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See prescribing summary on page 43

**9** Renagel<sup>®</sup> tablets

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#### The CANNT Journal

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# Looking after our health



We are again indebted at the **CANNT Journal** to the authors who have worked so hard to have their manuscripts accepted for publication in our journal and to the

members of the CANNT Journal manuscript review panel who have reviewed each of the manuscripts. In this issue, the manuscripts all have a different focus, but all are related to nephrology. While the majority of the manuscripts we publish communicate information about our patients and their health, we are especially pleased in this issue to have a research article focusing on the health of nephrology nurses.

Stress in nephrology nurses' work environment can lead to burnout, which, in turn, can lead to a decreased quality of patient care, decreased morale and absenteeism. Lori Harwood and her colleagues from the London Health Sciences Centre have examined in their research article entitled "Workplace empowerment and burnout in Canadian Nephrology Nurses" the relationship between workplace empowerment of nurses and burnout. A non-empowering work environment was found to have an influence on nurse burnout. The authors conclude their research by giving suggestions on how increasing workplace empowerment may decrease occupational burnout in nephrology nurses.

Our nephrology patients endure many losses while living with chronic kidney disease. The second article in this issue is entitled "Understanding the lived experience of loss and grieving in persons with end stage renal disease: A humanbecoming approach" by Jennifer Duteau, Clinical Practice Leader, Nephrology and Dialysis, Humber River Regional Hospital, Weston, Ontario. In her article, Jennifer uses Rosemary Parse's theory of humanbecoming to explore the phenomenon of loss and grieving, and provides nephrology nurses with a framework for practice that is based on a human science philosophy.

While home dialysis is promoted for our patients in many units across Canada, there is limited understanding on why patients may, or may not, choose this modality. The third article in this issue by Marie Angela Visaya, Geriatric Emergency Management Nurse, Grand River Hospital, Kitchener, Ontario, is entitled "Hemodialysis patients' perceptions of home hemodialysis and selfcare." In this research article, Marie found that, while many in-centre hemodialysis patients had positive perceptions of home dialysis, only a few would be deemed suitable for home dialysis. She concludes by giving suggestions on how the number of patients choosing home dialysis may be increased.

One of the more distressing symptoms for our patients on dialysis is restless leg syndrome. In their continuing education article for this issue, Colette Raymond, our pharmacy editorial board member, with her colleagues from Winnipeg Health Sciences Centre has given us some up-to-date information on medications that may decrease the severity of these symptoms for some patients. The authors conclude that it needs the support of the whole nephrology team to manage the symptoms of restless leg syndrome.

We trust you will enjoy reading all of these excellent articles and take some new ideas, whether it is for improving your health and that of your co-workers, or the health of your patients, back to your workplaces across the country.

#### Prendre soin de sa santé et de celle des patients

Au Journal de l'ACITN, nous sommes une fois de plus redevables envers les auteurs qui ont travaillé d'arrache-pied pour faire accepter leurs manuscrits en vue de leur publication et aussi envers les membres du Comité de révision qui ont révisé chacun des textes. Dans le présent numéro du Journal, les articles ont tous une orientation différente, mais qui touche de près à la néphrologie. Alors que la majorité des articles que nous publions portent principalement sur les patients et leur santé, nous sommes particulièrement fières de vous présenter un rapport d'étude sur la santé des infirmières en néphrologie.

Le stress dans l'environnement de travail des infirmières en néphrologie peut mener à un épuisement professionnel, qui à son tour peut entraîner une diminution de qualité dans les soins prodigués aux patients, une baisse du moral et une augmentation de l'absentéisme. Lori Harwood et ses collègues du London Health Sciences Centre ont examiné, dans leur recherche intitulée « Workplace empowerment and burnout in Canadian Nephrology Nurses » [Autonomie en milieu de travail et épuisement professionnel chez les infirmières en néphrologie au Canada], la relation entre l'environnement de travail favorisant l'autonomie chez les infirmières et l'épuisement professionnel. Les auteures ont constaté qu'un milieu de travail ne stimulant pas l'autonomie a une influence sur l'épuisement professionnel chez les infirmières. Elles concluent leur recherche en donnant des suggestions sur comment une autonomie croissante en milieu de travail peut réduire l'épuisement professionnel chez les infirmières en néphrologie.

Les patients en néphrologie subissent de nombreuses pertes en vivant au jour le jour avec une maladie chronique du rein. Le deuxième article s'intitule « Understanding the lived experience of loss and grieving in persons with end-stage renal disease: A humanbecoming approach » [Comprendre l'expérience de perte et de deuil vécue par les personnes atteintes d'insuffisance rénale terminale : Une approche de la théorie de l'humain en devenir], par Jennifer Duteau, chef de pratique clinique, Néphrologie et dialyse, au Humber River Regional Hospital, à Weston, en Ontario. Dans son article, Jennifer s'appuie sur la théorie de l'humain en devenir de Rosemary Parse, inf., Ph. D, afin d'explorer le phénomène de perte et de deuil et d'offrir aux infirmières en néphrologie un cadre de travail pour la pratique qui est fondé sur la philosophie et les sciences humaines.

Bien que l'on fasse la promotion de la dialyse à domicile auprès des patients dans de nombreuses unités de soins partout au Canada, il subsiste une compréhension incomplète des raisons pour lesquelles les patients doivent ou ne doivent pas choisir ce mode de traitement. Le troisième article, signé par Marie Angela Visaya, inf., Gestion des urgences en gériatrie, au Grand River Hospital, à Kitchener, en Ontario, s'intitule « Hemodialysis patients' perceptions of home hemodialysis and selfcare » [Perceptions des patients en hémodialyse sur la dialyse à domicile et les soins autogérés]. Dans son article scientifique, Marie observe que bien que de nombreux patients en centre d'hémodialyse aient des perceptions positives à l'égard de la dialyse à domicile, peu d'entre eux seraient jugés de bons candidats à la dialyse à domicile. L'auteure conclut en donnant des suggestions sur la manière d'augmenter le nombre de patients qui pourraient choisir la dialyse à domicile.

Le syndrome des jambes sans repos représente l'un des symptômes les plus incommodants pour les patients dialysés. Dans leur article d'éducation continue, Colette Raymond, membre de notre Comité de rédaction en pharmacie, et ses collègues du Winnipeg Health Sciences Centre nous tracent un tableau actualisé des médicaments qui peuvent réduire la gravité de ces symptômes chez certains patients. Les auteures soulignent qu'il est essentiel d'obtenir le soutien de toute l'équipe de néphrologie pour la prise en charge des symptômes associés au syndrome des jambes sans repos.

Nous sommes persuadées que vous vous délecterez à la lecture de ces excellents articles et que vous y puiserez quelques nouvelles idées, que ce soit pour améliorer votre propre santé, celle de vos collègues ou encore celle de vos patients, dans votre milieu de travail, d'un bout à l'autre du pays.

#### Le Journal ACITN

est la publication officielle de l'Association canadienne des infirmiers/infirmières et technologues en néphrologie, a/s 336 Yonge St., Ste. 322, Barrie, ON, L4N 4C8, téléphone : (705) 720-2819, télécopieur : (705) 720-1451, Courriel : cannt@cannt.ca. Publié quatre fois par année, ce journal est envoyé à tous les membres de l'Association. L'abonnement annuel est: Canada, 50 \$ (+TPS), E.-U., 60 \$, hors du Canada et E.-U., 85 \$. Les publications antérieures, lorsque disponsibles, coûtent 7,50 \$ (+TPS) chacune. Les opinions émises par les auteurs dans ce journal ne sont pas nécessairement partagées par l'Association ni par le rédacteur en chef. Nous invitons les lecteurs à nous faire part de leurs opinions. Toute correspondance devra être envoyée à l'ACITN, 336 Yonge St., Ste. 322, Barrie, ON L4N 4C8. Site web : www.cannt.ca

· Voici les échéanciers à rencontrer pour soumettre des articles/nouvelles au journal : Janvier-mars - le 15 janvier, pour publication le 15 mars Avril-juin – le 15 avril, pour publication le 15 juin Juillet-septembre - le 15 juillet, pour publication le 15 septembre Octobre-décembre - le 15 octobre, pour publication le 15 décembre Le journal CANNT est maintenant répertorié dans le "Cumulative Index to Nursing and Allied Health Literature (CINAHL)", "International Nursing Index" (INI), "MEDLINE", "EBSCO", "ProQuest", et "Thomson Gale". ISSN 1498-5136

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### The Declaration of Istanbul on Organ Trafficking and Transplant Tourism



to live in a country where regardless of your social or economic position in society, if physically and emotionally stable, you will be eligible for placement

We are fortunate

on the transplant list.

Unfortunately, we also live in a society that values money and believes that money can and should buy anything. Some individuals and countries feel that organs should be a commodity to buy, sell and purchase, having little regard for the consequences that can occur to individuals who sell their organs or are coerced into selling their organs to the highest bidder.

In the fall of 2009, CANNT was approached, as an organization, to support the Declaration of Istanbul. The Declaration of Istanbul on Organ Trafficking and Transplant Tourism, derived from an international summit meeting from April 30 to May 1, 2008, is a document endorsed and supported by numerous organizations throughout the world in opposition to unethical organ practices.

The declaration has three principal definitions that govern the policies and principles of practice that stand to

uphold and lobby countries and governments in opposition to organ trafficking, transplant commercialism and transplant tourism.

Organ trafficking, as defined by the declaration, is any part of the organ transplant process that has been achieved by the use of threat, force, coercion, fraud, deception or the abuse of power of one individual over another. Transplant commercialism is when an organ is treated as a commodity and used for material gain. Lastly, transplant tourism has two components. The movement of organs, donors, recipients or professionals across borders for transplant purposes alone is not usually a problem. It becomes transplant tourism when organ trafficking undermines the country's ability to provide organs to their own residents.

Viewing the list of organizations that have added their names to support the declaration, I am proud to say I believe CANNT is the only association comprising solely nurses and technologists supporting the declaration worldwide.

I believe, by adding our name to the list of supporters of this important document, CANNT is demonstrating its social responsibility to the nephrology community on an international level.

Rick Luscombe, RN, BSN, CNeph(C) CANNT President

### Please send all submissions, questions or comments to:

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### La Déclaration d'Istanbul contre le trafic d'organes et le tourisme de transplantation

Nous avons la chance de vivre dans un pays où, peu importe notre statut social ou économique, nous pouvons, si nous sommes physiquement et émotionnellement stables, faire inscrire notre nom sur la liste d'attente en vue d'une transplantation d'organes.

Malheureusement, nous vivons également dans une société qui valorise l'argent et qui croit que l'argent peut et devrait tout acheter. Certains individus, voire des pays, croient que les organes devraient être une marchandise que l'on peut acheter, vendre et réquisitionner tout en faisant peu de cas des conséquences qui peuvent survenir chez les personnes qui vendent leurs organes ou qui sont contraints de le faire au plus offrant.

À l'automne 2009, l'ACITN a été approchée, en tant qu'organisation, pour appuyer la Déclaration d'Istanbul. La Déclaration d'Istanbul contre le trafic d'organes et le tourisme de transplantation, formulée à l'issue du sommet international qui a eu lieu du 30 avril au 2 mai 2008 à Istanbul, est un document endossé et appuyé par de nombreuses organisations dans le monde pour s'opposer aux pratiques douteuses entourant le trafic et la vente d'organes.

La Déclaration s'appuie sur trois principes qui gouvernent les politiques et les principes de la pratique qui se dressent afin de faire pression sur les pays et les gouvernements pour s'opposer au trafic d'organes, au commerce de transplantation et au tourisme de transplantation.

Le trafic d'organes, tel qu'il est défini dans la Déclaration, consiste en toute portion du processus de transplantation d'organes qui est effectuée « en faisant usage de menaces, de violence ou de toute autre forme de coercition et d'abduction, par la fraude ou par tromperie, par abus de pouvoir ou en mettant à profit la vulnérabilité des individus »\*. Le commerce de transplantation est « une pratique au cours de laquelle un organe est traité comme une marchandise, notamment en étant acheté ou vendu, ou utilisé en vue d'un gain matériel ». Enfin, le tourisme de transplantation comporte deux éléments. Le « déplacement d'organes, de donneurs, de receveurs ou de professionnels de la transplantation au-delà des frontières juridictionnelles, dans un objectif de transplantation, »\* n'est habituellement pas un problème. Il « devient du tourisme de transplantation si les ressources utilisées pour la transplantation de patients venant de l'extérieur du pays réduisent les capacités du pays à répondre aux besoins de transplantation de sa propre population. »\*

Après avoir consulté la liste des organisations ayant signé la Déclaration d'Istanbul, je suis fier de vous informer que l'ACITN semble être la seule organisation professionnelle représentant uniquement des infirmières, des infirmiers et des technologues à appuyer la déclaration à l'échelle mondiale.

Je suis persuadé qu'en ajoutant notre nom à la liste des signataires de cet important document, l'ACITN fait preuve de responsabilité sociale au sein de la collectivité de la néphrologie à l'échelle internationale.

#### Rick Luscombe, inf., B.Sc.inf., CNéph(C) Président de l'ACITN

\* Déclaration d'Istanbul contre le trafic d'organes et le tourisme de transplantation [traduction par le docteur M.F. Mamzer]. Consultée en ligne le 7 mai 2010, sur http://www.soc-nephrologie.org /esociete/commissions/actions/transplant/ istambul.htm

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# **Reflections of ANNA**

Hello, CANNT members! I have just returned from San Antonio, Texas, where I attended the 41st National American Nephrology Nurses Association (ANNA) symposium, held from May 2 to May 5. San Antonio is a beautiful city-so quaint and clean, and the Riverwalk is definitely a sight to see. The goal of the symposium was to provide a learning and networking environment, and what better place to network with nephrology professionals from near and far than in San Antonio at the 'Big Event Dance Party' held on Monday, May 3. It was great fun!

This was my first time attending an ANNA symposium and I was extremely impressed. I would like to congratulate the ANNA planning committee for organizing such a successful symposium and the ANNA board of directors for its leadership and commitment to nephrology professionals.

The theme of the symposium was Integrating a Culture of Caring into a Technological World. The symposium attracted 1,038 delegates (30 delegates were from Canada) and 100 industry partners, and included 77 sessions, 85 speakers, and 41 poster presentations. In keeping with the conference theme, our industry partners displayed state-of-the-art technology, products and services, and presentations focused on the culture of caring and the challenges that we, as nephrology professionals, face in our technological world. Presentations can be viewed at www.annanurse.org.

On the last day of the symposium, nephrology professionals were celebrated and recognized during an awards, scholarship and grant ceremony. It was inspiring to sit among nephrology professionals from around the world, most of whom were strangers, in an environment of celebration, united by a common bond, and collectively applaud the achievements of our nephrology colleagues and partners.

Our visions and goals are common. I would encourage each and every one of you to recognize the valuable contribution that you make to patients with kidney disease, and to take time to celebrate your profession and promote the future of nursing.

Patty Quinan, RN, CNS, CANNT President-Elect



Above, Lori Harwood, President of CANNT 2006–2007, recipient of the ANNA Writing Award, Clinical Practice



Left: Donna J. Bednarski, ANNA Immediate Past-President, Centre: Patty Quinan, CANNT President-Elect, Right: Donna Painter, ANNA President, at the ANNA Symposium, May 2010

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# Workplace empowerment and burnout in Canadian nephrology nurses

By Lori Harwood, RN(EC), MSc, CNeph(C), Jane Ridley, RN(EC), MScN, CNeph(C), Barbara Wilson, RN, MScN, CNeph(C) and Heather K. Laschinger, RN, PhD, FAAN, FCAHS

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#### Abstract

Nephrology nurses, like nurses in other areas, are impacted by the stress in their work environment. As recruitment and retention issues become more apparent, research in the area of conditions of work life for nephrology nursing has emerged, as an important area of study. Burnout has been reported as high as one in every three nephrology nurses (Flynn, Thomas-Hawkins, & Clarke, 2009). This cross-sectional study examined the influence of empowerment on burnout. Total empowerment was negatively correlated with emotional exhaustion in the bivariate analysis. Multivariate analysis demonstrated that access to resources and nursing education had an influence on burnout for nephrology nurses. Access to resources was a significant negative predictor of burnout for nephrology nurses. Degree-prepared nurses were more likely to experience burnout. Application of these results by providing access to resources for nephrology nurses may impact on occupational burnout.

Key words: burnout, empowerment, nephrology nursing, nursing education

Nurses provide an essential service in the health care system in a current environment where service usage is under financial and resource pressures. We are in the midst of a nursing shortage where inadequate human resources affect health care service delivery. The incidence of chronic kidney disease continues to increase and it is a challenge to meet the health care needs of this population. All of these factors increase work demands and stress which may contribute to nurse burnout.

Burnout is a syndrome of emotional exhaustion, cynicism and reduced professional efficacy (Maslach, Jackson, & Leiter, 1997). It is a systems issue, not a personal issue. Emotional exhaustion is a key aspect of burnout whereby the individual experiences increased feelings that they are no longer able to give of themselves at their job. Gradually, the work stress becomes overwhelming, eroding emotional and physical resources. Emotional exhaustion is the most frequent measure of occupational burnout (Maslach, 2003). It is very common for research on burnout to only measure and report on emotional exhaustion and, at times, the concepts of burnout and emotional exhaustion are often referred to in the same context. Serious consequences of burnout are possible, as it can be a factor contributing to decreased quality of service and morale, increased job turnover, and absenteeism (Maslach et al., 1997).

Studies examining empowering work environments have demonstrated an effect on burnout for nurses in a number of work settings. Environmental factors such as workload, control, rewards, fairness and values can have a positive impact on engagement of staff, or a negative consequence on burnout (Laschinger & Finegan, 2005). New graduates who perceived their workplace to contain structural empowerment experienced less burnout, specifically emotional exhaustion (Cho, Laschinger, & Wong, 2006). The results of other studies have demonstrated burnout is not unique to new graduates such that the degree of empowerment correlates to job strain for nurses of varying years of experience (Laschinger et al., 2001). Empowering behaviours of leaders

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Submitted for publication: January 7, 2010. Accepted for publication in revised form: March 30, 2010 also impacts burnout, as supervisor incivility, cynicism and emotional intelligence are negatively related to nurses' job satisfaction (Greco, Laschinger, & Wong, 2006; Laschinger, Leiter, Day, & Gilin, 2009), workplace empowerment and organizational commitment (Young-Ritchie, Laschinger, & Wong, 2009). With the exception of a study by Ridley, Wilson, Harwood and Laschinger (2009), no studies have explored empowerment and burnout in Canadian nephrology nurses.

Nephrology nurses, like nurses in other areas of practice, are not immune to the effects of a stressful work environment. As recruitment and retention issues become more apparent, research in the area of conditions of work life for nephrology nursing is currently being examined. A recent cross-sectional study of Canadian nephrology nurses reported that 41% of those who participated experienced severe emotional exhaustion (Ridley et al., 2009). To date, little is known about predictors of burnout amongst nephrology nurses (Flynn, Thomas-Hawkins, & Clarke, 2009).

#### Literature review

Occupational burnout among nurses is a global concern, with researchers in various countries examining this issue. However, this literature review will focus on studies conducted with nephrology nurses. One of the largest studies (n=1,015) on burnout and American hemodialysis nurses was a cross-sectional, correlational study designed to investigate the effect of workload, environment and care processes on burnout (Flynn et al., 2009). The authors of this study concluded that burnout among nephrology nurses is unacceptably high, with one nurse in three reporting symptoms of burnout (Flynn et al., 2009). Furthermore, nurses who reported symptoms of burnout were three times more likely to leave their jobs. Nurses' workload, patient-nurse ratios, practice environments and work left incomplete were all significantly associated with burnout. Similar results were reported by Lewis, Bonner, Campbell, Cooper and Willard (1994) in their study with nurses who work in dialysis and personality, stress, coping, and sense of coherence, i.e., personal hardiness, as described by Antonovsky (1987). They concluded that a low sense of coherence, lack of support, personal stress, and heavy workload were all contributing factors to burnout, specifically, emotional exhaustion.

An Italian study, which compared levels of burnout between various nephrology health care professionals, reported that 30% of nurses experienced burnout compared to 18% of nephrology physicians. This difference was not statistically significant. However, the hours worked in the two years prior to the study significantly predicted burnout (Klersy et al., 2007). Levels of emotional exhaustion were significantly higher in the nursing group, as compared to the physician group (Klersy et al., 2007). Even more concerning were the results of another Italian study, which suggested that a high level of burnout amongst nephrology nurses and physicians was associated with poor patient satisfaction with their care (Argentero, Dell'Olivo, & Ferretti, 2008).

In London, England, hemodialysis staff who were older and more experienced reported higher levels of burnout, psychological distress, and job dissatisfaction (Ross, Jones, Callaghan, Eales, & Ashman, 2009). However, it is important to note that in this sample, 42% of the hemodialysis staff sampled were non-nurses. In another study that explored burnout in Turkish hemodialysis nurses, higher emotional exhaustion scores were reported in nurses who considered leaving the profession, who did not find the profession suitable, and who worked in units where there were no precautions against infectious disease (Kapucu, Akkus, Akdemir, & Karacan, 2009).

To date, only one Canadian study investigating burnout in nephrology nursing was found in this review of the literature. Ridley et al. (2009) explored conditions of work effectiveness, magnet hospital traits, burnout, physical and mental reactions to stress and empowerment among a randomly selected sample of Canadian nephrology nurses. In this study, 41% of the nurses sampled reported experiencing burnout (Ridley et al., 2009). The results of this study highlighted some concerns and areas of occupational stress for nephrology nurses. The findings demonstrated aspects of the nurses' working environments such as high standards of care expected and good peer working relationships that were favourable, but areas in need of improvement were noted such as assignments that promote continuity of care. The descriptive nature of this study assists in illustrating the problems. However, further studies are required in order to better understand these phenomena.

In summary, burnout appears to be a problem for nephrology nurses in many countries including Canada. Common contributors to burnout seem to be increased workload and nurse-patient ratios, as well as interpersonal stress and inadequate coping. The predicament of burnout in nephrology nursing is two-fold: burnout among the nurses and its impact on job retention is concerning, but equally disturbing is the reported association between burnout and the negative effect on patients' satisfaction with care. Although we are beginning to understand more about burnout with this population of nurses, several gaps remain. Empowering work environments, such as those that provide access to support, information, resources and opportunity contribute to positive working conditions and decrease burnout (Laschinger, Finegan, Shamian, & Wilk, 2001), yet empowerment in the nephrology nursing work environments and the effect on burnout remains understudied.

#### **Theoretical Framework**

The theoretical framework that guided this analysis was Kanter's (1977) theory of empowerment. According to Kanter (1977), work behaviours and attitudes are shaped by characteristics of the work environment, not intrapersonal traits. Work environments that provide access to support, information, resources and opportunities are considered to be empowering. Employees who are able to access these structures are empowered, active and productive within the organization, participate more actively in organizational activities and exhibit higher morale. In contrast, individuals in positions that limit access to empowerment structures become powerless, feel less committed, have reduced job satisfaction and higher levels of burnout (See Figure 1). Laschinger's (1996) body of research based on Kanter's (1977) theory of empowerment and its application and relevance to nursing has been demonstrated in a number of nursing settings.

#### **Purpose**

The purpose of this study was to examine the influence of workplace empowerment on burnout, specifically emotional exhaustion, in a sample of Canadian nephrology nurses. Our hypothesis, based on Kanter's theory (1977) and the subsequent body of work by Laschinger et al. (2001), is that of a negative relationship between empowerment scores and emotional exhaustion such that an increase in empowerment will be associated with a reported decrease in emotional exhaustion. A secondary aim of this study is to determine what, if any, components of empowerment are predictors of burnout among nephrology nurses.

#### **Research questions**

The research questions that guided this analysis are as follows:

- a) What is the relationship between nephrology nurses' perceptions of workplace empowerment (total and subscales) and their level of burnout (emotional exhaustion)?
- b) What components of empowerment are predictors of burnout (emotional exhaustion) in nephrology nurses?

#### Methods

#### Sample

This study was a secondary analysis of a larger study conducted by Ridley et al. (2009). The original sample consisted of 129 randomly selected nurses from the Canadian Association of Nephrology Nurses and Technologists who consented to be on a mailing list for research information. Following ethical approval from the local research ethics board, surveys were distributed by mail with a second mailing of the survey three months after the initial. The sample size was adequate for multiple regression, as described by Tabachnick and Fidell (2007) for up to nine independent variables.

#### Instrumentation

Nephrology nurses in the original study by Ridley et al. (2009) were asked to complete a series of questionnaires related to working conditions, empowerment, health outcomes and burnout. Information obtained from two of the questionnaires was used as the basis for this secondary analysis and consisted of the Maslach Burnout Inventory (MBI) (Maslach et al., 1997) and the Conditions of Work Effectiveness Questionnaire II (CWEQ) (Laschinger et al., 2001).

The MBI is a self-administered survey that was developed to measure burnout in occupations providing human services. The MBI General Survey version is a 16-item, seven-point



Figure 1

Likert scale (0 to 6) instrument with three subscales: emotional exhaustion, cynicism and professional efficacy. High levels of emotional exhaustion and cynicism and low levels of professional efficacy indicate burnout. The MBI is the most widely used instrument to measure burnout. Emotional exhaustion is the most reported subscale measurement of burnout (Maslach et al., 1997). The MBI is scored by computing an average rating of 0 to 6 for each subscale. Average scores greater than three on the emotional exhaustion subscale are indicative of burnout. Reliability for the EE subscale is .65, .60 for cynicism and .67 for professional efficacy (Maslach et al., 1997). The MBI has been used extensively in studies in the nursing profession and has been used with nephrology nurses (Argentero et al., 2008; Flynn et al., 2009; Klersy et al., 2007; Lewis et al., 1994).

The Conditions of Work Effectiveness Questionnaire II (CWEQ II) (Laschinger et al., 2001) was used to measure empowerment. This is a 19-item instrument that measures nurses' job satisfaction and perceptions of access to empowerment structures originally described by Kanter (1977). The questionnaire consists of six subscales, which include: opportunity, information, support, resources, formal power, the job activities scale and informal power-organizational relationship scale. Each item is scored on a five-point Likert scale (1 to 5) with higher scores indicating higher perceptions of empowerment. The scores from the six subscales are summed and averaged to compute a score for each subscale. A total empowerment score is the summation of the six subscales' average scores and ranges from six to 30. Reliability and validity have been established (Laschinger et al., 2001) and the CWEQ II has been used previously with nephrology nurses (Harwood, Ridley, Lawrence-Murphy et al., 2007).

#### Data analysis

SPSS version 16.0 was used for the descriptive, diagnostic and inferential statistics. The significance level for this analysis was set at 0.05. The assumptions of Multiple Linear Regression (MLR) diagnostics were tested and satisfactorily met. Standard MLR was used to test the association between empowerment (total and subscales) and emotional exhaus-

Table 1. Pearson's correlation analysis of CWEQ-II empowerment (total & subscales) and MBI emotional exhaustion		
Empowerment Emotional Exhaustion		
Total Empowerment	276**	
Opportunity	072	
Information	141	
Support	185*	
Resources	310**	
Job Activities Scale284**		
Organization Relationship Scale279**		
*p<.05, **p<.001		

tion, as well as the effect of sociodemographics such as age, years in nephrology nursing and nursing education in the model. The rationale for determining the variables was based on the theoretical framework, literature review and correlational results, which may have an influence on burnout. Pearson's correlation was used to examine the relationship between empowerment (total and subscales) and emotional exhaustion.

#### Results

#### Sample

The overall response rate from the original study was 48.1% (Ridley et al., 2009). SPSS deletes cases with missing data for regression analysis leaving a final sample size of 121. Essentially, the sample was almost entirely female (97%). The mean age was 46.3 years (SD 7.87). The mean total years of nursing experience was 23.3 (SD 8.9). The mean years working in nephrology nursing was 12.8 (SD 8.12). College-educated nurses represented 59.7% of the sample while 40.3% had degree preparation. More than half (n=61%) of the nurses were working in hemodialysis.

#### Empowerment and burnout

#### (emotional exhaustion)

The reliability coefficients were as follows: emotional exhaustion .90, total empowerment .90, and the empowerment subscales, opportunity .84, information .89, support .88, resources .70, job activities .82, and organizational relationships .77. In the original study (Ridley et al., 2009), 41% of the nurses experienced severe emotional exhaustion, as demonstrated by average scores greater than three in the emotional exhaustion subscale. The mean empowerment subscale scores can also be found in Ridley et al's. (2009) report. A Pearson correlation analysis indicated that emotional exhaustion was significantly negatively associated with the total empowerment score (r=-.276, p<0.001) (see Table 1). That is, nephrology nurses who perceived their workplace to be more empowering had less emotional exhaustion and,

Variable	В	Standardized Beta	β
Opportunity	.289	.181	1.5
Information	150	092	849
Support	.094	.060	.529
Resources	443*	225	-2.35
Job Activities Scale	291	190	-1.51
Organizational Relationship Scale	400	211	-1.87
Nursing Education	.540*	.185	2.10
Nursing Education.540*.1852.10 $R^2$ = .200, adjusted $R^2$ =.150 F(7, 121)=49.488, p<.001			

Table 2. Multiple regression of empowerment subscale

subsequently, less burnout. The empowerment subscales of support, resources, job activities and organizational relationships were also significantly negatively associated with emotional exhaustion.

Standard MLR was conducted between components of empowerment and the demographic variables such as age, years in nephrology nursing, and educational preparation on emotional exhaustion. Several regression models were explored. Nursing education was the only demographic variable that had an effect on burnout and was retained in the final model (see Table 2). The final model indicated that 20% of emotional exhaustion could be predicted by empowerment and nursing education, i.e., diploma versus degree preparation (see Table 2). The access to resources empowerment subscale was significantly negatively associated with emotional exhaustion. For every unit increase in resources, emotional exhaustion decreased by -.443.

Nursing education is also a predictor for burnout with nephrology nurses. Nephrology nurses who were degree prepared had significantly higher emotional exhaustion. For every unit increase in nursing education, emotional exhaustion increased by .540. Of the two factors, access to resources had a greater effect than education on burnout.

#### Discussion

This study conducted further analysis of the sample, as described previously by Ridley et al. (2009), with the goal to examining the influence of workplace empowerment on burnout, specifically emotional exhaustion, in a sample of Canadian nephrology nurses. Results of bivariate analysis suggest that burnout is negatively associated with total empowerment, support, resources, job activities and organizational relationships. The multivariate analysis indicates that lack of resources in the workplace and educational preparation were predictors of burnout. More specifically, nurses who felt they lack access to resources and were university prepared were more likely to experience burnout.

The findings of this study are consistent with two other studies conducted by Flynn et al. (2009) and Klersy et al. (2007), which reported that inadequate staffing, workload, and inadequate resources were strong predictors of burnout for nephrology nurses. Questions on the CWEQ II resources subscale pertain to not having enough time to do necessary paperwork, time to accomplish job requirements, and getting help when needed. Having adequate resources and time may be a consistent factor contributing to burnout among nurses, in general, regardless of the area of their practice. Poghosyan (2008) conducted a cross-national study in eight countries, not including Canada, and, despite variable levels of burnout present, nurse staffing and adequate resources were significant predictors of burnout.

Although it is becoming clearer that workload and resources influence burnout, the answer to addressing this issue is not as clear. Strategies aimed at decreasing nursing workloads and increasing resources are often associated with increased health care costs. Finding creative solutions in a health care environment faced with fiscal restraint can be challenging. It is important to note this was a national study and access to resources may vary between provinces, as well as the type of health care facility including urban academic health centres, community hospitals and satellite dialysis units. The influence of work setting on burnout and empowerment in nephrology nurses remains unknown.

The other interesting finding was the difference found between diploma- and degree-prepared nurses, whereby university-educated nurses were more likely to experience burnout. The reasons for this are unclear. In our study, degree education included both baccalaureate and master's preparation. Degree-prepared nurses may be employed in nursing leadership roles such as managers, educators and advanced practice nurses. Most of the research conducted on burnout in nephrology nursing to date is based on samples of staff nurses. The prevalence of empowerment and burnout in nephrology nursing leadership roles is unknown and may be problematic. Further research is needed in this area with a larger sample to explore empowerment and burnout in the various nephrology nursing roles.

With baccalaureate preparation as entry to practice in nursing in Canada, it is concerning to think what future perceptions of burnout will be for these individuals. We were unable to find further literature that examined the impact of nurses' level of education on empowerment and/or burnout. Further study in this area is warranted.

In summary, burnout is an important area of study for nephrology nursing, as it can contribute to decreased retention, further worsening the problem during a nursing shortage, thus affecting service delivery. The associated costs of recruitment and retraining and the impact on the quality of care delivered are also areas of concerns. As previously stated, the model by Laschinger et al. (2001) theorizes that increasing empowerment will decrease levels of burnout. The results of this study empirically provide some support for this theory and nephrology nurses.

#### **Study limitations**

One of the limitations of this study is the sample size. While it was adequate for this analysis, it is insufficient to allow for a more detailed analysis of differences in workplace empowerment and burnout across Canada and within the various practices in nephrology nursing (i.e., hemodialysis, peritoneal dialysis, etc.) and nursing roles. A larger sample size would also allow for further exploration and analysis of differences between college—(n=72) and university—(n=49) prepared nephrology nurses, nursing roles and areas of practice.

It is important to note that the sample in this study was procured from a national volunteer membership of a nephrology nursing organization with the mandate of professional development and cannot be generalized to all Canadian nephrology nurses. However, the question must, therefore, be asked, as to whether nurses who are volunteer members of professional associations differ with respect to their levels of burnout than those who are non-members. According to Maslach et al. (1997), those who experience emotional exhaustion are unable to give more of themselves in regards to their occupation. It seems reasonable to hypothesize that nurses who are experiencing burnout are less likely to join volunteer professional associations. If this is so, then the rates of burnout among this group of nurses may be even higher than previously documented.

#### Implications for nursing practice and research

On a macro-level, Canadian nephrology nurses who perceive their work environment as lacking in resources are more likely to experience burnout. As previously noted in the paper, burnout in nephrology nurses is associated with patient dissatisfaction with their care. Perhaps this evidence can be used to reinforce that adequate resources and staffing levels are not only important for nurses' work life, but for good patient care, as well.

At the unit level, interventions aimed at nurse resources such as charting, adequate time to accomplish their work and getting help when needed should, theoretically, have an impact on burnout for this population of nurses. Opportunities may be present in the workplace for task teams to examine nursing work activities. Are all activities nursingrelated, or could they be done by others? Are efficiencies maximized in the units for supplies, computers, and requisitions, etc.? Are they easily accessible for better use of nurses' time? The current charting system, whether computer- or paper-based, may need to be explored. Are these systems and paper forms 'nurse-friendly' and efficient? Unnecessary duplication of documentation may increase nursing charting time requirements than would otherwise be required.

Our finding of degree-educated nurses' perceptions of burnout was disconcerting and may reflect an entirely different population of nephrology nurses, such as those in leadership roles, who may not be employed in empowering work environments and may be experiencing a greater level of burnout. Further research in the area of perceptions of empowerment, burnout and level of nursing education and nursing roles is warranted.

#### Conclusion

This study supports previous research that non-empowering work environments have an influence on nurse burnout. Application of these findings in the clinical setting, whereby improving the work environment associated with resources such as time spent on documentation, getting help when needed and having enough time to accomplish their work may improve nephrology nurses' perceptions of empowerment and decrease occupational burnout. Further research is needed in the areas of burnout, empowerment, nursing education, practice areas and nursing roles within nephrology.

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# Understanding the lived experience of loss and grieving in persons with end stage renal disease: A humanbecoming approach

By Jennifer Duteau, RN, BScN

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#### Abstract

Grieving a loss is a devastating universal human experience that affects our emotional, physical and spiritual well being. End stage renal disease is a lifelong illness creating a serious and complex impact on individually defined quality of life. Losses such as that of independence, employment, self-esteem and physical functioning can leave individuals in a state of ongoing grief. Parse's humanbecoming theory provides nephrology nurses with a framework for practice that is based in a human science philosophy. The purpose of this paper is to explore the phenomenon of loss and grieving in the population with end stage renal disease, and how Parse's humanbecoming theory can have a positive impact on the lives of both nephrology nurses and the patients for whom they care.

#### Introduction

Chronic renal failure is the result of a number of pathological processes causing irreversible damage to kidney tissue, and is increasingly recognized as a global public health problem. The disease can be detected using simple laboratory tests, and treatment can delay or prevent complications of decreased kidney function, reduce the risk of cardiovascular disease and slow the progression of the disease. As the prevalence of chronic kidney disease continues to grow, the cost of

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Submitted for publication: January 11, 2010. Accepted for publication in revised form: March 30, 2010. providing dialysis and transplantation continues to escalate, as chronic renal failure eventually leads to end stage renal disease. Advances in care need to be translated into applicable worldwide public health measures in an effort to timely diagnose and treat chronic kidney disease. The relentless increase in the number of individuals who will die without treatment has become epidemic (Connolly & Woolfson, 2009). An analysis of the reported causes of death for those diagnosed with end stage renal disease revealed that more than 38.1% (one third) died of cardiac failure and 15.0% died because they refused treatment, or withdrew from therapy (Canadian Institute for Health Information, 2002).

Living with end stage renal disease is a "dynamic experience characterized by periods of stability, instability, and regained stability during the course of the illness trajectory" (Pelletier-Hibbert & Sohi, 2001, p. 411). The illness is all encompassing, affecting every aspect of the individual's life. As a nephrology nurse specializing in the care and treatment of patients with end stage renal disease, I have witnessed the devastating impact the disease can have on an individual's quality of life. Grieving and loss often become an intricate part of the life experience, as individuals attempt to live with changes in their physical and psychological world. The resulting complexity of the individual experience associated with end stage renal disease often leaves nurses with feelings of inadequacy when attempting to holistically care for patients. In order to provide excellence in patient care, nephrology nurses require a deeper understanding into the experience of loss and grieving in relation to patients with end stage renal disease.

# Theoretical views of loss and grieving

Grief is described as a multifaceted response to a loss, particularly to the loss of someone or something with which one has formed a bond (Pilkington, 1993). Throughout my journey to further understand loss and grieving, I have encountered various theoretical and philosophical views.

For many years, the psychosocial sciences have produced a large body of theoretical literature related to grieving. Although the literature has been informative, the knowledge generated from the psychosocial sciences is not necessarily transferable to that of nursing practice. For example, behavioural psychology and psychoanalytical theory often assume an objective stance in which the sole focus is to define what is normal and abnormal grieving. This approach to practice has led to a very generic and prescriptive view of how grief should be treated. Much of the language that currently surrounds grief in the psychosocial and medical sciences "is dichotomous" (Moules, Simonson, Fleiszer, Prins, & Glasgow, 2007) in that it attempts to categorize grief in terms of distinct stages. Dr. Kubler-Ross developed stage theories of grief resolution in which it was believed that loss could be resolved with a reorganization of life that centred on the "knowledge that there is permanent separation" (Florczak, 2008, p. 8). In spite of the views exhibited in the psychosocial sciences, newer theories have begun to emerge from those of psychology. Both Attig (2001) and Neimeyer (2001) have developed a newer worldview of grieving, which considers "loss to be a unique, intersubjective process in which the individual maintains connections with the absent and the meaning of the experience continually changes" (Florczak, 2008, p. 8).

# Nursing perspective of loss and grieving

It is important to note that nursing perspectives emphasize human subjectivity, with a focus on the seeking of understanding rather than "prediction and control of human experiences" (Pilkington, 2006, p. 299), the majority of knowledge generated from the psychosocial sciences is, therefore, incompatible with nursing practice. Nursing literature, unlike those of other disciplines, revolves around the individual lived experience, as nursing practice moves towards a more human science perspective. Within the nursing literature related to loss and grieving, various nursing scholars have reflected on a human science nursing philosophy as a guide to practice. Cody (1991) described the meaning of loss as being determined "individually, subjectively, and situationally by the person experiencing it" (p. 61), and not defined by an observer. In examining cultural perspectives in relation to grief, Cowles (1996) concluded that grief was defined as a "highly individualized process" (p. 293). Jacob (1993) described grief as a "normal, dynamic, individualized process, which evades every aspect (physical, emotional, social, spiritual) of persons experiencing the loss" (p. 1789). As grief and loss is evidently defined as a uniquely individualized experience, nursing practice requires a human science philosophy theoretical framework in which to guide practice. One such theoretical framework is Parse's humanbecoming theory.

The humanbecoming theory of nursing was developed by Rosemarie Rizzo Parse and was first published in 1981, as the man-living-health theory (Fawcett, 2001). As the theory evolved, the name was officially changed to the human becoming theory in 1992 (Parse, 1992). In 2007, the word human becoming was condensed into the one word of humanbecoming to reflect Parse's explicit idea of indivisibility (Parse, 2007). The humanbecoming theory of nursing presents an alternative to the conventional medical and biopsycho-social-spiritual approach found in most other nursing theories. The theory is grounded in existential-phenomenological thought, which supports the view of persons as experts in their own lives. Humans are considered unitary beings coexisting in a dynamic and mutual process with the universe. Humans freely choose meaning in their situations and live what is personally important to them, as they participate in creating their own unique lives. Health is described as an ever-evolving process of becoming and focuses on quality of life, as described and lived by the individual (Parse, 1992, 1994). Considering the universal impact of a loss, Parse's humanbecoming theory is in a unique position to guide nursing practice in its capacity to describe the complex, paradoxical and multidimensional aspects of the lived experience of grieving.

#### The humanbecoming theory

There are three major themes that emerge from the assumptions supporting Parse's humanbecoming theory. The three major themes are meaning, rhythmicity and cotranscendence (Parse, 2007). Each theme leads to a principle. The principles of Parse's humanbecoming theory provide a unique lens with which to view and interpret the human experience of loss and grieving. The first principle of Parse's humanbecoming theory is structuring meaning.

Structuring meaning is the "imaging and valuing of languaging" (Parse, 2007, p. 309). The principle of structuring meaning indicates that humans give meaning to their life situations, as they change and grow. Structuring meaning to life

#### Definitions

#### Existential

Is a term used to pertain to, or to relate to, the human existence or experience. It is an adjective form of the noun existentialism, which implies uniqueness of existing in an environment.

#### Hermeneutic

Refers to the study of interpreting. A search for as comprehensive an understanding of a human existence as possible.

#### Heuristic

Is an adjective for experience-based techniques that help in problem solving, learning and discovery.

#### Ontology

Refers to the philosophical study of the nature of being, existence or reality in general.

#### Phenomenology

Refers to the subjective experience. The experiencing subject can be the person or self.

#### Unitary

Refers to a whole being that cannot be reduced to parts.

situations is not static, but forever changing, as new experiences are encountered. Language is a method with which we communicate personal meaning and express what is important to us.

The second principle of Parse's humanbecoming theory is configuring rhythmical patterns of relating (Parse, 2007). Configuring rhythmical patterns of relating is the revealingconcealing and enabling-limiting of connecting-separating (Parse, 2007). In revealing-concealing, individuals experiencing a loss may reveal their emotions and choices to others, while at the same time concealing. For example, they may share their feelings of loss with the nurse, but not with those who are close to them. Enabling-limiting refers to the limitations and opportunities that are inherent in making choices. Individuals may choose to accept a loss, as they feel limited in how to overcome their grief. At the same time, they create new opportunities for themselves in constructing new ways of living. Connecting-separating are configuring rhythmical patterns of relating being cocreated by the individual, their lost loved one and the universe. When a loss occurs, it creates a separation from an object or person, which was loved. Loss and grief give rise to hope and a desire to remain connected through memories. Times of solitude mingled with times of being with others enable one to distance themselves from their loss and other individuals while paradoxically drawing closer while living the grieving experience (Pilkington, 1993). Parse (1992) states that humans participate with the universe in the cocreation of health, as they live rhythmical patterning of the human-environment interrelationship. Rhythmical patterns of relating are "paradoxical unities in that apparently opposite sides of a pattern are lived all at once" (Pilkington, 1993, p. 136). Contentment and gratitude for the loved ones that remain can lead to newly cherished connections that were not necessarily evident before the experienced loss. This discovery can inspire courage and strength in which one gains the ability to move forward in their life, despite the unknown. The ability to move forward through ongoing change is defined in Parse's third principle of cotranscending with possibles.

Cotranscending with the possibles is defined as "powering and originating of transforming" (Parse, 2007, p. 309). Both Cody (1991) and Pilkington (1993) distinctly defined powering and transforming as central to grieving. Powering underpins the courage to move forward through changes. Transforming continues as one lives with the loss, through cherishing. The experience of grieving a personal loss evolves dynamically in "living every day, as the individual propels self onward, interrelating with others and choosing from among possibilities in light of what is cherished" (Cody, 1991, p. 67). This is our unique way of living, as we move beyond through powering and change.

#### Literature of loss and grieving and the humanbecoming theory

There is a great deal of literature demonstrating how the humanbecoming theory informs nursing research, and practice, with persons/families experiencing loss and grieving. As loss and grieving are human experiences, Parse's phenome-

nological-hermeneutic research methodology flows directly from an ontological base and is, therefore, extremely beneficial in seeking to discover the personal meaning of the lived experience of loss and grieving. Through dialogue engagement, extraction-synthesis and heuristic interpretation, nursing is guided through the research process (Pilkington, 1993, 2006). A study by Jonas-Simpson and McMahon (2005) investigated how language played a vital role in how families began a lifelong journey of living and transforming after the loss of a baby. The authors used Parse's humanbecoming theory as a guide in developing a vehicle for reflecting on the meaning of words spoken by health care professionals during a time of loss and grief. A further study by Pilkington (2006) reflected on five research studies involving grieving in which the humanbecoming theory was used, as a theoretical base. The findings of the studies offered insight into the meaning of the lived experience of grieving from a humanbecoming perspective. Cody (2000) utilized Parse's research methodology in investigating the lived experience of grieving in 10 individuals inflicted with HIV through injection drug use. The study concluded that the grieving experience was defined as overwhelming anguish that shaped the individual's hopes and intentions. A "wretched aloneness" (Cody, 2000, p. 82) was punctuated with valued uplifting engagements, while gratitude inspired courage in the midst of uncertainty. In spite of the vast volume of nursing literature that demonstrates how the humanbecoming theory informs nursing practice with persons/families experiencing loss and grieving, there is very little literature that specifically addresses loss and grieving in the end stage renal disease population. One such article was authored by Harvey (2000).

Harvey (2000) defined grieving as a "process of mourning in relation to the experience of loss" (p. 36). The author stated that patients with end stage renal disease have complicated issues in relation to mourning, "not necessarily for another, but for the self that was and the life that was" (p. 36). Patients with end stage renal disease can have periods of denial and confusion in relation to anticipatory and retrospective grief. Along with these responses, there can be a resistance to the care that is being provided. The view of grieving was seen as reaching a plateau and then mellowing over time. In patients with end stage renal disease, mourning could be reinvoked at any time due to complications of the illness resulting in a change in life events. Complications had the potential to create a sense of loss such as a loss of employment, loss of independence or failure of a transplant. The emotion of grief, "such as shock, sadness, helplessness, frustration, self-blame and guilt" (p. 36), could be re-experienced, thus creating a form of secondary grief. Although some patients with end stage renal disease find ways to adjust to setbacks over time, several patients consistently struggle with the impact of the disease and continue to experience "underlying and unresolved grief/depression or a kind of malignant sadness" (p. 36). Although the article informed nephrology nursing practice by increasing the knowledge and understanding of loss and grieving in patients with end stage renal disease, there remains a lack of humanbecoming theory guided nursing practice in relation to loss and grief in those suffering from end stage renal disease.

#### Humanbecoming guided nursing practice in persons grieving a loss

As Parse's humanbecoming theory is grounded in existential-phenomenological thought and the human sciences, it can inform nephrology nursing practice with persons and families experiencing loss and grieving. In keeping with Parse's humanbecoming theory, the goal of nursing is understanding quality of life from the perspective of the individual. Nurses live the humanbecoming practice methodology by way of true presence. By being in true presence with the individual and/or family, through active listening and bearing witness, the nurse assists the individual and family in their exploration of paradoxical patterns and meaning that arise from the exploration (Cody, 1991). The nurse bears witness to the personal suffering and pain inflicted by the loss and does not pursue an agenda, but rather invites the individual and family to discuss their feelings and desires, as they see fit. The nurse recognizes the uniquely individual experience of loss and grieving, and does not attempt to label or stage the grief. Instead, the nurse acknowledges the personal grieving and goes with the individual's flow, as they evolve and find new ways of becoming. A nurse guided by Parse's humanbecoming theory is conscious of their way in being with others. The nurse is "truly present to the person who is grieving; as possibilities surface, views evolve and new possibilities unfold, participating in the struggle to move beyond the now moment to create new ways of becoming" (Cody, 1991, p. 68). As the humanbecoming theory proposes a humanistic, non-judgmental, individual and family focus, there is a greater reflection of what is truer to the lived experience than that of other conventional views. As a result, nursing practice is guided by the essence of human science with a focus on the uniquely lived experience based on personal value priorities. Nursing documentation reflects an individual's subjective experience, as patterns of hope and dreams and health guide the mutual plan of care. Nurses then find meaning in their relationships with patients and families knowing that they have made a difference in their quality of life.

#### Insights for practice

Parse's humanbecoming theory guides nursing practice by offering an alternative view to that which assumes an objective reality, linear time, predictability and judgment based on grieving norms. Individuals are seen as unique beings with their own experiences, values and beliefs.

Despite the enormous benefits of nursing practice guided by the humanbecoming theoretical perspective, there are possible ethical implications that can prove to be challenging for the nephrology nurse when caring for an end stage renal disease patient who is experiencing loss and grieving. Practising in the humanbecoming theory is different than conventional nursing practice in that there is no nursing process. A study by Legault & Ferguson-Pare (1999) found that several staff nurses practising on a surgical floor acknowledged that the humanbecoming theory was "unfamiliar, and a very different way of practice from traditional nursing" (p. 34). Nurses need to acknowledge not only their discomfort with the unfamiliar, but also the challenges of making a distinct change in their practice. Practising in the humanbecoming theory means that the nurse must be willing to move away from a paternalistic model of nursing care in which the nurse knows what is best for the patient, to one of surrendering control to the patient. The nurse is not "offering professional advice and opinions stemming from the nurse's own lived value system. Practising in the humanbecoming theory is not a canned approach to nursing care" (Parse, 1992, p. 40). The nurse needs to come to terms with the uniquely individual experience of loss and grieving.

Additional ethical implications can incur when practising nursing within the humanbecoming theory, when a nurse has difficulty accepting the individual experience and feels that the grieving process has extended beyond an acceptable timeframe. The nurse may be tempted to intervene and inflict his/her own agenda in relation to what she/he believes is the grieving process. Further ethical implications can occur when the nurse experiences conflicting beliefs and values related to an individual's response to a loss, for example, a surgical patient who refuses to eat and denies all nursing care after experiencing the loss of a limb through amputation. In such a situation, the nurse could be tempted to inflict care on the patient through medications and the obedience with organizational care plans related to post surgical care. The nurse may feel frustrated, as care plan goals are not being met. It is "important not to make judgments about or label people's ways of being, thinking, or feeling. It is essential to go with the person where the person is rather than attempting to judge, change, or control the person" (Parse, 1992, p. 40). The nurse needs to put her personal values aside and focus on the individual view of health and quality of life, rather than one of control. In doing so, the nurse is uniquely defining the profession and advocating for individualized patient-focused care.

#### **Future research**

In order for nephrology nurses to adequately care for individuals with end stage renal disease, they need to gain an understanding of the illness from the individual's perspective. In order to enhance required learning, there needs to be far more nursing literature produced on loss and grieving in patients with end stage renal disease from a human science philosophy perspective. Published literature focused on grieving related to chronic illness and specific life events, is helpful to nephrology nursing in that it does provide further understanding into the phenomenon of grieving and vows to help nurses in being truly present with those suffering a loss through end stage renal disease. In spite of this, the literature surrounding loss and grieving in end stage renal disease is small in number. The end stage renal disease population is uniquely different than those of other chronic illnesses. The disease is complex, requires ongoing dialysis treatments, can include other comorbidities and presents various multiple stressors, which create life-long challenges. Nurses need to understand how a patient with end stage renal disease views their quality of life and how their view of quality of life affects their grieving and ability to cope. For example, does

the ability to cope and adapt to a changing lifestyle determine survival? What can nurses do to enhance patient coping and, therefore, assist in the grieving process? Further studies are also needed on loss and grieving with respect to family members. As family members play a significant role in the well being and health of patients with end stage renal disease, nephrology nurses require significant knowledge in this area in order to better care for the end stage renal disease population.

#### Summary

Grieving a loss is an overwhelming and universal human experience. There is never a resolution or cure since the ongoing persistent nature of the loss is never gone (Pilkington, 1993). As end stage renal disease is a lifelong illness, the emotion of grief can be reinvoked at any time due to the physiological and psychological complications of the disease, as one weaves the familiar-unfamiliar patterns of life anew. Although malignant sadness arises again and again, each time the attached meaning changes, as the individual continues to live in the process of connecting-separating in their experiences of life (Parse, 2007). Despite published qualitative literature addressing loss and grieving, the findings from the research cannot be generalized and, therefore, not applicable to direct practice. It is the humanbecoming theory, rather than qualitative research findings, that guide nursing practice. The humanbecoming theory acts as a foundation to a nurse's deep commitment of individuality, a belief that persons are experts in their own lives and a comprehensive understanding of holistic nursing practice. The theory also connects to the concept of true presence, which is a central idea to Parse's practice methodology.

Throughout the composition of this paper, it has become evident that further research on loss and grieving in the end stage renal disease population needs to be conducted using Parse's humanbecoming methodology. As end stage renal disease is a multifaceted illness that affects health and impacts quality of life, Parse's humanbecoming theory methodology would further clarify the inherit living paradox of structuring meaning, configuring rhythmical patterns and cotranscending, as it relates to the experience of loss and grieving in the population with end stage renal disease. This newly gained understanding has the potential to guide nephrology nursing practice, as nurses use the humanbecoming theory to bear witness to those suffering from end stage renal disease, as they grieve. Shared knowledge will expand health professionals' understanding of what is emotionally involved in grieving a loss and how better to approach individuals with end stage renal disease in an open manner, resulting in sensitive and holistic care.

In spite of a very mechanistic and task-oriented health care system, it is possible for nephrology nurses to change their practice to one of a humanbecoming science and, thus, participate with persons who are suffering from a loss inflicted by end stage renal disease. The resulting benefit is the nurse's ability to positively affect the individual's healing journey by cocreating what they have defined as health and quality of life.

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# Hemodialysis patients' perceptions of home hemodialysis and self-care

By Marie Angela Visaya, RN, BScN, MScN

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#### Abstract

Home hemodialysis (HHD) is an optimal option for patients requiring renal replacement therapy. It has been noted through research that this type of therapy is more cost-effective than in-centre therapies, and the benefits to patients are well documented (Harwood & Leitch, 2006). As stated by the Ministry of Health and Long-Term Care (MoHLTC), a total of 40% of renal failure patients are expected to do home dialysis (either peritoneal dialysis or HHD) by the year 2010 (Kashani & Motiwala, 2007). Even though the literature indicates that the numbers of those doing home dialysis are declining every year, there is no evidence to demonstrate why the numbers are declining.

A quantitative cross-sectional descriptive study was conducted using the Patient Perception Survey and the Jo Pre-Training Assessment Tool (JPAT) to assess in-centre hemodialysis patients' perceptions regarding home dialysis, as well as their self-care ability. The two frameworks utilized were the Theory of Planned Behavior and Orem's Theory of Self-Care. According to the Theory of Planned Behavior, the 26 patients out of 49 who had positive perceptions regarding home dialysis would be expected to participate in home dialysis. However, according to the patients' responses to the domains within the JPAT, only eight out of the 26 would be considered suitable to participate in home dialysis. Only two of the domains, communication and social support, were found to be significantly related to patients' perceptions regarding home dialysis. Health care professionals need to implement interventions that incorporate assessment of communication and social support when addressing home dialysis therapy with a patient with end-stage renal disease (ESRD).

#### Introduction

Home hemodialysis (HHD) is a favourable option for patients requiring renal replacement therapy. It has been noted through research that this type of therapy is more cost-effective than in-centre therapies and the benefits to patients are well documented (Harwood & Leitch, 2006). HHD first started in the early 1960s, as a means of providing a more cost-effective treatment modality. Literature suggests that home dialysis is more convenient and improves quality of life for renal failure

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patients (Kashani & Motiwala, 2007). The other benefits to patients dialyzing at home include more flexibility in dialysis schedules, convenience, no transportation issues, more time with the family, less time in a hospital setting, increased knowledge regarding dialysis, and improvements to personal health and independence (Harwood & Leitch, 2006). Statistics demonstrate that there is an increase in numbers of patients with end stage renal disease (ESRD): there were 14,567 dialysis patients with ESRD in Canada on December 31, 2000, a number that continues to climb and that has more than doubled from 6,811 patients in 1991. Canadian Institute of Health Information's (CIHI) data also show that 4,386 new patients started treatment during 2000, 60% higher than the number who began treatment in 1991 (CIHI, 2004). CIHI indicated that a quarter of a million individuals in Canada were on dialysis in 2007. Of those, 48% remained on hemodialysis therapy, 12% remained on peritoneal dialysis (PD) and 40% had kidney transplants (CIHI, 2007). The prevalence of individuals on HHD is 0.4% to 0.6% and peritoneal dialysis is slightly higher at 8.4% to 10.4% (CIHI, 2007). The growth of home dialysis continued until the early 1980s and then started to decline, despite the evidence showing beneficial outcomes. Home dialysis (combining both PD and HHD) slowly decreased since 1981, from 23% to 11% in 2001. In-centre hemodialysis treatments went from 59% in 1993 to 74% in 2001 (CIHI, 2004). Research shows that the population of those with renal failure and those having to undergo hemodialysis treatments is vastly growing (Schatell, 2005). However, the patient population doing home dialysis is falling. Ontario's Ministry of Health and Long-Term Care (MoHLTC) has set provincial targets for dialysis modality distribution, which all dialysis programs are expected to achieve by 2010. The goal is that only 60% of patients are to dialyze in in-centre hemodialysis, 30% in home PD, and 10% in HHD (Kashani & Motiwala, 2007).

As stated by the MoHLTC, a total of 40% of renal failure patients are expected to do home dialysis, which includes both PD and HHD. Even though the literature indicates that those doing home dialysis are declining every year, there is no evidence to demonstrate why the numbers are declining. There is limited research focusing on hemodialysis patients' perceptions regarding home dialysis therapy.

#### Literature review

Previous literature provides information such as the 'lived experiences of home dialysis patients' (Blogg & Hyde, 2006). Ageborg, Allenius and Cederfjall (2005), Curtin et al. (2004), Manns et al. (2005) and Richard (2006) discuss the importance of self-care management in dialysis patients. The importance of self-care management in dialysis patients is depicted within studies, but little or no research discusses the correlation between the patients' perceptions of HHD and self-care ability. Research has been conducted related to renal failure patients who have not yet chosen a treatment modality, that being HHD, peritoneal dialysis or in-centre hemodialysis (Mehrotra, Marsh, Vonesh, Peters, & Nissenson, 2005). One study identified that patients experienced lack of information, conveyance of disease-related knowledge, and overall view of and involvement in care decisions. These factors impacted the patients' decision for treatment modality (Pagels, Wang, & Wengstrom, 2008). The focus of this study was aimed at motivating, guiding, and supporting the patient, as well as providing education in regard to renal failure. The results were that more than half the patients (59%) chose home dialysis as their treatment modality (Pagels, Wang, & Wengstrom, 2008).

By understanding a patient's attitude and belief system regarding a particular therapy, it can help to predict future behaviour (Ward-Griffin & Bramwell, 1990). It can also fill in the knowledge gaps that patients have towards HHD. By identifying the perceptions patients may have towards home dialysis, the health care team can formulate strategies to overcome the identified barriers. Patient perception is now accepted as one of the fundamental outcomes of care. Measurement of patient perception serves many purposes for establishing effective patient care. There is a need to identify a structured mechanism for patient feedback and communication. Patient preferences can then be used to assist in deciding the way that care is provided (Sweeney, Brooks, & Leahy, 2003). The purpose of this study was to investigate the relationship between hemodialysis patients' perceptions of home hemodialysis and self-care ability.

#### **Conceptual framework**

#### Theory of Planned Behavior

The Theory of Planned Behavior is an addition to the Theory of Reasoned Action proposed by Icek Ajzen in 1985. Derived from the social psychology setting, the Theory of Reasoned Action was proposed by Fishbein and Ajzen (1975). The components of Theory of Reasoned Action are three general constructs: behavioural intention, attitude, and subjective norm. Theory of Reasoned Action suggests that a person's behavioural intention is dependent on the person's attitude about the behaviour and subjective norms (Fishbein & Ajzen, 1975). The Theory of Planned Behavior states that attitudes, social norms, and perceived behavioural control are theorized as causal variables relating to the intention to perform a behaviour. This intention ultimately prompts a person to actually carry out that behaviour. If a patient has a positive attitude regarding home dialysis and the patient's friends and family members are encouraging of this behaviour, then the patient will do home dialysis therapy. Moreover, if the patient feels as though he or she can perform the activities needed in order to do HHD, such as being able to operate the hemodialysis machine, then he or she will actually carry out home dialysis.

#### Orem's Theory of Self-Care

The other framework chosen as a guide is Orem's **Conceptual Framework of Self-Care**. In general, self-care includes those actions and decisions that contribute to and maintain an individual's optimal level of health and well being (Orem, 1995). Since the self-care model focuses on the individual's responsibility for health, it provides a useful framework for description of hemodialysis patients in their search for continued independence and self-care (Ward-Griffin & Bramwell, 1990). Self-care is the performance or practice of activities that

individuals initiate and perform to maintain life, health, and well being. When self-care is effectively performed, it helps to maintain structural integrity and human functioning (George, 1995). Self-care agency is the human's ability or power to engage in self-care. The therapeutic self-care demand is modelled on deliberate action. It is the action deliberately performed by some members of a social group to bring about events and results that benefit others in specified ways (George, 1995). According to Orem's Theory of Self-Care, hemodialysis patients must be able to perform self-care tasks in order to provide continuous effective care in the home. The hemodialysis patient is ready to function in a self-care capacity when he or she practises activities that maintain life, health and well being (George, 1995).

#### **Methods**

#### Design

The study was a quantitative cross-sectional descriptive research design investigating the relationship between hemodialysis patients' perceptions and self-care ability. The Patient Perception survey assessed hemodialysis patients' perceptions regarding HHD and the JPAT was used to assess the self-care ability of hemodialysis patients. Using the Statistical Package for the Social Sciences (SPSS) software version 15.0, data were analyzed using descriptive and inferential statistics. Kendall's Tau-C was used to examine the strength of association between the ESRD patients' perceptions of home dialysis and the patients' suitability as a candidate for home dialysis. Kendall's Tau-C is a measure of association for ordinal variables that are reported in categories. This non-parametric test is used with rectangular tables, where the number of rows and columns differ (Portney & Watkins, 2000).

#### Setting

The study took place in an outpatient hemodialysis unit, located in southwestern Ontario. Patients within the outpatient hemodialysis unit all require hemodialysis as a treatment modality. Each patient was either ambulatory or ambulates assisted by different devices (e.g., cane or a walker). A few patients are accompanied by family members and require a wheelchair to assist them to each pod. There are 36 hemodialysis chairs in the unit, all divided by pods consisting of six chairs each.

#### Participants

The population consisted of patients with ESRD. The study sample met the following inclusion criteria:

- 1) On hemodialysis
- 2) 18 years of age or older
- 3) Alert and oriented
- 4) Visual acuity level sufficient to accurately read home dialysis written materials and to do home dialysis safely
- 5) Able to speak or read English or have a family member with them at the time to interpret the questions
- 6) Able to fill out a questionnaire or have a family member with them who was able to interpret and fill out the questionnaire according to the patient's responses.

#### Data collection

Study packets, which consisted of a prepared letter explaining the study, the JPAT, and the Patient Perception Survey, were distributed by the desk clerk to all eligible patients previously identified by the researcher. The patients were informed that they were being invited to participate in a study and by whom. They were instructed to read the enclosed letter in the study packet for further explanation. It was stressed that their participation was voluntary and the information they provided would remain anonymous, as they would not leave any identifying marks to retrace the information back to them. Materials were distributed at the beginning of each patient's hemodialysis treatment, providing adequate time for completion. After patients completed their surveys, they were to place it in the envelope provided and hand it to their assigned nurse.

#### Ethical considerations

Approval from the research ethics review board (REB) of the hospital was obtained prior to conducting the study. Participants were informed by an explanatory letter distributed to them, who was conducting the study and its purpose. The 50 hemodialysis patients recruited for the study were asked to give 30 to 45 minutes of their time to complete two tools, one assessing their perceptions regarding home dialysis and the other to assess their self-care ability. They were informed there may be no direct benefit for participating in the research study, but that their participation could be helpful in determining suitability for home dialysis and identifying barriers to doing home dialysis. The patients were notified that any information they provided would be anonymous, meaning that their name would not be associated with their information, no one could identify them and information would be reported in group form.

#### Instruments

Jo Pre-Training Assessment Tool (JPAT). The JPAT is a tool used for assessing the suitability of candidates for HHD. The JPAT was developed, pilot-tested at one hospital and field-tested at two major teaching hospitals in Sydney, Australia. The JPAT served as a reliable and valid tool used to assess the suitability of candidates for HHD (Chow, 2007). Reliability and validity testing of JPAT version 2.1 was conducted with 60 renal patients prior to their commencement of home hemodialysis training. JPAT version 2.1 had high Cronbach's alpha, suggesting that the scale is internally consistent. The reliability results of the six subscales were: physical stability (7.8% of the variance), nutritional status (5.6% of the variance), communication ability (15.1% of the variance), ability to maintain self-care (4.7% of the variance), social support (13.6% of the variance), and psychological suitability (8.7% of the variance). Analyses yielded coefficients of 0.82, 0.84, 0.79, 0.86, 0.92 and 0.86 for the six subscales, with a total scale alpha of 0.92 (n=60). Spearman's rank-order correlation and paired samples T-test between the subscales and the domains of the Medical Outcomes Study Short-Form 36-Item Health Survey was significant. Overall, results suggest that JPAT version 2.1 is sufficiently reliable to be used as a tool for assessing patients with ESRD, and to identify patients most likely to succeed in a home hemodialysis program (Chow, 2007).

JPAT version 2.1 is a questionnaire consisting of 38 assessment items in six sections: physical stability, nutritional status, and communication ability, ability to maintain self-care, psychological suitability and social support (Chow & Bennett, 2001).

Using the JPAT, the nurse interviews the patient prior to initiating any form of treatment. The information obtained from the patient provides the home dialysis nurse the opportunity to determine the patient's physical strength to handle the equipment and supplies, dexterity, vision, and communication skills. Addressing such issues as ability to read, colour blindness, and hearing difficulties assists the nurse in making adjustments to training material and teaching tools in preparation for training (Harwood & Leitch, 2006). The person's emotional and psychological suitability is assessed prior to training with the assistance of the social worker and the nephrologist. For the purpose of this study, the JPAT was used as a self-administered survey, distributed to all hemodialysis patients who met the inclusion criteria. Some of the questions were altered in order to make it suitable for a self-administered survey, although the intent of the questions remained the same. The researcher found it most effective to administer a self-administered survey in order to generate a reasonable patient study sample. Due to time constraints, the unit manager encouraged the development of a self-administered survey, which allowed patients to complete their surveys during their hemodialysis treatment.

The JPAT is scored according to numbers ranging from zero to five that are placed beside each question. A weight of 0-5 is allocated to each category and a final summative grade was calculated. The researcher added up the scores at the end of each completed survey. There are three categories: good, marginal and inadequate. Each category determines if the patient has selfcare ability and is a suitable candidate for home dialysis. Each section in the JPAT varies in scoring. A patient who scores very low is suggested to be a good candidate for home dialysis. That is, the patient has adequate skills and support in all aspects and no or minimal health-related problems that will affect home dialysis training. A marginal score suggests that the patient demonstrates mild to moderate deficit in the psychosocial and/or physiological aspects, plus the patient reveals a mild to moderate degree of problems that will hinder the home dialysis training process. Inadequate home dialysis suitability suggests that a patient is dependent and demonstrates inability to selfcare (Chow, 2007).

Patient Perception Survey. Francis et al. (2004) developed a manual for health care researchers to assist in constructing questionnaires based on the Theory of Planned Behavior constructs. For the purpose of this study, the researcher used the manual as a guide when developing the Patient Perception Survey and adapted the questions to suit the intended study. The Patient Perception Survey developed by the researcher measured four concepts. Questions one and two measured the patient's behavioural intentions and questions three and four measured the patient's attitudes. Questions five and six measured the patient's subjective norms and questions seven and eight measured the patient's perceived behavioural control. The survey consisted of eight Likert-scale items, which were ranked on a scale from 1 to 4, where 1 is strongly disagree and 4 is strongly agree. Two university professors knowledgeable in the Theory of Planned Behavior were used to review the survey for face and content validity and asked to identify information to be added. Each was verbally contacted by the researcher and provided with the Patient Perception Survey and evaluation form addressing principles of the Theory of Planned Behavior, comprehensiveness, readability, relevancy, and usefulness in identifying patient perceptions. Suggestions were made by the professors and changes were made accordingly by the researcher.

#### Results

There were a total of 111 hemodialysis patients located at the study site. Out of the 111 hemodialysis patients, 51 of those patients were excluded, as they did not meet the inclusion criteria. Forty-nine out of 60 patients returned their surveys for a response rate of 81.6%. Of the 49 participants, 24 were male, and 25 were female. Table 1 details the descriptive statistics for the demographics of age, gender, education, and employment. Table 2 outlines the descriptive statistics for the demographics of available assistance with dialysis treatments and length of time each patient has been on hemodialysis.

This study utilized the Patient Perception Survey to obtain measures of hemodialysis patient perceptions regarding HHD. Results from this sample of 49 patients found that 46.9% of the patients identified negative perceptions of HHD and 53.1% of the 49 patients identified positive perceptions of HHD.

The JPAT was used to obtain measures of hemodialysis patients' suitability for HHD. The ESRD patient's suitability for HHD was determined by a score of "good", that is less than or equal to five on each of the six subscales of the JPAT. Of the 49 participants who responded, only eight scored "good" in all six subscales, making these eight patients suitable for HHD. The eight patients were identified by those who scored less than five in each of the six subscales. The remaining 41 patients each varied in their JPAT questionnaires between good, marginal and inadequate in each of the subscales. Therefore, it is not possible to calculate the mean score of the

 Table 1. Descriptive statistics for the demographics of age, gender, education and employment

Demographics	Frequency	Per cent
Age		
18-40	4	8.2
41–60	18	36.7
61–70	11	22.4
71-80	14	28.6
>80	2	4.1
Gender		
Male	24	49
Female	25	51
Education		
College/University	17	34.7
High School	26	53.1
No formal education	6	12.2
Employment		
Full-Time	6	12.2
Part-Time	1	2
Unemployed on social benefit	9	18.4
Unemployed not on social benefit	5	10.2
Retired	27	55.1
Other	1	2

remaining 41 patients. Table 3 outlines the percentage of participants who scored good, marginal and inadequate in each of the six subscales.

In terms of the relationship between hemodialysis patients' perceptions, HHD and self-care, 26 out of the 49 participants had positive perceptions regarding HHD. These 26 patients are expected to perform HHD therapy according to the TPB. However, only eight participants were suitable for HHD therapy, as indicated by their scores on the JPAT. Therefore, these results indicate a limitation to the TPB, noting that although patients have positive perceptions regarding a behaviour (self-care), there are variables that may impede their ability to partake in the behaviour.

The relationship between hemodialysis patient perceptions of HHD, as measured by the Patient Perception Survey, and self-care ability, as measured by the JPAT, was determined using Kendall's Tau-C. A hemodialysis patient's perception regarding HHD was significantly and negatively associated with both social support, Kendall's Tau-C = -0.288, p = 0.038and communication, Kendall's Tau-C = -0.353, p = 0.001. This indicates that when a patient scores high on the Patient Perception Survey, meaning he or she has negative perceptions regarding HHD, the patient as well has low levels of social support and communication. The associations between a hemodialysis patient's perception regarding HHD and all other subscales were not significant. Table 4 shows the strength of the association between patient perceptions and each of the six subscales, such as physical, communication, ability to maintain self-care, social support, psychological status, and nutritional status.

#### Discussion

The research findings for this study suggest that a relationship exists between communication and patient perceptions regarding home dialysis. A hemodialysis patient's ability to communicate effectively impacts his or her decision to engage in home dialysis therapy. A study conducted by Hollis et al. (2006) noted similar findings. A cross-sectional postal survey of PD patients was created to assess factors that influenced their management of the prescribed PD regimen. Their research findings identified that patients who had greater contact and

Table 2. Descriptive statistics for the demographics of

available assistance with dialysis treatments and length of time on hemodialysis		
Demographics	Frequency	Per cent
Available assistance with dialysis treatments		
Yes	26	53.1
No	23	46.9
Length of time on dialysis		
1–5 months	9	18.4
6 months-1 year	6	12.2
2–7 years	30	61.2
>7 years	4	8.2

communication with the peritoneal dialysis team were more likely to modify their treatment. Contact could include hospital visits, home visits or telephone calls (Hollis et al., 2006). Another study also looked at strategies for teaching a deaf patient nocturnal home dialysis. Teaching an ESRD patient, especially one with a physical disability, to become proficient in doing home hemodialysis can be challenging. Communication was done through sign language, lip-reading and written notes. At home, communication may be designed for the client to communicate with the team on the internet (Fung, Faratro, D'Gama, & Wong, 2007). Effective strategies need to be discussed with a hemodialysis patient so that interventions can be implemented to assist with any communication barriers.

The research findings for this study also identified that social support influences a hemodialysis patient's perception of engaging in home dialysis therapy. A study assessing patients' attitudes towards home dialysis therapy found that if a patient had a close family relationship, especially a partner or dependent children, this motivated him or her to continue to carefully perform the treatment in order to be able to maintain these relationships (Polaschek, 2007). Therefore, health care professionals must take the time to explore patients' support systems and identify resources or other options that may be available to them.

According to the Patient Perception Survey, which supports the Theory of Planned Behavior, 53% of the 49 patients are predicted to participate in HHD therapy, while 47% are identified as non-participants in HHD therapy. Although 53% are predicted to do HHD therapy based on the TPB, 84% are not suitable for HHD therapy according to the JPAT. The findings clearly do not support the TPB, stating that a patient will adhere to a particular behaviour if he or she has positive perceptions regarding the behaviour.

According to Orem's Theory of Self-Care, a hemodialysis patient must first be able to tend to activities such as human functioning, human well being and the development within social groups. In terms of human well being, only 24.5% scored 'good' in the physical subscale conducted in this study. In regards to human functioning, only 61.2% scored 'good' in the ability to maintain self-care and only 57.1% scored 'good' in the social support subscale. These findings indicate that not all of the study population are suitable for self-care, as not all are able to tend to activities such as human functioning, human

Table 3. Percentage of participants who scored good, marginal, and inadequate in each of the six subscales on the modified JPAT (N = $49$ )			
Subscale	Good Per cent	Marginal Per cent	Inadequate Per cent
Physical	24.5	67.3	8.2
Communication	79.6	18.4	2
Ability to Maintain Self-Care	61.2	26.5	12.2
Social Support	57.1	32.7	10.2
Psychological 67.3 20.4 12.2			
Nutritional	100	0	0

well being and the development within social groups. This coincides with Orem's Theory, stating that an individual can only engage in self-care once addressing basic conditioning factors such as developmental state and health care factors. In this study, 83.7% of the participants have altered physical status, as determined by the JPAT, which impedes their ability to be suitable for HHD therapy, as indicated by the JPAT scoring sheet.

#### Limitations

For the purpose of this study, the JPAT was modified to be a self-administered survey, as opposed to the original survey, which was an interview format. This would necessitate the need to conduct reliability and validity testing to the modified version, which was not done for this study. Thus, the results of this study are only tentative.

The original JPAT was conducted on new ESRD patients starting on hemodialysis therapy. In terms of gaining an adequate sample size within the timeframe that was allotted for this study, the inclusion criteria consisted of patients who were already on in-centre hemodialysis therapy. It is recommended that another researcher use the JPAT in future research studies, as the original interview format. As part of modifying the JPAT, some of the questions were altered in order to make it suitable for self-administration, although the intent of the questions remained the same. It was clear that upon reading the newly developed JPAT, some of the questions seemed only appropriate to answer based on an interview and through observation (e.g., how would you describe your appearance? Would you say you like to remain neat and tidy?). A question such as this could create bias, based on inaccurate self-report. This can pose a challenge for the validity of this research study.

This was the first use of the Patient Perception Survey, which was created using the Theory of Planned Behavior. It is recommended that future researchers use the Patient Perception Survey to assess hemodialysis patients' perceptions regarding HHD in order to assess the usefulness of this survey.

#### **Recommendations for future research**

In order to assess the relationship between hemodialysis patient perceptions regarding HHD and self-care ability, research needs to first identify similar themes as to why a hemodialysis patient may refuse to take part in the self-care

Table 4. Kendall's Tau-C values showing the association between Patient Perception Survey Scores and the total scores of the six subscales			
Subscale         Kendall's Tau-C value         p value			
Physical	-0.130	0.329	
Communication	-0.353	0.001	
Ability to Maintain Self-Care	-0.187	0.185	
Social Support -0.288 0.038		0.038	
Psychological	-0.237	0.076	

Nutritional status cannot be computed because all of the 49 participants scored "good" in this subscale. Due to the variable being constant, it cannot be computed against another variable.

tasks involved in home dialysis therapy. The Patient Perception Survey was very limiting as to reasons why a hemodialysis patient may refuse or engage in HHD. A qualitative research design would add what is currently known by increasing our understanding of patients' perceptions regarding HHD.

It is noted in the findings of this study, that at least eight (16%) of the 49 hemodialysis patients were fully capable, as determined by the JPAT, of doing home dialysis, but clearly were on in-centre hemodialysis.

A patient's ability to perform home hemodialysis tasks can be overwhelming. Therefore, screening with the JPAT is a potential method of identifying those patients who are most appropriate or suitable for home hemodialysis.

#### Conclusion

In this study, 53% of the patients on in-centre hemodialysis were identified to have positive perceptions of HHD using the Patient Perception Survey. Of note, those in-centre hemodialysis patients with positive perceptions regarding HHD were found to have good communication skills and strong social supports. While 16% of the patients were determined to be suitable for home dialysis through scoring "good"

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in all six subscales of the JPAT, none of these patients were on home dialysis. Use of the JPAT by health care practitioners in a predialysis clinic may help identify those patients who would be able to perform home dialysis, thus potentially increasing the number of patients on home dialysis.

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# Treatment of restless legs syndrome in patients with chronic kidney disease: A focus on medications

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#### **Objectives**

After reading the article, the reader will be able to:

- Describe symptoms of restless legs syndrome (RLS)
- Describe the differences between intermittent, daily and refractory RLS
- Describe conditions and medications associated with RLS
- Describe non-pharmacologic measures that patients can employ to manage RLS symptoms
- Compare and contrast currently available pharmacologic agents to treat RLS symptoms.

#### Introduction

Restless legs syndrome (RLS) is a sleep disorder characterized by unpleasant sensations in the legs, which are relieved by movement.

Table 1. Signs and symptoms of restless legs syndrome
<ul> <li>Essential diagnostic criteria (International Restless Legs Study Group)</li> <li>Urge to move legs accompanied by uncomfortable and unpleasant sensations in legs</li> <li>Urge to move or unpleasant sensations begin or worsen during periods of rest or inactivity</li> <li>Symptoms are partially or completely relieved by movement</li> <li>Symptoms worse in evening or night than during the day</li> </ul>
<ul> <li>Supportive clinical features</li> <li>Family history</li> <li>Abnormally frequent periodic limb movements when resting or asleep, including sudden jerking leg movements</li> <li>Response to dopaminergic therapy</li> </ul>
Associated features • Sleep disturbance • Insomnia • Daytime fatigue/sleepiness • Mood disturbances
(Allen et al., 2003; Novak et al., 2006)

#### Diagnosis

The diagnosis of RLS is based on clinical signs and symptoms. Essential criteria for the diagnosis of RLS, according to the International Restless Legs Study Group (IRLSSG), include an urge to move the legs at rest that is worse in the evening or night and is relieved by movement (Allen et al., 2003). The signs and symptoms of RLS are listed in Table 1. Symptoms are usually bilateral and appear within 15 to 30 minutes of going to bed. In mild cases, patients fidget, move around, kick or massage their legs, while in more severe cases, patients must get out of bed and walk around to relieve the symptoms (Tarsy & Sheon, 2009).

Patients describe the feeling of discomfort in their legs as sensations that are deep in the tissue rather than superficial. Patients with RLS do not typically experience skin sensitivity or pain and tingling such as with neuropathic pain (Tarsy & Sheon, 2009). Patients describe RLS symptoms with words such as "creepy-crawly, jittery, pulling, moving worms, electric currents, shocks, burning, or grabbing." (Allen et al., 2003). In

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patients who are cognitively impaired, criteria for diagnosis of RLS include rubbing or kneading the legs, groaning while holding the legs, and demonstrating motor activity in the lower legs through pacing, fidgeting, repetitive kicking or foot tapping (Allen et al., 2003). Of note, RLS should not be confused with leg cramps or neuropathic pain, although patients with end stage renal disease often experience these conditions. Additionally, referral to a sleep specialist to rule out sleep apnea may be necessary, as sleep apnea and RLS often co-exist (Novak, Mendelssohn, Shapiro, & Mucsi, 2006).

# Pathophysiology and associated medical conditions

The pathophysiology of RLS is unclear. However, it is felt to involve a disruption in the dopaminergic function of the central nervous system with a possible genetic component. Brain iron metabolism may also be involved (Novak et al., 2006). RLS can be idiopathic or secondary to several medical conditions (see Table 2). Uremia can contribute to RLS in patients receiving dialysis, however, the mechanism is unclear (Molnar, Novak, & Mucsi, 2006). RLS symptoms have been noted to improve after renal transplantation (Winkelmann, Stautner, Samtleben, & Trenkwalder, 2002). However, dialysis-related factors such as dialysis dose, length of dialysis or type of membrane are not clearly related to RLS. Other factors such as anemia, iron deficiency, immobility during dialysis and medical co-morbidities are also associated with RLS in patients receiving dialysis (see Table 2) (Molnar et al., 2006).

Table 2. Risks for restless legs syndrome	
Secondary causes of restless legs syndrome	
• Iron deficiency anemia	
• End stage renal disease	
• Diabetes	
• Diabetic neuropathy	
• Multiple sclerosis	
• Parkinson's disease	
• Pregnancy	
Rheumatic disease	
<ul> <li>Venous insufficiency (e.g., varicose veins)</li> </ul>	
• Peripheral neuropathy	
• Spinal conditions (e.g., spinal stenosis, lumbar	
radiculopathy)	
• Obesity	
• Hypothyroidism	
• Vitamin deficiencies	
• Low serum parathyroid hormone concentration	
<ul> <li>Factors which can worsen restless legs syndrome</li> <li>Medications: selective serotonin reuptake inhibitors (SS lithium, dopamine antagonists (e.g., metoclopramic tricyclic antidepressants (e.g., amitriptyline, nortriptyl mianserin, sedating antihistamines (e.g., diphenhydrar chlorpheniramine), calcium channel blockers (e.g., amlodipine, nifedipine)</li> <li>Caffeine</li> <li>Nicotine</li> </ul>	RIs), le), ine), nine,

RLS can have a significant impact on sleep quality and can result in mood disturbances and, subsequently, reduced quality of life (Novak et al., 2006; Szentkiralyi et al., 2009). In a study of patients receiving dialysis, RLS was associated with low quality of life, premature discontinuation of dialysis and increased mortality (Unruh et al., 2004).

#### Epidemiology

RLS occurs commonly among patients with chronic kidney disease (CKD) and receiving dialysis. Mild RLS occurs in 5% to 15% of the general population, with increased prevalence in women and in the elderly (Tarsy & Sheon, 2009). Very little data describe RLS in patients with CKD not receiving dialysis. In a single centre study, RLS was observed in 6% of CKD patients not receiving dialysis (Mendelssohn et al., 2004). However, it has been estimated that from 6% to 60% of patients receiving dialysis experience RLS (Kavanagh, Siddiqui, & Geddes, 2004; Tarsy & Sheon, 2009). The use of different methodologies to identify RLS accounts for the wide variation in the prevalence of RLS among dialysis patients. With the use of the more specific IRLSSG diagnostic criteria, the prevalence of RLS in patients receiving dialysis is estimated to be 7% to 33% (Molnar et al., 2006).

#### **Treatment of RLS**

Before considering pharmacotherapy, principles for treating RLS include minimizing risk factors and non-pharmacological therapy. Not all patients with RLS require pharmacotherapy. The first step in managing RLS is to remove any risk factors, where possible (see Table 2), and to employ non-pharmacologic therapy such as calf-stretching exercises (see Table 3) (Molnar et al., 2006). Second, it is important to manage anemia with iron and erythropoietic therapies, as studies have demonstrated a decrease in RLS symptoms in patients receiving dialysis with use of intravenous iron or erythropoietin (Earley, Heckler, & Allen, 2004; Rijsman, de Weerd, Stam, Kerkhof, & Rosman, 2004; Sloand, Shelly, Feigin, Bernstein, & Monk, 2004).

The third step in the management of RLS is pharmacotherapy. Studies that evaluate the treatment of RLS in patients with CKD and receiving dialysis are limited in quantity and quality, so many treatment recommendations for this patient population are based on extrapolation from studies that evaluate therapies to treat RLS in the general population (Molnar et al., 2006). Generally, first line drug therapy for RLS in patients with CKD consists of dopaminergic therapies (levodopa for intermittent RLS, or dopamine agonists), while

Table 3. Non-pharmacologic therapy for restless legs syndrome
Avoid caffeine, alcohol, and nicotine
Activities leading to mental alertness (e.g., crossword puzzles) during times when patients are likely to experience restless legs symptoms
Exercises—calf stretching

- Intradialytic aerobic exercise
- Sleep hygiene

(Molnar et al., 2006; Novak et al., 2006; Sakkas et al., 2008; Tarsy & Sheon, 2009; Trenkwalder et al., 2008)

Table 4. Pharmacotherapy for restless legs syndrome in chronic kidney disease			
Drug Class (initial dose, maximum dose)	Advantages	Disadvantages	
Levodopa with carbidopa (Sinemet®, Sinemet CR®) (50–400 mg levodopa daily)	<ul> <li>effective for RLS without CKD</li> <li>effective for RLS in CKD</li> <li>rapidly absorbed with rapid onset</li> <li>useful for intermittent RLS only</li> <li>unlikely that dose adjustments</li> <li>are required for CKD, not removed</li> <li>by dialysis</li> </ul>	<ul> <li>decreasing response with continual treatment</li> <li>(i.e., tachyphylaxis)</li> <li>possible worsening of daytime RLS symptoms early in the day after evening dose (i.e., augmentation) occurs in up to 70% of patients</li> <li>early morning RLS, as the drug is wearing off</li> <li>(i.e., rebound)</li> <li>RLS symptoms return in the second half of the night (i.e., recurrence)</li> <li>adverse effects: insomnia, gastrointestinal disturbances, orthostatic hypotension, hallucinations</li> </ul>	
Dopamine agonists - pramipexole (Mirapex <sup>®</sup> ) (0.125–1.5 mg daily) - ropinirole (Requip <sup>®</sup> ) (0.25–2 mg daily)	<ul> <li>effective for RLS without CKD</li> <li>effective for RLS in CKD</li> <li>useful for daily RLS</li> <li>last longer than levodopa</li> <li>less augmentation than with</li> <li>levodopa, if augmentation occurs,</li> <li>additional doses can reduce the</li> <li>intensity of augmentation</li> <li>if augmentation develops with one</li> <li>agent, it may not develop with the other</li> <li>adverse effects mild, usually resolve</li> <li>10-14 days</li> <li>no evidence that sudden sleep</li> <li>attacks (reported adverse effect of</li> <li>dopamine agonists) occur with</li> <li>treatment of RLS</li> </ul>	<ul> <li>possible worsening of daytime RLS symptoms early in the day after evening dose (i.e., augmentation) occurs in up to 33% of patients taking pramipexole, unknown for ropinirole</li> <li>early morning rebound RLS</li> <li>adverse effects: insomnia, gastrointestinal disturbances, orthostatic hypotension, hallucinations, nausea, fatigue, dizziness, nasal stuffiness, constipation, insomnia, leg edema, impulse control disorders (e.g., compulsive gambling, shopping, hypersexuality), sudden sleep attacks</li> <li>onset 90–120 minutes</li> <li>slow dose titration is important</li> <li>requires dose adjustment for CKD (pramipexole).</li> <li>not recommended in dialysis (pramipexole).</li> <li>no data in dialysis (ropinirole) from manufacturer, but one published study available.</li> </ul>	
Antiepileptics - gabapentin (Neurontin <sup>®</sup> ) (100–300 mg post-dialysis) For CKD: CrCl 30–59 mL/min 200–600 mg daily) CrCl 15–29 mL/min 100–300 mg daily CrCl <15 mL/min 100–200 mg daily	<ul> <li>effective for RLS without CKD</li> <li>effective for RLS in CKD</li> <li>alternative agent for daily RLS</li> <li>may be useful for painful RLS</li> <li>useful in mild RLS</li> </ul>	- adverse effects: sedation, fatigue, dizziness, ataxia - requires dose adjustment for CKD - slow dose titration is important	
Benzodiazepines - clonazepam (0.25–2 mg daily)	<ul> <li>effective for RLS in CKD</li> <li>alternative for intermittent RLS</li> <li>useful for sleep disruption from RLS</li> <li>useful for mild cases in younger patients</li> <li>no dose adjustments required in CKD</li> </ul>	<ul> <li>potential for dependence</li> <li>adverse effects: drowsiness, sedation, decreased</li> <li>cognition (especially with longer acting agents)</li> <li>little data demonstrate efficacy in patients</li> <li>without CKD</li> </ul>	
Opioids - tramadol (Tramacet®) (50–200 mg daily) - oxycodone (5–20 mg daily)	<ul> <li>effective for RLS in CKD (oxycodone)</li> <li>alternative for intermittent RLS</li> <li>alternative agent for daily RLS</li> </ul>	<ul> <li>dependence/tolerance</li> <li>adverse effects: sedation, pruritis, gastrointestinal disturbances, constipation</li> <li>reduce dose in renal dysfunction</li> <li>no studies for RLS in CKD patients</li> <li>little data demonstrate efficacy in patients without CKD (tramadol)</li> </ul>	

RLS: restless legs syndrome, CKD: chronic kidney disease, CrCl: creatinine clearance

(Janzen, Rich, & Vercaigne, 1999; Micozkadioglu et al., 2004; Miranda et al., 2004; Molnar et al., 2006; Novak et al., 2006; Pellecchia et al., 2004; Read, Feest, & Nassim, 1981; Sandyk et al., 1987; Silber et al., 2004; Tan, Derwa, Sanu, Rahman, & Woodrow, 2006; Tarsy & Sheon, 2009; Thorp, Morris, & Bagby, 2001; Trenkwalder et al., 1995; Walker, Fine, & Kryger, 1996) gabapentin, benzodiazepines and opioids are alternatives. The pharmacotherapeutic alternatives for the treatment of RLS are reviewed in Table 4 (Novak et al., 2006).

RLS symptoms are categorized as intermittent, daily or refractory, and pharmacologic management depends on the type of RLS (Novak et al., 2006). Intermittent RLS is bothersome enough to require occasional treatment, but does not require daily treatment (Silber et al., 2004). For patients with intermittent RLS, treatment may be utilized if RLS symptoms develop, such as during a hemodialysis session. For these patients, levodopa/carbidopa may be used (Novak et al., 2006). Although levodopa/carbidopa is effective for RLS symptoms and has a fast onset of action (within one hour), it is associated with undesirable effects such as augmentation (RLS symptoms occur earlier in the day, increase in intensity or spread to other body parts during the day after an evening dose), rebound RLS and the side effect of insomnia. Alternate agents for the treatment of intermittent RLS include dopamine agonists, opioids, benzodiazepines (Tarsy & Sheon, 2009). Daily RLS is present daily and requires daily treatment, usually with a dopaminergic agent (Silber et al., 2004). Due to the disadvantages of levodopa treatment such as augmentation and rebound RLS symptoms (which worsen with more frequent use), dopaminergic agonists (ropinirole and pramipexole) are the preferred agents for treatment of daily RLS. Other options for daily RLS include gabapentin, and opioids (Tarsy & Sheon, 2009). Refractory RLS is defined as daily RLS that does not respond to dopamine agonists (Silber et al., 2004). For these patients, alternatives

include: changing to gabapentin, changing to a different dopamine agonist, addition of a second agent (e.g., gabapentin, benzodiazepine or opioid) or changing to an opioid or tramadol (Tarsy & Sheon, 2009).

The use of all medications for the treatment of RLS in patients with CKD must involve careful dose titration, dose adjustment for renal dysfunction and monitoring for adverse effects, which may be additive with other medications commonly used in this patient population (Molnar et al., 2006).

#### Implications for practice

Patients with CKD experience sleep disorders, including RLS, frequently. These symptoms can disturb sleep, produce insomnia and significantly impact quality of life. They may even impact mortality.

The process of managing RLS requires a multifaceted approach to treat symptoms while avoiding adverse effects of therapy. This requires reducing risk factors where possible, treating symptoms, maintaining treatment efficacy, avoiding adverse effects of therapy or worsening of RLS symptoms. Patients with RLS require frequent monitoring for side effects, worsening or improving of RLS symptoms, patient education and an interdisciplinary renal health team. Members of the renal health team, including nephrologists, nurses, dietitians, pharmacists, social workers, occupational therapists and physiotherapists can work together in order to provide patients with the education and comprehensive team-based care required to manage symptoms of RLS.

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# Treatment of restless legs syndrome in patients with chronic kidney disease: A focus on medications

By Colette B. Raymond, PharmD, MSc, Lance Breland, BScPharm, Lori D. Wazny, PharmD, Amy R. Sood, PharmD and Cali D. Orsulak, BScPharm

# 1. Clinical manifestations of restless legs syndrome (RLS) include:

(a) urge to move the legs, leg cramps, sudden jerking leg movements, varicose veins

(b) urge to move the legs, worse at night, worse with rest or inactivity and relieved by movement

(c) urge to move the legs, sudden jerking leg movements, skin sensitivity, pain and tingling in the legs

(d) urge to move the legs, insomnia, mood disorders, obstructive sleep apnea

2. Mr. S.R. is a 58-year-old male receiving hemodialysis with anemia, diabetes, diabetic gastroparesis, obstructive sleep apnea, hypertension, hyperphosphatemia and hyperparathyroidism. Mr. S.R. receives the following medications: epoetin alfa, intravenous iron, insulin, metoclopramide, calcium carbonate and calcitriol. He has just been diagnosed with intermittent RLS. What risk factors does Mr. S.R. have for RLS?

(a) end stage renal disease, hyperphosphatemia

(b) anemia, hyperparathyroidism, obstructive sleep apnea

(c) end stage renal disease, hypertension, obstructive sleep apnea

(d) end stage renal disease, diabetes, anemia

3. The medication that could possibly contribute to his RLS includes:

- (a) erythropoietin
- (b) intravenous iron
- (c) captopril
- (d) metoclopramide

4. Ms. C.O. is a 69-year-old female receiving hemodialysis. She was diagnosed with RLS after she presented an urge to move her legs, which occurred during dialysis sessions and also occasionally at night, but is relieved by movement. Therapeutic options for Ms. C.O. include:

(a) reduce caffeine, alcohol and nicotine, perform mentally alerting activities during dialysis, perform calfstretching exercises

(b) increase caffeine intake, especially before dialysis sessions, sleep during dialysis sessions

(c) reduce caffeine, alcohol and nicotine, perform relaxation exercises during dialysis, avoid intradialytic aerobic exercise

(d) reduce caffeine, alcohol and nicotine, perform mentally alerting activities during dialysis, apply hot compresses to legs during dialysis sessions

5. Pharmacotherapeutic alternatives for Ms. C.O. include:

- (a) dopamine, ropinirole, gabapentin
- (b) levodopa/carbidopa, ropinirole

(c) metoclopramide, ropinarole, pramipexole

(d) hydromorphone, gabapentin, quinine

6. Ms. J.K. is a 63-year-old female with stage 4 chronic kidney disease and RLS. Her RLS occurs every night and causes sleep disruption and, as a result, she feels tired and depressed. Medication options to treat Ms. J.K. include:

(a) levodopa/carbidopa, gabapentin, oxycodone

(b) levodopa/carbidopa, ropinirole, gabapentin

(c) pramipexole, gabapentin, tramacet(d) ropinirole, zopiclone, quinine

7. Mr. J.T. is a 47-year-old hemodialysis patient who was recently diagnosed with RLS. He has received a prescription for ropinirole 0.25 mg daily at bedtime. He should be aware of the following adverse effects:

(a) gastrointestinal disturbances, insomnia, orthostatic hypotension, nasal stuffiness, impulse control disorders (b) decreasing response to therapy, insomnia, worsening of RLS symptoms in the daytime, gastrointestinal disturbances, insomnia, orthostatic hypotension

(c) dizziness, drowsiness, ataxia, hallucinations, fatigue, gastrointestinal disturbances, insomnia, orthostatic hypotension

(d) sedation, pruritis, hallucinations, constipation, gastrointestinal disturbances

8. The correct pairing of type of RLS and most commonly recommended treatment options listed below is:

(a) intermittent RLS: levodopa/carbidopa, dopamine agonists(b) intermittent RLS: benzodiazepines, opioids

(c) daily RLS: levodopa/carbidopa, dopamine agonists

(d) daily RLS: levodopa/carbidopa, gabapentin

### 9. The true statement below about the epidemiology of RLS is:

(a) 6% to 60% of patients with CKD not receiving dialysis experience RLS(b) the prevalence of RLS among dialysis patients is 7% to 33%

(c) up to 33% of the general population experiences RLS at least once in their lifetime

(d) younger adults experience more RLS than older adults

10. The true statement about the pathophysiology of RLS listed below is:

(a) altering the dialysis membrane can improve RLS symptoms

(b) RLS is related to elevated serotonin and norepinephrine

(c) RLS is related to altered dopaminergic function

(d) RLS symptoms is worsened by iron overload

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Volume 20, Number 2

### Treatment of restless legs syndrome in patients with chronic kidney disease:

# A focus on medications

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#### Research review

### Conservative management of end stage renal disease and withdrawal of dialysis

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Murtagh, F.E.M., Spagnolo, A.G., Panocchia, N., & Gambaro, G. (2009). Conservative (non-dialytic) management of end-stage renal disease and withdrawal of dialysis. *Progress in Palliative Care, 17*(4), 179–186.

#### Reviewed by Kalli Stilos, RN, MScN, CHPCN(C), Advanced Practice Nurse, Palliative Care Consult Team, Sunnybrook Health Science Centre, Toronto, ON

This paper was written by the following four physicians: Dr. Murtagh from the Department of Palliative Care, Policy and Rehabilitation, King's College London, London, United Kingdom; Dr. Spagnolo from the Department of Educational Sciences & Board of Directors for Bioethics in Rome, Italy; Dr. Panocchia from the Department of Surgical Sciences, Section of Hemodialysis, Gemelli University Hospital, Catholic University, School of Medicine, Renal Program, Rome, Italy; and Dr. Gambaro from the Division of Nephrology and Dialysis, Columbus-Gemelli University Hospital, Catholic University, School of Medicine, Renal Program, Rome, Italy.

This article outlines that the end stage renal disease (ESRD) population is progressively increasing in developing countries; the majority of patients being the elderly with multiple health issues and poor performance status. Nephrologists struggle with complicated decisions about the best therapeutic options available and what is best for their patients. As dialysis becomes more accessible in developed countries this creates an opportunity for therapy that most would not have had otherwise. The increased access to dialysis not only creates issues of "who should be put forward for dialysis", but "who, if any, should not be put forward for dialysis" (p. 179-180).

Within the ESRD patient group, there is a subgroup of patients that need to be acknowledged, for they are patients who do not start dialysis—they are the patients who are managed conservatively. This group of patients is important to study, as the care they require can be similar to those approaching end-of-life and palliative care. Little is known about this subgroup, as research studies tend to exclude them, providing a partial picture of the whole ESRD population. Determining which patients fall into the subgroup has become clinically and ethically challenging, along with what is the best practice for the patients who are not offered dialysis, or when it is withdrawn.

This article raises a number of issues. They include: the evidence around survival, quality of life, and typical course of illness following conservative management or dialysis withdrawal; criteria used for deciding on conservative management or withdrawing dialysis, and how they are justified; decision-making process when patients are cognitively impaired and cannot make decisions for themselves.

The decision criterion for initiating dialysis is controversial. Some nephrologists feel patients with irreversible, profound neurological impairment are not suitable for dialysis while others feel that no patient is too sick for dialysis. The Renal Physicians Association (RPA) and the American Society of Nephrology (ASN) developed guidelines for the withholding or withdrawing of dialysis: Shared Decision-Making in the Appropriate Initiation of and Withdrawal from Dialysis. In 1990 and 2005, the RPA/ASN conducted surveys of dialysis decision-making and found that "the decisions to withdraw dialysis with dementia have increased over time, and 80% of those interviewed had also requested bio-ethical consultation" (p. 180), pointing out the ethical difficulty physicians are faced with. Yet, only 50% of nephrologists follow the RPA/ASN guidelines (Holley, Davison, & Moss, 2007).

Conservative management is considered management without dialysis. It consists of vigorous management of the renal disease (physical or psychological symptoms). The following criteria are



considered by nephrologists across countries when making decisions for conservative management: age, co-morbidities, cognitive state, anticipated symptoms and quality of life on the selected pathway, and anticipated prognosis.

Dialysis patients, in general, are older today, have increased medical issues and poorer performance status requiring many resources to make dialysis available to them. Nephrologists question the appropriateness of starting dialysis on these older patients. Research has been limited in comparing outcomes for older patients on dialysis and without dialysis. Research findings from the United States show that 80+ year-old patients commencing dialysis have a modest survival rate (Kurella, Covinsky, Collins, & Chertow, 2007). Judging a patient by his or her age also raises many ethical issues such as justice and equity. It is important that each patient is attended to in a holistic, patientcentred approach and the additional factors like patient wishes, quality of life, prognosis and concurrent medical issues are addressed in the equation.

Nephrologists question whether it is reasonable to dialyze patients with multiple co-morbidities. Levinsky (2003) notes the difficulty of predicting survival and quality of life for patients with comorbidities and believes it is better to dialyze a patient who may not improve than to rule out dialysis as an option for a patient who may benefit. Research findings are mixed as to whether co-morbidities affect survival in the conservative management patients in comparison to the dialysis group.

Symptom management and quality of life are important aspects for patients in deciding on whether to proceed with dialysis or not. Symptoms are common to both the dialysis population and the conservatively managed group. Limited findings on the conservative management group vary from a slow decline, low symptom burden and performance status to a very quick decline. An argued point is that loss of quality of life on dialysis is not as important for older patients versus younger ones and, thus, moving towards a conservative management approach to care would be difficult to support for older patients. Knowing more about the disease trajectory will only help individualize treatment options with patients and their families.

Observational studies are available to nephrology practitioners to inform them on the topic of prognosis. The studies that exist all have small sample sizes. Smith et al. (2003) found that there was little difference in survival between the conservatively managed group and the dialysis group. Murtagh's (2007) study reviewed all patients greater than 75 years of age with stage 5 chronic kidney disease (CKD) in nephrology care and found that those who chose dialysis versus those who chose conservative management saw little survival advantage. One point raised is the use of the criteria such as high co-morbidity and functional status as influencing the option of dialysis. There are opposing views to this point that dialysis should be presented even if a patient has a prognosis of weeks.

Cognitive state is another factor that is being considered in the dialysis decisionmaking process. Approximately 70% of hemodialysis patients have some degree of cognitive impairment, which is often undetected (Murray 2008). For this reason, health care professionals need to be aware of the patients' understanding of their illness, treatment and side effects, and their ability to recall the information. There is a common principle that dialysis is not suitable for patients with advanced dementia or long-term vegetative state. There is a concern that, as the number of patients with dementia rises, practitioners might refuse dialysis as a treatment. The authors then question, "What is the definition of quality of life" for cognitively impaired patients and "the important distinction between 'best interests', as determined by the patients themselves (or their proxy when capacity is limited), and the estimation made by others about the value of their life" (p. 182). Three suggestions are made to address this issue for those who lack capacity: 1) physicians should engage in advance care planning discussions with patient/family early on in the patient's disease, 2) seek the opinions of family members/caregivers about the patient's wishes, and 3) appoint a substitute decision-maker when no guidance

is available from family/caregivers. In addition, seek a second opinion from another independent physician or ethicist (not obligatory) if capacity is severely compromised.

Time-limited trials of dialysis are also an option in the RPA/ASN guideline on shared decision-making. The purpose of these trials is to illustrate to patients and their families the realities of treatment and to assess patient tolerance of the treatment. There are, however, no supporting findings to state whether timelimited trials achieve this goal.

American statistics indicate that 24.5% of dialysis patients choose to withdraw from dialysis and this is comparable to France where the figure is 20%. Murtagh, Cohen, and Germain's (2007) review of the literature on dialysis withdrawal found "wide variability between countries, cultures and individual centres" (p. 183). Highlighted in the evidence was that older patients, living alone, socially isolated, with high symptoms burden (particularly pain), increased co-morbidity, and poor quality of life were more likely to discontinue dialysis. A key point for health care professionals is to note the patient's social history/factors that can influence a patient from stopping dialysis.

We see cultural and national variations in who makes decisions to withdraw dialysis. In Western culture, it is more the patient's wishes and autonomy that drive dialysis withdrawal, whereas in southern European countries it is the physician's decision that weighs more in the decision-making process. The literature comments on the three decisionmaking views about who makes the dialysis decision: 1) primarily the health care professional decides; 2) primarily the patient decides; and 3) the shared decision-making model. The shared decision-making model is the preferential approach according to the literature.

Last, the use of advance directives is recommended in the RPA/ASN guidelines and is being utilized by many countries. Advanced directives are valuable when a patient is no longer able to express his or her own wishes and can aid physicians and family members in discontinuing dialysis. A point made is how advance directives do not include the discontinuation of dialysis, as dialysis is believed to be a routine part of the patient's life and not a life-sustaining measure. What dialysis patients look for in the advance care planning process is information on how these decisions will impact their day-to-day quality of life and not so much on statistics to guide their decision-making.

In summary, this article maintains that deciding between conservative management and discontinuing dialysis is becoming challenging, as health resources become scarce and as the population ages. Several factors come into play with these decisions such as the variation in clinical practice across health care settings, countries and cultures. What is lacking is strong evidence on patients who are managed conservatively and the kinds of symptoms they experience, quality of life issues they face, their disease trajectory pattern and how this patient subgroup impacts the entire ESRD population.

More data on the conservative (nondialytic) ESRD patients will provide health care professionals with a complete picture of the whole ESRD population. This information will also be useful to patients and their loved ones during the decision-making process of deciding between initiating dialysis or conservative (non-dialytic) management.

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### Bedside Matters...

# **Renal recycling**



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#### What has your take on recycling within your unit been?

My colleagues and I are wondering where we stand in our efforts to do our part in keeping the environment clean. There have been a few dedicated staff members who have taken recycling seriously in their homes for several years. They started asking questions like... "Why don't we save our pop and water bottles and return them for money we can use in our 'kitty'?"...and "Why are we throwing all these K bath containers in the garbage?"

One RN gathered the bottles, and she still takes them for recycling after several years. Cardboard was flattened by techs and put in a special bin for housekeeping.

When it came to K bath and bicarb containers, things have been slower in solution-finding. One leader in the community-centred unit, who has to arrange housekeeping and garbage collection, set out to find a service that would pick up plastics. That has been a successful system for years now.

At the hospital level, even within the same region, practices have differed.

It seems to have taken the determined quest of one or two people in our unit to keep bringing up the issues at staff meetings and talking to

at Surrey Hospital, Surrey, British Columbia

By Lee Beliveau, RN, CNeph(C), staff nurse, hemodialysis unit,

the manager, as well as getting in on general staff committees that had similar concerns.

Who would separate the materials? A system has to function so well that staff doesn't have to think about it. Where would collections be kept? These questions went round and round, deciding who would have which responsibility to set this up.

About one year ago, the region hired a coordinator for the recycling challenge. This was someone dedicated to the universal problem. He was prompt to answer our call for help. He looked at the current practices, where bins could be made easily available and added his ideas of what we could recycle.

Another turning point was the return of Fran, one of our techs. Last April, she came back to the hospital unit from the community where she saw how recycling could work. And because she cares, she has researched how many plastics we use and the cost of some materials we use. These things make us all more aware. We now know how much each piece of a set-up is costing, and that disposing used plastics and paper in hazardous waste garbage is measured and billed by weight.

As a result, clean used plastics like IV bags and K baths immediately go into a handy plastic bag at the bedside. Blue bins are also used, and Fran discovered the price for **each** of these is \$32.00 cheaper if we purchase them at a local supply store.

Bicarb is now draining through the dialysis machines and through a neutralizer, saving the huge amounts of water we used to use to drain bicarb in the utility sinks.

By the way, did you know gelfoam costs \$64.00 per box? And that Tip Stops seem to work just as well for a quarter of the price? Imagine all the times we follow the note in the Kardex and continue using what might have been a one-time solution for months and years. And sometimes a patient may request two gelfoam, believing it is truly necessary, without our trying something else?

Can you imagine the possibilities now? What if manufacturers provided recycling arrangements when contracts are signed, across the world?

Can we encourage each other by incentives like bringing in all our pens that have made it home in our pockets? Or can we all participate in a contest about how to save costs or cut down on disposables?

Please consider writing to me or to the editor, Gillian, to share your ideas and the recycling habits in your unit.

The Kidney Foundation urges us all to recycle our organs. Let's recycle everything we can.

Please share a meaningful moment of learning from your professional life. Send me your idea and I'll help you publish it. Send to Lee Beliveau at e-mail: 5410603@telus.net

# Guidelines for authors

The Canadian Association of Nephrology Nurses and Technologists (CANNT) Journal invites letters to the editor and original manuscripts for publication in its quarterly journal. We are pleased to accept submissions in either official language—English or French.

#### Which topics are appropriate for letters to the editor?

We welcome letters to the editor concerning recently published manuscripts, association activities, or other matters you think may be of interest to the CANNT membership.

#### What types of manuscripts are suitable for publication?

We prefer manuscripts that present new clinical information or address issues of special interest to nephrology nurses and technologists. In particular, we are looking for:

- Original research papers
- Relevant clinical articles
- Innovative quality improvement reports
- Narratives that describe the nursing experience
- Interdisciplinary practice questions and answers
- Reviews of current articles, books and videotapes
- Continuing education articles.

#### How should the manuscript be prepared?

Form: The manuscript should be typed double-spaced, oneinch margins should be used throughout, and the pages should be numbered consecutively in the upper right-hand corner. More formal research or clinical articles should be between five and 15 pages. Less formal narratives, question and answer columns, or reviews should be fewer than five pages.

Style: The style of the manuscript should be based on the Publication Manual of the American Psychological Association (APA), Sixth Edition (2009), available from most college bookstores.

Title page: The title page should contain the manuscript title, each author's name (including full first name), professional qualifications [e.g. RN, BScN, CNeph(C)], position, place of employment, address, telephone, fax numbers and e-mail address. The preferred address for correspondence should be indicated.

Abstract: On a separate page, formal research or clinical articles should have an abstract of 100 to 150 words. The abstract should summarize the main points in the manuscript.

Text: Abbreviations should be spelled out the first time they are used with the abbreviation following in brackets, for example, the Canadian Association of Nephrology Nurses and Technologists (CANNT). Generic drug names should be used. Measurements are to be in Standards International (SI) units. References should be cited in the text using APA format. A reference list containing the full citation of all references used in the manuscript must follow the text. Tables/Figures: Manuscripts should only include those tables or figures that serve to clarify details. Authors using previously published tables and figures must include written permission from the original publisher. Such permission must be attached to the submitted manuscript.

#### How should the manuscript be submitted?

E-mail your manuscript to: gillianbrunier@sympatico.ca

Include a covering letter with contact information for the primary author and a one-sentence biographical sketch (credentials, current job title and location) for each author.

#### How are manuscripts selected

for the CANNT Journal?

Each manuscript will be acknowledged following receipt. Research and clinical articles are sent out to two members of the CANNT Journal manuscript review panel to be reviewed in a double-blind review process. All manuscripts may be returned for revision and resubmission. Those manuscripts accepted for publication are subject to copy editing; however, the author will have an opportunity to approve editorial changes to the manuscript. The criteria for acceptance for all articles include originality of ideas, timeliness of the topic, quality of the material, and appeal to the readership. Authors should note that manuscripts will be considered for publication on the condition that they are submitted solely to the CANNT Journal. Upon acceptance of submitted material, the author(s) transfer copyright ownership to CANNT. Material may not be reproduced without written permission of CANNT. Statements and opinions contained within the work remain the responsibility of the author(s). The editor reserves the right to accept or reject manuscripts.

#### Checklist for authors

- $\sqrt{\text{Cover letter}}$
- √ Article
- Title page to include the following:
- title of article
- each author's name (including full first name)
- professional qualifications
- position
- place of employment
- author to whom correspondence is to be sent, including address, phone, fax number, and e-mail address
- Text of article, with abstract if applicable, double-spaced, pages numbered
- References (on a separate sheet)
- Tables (one per page)
- Illustrations (one per page)
- Letters of permission to reproduce previously published material.

# Lignes directrices à l'intention des auteurs

Le Journal de l'Association canadienne des infirmières et infirmiers et des technologues de néphrologie (ACITN) vous invite à faire parvenir articles, textes et manuscrits originaux pour publication dans son journal trimestriel. Nous sommes heureux d'accepter vos documents soumis dans l'une ou l'autre des langues officielles, anglais ou français.

#### Quels sont les sujets d'article appropriés ?

Nous acceptons les articles portant sur des manuscrits récemment publiés, des activités de l'Association ou tout sujet d'intérêt pour les membres de l'ACITN.

#### Quels types de manuscrits conviennent à la publication ?

Nous préférons des manuscrits qui présentent de nouveaux renseignements cliniques ou qui traitent des enjeux propres aux champs d'intérêt des infirmières et infirmiers et des technologues en néphrologie. Nous recherchons plus particulièrement : • Exposés de recherche originaux

- Articles cliniques pertinents
- Rapports sur des approches innovatrices en matière
- d'amélioration de la qualité • Textes narratifs relatant une expérience de pratique
- infirmière ou technologique
- Textes sous forme de questions et de réponses sur la pratique interdisciplinaire
- Revues d'articles courants, de livres et films
- Articles en éducation continue.

#### Comment les manuscrits doivent-ils être présentés ?

**Forme :** Le manuscrit doit être présenté à double interligne avec une marge de 1 po et une numérotation consécutive des pages dans le coin supérieur droit de la page. Les articles plus formels de recherche ou d'études cliniques doivent compter de 5 à 15 pages. Les articles moins formels, tels que textes narratifs, questions-réponses ou revues, doivent compter moins de 5 pages. **Style :** Le style du manuscrit doit être conforme au **manuel de publication de l'Association américaine de psychologie** (AAP), 6<sup>e</sup> édition (2009), offert dans la plupart des librairies universitaires.

**Page titre :** La page titre doit inclure le titre du manuscrit ainsi que les renseignements suivants : nom de chacun des auteurs (incluant prénoms au complet), titres professionnels (c.-à-d., inf., B.Sc.Inf., CNéph[C]), titre du poste occupé, nom de l'employeur, adresse, numéros de téléphone et de télécopieur et adresse courriel. L'adresse privilégiée de correspondance doit aussi être indiquée.

**Résumé :** Sur une page distincte, les articles formels de recherche ou d'études cliniques doivent être accompagnés d'un résumé de 100 à 150 mots, reprenant brièvement les principaux points du manuscrit.

Texte : Les sigles, abréviations ou acronymes doivent être écrits au long la première fois qu'ils apparaissent dans le texte, suivis de l'abréviation entre parenthèses ; p. ex., Association canadienne des infirmières et infirmiers et des technologues de néphrologie (ACITN). Les noms génériques des médicaments doivent être employés. Les unités de mesure doivent être indiquées selon le Système international d'unités (SI). Les références doivent être citées dans le texte en utilisant le format de l'AAP. Une liste de références comprenant la bibliographie complète de toutes les références utilisées doit suivre le texte. Tableaux/Figures : Les manuscrits ne doivent inclure que les tableaux et figures (incluant schémas, illustrations, croquis, etc.) visant à clarifier certains détails. Les auteurs qui utilisent des tableaux et des figures qui ont déjà fait l'objet d'une publication doivent fournir l'autorisation écrite de l'éditeur d'origine et la joindre au manuscrit soumis.

#### De quelle manière doit-on soumettre les manuscrits ? Veuillez envoyer par courriel votre manuscrit à : gillianbrunier@sympatico.ca

Veuillez inclure une lettre de présentation en précisant les coordonnées de l'auteur principal ainsi qu'une notice biographique d'une phrase (incluant titres de compétences, titre du poste actuel et lieu de travail) pour chaque auteur.

## Quel est le processus de sélection des manuscrits pour publication dans le Journal de l'ACITN ?

À la réception de chaque manuscrit, un accusé de réception est envoyé. Les articles de recherche et d'études cliniques sont envoyés à deux membres du comité de révision du **Journal de** l'ACITN afin d'être révisés suivant un processus à double insu. Tous les articles peuvent être retournés aux auteurs pour révision et nouvelle soumission par la suite. Les manuscrits acceptés pour publication peuvent subir des changements éditoriaux ; toutefois, les auteurs pourront approuver ces changements. Les critères d'acceptation pour tous les manuscrits comprennent l'originalité des idées, l'actualité du sujet, la qualité du matériel et l'attrait des lecteurs.

Les auteurs doivent prendre note que les manuscrits seront considérés pour publication à la condition qu'ils ne soient soumis qu'au **Journal de l'ACITN.** Sur acceptation du matériel soumis, les auteurs transfèrent leur droit d'auteur à l'ACITN. Aucune reproduction n'est permise sans l'autorisation écrite du Journal de l'ACITN. Les déclarations et opinions émises par les auteurs dans leurs articles, textes ou manuscrits demeurent leur responsabilité. La rédactrice en chef se réserve le droit d'accepter ou de refuser tout manuscrit.

#### Aide-mémoire à l'intention des auteurs

- $\sqrt{}$  Lettre de présentation
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- Nom et adresse de l'employeur
- Nom de l'auteur à qui la correspondance doit être envoyée (incluant adresse, numéros de téléphone et de télécopieur et adresse courriel)
- Texte de l'article avec résumé, s'il y a lieu à double interligne et pages numérotées
- Références (sur une feuille distincte)
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- Lettre d'autorisation pour tout matériel ayant déjà fait l'objet d'une publication

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#### Prescribing Summary

#### **Patient Selection Criteria**

THERAPEUTIC CLASSIFICATION

#### Phosphate Binde INDICATIONS AND CLINICAL USE

RENAGEL (sevelamer hydrochloride) is indicated for:

the control of hyperphosphatemia in patients with end-stage renal disease (ESRD) undergoing dialysis.

#### CONTRAINDICATIONS

RENAGEL (sevelamer hydrochloride) is contraindicated in the following situations:

patients with hypophosphatemia patients with bowel obstruction

patients hypersensitive to sevelamer hydrochloride or one of the other ingredients in the product (colloidal silicon dioxide, stearic acid). SPECIAL POPULATIONS

For use in special populations, see WARNINGS AND PRECAUTIONS, Special Populations.

#### 뻥 Safety Information

#### WARNINGS AND PRECAUTIONS

General

RENAGEL (sevelamer hydrochloride) tablets should be swallowed intact and should not be crushed, chewed, or broken into pieces. Patients with renal insufficiency may develop hypocalcemia. As RENAGEL does not contain calcium, serum calcium levels should be monitored and elemental calcium should be supplemented whenever considered necessary. In cases of hypocalcemia, patients should be given an evening calcium supplement. Approximately 1000 mg elemental calcium is recommended.

Caution should be exercised to avoid hypophosphatemia, a serum phosphorus of < 0.8 mmol/L (see DOSAGE AND ADMINISTRATION). The safety and efficacy of RENAGEL in patients with renal disease who are not undergoing dialysis has not been studied

#### Gastrointestinal

The safety and efficacy of RENAGEL in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders, or major GI tract surgery have not been established. Caution should be exercised when RENAGEL is used in patients with these GI disorders.

#### Special Populations

Pregnant Women: The safety of RENAGEL has not been established in pregnant women. In preclinical studies, there was no evidence that RENAGEL induced embryolethality, fetotoxicity or teratogenicity at the doses tested (up to 1 g/kg/day in rabbits; up to 4.5 g/kg/day in rats). RENAGEL should only be given to pregnant women if the benefits outweigh the risks.

Nursing Women: There have been no adequate, well-controlled studies in lactating, or nursing women.

Pediatrics: The safety and efficacy of RENAGEL has not been established in pediatric patients. The minimum age of patients treated with RENAGEL in clinical trials was 18 years old.

Geriatrics: No special considerations are needed for elderly patients.

#### Monitoring and Laboratory Tests

rum phosphorus and serum calcium should be monitored every 1 to 3 weeks until the target phosphorus level is reached. The dose of RENAGEL should be adjusted based on serum phosphorus concentration and titrated to a target serum phosphorus of .< 1.8 mmol/L.

RENAGEL does not contain calcium or alkali supplementation; serum calcium, bicarbonate, and chloride levels should be monitored.

#### ADVERSE REACTIONS

(See Supplemental Product Information for full listing) Clinical Trial Adverse Drug Reactions In a combined safety database comprised of 483 patients with end-stage renal disease undergoing hemodialysis, the most common adverse events were naused (25.3%), vomiting (24.4%), diarrhea (21.2%), headache (18.4%), dyspeptia (15.7%) and dysprea (15.7%). From this database, the most common adverse events from a single 52-week randomized clinical study of RENAGEL vs. calcium (calcium acteate and calcium carbonate) were vomiting (22.2% vs. 21.8%), nausea (20.2% vs. 19.8%), diarrhea (19.2% vs. 22.8%), dyspepsia (16.2% vs. 6.9%) and nasopharyngitis (14.1% vs. 7.95). The adverse events are not necessarily attributed to RENAGEL treatment. The incidence of these events was

not dose related In one hundred and forty three patients with end-stage renal disease undergoing peritoneal dialysis with treatment duration of 12 weeks, adverse events reported at an incidence ≥10% were dyspepsia (17.5%), vomiting (11.3%) and peritonitis (11.3%). These adverse events are not necessarily attributed to RENAGEL treatment. The incidence of these events was not dose related.

The most frequently occurring serious adverse event with RENAGEL use was peritonitis at 8.2%, compared to 4.3% with calcium. Patients receiving dialysis are subject to certain risks for infection specific to the dialysis modality. Peritonitis is a known complication in patients receiving peritoneal dialysis (PD). Therefore, patients on PD should be closely monitored to ensure the reliable use of appropriate aseptic technique with the prompt recognition and management of any signs and symptoms associated with peritonitis.

#### Less common clinical trial adverse events

The following adverse events have been observed with RENAGEL use with an incidence of <10%, but greater than calcium and without attribution to causality, including: abdominal distension, constipation, diarrhea, nausea, chest pain, fatigue, pyrexia, catheter site infection, anorexia, headache, cough and pruritis.

Some patients experienced adverse events related to hypercalcemia in the calcium group but not in the RENAGEL group.

#### Supplemental Product Information ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions Because clinical trials are conducted under very specific conditions the adverse reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

In a combined safety database comprised of 483 patients with end-stage renal disease undergoing hemodialysis, adverse events reported at an incidence 10% are provided in Table 1 below. From this database, adverse events are also presented separately from a single long-term randomized clinical study for RENAGEL and calcium. The adverse events presented in the table below are not necessarily attributed to RENAGEL treatment. The incidence of these events was not dose related

#### Table 1: Adverse Events in Patients with End-Stage Renal Disease undergoing Hemodialysis

	Total AEs reported	52 weeks Study o (calcium acetate	of RENAGEL vs. calcium and calcium carbonate)
System Organ Class Event	<b>RENAGEL</b> N = 483 %	<b>RENAGEL</b> N = 99 %	calcium N = 101 %
Gastrointestinal Disorders			
Vomiting	24.4	22.2	21.8
Nausea	25.3	20.2	19.8
Diarrhea	21.1	19.2	22.8
Dyspepsia	15.7	16.2	6.9
Constipation	13.3	8.1	11.9
Infections and Infestations			
Nasopharyngitis	13.9	14.1	7.9
Bronchitis	5.4	11.1	12.9
Upper Respiratory Tract Infection	7.0	5.1	10.9
Musculoskeletal, Connective Tissue and Bon	e Disorders		
Pain in Limb	13.7	13.1	14.9
Arthralgia	11.4	12.1	17.8
Back Pain	6.0	4.0	17.8

#### Renagel Tablets

Renagel® is a registered trademark of Genzyme Canada Inc. (sevelamer hydrochloride) Genzyme Canada Inc., Mississauga, ON L4W 4V9

#### Post-Market Adverse Drug Reactions

During post-marketing experience with RENAGEL, the following have been reported without attribution to causality: pruritis, rash, and abdominal pain.

#### DRUG INTERACTIONS

#### **Drug-Drug Interactions**

RENAGEL (sevelamer hydrochloride) was studied in human drug-drug interaction studies with digoxin, warfarin, enalapril, metoprolol and iron. RENAGEL had no effect on the bioavailability of these medications. However, in a study of 15 healthy subjects, a co-administered single dose of 7 RENAGEL Capsules (approximately 2.8g) decreased the bioavailability of ciprofloxacin by approximately 50%. Consequently, RENAGEL should not be taken simultaneously with ciprofloxacin.

When administering any other medication where a reduction in the bioavailability of that medication would have a clinically significant effect on safety or efficacy, the physician should consider monitoring blood levels or dosing that medicine apart from RENAGEL (at least one hour before or three hours after RENAGEL). Patients taking anti-arrhythmic and anti-seizure medications were excluded from the clinical trials. Special precautions should be taken when prescribing RENAGEL to patients also taking these medications.

#### **Drug-Food Interactions**

There have been no adequate, well-controlled studies regarding the effect of a variety of foods on the intestinal phosphorus binding of RENAGEL

#### **Drug-Herb Interactions**

There have been no adequate, well-controlled studies regarding drug-herb interactions.

#### **Drug-Laboratory Interactions**

There have been no adequate, well-controlled studies regarding drug-laboratory interactions.

#### **Drug-Lifestyle Interactions**

There have been no adequate, well-controlled studies regarding drug-lifestyle interactions.

For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Supplemental Product Information.

To report a suspected adverse reaction, please contact Genzyme Canada by:

Toll-free telephone: 1-877-220-8918 Fax: 905-625-7811

Or by regular mail: Genzyme Canada Ltd., 2700 Matheson Blvd. East, West Tower, Suite 800, Mississauga, Ontario L4W 4V9

**Administration** 

#### DOSAGE AND ADMINISTRATION

#### Dosing Considerations

- The tablets should not be bitten, chewed or broken apart prior to dosing.
- RENAGEL (sevelamer hydrochloride) should be taken immediately prior to or with meals, since its action is to bind ingested phosphate (see ACTION AND CLINICAL PHARMACOLOGY, Mechanism of Action in the product monograph)
- When administering any other medication where a reduction in the bioavailability of that medication would have a clinically significant effect on safety or efficacy, the physician should consider monitoring blood levels or dosing that medicine apart from RENAGEL to prevent GI binding (at least one hour before or three hours after RENAGEL).

#### **Recommended Dose and Dosage Adjustment**

The recommended dosing to be used when initiating RENAGEL in patients not using another phosphate binder are outlined below:

Starting Dose			
Initial Serum Phosphorus	RENAGEL Tablets 800 mg		
> 1.8 and < 2.4 mmol/L	3 tablets per day (2.4 grams)		
≥ 2.4 mmol/L	6 tablets per day (4.8 grams)		

When switching from calcium-based phosphate binders to RENAGEL, an equivalent starting dose on a mg/weight basis of RENAGEL should be prescribed.

Dosage adjustments, when necessary should be recommended every 1 to 3 weeks by increasing one tablet per meal (3 per day) until the target serum phosphorus levels are met.

The total daily dose should be divided according to meal portions during the day.

Average Maintenance Dose: Dosage should be adjusted based upon the target serum phosphorus levels. The dose may be increased or decreased by one tablet per meal at two week intervals as necessary. The average final dose in the chronic phase of a 52 week Phase 3 clinical trial designed to lower serum phosphorous to 1.6 mmol/L or less was approximately 7.1 grams, (approximately nine 800 mg tablets per day equivalent to three 800 mg tablets per meal). The maximum average daily RENAGEL dose studied was 13 grams

#### Missed Dose

If a dose is forgotten, it should be skipped. Double dosing is not advisable.

STORAGE AND STABILITY

Store at controlled room temperature 15°C to 30°C. Protect from moisture

#### Study Reference

1. Renagel<sup>®</sup> product monograph, Genzyme Canada, October 2007.

able 1: Adverse Events in Patients with End-Stage Renal Disease undergoing Hemodialysis (cont'd.)			
<b>Skin Disorders</b> Pruritus	10.4	13.1	9.9
Respiratory, Thoracic and Mediastinal Disorders			
Dyspnea	15.7	10.1	16.8
Cough	11.6	7.1	12.9
Vascular Disorders			
Hypertension	9.3	10.1	5.9
Nervous System Disorders			
Headache	18.4	9.1	15.8
General Disorders and Site Administration Disorders			
Dialysis Access Complication	43	61	10.9

8.7 Pyrexia In one hundred and forty three patients with end-stage renal disease undergoing peritoneal dialysis with treatment duration of 12 weeks, adverse events reported at an incidence  $\geq$  10% are provided in Table 2 below. The adverse events presented in the table below are not necessarily attributed RENAGEL treatment. The incidence of these events was not dose related. ted to

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#### Table 2: Adverse Events in Patients with End-Stage Renal Disease Undergoing Peritoneal Dialysis

System Organ Class Event	RENAGEL (N=97) %	calcium (N=46) %		
Gastrointestinal disorders				
Dyspepsia	17.5	8.7		
Vomiting	11.3	4.3		
Peritonitis	11.3	4.3		

#### OVERDOSAGE

Since REMAGEL (sevelamer hydrochloride) is not absorbed, the risk of systemic toxicity is minimal. RENAGEL has been given to healthy volunteers at doses up to 14 grams per day for 8 days with no adverse effects. The maximum average daily dose of RENAGEL that has been given to hemodialysis patients is 13 grams.

Full product monograph is available from : Genzyme Canada Ltd., 2700 Matheson Blvd. East, West Tower, Suite 800, Mississauga, Ontario L4W 4V9

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## The fruit of exploration: Dialysis monitoring evolves



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