ 3 2 - 4 days a month
- ○ 4 5 - 15 days a month
- ○ 5 Most days (16 - 23 days a month)
- ○ 6 Daily (6 days a week or more)
- ○ 9 I don't know

22. How bothersome or troublesome is this symptom? (Answer based on most frequent symptom). Does it bother you (Check one):
- ○ 0 Never
- ○ 1 Hardly
- ○ 2 A little
- ○ 3 Moderately
- ○ 4 A lot
- ○ 5 Extremely

23. These symptoms are most likely to occur when you are *(Check the one best answer)*:
- ○ 0 I don't have these symptoms
- ○ 1 Resting, sitting or lying down
- ○ 2 Exercising or just stopped exercising
- ○ 3 Standing or walking
- ○ 4 Having a leg cramp or "Charlie horse"
- ○ 9 I don't know

24. Are they worse when you are sitting or lying down than when you are moving around or walking?
- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

Please continue on the next page

25. Do the symptoms improve if you get up and start walking?

- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

26. What time of the day do these symptoms occur? *(Check the one best answer)*:

- ○ 0 I do not have these symptoms
- ○ 1 Daytime only (before 6 PM)
- ○ 2 Bedtime only
- ○ 3 Evening or nighttime only (after 6 PM)
- ○ 4 Both day and night

27. Has anyone in your family had these unpleasant or uncomfortable feelings in their legs (e.g., grandparents, mother, father, brothers, sisters, nieces/nephews, cousins)?

- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

28. How long have you had these uncomfortable feelings or urge to move your legs?

- ○ 0 I do not have these uncomfortable feelings or urges to move my legs
- ○ 1 Less than 1 year
- ○ 2 1 – 5 years
- ○ 3 5 – 10 years
- ○ 4 More than 10 years
- ○ 5 Since childhood

29. Has a doctor or health care provider ever told you that you have the Restless Legs Syndrome?

- ○ 0 No
- ○ 1 Yes
- ○ 9 I don't know

Latino Spiritual Perspective Scale

Directions: The following questions are designed to gain an understanding of your spiritual beliefs and practices. Please circle the answer that best describes how much you agree or disagree. There are no right or wrong answers.

1. I believe God (or a Higher Power) is loving and kind.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

2. Talking every day with God or my Higher Power is important to me.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

3. I feel close to the Virgin Mary.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

4. My religion or spirituality guides me to do what is right.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

5. I depend on God or my Higher Power to help me with my problems.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

6. I feel close to Jesus.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

7. My well-being is in God's/Higher Power's hands.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

8. My spirituality helps me get through bad times.

Agree strongly	Agree	Agree a little	Disagree a Little	Disagree	Disagree Strongly
6	5	4	3	2	1

Please list anything you would like to add about your views on spirituality.

_____

_____

_____

Hospital Anxiety and Depression Scale (HADS)

GL assessment
the measure of potential

Name: _____ Date: _____

FOLD HERE

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

A	D			A	D
		I feel tense or 'wound up'	**I feel as if I am slowed down**		
3		Most of the time	Nearly all the time		3
2		A lot of the time	Very often		2
1		From time to time, occasionally	Sometimes		1
0		Not at all	Not at all		0
		I still enjoy the things I used to enjoy	**I get a sort of frightened feeling like 'butterflies' in the stomach**		
	0	Definitely as much	Not at all	0	
	1	Not quite so much	Occasionally	1	
	2	Only a little	Quite often	2	
	3	Hardly at all	Very often	3	
		I get a sort of frightened feeling as if something awful is about to happen	**I have lost interest in my appearance**		
3		Very definitely and quite badly	Definitely		3
2		Yes, but not too badly	I don't take as much care as I should		2
1		A little, but it doesn't worry me	I may not take quite as much care		1
0		Not at all	I take just as much care as ever		0
		I can laugh and see the funny side of things	**I feel restless as if I have to be on the move**		
	0	As much as I always could	Very much indeed	3	
	1	Not quite so much now	Quite a lot	2	
	2	Definitely not so much now	Not very much	1	
	3	Not at all	Not at all	0	
		Worrying thoughts go through my mind	**I look forward with enjoyment to things**		
3		A great deal of the time	As much as I ever did		0
2		A lot of the time	Rather less than I used to		1
1		Not too often	Definitely less than I used to		2
0		Very little	Hardly at all		3
		I feel cheerful	**I get sudden feelings of panic**		
	3	Never	Very often indeed	3	
	2	Not often	Quite often	2	
	1	Sometimes	Not very often	1	
	0	Most of the time	Not at all	0	
		I can sit at ease and feel relaxed	**I can enjoy a good book or radio or television programme**		
0		Definitely	Often		0
1		Usually	Sometimes		1
2		Not often	Not often		2
3		Not at all	Very seldom		3

Now check that you have answered all the questions

	A	D
TOTAL		

APPENDIX B

2. SPANISH INSTRUMENT

Formulario Demográfico

<u>Instrucciones</u>: Conteste las siguientes preguntas llenando los espacios vacios o los círculos al frente de las respuestas. Sus datos serán completamente confidenciales.

1. ¿Cuál es la fecha de hoy? Mes ____ Día ____ Año _____

2. ¿Cuál es su estatura? _____ cm

3. ¿Cuál es su peso? _____ kg

4. ¿Cuál es su sexo?
   - ○ 1 Masculino
   - ○ 0 Femenino

5. ¿Cuál es su edad? _____ (*Número de años)*

6. ¿Cuál es su fecha de nacimiento? Mes ____ Día ____ Año _____

7. Presión Arterial _____Tomada (fecha)_____

7. ¿En dónde nació (ciudad, estado, y país)?
_____

8. ¿En dónde ha vivido la mayoría de su vida adulta (ciudad, estado, y país)?
_____

9. ¿Cuántos años de escuela ha completado? _____ (Número de años)

10. ¿Qué nivel de escuela a completado?
   - ○ 0 Nunca atendí la escuela
   - ○ 1 Menos de 6 años (escuela primaria)
   - ○ 2 6 a 8 años (escuela secundaria)
   - ○ 3 9 a 11 años (escuela preparatoria)
   - ○ 4 Preparatoria o GED
   - ○ 5 Grado de Asociado o equivalente
   - ○ 6 Licenciatura o equivalente
   - ○ 7 Maestría o equivalente
   - ○ 8 Doctorado o equivalente

11. Estado Civil:
   - ○ 4 Casado/a o viviendo con pareja
   - ○ 3 Separado/a o Divorciado/a
   - ○ 2 Soltero/a
   - ○ 1 Viudo/a

12. Contándose a sí mismo/a, ¿cuántas personas viven en su casa o apartamento? Por favor incluya adultos, bebés y niños/as que habitualmente viven con usted.
Número de personas: _____

13. ¿Cuál es su historial de fumar?
   - ○ 0 Nunca he fumado
   - ○ 1 Fumo
   - ○ 2 Antes fumaba pero ya no

14. ¿Qué tipo de seguro médico tiene usted? (Elija todo lo que se refiera a Ud.)

Ninguno ……..…..….. 1 _____
IMSS……..…..…. 2 _____
ISSSTE……... 3 _____
Particular, seguro médico con pago de cuota (ej. Prudencial….. 4 _____
PEMEX……. 5 _____
SEDENA……. 6 _____
Seguro Popular…….. 7 _____

15. ¿Cuál fue su ingreso total en el mes pasado (considerando todas las entradas como por ejemplo el dinero que recibe del gobierno para sus hijos, por estar desempleado, o por estar deshabilitado o del seguro social). Recuerde que sus respuestas son confidenciales.

Por favor marque con una X su respuesta a la siguiente información ($54.47):

Ninguno…… …… 1 _____

Menos de 1SM ($1661.335)…… 2 _____
Entre 1SM y menos de 2SM
($1661.335- 3322.67)……..…… 3 _____
Entre 2SM y menos de 3SM
($3322.67-4984.005)…….……..…… 4 _____
Entre 3SM y menos de 4SM
($4984.005-6645.34)…….……..…… 5 _____
Entre 4SM y menos de 5SM
($6645.34-8306.675)…….……..…… 6 _____
5SM o más
($8306.675- más)……..……..…….. 7 _____

16. ¿Cuál es su religión?

Católica 1_____
Cristiana 2_____
Testigos de Jehová 3_____
Judía 4_____
Budista 5_____
Otro_____ 6_____

17. ¿Cuántas personas son en su familia?
En qué posición se encuentra usted?

18. ¿A qué se dedica?
¿continúa trabajando en lo mismo? Si_____1
No____2
No igual que antes____3

19. ¿Cuántas veces al mes viene a esta clínica u hospital debido a su tratamiento?_____

20. ¿Cuánto dinero gasta en promedio cada vez que viene a esta clínica u hospital?_____

21. Pierde usted el día de trabajo, o su acompañante cada vez que viene?

Formulario Médico

20. ¿Cuál es la enfermedad que causó su insuficiencia renal?

Diabetes Mellitus 1___
Hipertensión 2___
Riñones poliquísticos 3___
Glomerulonefritis 4___
Otro _____ 5___
Desconoce 6___

21. ¿Cuál es el tipo de tratamiento de diálisis que ha tenido los últimos seis meses?

Diálisis peritoneal continua ambulatoria (DPCA) 1____
Diálisis peritoneal automatizada 2____
Hemodiálisis 3____

22. Si tiene diálisis peritoneal,

¿Cuántos cambios se hace por día?
De uno a dos _____1
De 3 a 4 _____2
De 5 a 6 _____3
No aplica _____4 (DPA)

¿Cómo se aplica el tratamiento generalmente? No. De bolsas ____2000ml____1
5000ml____2

Concentración 1.5%___
2.5%___
4.25%___

¿Qué tipo de catéter tiene?
Tenckhoff ____1
Cola de cochino____2
Cuello de cisne ____3
Otro ____4
Desconoce ____5

¿Desde hace cuánto le instalaron el catéter?
Hace menos de 1 año ____1
De 1 año a 2 años ____2
De 3 a 5 años ____3
Más de 5 años ____4

¿Cuándo le cambiaron su línea de transferencia?
Hace menos de 6 meses ___1
Hace más de 6 meses ___2

23. Si tiene hemodiálisis,

1. ¿Cuál es su horario de tratamiento?_____
Mañana____1
Tarde ____2
Noche ____3
Variable____4

2. ¿Cuánto tiempo espera antes de la diálisis?_____

3. ¿Cuánto tiempo dura conectado a la máquina de hemodiálisis?_____
   Más de 4 horas____1
   Entre 3 y 4 hrs. ____2
   Menos de 3 hrs.____3

4. ¿Cuántas veces por semana recibe el tratamiento?
   Una _____1
   Dos _____2
   Tres _____3
   Cuatro _____4
   Cinco o más _____5

5. ¿Cuántas veces estuvo hospitalizado en este último año?
   Una _____1
   Dos _____2
   Tres _____3
   Cuatro _____4
   Cinco o más _____5

6. ¿Cuánto tiempo duró hospitalizado la última vez?
   Tres días o menos _____1
   De 4 a 10 días _____2
   De 11 a 15 días _____3
   De 15 a 30 días _____4
   Más de 1 mes _____5

7. ¿Cuál fue el motivo de su hospitalización?_____

24. Si usted toma anti-hipertensivos, cuántos tipos toma?
1_____
2_____
3_____
4_____

25. ¿Cuándo fue la visita domiciliaria más reciente que tuvo por parte del equipo de salud?
Hace menos de un mes _____1
Hace más de un mes _____2
Hace más de tres meses _____3
Hace más de seis meses _____4

26. ¿Quién fue el que lo visitó?
Médico _____1
Enfermera(o) _____2
Trabajador social _____3
Otro_____ _____4

27. ¿Cuándo tuvo su última consulta médica con el especialista (nefrólogo)?
Hace menos de un mes _____1
Hace más de un mes _____2
Hace más de tres meses _____3
Hace más de seis meses _____4

28. ¿Tiene un cuidador principal? Si_____1
No____2

29. ¿Cuál es su parentesco con el cuidador?
Familiar (hijo) _____1
Familiar (esposo) _____2
Familiar (padre) _____3
Familiar (hermano) _____4
Familiar (otro_____) _____5
No es familiar _____6

30. ¿Quién le hace las diálisis?
Familiar (hijo) _____1
Familiar (esposo) _____2
Familiar (padre) _____3
Familiar (hermano) _____4
Familiar (otro_____) _____5
No es familiar _____6

31. ¿Recibió capacitación? Si_____1
No____2

32. ¿Dónde la recibió? _____

33. ¿Hace cuánto tiempo?
Menos de tres meses _____1
Tres a 6 meses _____2
6 meses a 1 año _____3
Más de 1 año _____4
Más de 3 años _____5

34. ¿Qué tipo de insulina utiliza?
NPH _____1
Acción lenta _____2
Acción rápida _____3
No utiliza _____4

35. ¿Por qué vía se aplica la insulina?
Intraperitoneal _____1
Subcutánea _____2

36. ¿Utiliza usted eritropoyetina regularmente?
Si_____1
No____2

37. ¿Cuándo fue la última vez que se la aplicaron?_____

38. Cifras de laboratorio recientes: 19.1 Hemoglobina_____.
19.2 Albúmina_____. 19.3 Creatinina_____.19.4 Urea_____. 19.5 BUN_____.

Uso de Medicina Alternativa Complementaria

8. **Ha utilizado alguna vez una terapia o remedio tradicional como los siguientes?**

Acupunctura	_____1	
Ayurveda	_____2	
Biofeedback	_____3	
Terapia de Chelación	_____4	
Qiropráctica	_____5	Comentarios_____
Terapia de Energía curativa	_____6	_____
Hipnosis	_____7	_____
Masajes	_____8	
Naturopatía	_____9	
Curanderos tradicionales	_____10	
Terapias de Movimiento	_____11	
Herbolaria	_____12	
Uso de suplementos no-vitaminicos	_____13	
Vitaminas y minerales	_____14	
Homeopatía	_____15	
Dietas especiales	_____16	
Yoga/tai chi/qi gong	_____17	
Técnicas de relajación	_____18	
Oración o rezo para la salud	_____19	
Brujería (barrido)	_____20	
Otros _____	_____21	

9. **¿Cuáles ha utilizado en los pasados 12 meses**?

10. **¿En cuántas ocasiones ha visitado a la persona que le proporciona esta terapia**?

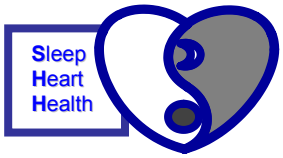
Sólo 1 vez	____1
Menos de 5 veces	____2
De 5 a 15 veces	____3
Más de 15 veces	____4

11. **¿Para qué afección consultó a estas personas**? _____
    relacionado a IRC_____1
    No relacionado IRC_____2

12. **¿Recibió y tomó algún tipo de tratamiento recetado por estas personas?**
    Si_____1
    No_____2
    Especifique_____

13. **¿Considera que el tratamiento recibido fue efectivo?**
    Si_____1
    No____2
    ¿por qué?_____
    _____

14. **¿Se ha automedicado alguna vez?**
    Si_____1
    No____2
    ¿por qué?_____



SHHS Encuesta de los Hábitos del Sueño-Español
Short Form Revised (S-SHQ-r)

<u>Instrucciones</u>: Llene la respuesta correcta para usted en la pregunta 1.

1. ¿Cuál es su horario de trabajo?
   - ○ 0 Yo no trabajo fuera del hogar
   - ○ 1 Trabajo días
   - ○ 2 Trabajo noches
   - ○ 3 Mi horario de trabajo cambia regularmente de día a noche

<u>Instrucciones</u>: Muchas personas duermen por la noche, pero muchas personas trabajan de noche y duermen durante el día. Su periodo de sueño principal es la hora del día o noche cuando duerme por más tiempo. Piense en su periodo de sueño principal cuando conteste las preguntas en esta encuesta. Escriba un número para contestar las preguntas 2, 3, y 4.

2. ¿Usualmente cuantos minutos le toma para dormirse a la hora de acostarse?

   _____ *(Número de minutos)*

3. ¿Usualmente cuantas horas duerme en la noche entre semana o los días que trabaja?

   _____ *(Número de horas)*

4. ¿Usualmente cuantas horas duerme en la noche los fines de semana o los días que no trabaja?

   _____ *(Número de horas)*

<u>Instrucciones</u>: Llene el circulo correcto para usted en la pregunta 5.

5. ¿Trata de hacer tiempo en su horario para una siesta?
   - ○ 0 Nunca o raramente
   - ○ 1 A veces
   - ○ 2 A menudo
   - ○ 3 Todos los días o casi todos los días

<u>Instrucciones</u>: Escriba un número en el espacio para contestar la pregunta 6.

6. ¿Cuándo toma una siesta, por cuánto tiempo duerme?

   _____ *(Número de minutos)*

   - ○ 0 Nunca o muy raro tomo siestas

7. ¿Cuándo toma una siesta, cuáles son sus razones para toma una siesta regularmente en la tarde? (Marque todas las que apliquen):

A. ○ 1 Si o ○ 0 No No duermo lo suficiente en la noche.

B. ○ 1 Si o ○ 0 No Tomo una siesta a causa de una enfermedad o condición médica.

C. ○ 1 Si o ○ 0 No Tomo una siesta porque me hace sentir recuperado en general.

D. ○ 1 Si o ○ 0 No Otra razón (por favor explique).

_____

<u>Instrucciones</u>: Las Preguntas 8, 9, y 10 se refieren a la calidad de su sueño. Marque el circulo al número que corresponde.

8. ¿En general cómo calificaría la calidad de su sueño?

○ 0 Ligero (Me despierto muy fácilmente)
○ 1 Algo ligero (Me despierto fácilmente)
○ 2 Moderado (A veces me despierto pero no fácilmente)
○ 3 Algo profundo (Duermo bien)
○ 4 Profundo (Duermo muy bien)

9. ¿En general cómo calificaría la calidad del tiempo de su sueño?

○ 0 Corto (Siento que me acabo de ir a dormir aunque haya dormido 8 horas)
○ 1 Algo corto (Siento como que he dormido 2 horas aunque haya dormido 8 horas)
○ 2 Moderado (Siento como que he dormido 4 horas aunque haya dormido 8 horas)
○ 3 Algo Largo (Siento como que he dormido 6 horas aunque haya dormido 8 horas)
○ 4 Largo (Siento como que dormí 8 horas o más aunque haya dormido 8 horas)

10. ¿En general cómo calificaría la calidad de su sueño?

○ 0 Inquieto (Me muevo mucho y no descanso)
○ 1 Algo inquieto (Me muevo un poco y no descanso)
○ 2 Moderado (Me muevo muy poco y descanso poco)
○ 3 Algo Descansado (No me muevo en la noche y tengo un sueño descansado)
○ 4 Tranquilo (No me muevo en la noche y duermo bien)

<u>Instrucciones</u>: Las siguientes preguntas se refieren a que tan seguido tiene problemas de sueño. Marque con un círculo al número que corresponde para las preguntas (A-K).

11.	Por favor indique que tan seguido le ocurren las siguientes cosas (*Marque solamente una caja por cada pregunta de la A – K*):	**Nunca** (0)	**Raramente** (1 vez cada mes o menos)	**A veces** (2 – 4 veces cada mes)	**A menudo** (5 – 15 veces cada mes)	**Casi siempre** (16 – 30 veces cada mes)
A	Tiene dificultad en dormirse	0	1	2	3	4
B	Se despierta durante la noche y después tiene dificultad en quedarse dormido	0	1	2	3	4
C	Se despierta muy temprano en la mañana y no puede volver a dormir	0	1	2	3	4
D	Se siente cansado durante el día no importa cuántas horas haya dormido	0	1	2	3	4
E	Se siente excesivamente cansado durante el día	0	1	2	3	4
F	No duerme lo suficiente	0	1	2	3	4
G	Toma pastillas para dormir u otro medicamento para ayudarle a dormir	0	1	2	3	4
H	Congestión nasal, obstrucción, o desecho nasal en la noche	0	1	2	3	4
I	Movimientos bruscos (involuntarios) en las piernas	0	1	2	3	4
J	Calambres en las piernas	0	1	2	3	4
K	Pesadillas o malos sueños	0	1	2	3	4

<u>Instrucciones</u>: Las siguientes preguntas se refieren a que tan seguido algo lo despierta mientras duerme. Marque con un círculo al número que corresponde para las preguntas (A-L).

12.	¿En este año pasado, que tan seguido ha sido usted despertado por las siguientes cosas? (*Marque solamente una caja por cada pregunta de la A – M*):	**Nunca** (0)	**Raramente** (1 vez cada mes o menos)	**A veces** (2 – 4 veces cada mes)	**A menudo** (5 – 15 veces cada mes)	**Casi siempre** (16 – 30 veces cada mes)
A	Tos o silbido (resuello)	0	1	2	3	4
B	Nariz tapada (mormada/o)	0	1	2	3	4
C	Sinusitis	0	1	2	3	4
D	Eructando (repitiendo)	0	1	2	3	4
E	Dolor o presión en el pecho	0	1	2	3	4
F	Falta de respiración	0	1	2	3	4
G	Bochornos o sofocos de calor (sudores)	0	1	2	3	4
H	Ruido en sus alrededores	0	1	2	3	4
I	Dolor en sus coyunturas, músculos o espalda	0	1	2	3	4
J	Acidez estomacal o indigestión	0	1	2	3	4
K	Después de una comida picante	0	1	2	3	4
L	Calambres o movimientos (involuntarios) en las piernas.	0	1	2	3	4
M	Necesidad de ir al baño	0	1	2	3	4

<u>Instrucciones</u>: Las siguientes preguntas se refieren al roncar y respirar mientras duerme. Para contestar estas preguntas por favor considere lo que otros le han dicho y lo que usted sabe de usted mismo. Marque el círculo al número que corresponde.

13. ¿Ha usted roncado alguna vez (ahora o en el pasado)?

○ 0 No
○ 1 Si
○ 9 Ya no ronco

14. ¿Por cuántos años ha estado roncado?

_____ *(Número de años)*

○ 999 No sé

15. ¿Qué tan seguido ronca? (*Marque una*)

- ○ 0 Nunca
- ○ 1 Raramente—menos de una noche por semana
- ○ 2 A veces—1 o 2 noches por semana
- ○ 3 Frecuentemente—3 a 5 noches por semana
- ○ 4 Siempre o casi siempre—6 o 7 noches por semana
- ○ 9 No sé

16. ¿Qué tan fuerte ronca? (*Marque una*)

- ○ 0 Nunca Ronco
- ○ 1 Un poco más alto que una respiración pesada
- ○ 2 Casi igual de alto que al murmurar o hablar calladito
- ○ 3 Más fuerte que hablar
- ○ 4 Extremadamente alto—se puede oír con la puerta cerrada
- ○ 9 No sé

17. ¿Ha habido veces que ha dejado de respirar mientras duerme?

- ○ 0 No
- ○ 1 Si
- ○ 9 No sé

18. ¿Alguna vez le han dicho que lo vieron dejar de respirar mientras dormía?

- ○ 0 No
- ○ 1 Si
- ○ 9 No sé

19. ¿Alguna vez le ha dicho un doctor que tiene apnea (una condición en la cual deja de respirar brevemente mientras duerme)?

- ○ 0 No
- ○ 1 Si
- ○ 9 No sé

<u>Instrucciones</u>: Las siguientes preguntas se refieren a sensaciones incomodas que la gente siente en las piernas que son difícil de describir. Marque el círculo que más le corresponda.

20. ¿En este año pasado, ha estado sentado o acostado, tuvo alguno de los siguientes síntomas?

A. Urgencia/necesidad de mover sus piernas
- O 0 No
- O 1 Si
- O 9 No sé

B. Una sensación desagradable/incomoda en las piernas
- O 0 No
- O 1 Si
- O 9 No sé

21. ¿Que tan frecuente tiene estos síntomas? (*Marque la mejor respuesta.*)
- O 0 Nunca
- O 1 Menos de una vez al mes
- O 2 Aproximadamente una vez por mes
- O 3 2 - 4 días al mes
- O 4 5 - 15 días al mes
- O 5 Casi todos los días (16 - 23 días al mes)
- O 6 Diariamente (6 días a la semana o más)
- O 9 No sé

22. ¿Qué tan desagradable o molesto es este síntoma? (Conteste la pregunta basándose en el síntoma más frecuente) Le molesta (*marque la mejor respuesta*):
- O 0 Nunca
- O 1 Casi nada
- O 2 Un poco
- O 3 Moderadamente
- O 4 Mucho
- O 5 Extremadamente

23. Estos síntomas suelen suceder cuando usted está (*Marque la mejor respuesta*):
- O 0 No tengo estos síntomas
- O 1 Descansando, sentado, o acostado
- O 2 Haciendo ejercicio o terminando de hacer ejercicio
- O 3 Parado o caminando
- O 4 Teniendo un calambre en la pierna
- O 9 No sé

24. ¿Son los síntomas peores cuando está sentado o acostado en comparación a cuando se está moviendo o caminando?
- O 0 No
- O 1 Si
- O 9 No sé

25. ¿Mejoran los síntomas si se levanta y empieza a caminar?
- O 0 No
- O 1 Si
- O 9 No sé

26. ¿A qué hora del día ocurren los síntomas? (*Marque la mejor respuesta*):

- ○ 0 No tengo incomodidad o ganas de mover mis piernas
- ○ 1 Únicamente durante el día (antes de las 6 PM)
- ○ 2 Únicamente a la hora de dormir
- ○ 3 Únicamente en la noche (después de las 6 PM)
- ○ 4 Únicamente en la noche (después de las 6 PM)
- ○ 5 En el día y en la noche

27. ¿Hay alguien más en su familia que sufre de una sensación desagradable o incomoda en las Piernas (como abuelo/as, madre, padre, hermano/as, sobrino/as, nieto/as)?

- ○ 0 No
- ○ 1 Si
- ○ 9 No sé

28. ¿Por cuánto tiempo a tenido la sensación incomoda o ganas de mover sus piernas?

- ○ 0 No tengo incomodidad o las ganas de mover mis piernas
- ○ 1 Menos de 1 año
- ○ 2 1 – 5 años
- ○ 3 5 – 10 años
- ○ 4 Más de 10 años
- ○ 5 Desde la infancia

29. ¿Le ha dicho un doctor que tiene el síndrome de las piernas inquietas (Restless Leg Síndrome)?

- ○ 0 No
- ○ 1 Si
- ○ 9 No sé

<u>Instrucciones</u>: Las siguientes preguntas se refieren a la hora y lugares donde usted siente que se quiere dormir. Marque con un círculo el número que corresponde para cada situación de la (A-J). Si usted nunca o raramente esta en esta situación, por favor de marcar su mejor respuesta

30.	¿Cuál es la posibilidad de que usted cabecea (no únicamente "sentirse cansado")? (*Marque solamente una caja por cada posibilidad de la A – J*):	**No hay posibilidad**	**Una leve posibilidad**	**Una posibilidad moderada**	**Una gran posibilidad**
A	Sentado y leyendo	0	1	2	3
B	Mirando la televisión	0	1	2	3
C	Sentado inactivo en un lugar público (por ejemplo en el cine o en una junta)	0	1	2	3
D	Sentado en un auto como pasajero por una hora sin descanso	0	1	2	3
E	Acostado y descansando en la tarde si las circunstancias lo permiten	0	1	2	3
F	Sentado y platicando con alguien	0	1	2	3
G	Sentado tranquilamente después de un almuerzo y sin haber bebido alcohol	0	1	2	3
H	En el auto, mientras esta estacionado en el tráfico por unos minutos	0	1	2	3
I	En la mesa mientras cena	0	1	2	3
J	Mientras conduce su auto	0	1	2	3

CUESTIONARIO DE SALUD SF-36 VERSIÓN ESPAÑOLA 1.4 (junio de 1999)

INSTRUCCIONES: Las preguntas que siguen se refieren a lo que usted piensa sobre su salud. Sus respuestas permitirán saber cómo se encuentra usted y hasta qué punto es capaz de hacer sus actividades habituales. Conteste cada pregunta tal como se indica. Si no está seguro/a de cómo responder a una pregunta, por favor conteste lo que le parezca más cierto.

Correspondencia: Dr. Jordi Alonso. Unidad de Investigación en Servicios Sanitarios I.M.I.M.
Doctor Aiguader, 80.E- 08003 Barcelona, España
Tel. + 34 3 221 10 09 Fax. + 34 3 221 32 37.E-mail: pbarbas@imim.es

MARQUE UNA SOLA RESPUESTA

1. En general, usted diría que su salud es:
1 □ Excelente. 2 □ Muy buena. 3 □ Buena. 4 □ Regular. 5 □ Mala.

2. ¿Cómo diría que es su salud actual, comparada con la de hace un año?
1 □ Mucho mejor ahora que hace un año. 2 □ Algo mejor ahora que hace un año
3 □ Más o menos igual que hace un año. 4 □ Algo peor ahora que hace un año
5 □ Mucho peor ahora que hace un año

LAS SIGUIENTES PREGUNTAS SE REFIEREN A ACTIVIDADES O COSAS QUE USTED PODRÍA HACER EN UN DÍA NORMAL.

3. Su salud actual, ¿le limita para hacer **esfuerzos intensos**, tales como correr, levantar objetos pesados, o participar en deportes agotadores?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

4. Su salud actual, ¿le limita para hacer **esfuerzos moderados**, como mover una mesa, pasar la aspiradora, jugar a los bolos o caminar más de una hora?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

5. Su salud actual, ¿le limita para **coger o llevar la bolsa de las compras?**
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

6. Su salud actual, ¿le limita para **subir varios pisos** por la escalera?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

7. Su salud actual, ¿le limita para **subir un solo piso** por la escalera?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

8. Su salud actual, ¿le limita para **agacharse o arrodillarse?**
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

9. Su salud actual, ¿le limita para caminar **un kilómetro o más**?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

10. Su salud actual, ¿le limita para caminar **varias manzanas** (varios centenares de metros)?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

11. Su salud actual, ¿le limita para caminar **una sola manzana** (unos 100 metros)?
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

12. Su salud actual, ¿le limita para **bañarse o vestirse por sí mismo?**
1 □ Sí, me limita mucho 2 □ Sí, me limita un poco 3 □ No, no me limita nada

LAS SIGUIENTES PREGUNTAS SE REFIEREN A PROBLEMAS EN SU TRABAJO O EN SUS ACTIVIDADES COTIDIANAS.

13. Durante las 4 últimas semanas, ¿tuvo que **reducir el tiempo** dedicado al trabajo o a sus actividades cotidianas, a causa de su salud física?
1 □ Sí 2 □ No

14. Durante las 4 últimas semanas, ¿**hizo menos** de lo que hubiera querido hacer, a causa de su salud física? 1 □ Sí 2 □ No

15. Durante las 4 últimas semanas, ¿tuvo que **dejar de hacer algunas tareas** en su trabajo o en sus actividades cotidianas, a causa de su salud física?
1 □ Sí 2 □ No

16. Durante las 4 últimas semanas, ¿tuvo **dificultad** para hacer su trabajo o sus actividades cotidianas (por ejemplo, le costó más de lo normal), a causa de su salud física?
1 □ Sí 2 □ No

17. Durante las 4 últimas semanas, ¿tuvo que **reducir el tiempo** dedicado al trabajo o a sus actividades cotidianas, a causa de algún problema emocional (como estar triste, deprimido, o nervioso? 1 □ Sí 2 □ No

18. Durante las 4 últimas semanas, ¿**hizo menos** de lo que hubiera querido hacer, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)?
1 □ Sí 2 □ No

19. Durante las 4 últimas semanas, ¿no hizo su trabajo o sus actividades cotidianas tan **cuidadosamente** como de costumbre, a causa de algún problema emocional (como estar triste, deprimido, o nervioso)? 1 □ Sí 2 □ No

20. Durante las 4 últimas semanas, ¿hasta qué punto su salud física o los problemas emocionales han dificultado sus actividades sociales habituales con la familia, los amigos, los vecinos u otras personas?
1 □ Nada. 2 □ Un poco. 3 □ Regular. 4 □ Bastante. 5 □ Mucho.

21. ¿Tuvo dolor en alguna parte del cuerpo durante las 4 últimas semanas?
1 □ No, ninguno
2 □ Sí, muy poco
3 □ Sí, un poco
4 □ Sí, moderado
5 □ Sí, mucho
6 □ Sí, muchísimo

22. Durante las 4 últimas semanas, ¿hasta qué punto el dolor le ha dificultado su trabajo habitual (incluido el trabajo fuera de casa y las tareas domésticas)?
1 □ Nada
2 □ Un poco
3 □ Regular
4 □ Bastante
5 □ Mucho

LAS PREGUNTAS QUE SIGUEN SE REFIEREN A CÓMO SE HA SENTIDO Y CÓMO LE HAN IDO LAS COSAS DURANTE LAS 4 ÚLTIMAS SEMANAS. EN CADA PREGUNTA RESPONDA LO QUE SE PAREZCA MÁS A CÓMO SE HA SENTIDO USTED.

23. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió lleno de vitalidad?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

24. Durante las 4 últimas semanas, ¿cuánto tiempo estuvo muy nervioso?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

25. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió tan bajo de moral que nada podía animarle?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

26. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió calmado y tranquilo?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

27. Durante las 4 últimas semanas, ¿cuánto tiempo tuvo mucha energía?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

28. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió desanimado y triste?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

29. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió agotado?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

30. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió feliz?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

31. Durante las 4 últimas semanas, ¿cuánto tiempo se sintió cansado?
1 □ Siempre
2 □ Casi siempre
3 □ Muchas veces
4 □ Algunas veces
5 □ Sólo alguna vez
6 □ Nunca

32. Durante las 4 últimas semanas, ¿con qué frecuencia la salud física o los problemas emocionales le han dificultado sus actividades sociales (como visitar a los amigos o familiares)?
1 □ Siempre
2 □ Casi siempre
3 □ Algunas veces
4 □ Sólo alguna vez
5 □ Nunca

POR FAVOR, DIGA SI LE PARECE CIERTA O FALSA **CADA UNA** DE LAS SIGUIENTES FRASES.

33. Creo que me pongo enfermo más fácilmente que otras personas.
1 □ Totalmente cierta
2 □ Bastante cierta
3 □ No lo sé
4 □ Bastante falsa
5 □ Totalmente falsa

34. Estoy tan sano como cualquiera.
1 □ Totalmente cierta
2 □ Bastante cierta
3 □ No lo sé
4 □ Bastante falsa
5 □ Totalmente falsa

35. Creo que mi salud va a empeorar.
1 □ Totalmente cierta
2 □ Bastante cierta
3 □ No lo sé
4 □ Bastante falsa
5 □ Totalmente falsa

36. Mi salud es excelente.
1 □ Totalmente cierta
2 □ Bastante cierta
3 □ No lo sé
4 □ Bastante falsa
5 □ Totalmente falsa

ESCALA DE LA PERSPECTIVA ESPIRITUAL LATINA

Instrucciones: Las siguientes preguntas han sido preparadas para entender sus creencias y prácticas espirituales. Por favor, marque la respuesta que Ud. Piensa que más refleja su opinión. No hay respuesta que sea correcta o incorrecta.

1. Creo en Dios (o un Poder Superior) que es amable y cariñoso.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

2. Para mí es importante hablar con Dios o mi Poder Superior todos los días.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

3. Me siento cerca a la Virgen María.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

4. Mi religión o espiritualidad me guía a hacer lo que es correcto.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

5. Yo dependo de Dios o mi Poder Superior para ayudarme con mis problemas.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

6. Me siento cerca de Jesús.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

7. Mi bienestar está en las manos de Dios/Poder Superior.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

8. Mi espiritualidad me ayuda durante tiempos malos.

Estoy muy de acuerdo	Estoy de acuerdo	Estoy un poco de acuerdo	Estoy un poco en desacuerdo	Estoy en desacuerdo	Estoy fuertemente en desacuerdo
6	5	4	3	2	1

Por favor, si desea, incluya comentarios adicionales sobre su espiritualidad.

_____

_____

_____

_____

Cuestionario de ansiedad y depresión en hospitales y centros de atención médica (HADS)

GL assessment
the measure of potential

Nombre: _____ Fecha: _____

DOBLAR AQUÍ

Los médicos están conscientes del papel importante que desempeñan las emociones en la mayoría de las enfermedades. Si su médico conoce estas emociones podrá ayudarle más.

Este cuestionario está diseñado para ayudar a que su médico sepa cómo se siente usted. Lea cada una de las preguntas escritas abajo y **subraye la respuesta** que refleja de mejor manera cómo se ha sentido en los últimos 7 días. Ignore los números impresos en los márgenes del cuestionario.

No se tarde mucho en dar la respuesta, su reacción inmediata a cada una de las preguntas probablemente sea más exacta que una respuesta que haya sido muy pensada.

DOBLAR AQUÍ

A	D		A	D
		Me siento tenso/a o nervioso/a		
3		La mayor parte del tiempo		
2		Mucho tiempo		
1		De vez en cuando, ocasionalmente		
0		Nunca		
		Aún disfruto las cosas que solía disfrutar		
	0	Definitivamente igual que antes		
	1	No tanto como antes		
	2	Sólo un poco		
	3	Casi nada		
		Tengo una especie de miedo, como si algo muy malo fuera a pasar		
3		Muy definitivamente y muy intenso		
2		Sí, pero no tan intenso		
1		Un poco pero no me preocupa		
0		Nunca		
		Me puedo reír y ver el lado gracioso de las cosas		
	0	Tanto como siempre		
	1	No tanto ahora		
	2	Definitivamente mucho menos ahora		
	3	Nunca		
		Vienen a mi mente pensamientos de preocupación		
3		La mayor parte del tiempo		
2		Mucho tiempo		
1		No muy seguido		
0		Muy poco		
		Me siento contento/a		
	3	Nunca		
	2	No muy seguido		
	1	Algunas veces		
	0	La mayor parte del tiempo		
		Me puedo sentar en calma y sentirme relajado/a		
0		Definitivamente sí		
1		Habitualmente		
2		No muy seguido		
3		Nunca		
		Siento como si estuviera más lento/a de lo habitual		
		Casi todo el tiempo		3
		Muy frecuentemente		2
		Algunas veces		1
		Nunca		0
		Siento una especie de miedo, como si tuviera un nudo en el estómago		
		Nunca	0	
		Ocasionalmente	1	
		Frecuentemente	2	
		Muy frecuentemente	3	
		He perdido interés en mi apariencia personal		
		Definitivamente		3
		No me cuido tanto como debería		2
		Quizá no me cuido tanto como debería		1
		Me cuido igual que siempre		0
		Me siento inquieto/a, como si tuviera que estar en movimiento constante		
		Muchísimo	3	
		Mucho	2	
		No mucho	1	
		Nunca	0	
		Espero las cosas con gusto		
		Tanto como siempre		0
		Un poco menos de lo que solía hacerlo		1
		Definitivamente menos de lo que solía hacerlo		2
		Casi nada		3
		Tengo sensaciones súbitas de miedo		
		Muy frecuentemente	3	
		Frecuentemente	2	
		De vez en cuando	1	
		Nunca	0	
		Puedo disfrutar de un buen libro o de un programa de radio o televisión		
		Con frecuencia		0
		Algunas veces		1
		No muy seguido		2
		Muy rara vez		3

Ahora verifique que ha contestado todas las preguntas

	A	D
TOTAL		

APPENDIX C

CLINIC PERMISSION

INSTITUTO DE SEGURIDAD Y SERVICIOS SOCIALES DE LOS TRABAJADORES DEL ESTADO

ISSSTE 50 años

CLINICA HOSPITAL CELAYA

DIRECCION

CELAYA, GTO. A 18 DE ABRIL DEL 2011

M en C. CIPRIANA CAUDILLO CISNEROS
DIRECTORA
UNIVERSIDAD DE GUANAJUATO
CAMPUS LEON
DEPTO. DE ENFERMERIA Y OBSTETRICIA

PRESENTE.

Por medio de este conducto y en atención a su oficio de fecha 22 de marzo del año en curso en el que solicita autorización para llevar a cabo el Proyecto llamado "Dialysis Modality and Quality of Persons with End Stage Renal Disiase" en relación a los pacientes con Insuficiencia Renal, se hace de su conocimiento que en reunión del día 15 del presente mes el Comité de Enseñanza e Investigación Analizó, y Aprobó la realización del Proyecto, por lo que se Autoriza el mismo.

Sin más por el momento hago propicia la ocasión para enviarle un cordial saludo.

ATENTAMENTE

DR. JULIAN OLALDE MOLINA
DIRECTOR

C.c.p. Dr. Juan Antonio Vera Arredondo – Coord. De enseñanza e Inv.

"UN NUEVO ISSSTE PARA SERVIR MEJOR"

Av. El Sauz esq. con Esmeralda Col. San Juanico, Celaya Gto. C.P. 38020 Tel: (01)(461) 61 402 41 Tel/Fax: (01)(461) 61 417 31

APPENDIX D

1. UNIVERSITY OF GUANAJUATO APPROVAL BY GUANAJUATO ETHICS COMMITEE

Universidad de Guanajuato

CAMPUS LEÓN
DIVISIÓN DE CIENCIAS DE LA SALUD
DEPARTAMENTO DE CIENCIAS MÉDICAS

"2010. Año del Bicentenario de la Independencia Nacional y del Centenario de la Revolución Mexicana"

A quien corresponda:

León Gto., a 20 de Febrero de 2011.

Por este conducto se hace constar que en los archivos del H. Comité de Ética del Departamento de Ciencias Medicas de la Universidad de Guanajuato se encuentra registrado el protocolo de investigación titulado "Dialysis Modality and Quality of Life of Persons with End Stage Renal Disease" de la Maestra Luxana Reynaga-Ornelas. El protocolo fue aprobado por este comité.

Se extiende la presente para los fines que a la interesada convengan a los 20 días del mes de febrero del año 2011 en León, Guanajuato.

Dr. Carlos Kornhauser Aráujo
Presidente del Comité de Ética

c.c.p Archivo folio 2011-02
c.c.p Interesado

20 de Enero No. 929; Col. Obregón, León, Gto. México, C.P. 37000
Teléfono: 01 (477) 714 38 12, 714 84 55, 714 25 12 y 714 63 77 ext. 23; Fax: 716 83 54
www.ugto.mx

APPENDIX D

2. ARIZONA STATE UNIVERSITY APPROVAL BY THE INSTITUTIONAL REVIEW BOARD

ASU Knowledge Enterprise Development

Office of Research Integrity and Assurance

To:	Carol Baldwin NHI
From:	Mark Roosa, Chair Soc Beh IRB
Date:	04/08/2011
Committee Action:	**Expedited Approval**
Approval Date:	04/08/2011
Review Type:	Expedited F7
IRB Protocol #:	1104006292
Study Title:	Modalidad de Diálisis y Calidad de Vida en Personas con Insuficiencia Renal Crónica en Etapa Avanzada (Dialysis Modality and Quality of Life of Persons with Advanced Stage Chronic Renal Insufficiency)
Expiration Date:	04/07/2012

The above-referenced protocol was approved following expedited review by the Institutional Review Board.

It is the Principal Investigator's responsibility to obtain review and continued approval before the expiration date. You may not continue any research activity beyond the expiration date without approval by the Institutional Review Board.

Adverse Reactions: If any untoward incidents or severe reactions should develop as a result of this study, you are required to notify the Soc Beh IRB immediately. If necessary a member of the IRB will be assigned to look into the matter. If the problem is serious, approval may be withdrawn pending IRB review.

Amendments: If you wish to change any aspect of this study, such as the procedures, the consent forms, or the investigators, please communicate your requested changes to the Soc Beh IRB. The new procedure is not to be initiated until the IRB approval has been given.

Please retain a copy of this letter with your approved protocol.

APPENDIX E

HADS LICENSE

GL Assessment Ltd
Hospital Anxiety and Depression Scale (HADS)
USER AGREEMENT

Agreement Dated : ……

1. LICENSEE'S NAME ***Please type all details and send back as Word doc attachment***

LICENSEE : : ……Luxana Reynaga-Ornelas……..***(note 1)***.....

Address : Blvd. Puente del Milenio No.1001 Fracción Predio San Carlos.

CP 37670. León Guanajuato.....

Country : México

VAT Number (if applicable) : .....

Contact Name if Different from above:

Name : ……..

Title : ……..

Phone : …….. Fax :……..

Email ……..

Invoice Address if Different from above: (*credit account form is required for invoicing – **note 3**)*

Universidad de Guanajuato. Lascurain de Retana No. 5. Guanajuato, Gto. CP 36000 RFC.

450325-KY2 …… Credit Card Payments please phone 0845 602 1937 or fax to 0845 601 5358 ……...

READER CODE **(Mandatory- *note 4*)**……156581.....

GL QUALIFICATION CODE **(Mandatory – *note 4*)**…….10110……

*For student licensees the following are also required- (**note 5**):*

University Course and supervisor's name : ……

Supervisor's GL Reader Code

Supervisor's GL Qualification Code

2. CONTEXT OF HADS USE

- **PROJECT (*note 6*):** ……Dialysis Modality and Quality of Life of Persons with End Stage Renal Disease
- **Number of expected study participants :** **100**
- **Number of administrations of the questionnaire per participant :** **1**
- **TOTAL NUMBER OF ADMINISTRATIONS (*note 7*)** : 100
- **Planned study date**: *start* 03 | 2011 (month/year) *end* 08 | 2011 (month/year)

3. STUDY FINANCING

PLEASE INDICATE HERE IF YOUR USE OF HADS WILL BE FOR COMMERCIAL USE, OR ACADEMIC RESEARCH/NON-COMMERCIAL USE. (See FAQs in Permission

Information Doc for definitions) : ……For academic research/non-commercial use……

Fee for commercial study:	**0-1000 @ £0.55 each**
Price shown is per administration/use	**0-2500 @ £0.50 each**
	2500 + @ £0.45 each

Fee for academic research/non-commercial use:	**0-1000 @ £0.30 each**
Price shown is per administration/use	**0-2500 @ £0.25 each**
	2500 + @ £0.20 each

Please Note: An additional administration fee of £50 will be applicable to orders under £50

TOTAL COPYRIGHT FEE:

£50……..

---

4. HADS VERSIONS & TRANSLATIONS ***(NOTE 9)*** *(THIS WILL BE SENT TO YOU AS A PDF ATTACHMENT)*

DO YOU REQUIRE THE HADS IN ENGLISH? .....NO.....

IF SO, WHICH VERSION; ORIGINAL TEMPLATE, WORD, OR US VERSION? ……..

PLEASE INDICATE HERE IF YOU WILL REQUIRE TRANSLATIONS (A separate translation agreement will be required between the LICENSEE and the Mapi Research Trust and it is not part of this agreement). If appropriate, please indicate in which language(s) and for which country(ies) the **HADS** is needed:

Languages:	**Spanish**	**Mexico**			

MEMORANDUM OF AGREEMENT, made on the date of this document between GL Assessment Limited of The Chiswick Centre, 414 Chiswick High Road, London W4 5TF (hereinafter called 'the Publishers') and the LICENSEE as defined on the first page of this agreement.

NOW IT IS MUTUALLY AGREED between the parties hereto as follows:

The Publishers hereby grants permission for the Licensee to reproduce in the printed format up to the TOTAL NUMBER OF ADMINISTRATIONS of the HOSPITAL ANXIETY AND DEPRESSION SCALE (HADS) ('the Material') subject to the following conditions to which the Licensee hereby agrees:

1. The Licensee hereby agrees that the Material is to be used for the Licensee's own research purposes only, and never under any circumstances for any commercial, non-research or other use unspecified in this Agreement.
   The specified use and purpose of the Material is for the PROJECT as defined on the front page of this agreement.

2. The Licensee hereby agrees to pay to the Publishers the TOTAL COPYRIGHT FEE as defined above for the number of administrations detailed above. Further

administrations over and above the specified amount may be negotiated as required on terms to be agreed.

3. The Licensee will correspond with the MAPI Research Trust Contact@mapi-trust.org regarding the availability of translated versions of the Material, if applicable.
4. The Licensee will not make any changes to the Material as supplied by the Publishers or by the MAPI Research Trust, without first consulting the Publisher.
5. The Licensee hereby agrees to delete the Word file containing the Material as soon as the agreed number of administrations have been reproduced.
6. The Material must be returned to the Licensee, who is a qualified and registered GL Assessment test user in relation to the scoring and interpretation of the data from the use of the Material. The HADS manual shall be used for scoring and interpretation and is available by contacting the Publishers.
7. The Licensee will include the following copyright and acknowledgement notice in full on each copy of the Material:

8. The Material must not be reproduced in any publication or journal resulting from the research study nor should the Material be used in any other way other than that described above.
9. The Licensee will send to the Publishers as soon as possible one copy of any published article, report or publication of the data collection and analysis resulting from the use of the Material.
10. The Licensee agrees to exercise the utmost vigilance in protecting the Publishers' copyright privileges on the material involved, both in the English language and as translated. Unauthorised persons must not be given access to these materials and the copyright notice must appear in full on each copy of the Material.
11. The Publishers cannot verify the accuracy of the Material or whether the Material has been validated or not.
12. A person who is not a party to this Agreement has no rights under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement but this does not affect any right or remedy of a third party that exists or is available apart from that Act.
13. The Licensee shall not assign or in any way transfer this licence without the prior written consent of the Publishers.
14. This Agreement shall be terminated without further notice in any of the following circumstances:

    (a) If the Licensee fails to make any payment specified in this Agreement on the due date.

    (b) If the Licensee shall at any time be in breach of any of the terms and conditions of this Agreement and such breach is not remedied within 15 days of receipt of written notice thereof.

(c) If the Licensee is declared insolvent or bankrupt or goes into liquidation (other than voluntary liquidation for the purpose of reconstruction only) or if a Receiver is appointed.

Termination shall be without prejudice to any monies which may be due to the Publishers from the Licensee and without prejudice to any claim which the Publishers may have for damages and/or otherwise.

Upon termination of this Agreement for any reason the Licensee shall immediately cease to use the Material.

15. This Agreement constitutes the entire agreement between the parties in respect of the Translated Material and supersedes all prior oral or written proposals, agreements or undertakings concerning the same.

16. This Agreement shall not be amended or modified in any way other than by an agreement in writing and signed by both parties or their duly authorised representatives and shall come into effect on receipt of the payment in full as specified above and a counter-signed copy of this Agreement.

17. This Agreement shall be governed by and construed in all respects in accordance with English Law.

AS WITNESS THE HANDS OF THE PARTIES
hereto the day and year first above written

Signed on behalf of GL Assessment Limited

.....

Signed by the Licensee: ***Please print this page, sign, and attach this signature page as a scanned document along with your typed User Agreement form, sent as a Word doc***

User's Signature (handwritten): Title: PhD(c), MSN Company/Organisation: University of Guanajuato Date: Feb 22nd, 2011.	**Company/Organisation Stamp (if applicable):** UNIVERSIDAD DE GUANAJUATO CAMPUS LEON DIVISION DE CIENCIAS DEPTO. DE ENFERMERIA Y OBSTETRICIA. SEDE LEON

BIOGRAPHICAL SKETCH

Luxana Reynaga-Ornelas was born in León, Guanajuato, Mexico, on March 4, 1970. She received her elementary education at the Instituto Jassá. Her secondary and high school education were completed at the Instituto Lux. In 1988, Luxana entered the College of Nursing and Obstetrics at the University of Guanajuato at León. Upon graduation in 1993, she spent one year receiving specialized training in Critical Care Nursing at the College, University of Nuevo León in Monterrey, Mexico. She also received her Master of Science in Nursing at the University of Nuevo Leon and was supported by a two-year scholarship from CONACYT. Since 2004, Luxana has been an associate professor at the University of Guanajuato College of Nursing and Obstetrics, León campus. In 2008, she entered Arizona State University to pursue her doctoral degree in Nursing and Healthcare Innovation. During her doctoral studies, she received a two-year scholarship from the Bardewyck Foundation (2008-2010), and a Mexican Ministry of Education PROMEP scholarship (2010-2011). She has been a member of Sigma Theta Tau International (STTI), Beta Upsilon Chapter, since 2007. Luxana has co-authored a peer-reviewed paper and book chapter on sleep and health of US minorities and has presented numerous papers and posters at national and international conferences, including the Associated Professional Sleep Societies, PAHO-sponsored research and education congresses throughout Latin America, and STTI International Research Congresses in Asia, North America and Mexico.