

# Renal Nutrition Forum

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## A Dietitian's Review of the RIFLE Classification of Acute Renal Failure and What It Means for Nutrition Therapy

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**This article has been approved for 2 CPE units. The online CPEU quiz and certificate of completion can be accessed in the Members Only section of the RPG web site via the My CPEU link. This CPE offering is available to current RPG members only and the expiration date is January 20, 2011.**

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Until the past few years, there has been much ambiguity surrounding the diagnosis of acute renal failure (ARF) and the variety of terms used to describe renal dysfunction; i.e. renal insufficiency, acute kidney injury (AKI), and renal impairment (1). In an effort to add clarity and staging to acute renal dysfunction, the Acute Dialysis Quality Initiative (ADQI) Work Group met in May 2002 to develop criteria for better classifying acute renal dysfunction (2). They named these criteria the RIFLE system,

for the stages of renal dysfunction into which it separates patients:

- 1) Risk of renal dysfunction
- 2) Injury to the kidney
- 3) Failure of kidney function
- 4) Loss of kidney function
- 5) End stage renal disease (ESRD)

The last two classifications, Loss and ESRD, are outcome categories that extend beyond temporary renal dysfunction. The categories of renal dysfunction are defined by changes in blood creatinine or glomerular filtration rate (GFR) from a baseline value and rates of urinary output per body weight over a specified time period, as shown in Table 1 (3). Criteria was defined to allow clinicians/physicians to better track and stage the development of ARF as well as allowing for better comparisons and research studies. In the past, the incidence and outcomes of AKI across many studies has been inconsistent and limited in scope due to variations in how AKI was defined (3).

Over the past few years, many large retrospective studies have been done to test the RIFLE criteria on intensive care unit (ICU) patients. Recently a study by Bagshaw et al, involving 120,123 patients from 57 ICU's was done to quantify the occurrence of AKI within twenty-four hours of ICU admission using the RIFLE criteria (3). Of these patients, the median age was 64.3 years, 59.5% were male, 28.6% had co-morbidities, 50.3% were medical admissions and the initial mean Acute Physiologic Assessment and Chronic Health Evaluation (APACHE) Scoring System II score was 16.9. Patients with pre-existing ESRD on

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Articles about successful programs, research interventions, evaluations and treatment strategies, educational materials, meeting announcements and information about educational programs are welcome and should be emailed to the editor by the next deadline.

Future Deadlines:  
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March 1, 2011

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# From the Editor's Desk

## Stacey C. Phillips, RD

Editor



With all of the hustle and bustle during the holiday season, it can be easy to forget the importance of our commitment in providing excellent patient-centered care as dietitians. In late October, I was able to attend an educational program offered by the National Kidney Foundation in Western MI. While there were many great speakers that day, I was fortunate to hear a presentation and the life story of a man by the name of Shad Ireland. For those of you unfamiliar with him, Shad explained how at an early age he was started on hemodialysis with the expectation of living until he was maybe twenty-five years old. Realizing that his life was going to be short, he became one of those patient's that we all struggle with, a noncompliant renal patient. It was not until after struggling to recover from his first failed kidney transplant and weighing in at only seventy-five pounds did something in Shad's life change. After watching two competitors struggle to the finish line in a triathlon, Shad became what he described as "inspired." Nine years later, in 2004, he became the first dialysis patient to participate in and complete an Ironman triathlon competition. It is stories like these that provide us with inspiration in our work as well. They illustrate that even the little things contributed in our daily routines can mean a lot in a patient's life.

As you read the Forum, please take note of the variety of articles offered along with the four CPEU credits. First time author Julie Hemann, RD, LD offers an article entitled, "A Dietitian's Review of the RIFLE Classification of Acute Renal Failure and What It Means for Nutrition Therapy." This feature article covers the RIFLE system, which classifies renal dysfunction, and provides readers with a case study example which can be transitioned easily into use for clinical care. Reading the article and answering the CPEU questions credits the reader with two CPEU units.

Supporting the feature article is a review article of the use and outcomes of using nutritional supplements within the renal population. Additionally, the latest and final of the Nutrition Care Process articles is included in the Winter Forum. After reading the Advances in Practice Article and Nutrition Care Process article and completing the CPEU quizzes, readers can earn one CPEU credit for each.

In the Spring *Renal Nutrition Forum*, please note one major change. As mentioned in past Forum's, in an effort to be more environmental and budget-conscious, the Spring Forum will be in an electronic format only. For those of you who do not have internet capabilities, please contact Assistant Editor, Megan Sliwa, or any member of the editorial board to ensure that you are not missing out with the change in normal publishing procedures.

As gathered from member surveys and web site data, the first e-supplement of educational materials printed over the summer was well received. We would like to compile handouts for a second e-supplement to be published in 2010. If you are willing to donate material, please forward it to an editorial team member.

In closing, and as you are reading through the Forum, please feel free to write down and send any of the editorial board members ideas that you may wish to see included in upcoming issues. In recent months it has been a very pleasant experience to work with new and seasoned authors. I encourage anyone that may have an interest in article writing, experienced or not, to let us know as we would be happy to foster article writing among members. Remember, without our dedicated Renal Dietitians Dietetics Practice Group members, the Forum would not be a success! ♦

*Stacey C. Phillips, RD*

# Feature Article....

**Table 1**

RIFLE Criteria for Acute Renal Dysfunction

	GFR	Urine Output (UO) Criteria
<b>Risk</b>	Increased creatinine x 1.5 or GFR decreased > 25%	UO < 0.5 mL/kg/hr x 6 hr
<b>Injury</b>	Increased creatinine x 2 or GFR decreased > 50%	UO < 0.5 mL/kg/hr x 12 hr
<b>Failure</b>	Increased creatinine x 3 or GFR decreased > 75%	UO < 0.3 mL/kg/hr x 24 hr or anuria x 12 hr
<b>Loss</b>	Persistent ARF = complete loss of renal function > 4 weeks	
<b>End Stage</b>	ESRD	

chronic dialysis or with a prior kidney transplant were excluded from the study. According to the RIFLE criteria, AKI occurred in 36.1% of ICU patients within twenty-four hours of admission. Statistics also showed that 16.3% of patients fell into the Risk for renal dysfunction category, 13.6% fell in the Injury to the kidney category, and 6.3% fell into the Failure of kidney function group. Loss of kidney function and ESRD categories were not used since the patient population was assessed during the first twenty-four hours of hospital admission and these two categories are related to clinical outcomes.

These estimates suggest that the occurrence of AKI is much higher than previously realized. The study found that the odds of AKI were higher in older patients, females, and those with comorbid disease (3). These patients were also more likely to be medical, rather than surgical patients, and have a primary cardiac, septic, or hepatic diagnosis. More advanced RIFLE categories were associated with increased severity of illness, as measured by the 2nd Simplified Acute Physiology Score (SAPS), APACHE II, and APACHE III scores. The higher the scores, the more at risk the patient is for hospital death. Likewise, increased RIFLE category was associated with decreased mean arterial pressures, increased heart rates, decreased serum pH and increased serum potassium levels.

In addition to categorizing levels of renal dysfunction by the RIFLE criteria, patients were also followed for hospital mortality (3). It was observed that AKI as defined by RIFLE criteria was associated with increases in hospital mortality. As RIFLE classification grades of severity increased, mortality rates increased. Mortality rates for the Risk category were 17.9%, for Injury were 27.7% and for Failure were 33.2%. As suspected by

these results, AKI was associated with longer durations of ICU and overall hospital stay. Bagshaw et al, concluded that the RIFLE criterion is a simple tool that can be used for the detection, monitoring, and classification of AKI and for correlation with clinical outcomes (3).

Similarly to the above study, researchers in Japan also conducted a large retrospective study involving 20,126 patients to assess the ability of RIFLE criteria to predict mortality in hospital patients (4). The results of the study found that close to

20% of patients had some degree of acute renal impairment and the RIFLE criteria was useful in predicting hospital mortality.

Recently, the Acute Kidney Injury Network (AKIN) Working Group, an international group of nephrologists and intensivists, worked to further improve the RIFLE criteria. They recommended that a smaller change in serum creatinine ( $\geq 0.3$  mg/dL) be used as a threshold for identifying the presence of AKI and that a time frame of 24-48 hours be used to ensure the process was acute (3). In addition, using the new AKIN model of defining AKI, patients starting renal replacement therapy are automatically classified as Stage 3 (or in Failure of kidney function using RIFLE) regardless of their creatinine and urinary output (5). Finally, the AKIN criteria eliminated the outcome categories of Loss and End Stage renal disease that appear on the RIFLE criteria. Table 2 illustrates the AKIN criteria.

In the study by Bagshaw et al, only cumulative 24-hour urine output was available and no patient weights were described (3). Therefore the study used a minor modification of the RIFLE urine output criteria, assuming an average patient weight of 70 kg,  $< 35$  mL/hr (Risk),  $< 21$  mL/hr (Injury), and  $< 4$  mL/hr (Failure). In addition, baseline serum creatinine values were estimated by the Modification of Diet in Renal Disease equation as recommended by the ADQI working group.

A study by Joannidis et al, in Australia compared classification of AKI in critically ill patients with both the AKIN versus RIFLE criteria and found that each associated AKI with increased hospital mortality (6). They concluded that despite presumed increased sensitivity by the AKIN classification, RIFLE had a higher detection rate of AKI during the first 48 hours of ICU admission. This was likely due to the use of GFR in the RIFLE

# Feature Article....

**Table 2**

AKIN Criteria for Acute Renal Dysfunction

	Creatinine Criteria	UO Criteria
<b>Stage 1</b>	Increased creatinine $\times$ 1.5 or $\geq 0.3$ mg/dL	UO $< 0.5$ mL/kg/hr $\times$ 6 hr
<b>Stage 2</b>	Increased creatinine $\times$ 2	UO $< 0.5$ mL/kg/hr $\times$ 12 hr
<b>Stage 3</b>	Increased creatinine $\times$ 3 or creatinine $\geq 4$ mg/dL (with acute rise of $\geq 0.5$ mg/dL)	UO $< 0.3$ mL/kg/hr $\times$ 24 hr or anuria $\times$ 12 hr

Note: Patients who receive renal replacement therapy are considered to have met the criteria for stage 3 irrespective of the stage that they are in at the time of commencement of renal replacement therapy.

criterion. A review by Cruz et al, in a recent publication in *Critical Care* cautions that using estimated GFR in place of the true GFR criterion may lead to inappropriate conclusions (5).

## What Does This Mean for Nutrition Professionals?

Renal failure is responsible for an increase in severity and duration of critical illness and the catabolic phase (1). ARF is associated with metabolic alterations in protein, carbohydrate, and lipid metabolism. As outlined in the studies on AKI, renal dysfunction affects more than 20% of ICU patients and is closely associated with morbidity and mortality (3,4). Thus, it is the job of nutrition professionals to optimally support these critically ill patients and prevent nutritional deficiencies, which cause further detriment to their clinical course and outcomes.

A recent article by Valencia et al, in *Current Opinion in Clinical Nutrition and Metabolic Care*, yields a call out to nutritional professionals for the need of nutrition therapy protocols or guidelines based on RIFLE criteria (1). Valencia brings to the table the option of better identifying those patients who are most nutritionally depleted and to treat them accordingly based on their need for protein restriction or supplementation. He categorizes patients with ARF into three different groups:

- **Group I:** Patients without excess catabolism and a urea nitrogen appearance (UNA) of  $< 6$  g nitrogen (N) above N intake/day.
- **Group II:** Patients with moderate hypercatabolism and a UNA exceeding N intake by 6 -12 g N/day.
- **Group III:** Patients with ARF in association with severe trauma, burns, or overwhelming infection. UNA is markedly elevated ( $>12$  g N above N intake). Nutrition requirements are high.

## Using Measures of UNA for AKI

UNA is an estimated measure of the urea nitrogen that is

eliminated from the body in the form of urine, dialysate, drainages, etc. It takes into account changes produced in total body N for a specified period of time. Since urea is the major byproduct of protein catabolism, the amount of urea N excreted each day can be used to estimate the rate of protein catabolism for a patient and determine the amount of protein intake needed to support his/her needs (7).

Many dietitians use urinary urea nitrogen (UUN) balance to determine the degree of hypercatabolism in their patients and to estimate protein needs. Nitrogen balance using UUN can be calculated as:

$$\text{Nitrogen balance} = (\text{protein intake (g)} \div 6.25) - (24\text{-hour UUN (g)} + 4)$$

This equation cannot be used in patients with low urine outputs, fluctuating weights, or changing blood urea nitrogen (BUN) levels, excluding patients entering into some degree of renal failure. The value of 4 g added to the UUN is an estimate of the unmeasured N loss in the urine, sweat, etc (8). The factor 6.25 adjusts for the grams of protein needed for one gram of N.

UNA does take into account changes in BUN and body weight, and thus is a better measure of protein catabolism for the renal failure population (7). The equation for UNA is shown below (9):

$$\text{UNA (g/day)} = \text{UUN (g/24 hr)} + [(\text{BUN}_2 - \text{BUN}_1) \times 0.6 \times \text{BW}_1] + [(\text{BW}_2 - \text{BW}_1) \times \text{BUN}_2]$$

BUN<sub>2</sub> = predialysis BUN (g/dL); BUN<sub>1</sub> = postdialysis BUN (g/dL); BW<sub>1</sub> = postdialysis weight (kg); BW<sub>2</sub> = predialysis weight (kg)

According to the 2000 KDOQI Guidelines, the best weight

# Feature Article....

to use for estimating energy and protein needs in patients with chronic kidney disease is the adjusted edema-free body weight ( $aBW_{ef}$ ) (10). This can be calculated with the following equation:

$$aBW_{ef} = BW_{ef} + [(SBW - BW_{ef}) \times 0.25]$$

where  $BW_{ef}$  is the actual edema free body weight of the patient, and SBW is the standard body weight for the patient as determined by NHANES II data.

## Nutrition Interventions

According to the proposals of Valencia et al, nutrition therapy can be tailored to the RIFLE criteria and patient's UNA values (1). Below, nutrition therapy goals are separated by the group classifications described before based on UNA calculations.

- **Group I:** Supplement 0.6-0.8 g of protein/kg/day with the goal of reducing ureagenesis and avoiding the need for dialysis. If this low-protein nutrition therapy continues for more than one to two weeks, discussion should include the future goals for this patient and the need to optimize nutrition support.
- **Group II:** Protein intake goal should be between 0.8-1.2 g/kg/day.
- **Group III:** If the UNA is elevated, patients will likely require 1.2-1.5 g/kg/day. Patients who are malnourished and severely hypercatabolic may even need as much as 1.8 g/kg/day of protein.

The advantage of calculating a UNA is that the degree of protein catabolism, elimination, and daily intake needs no longer become subjective, but rather objective.

## Case Study Example

Patient X is a 66 year old man, with a height of 5'10" and usual weight of 78 kg, who was admitted to the medical ICU with a diagnosis of sepsis. On the day of ICU admit, the patient's creatinine was 1.0 mg/dL. On day three of the ICU stay, the patient's creatinine increased to 3.0 mg/dL and his urine output was < 10 mL/hr for the past 24 hours. The medical team, using the RIFLE and AKIN criteria, soon realized the patient was entering stage 3 of AKI. Since the patient was intubated and NPO, on day four of ICU stay, a decision was made to start enteral nutrition support. By this time, dialysis treatment was also started. The dietitian estimated the patient's nutritional needs using a standard equation and began nutrition support, ordering a UUN to be obtained the following day – day five. Once the UUN was obtained, the dietitian could better estimate the patient's protein

needs. Below is the data obtained and formulas used to calculate a UNA:

- Protein intake on day 5: 75 g protein
- UUN on day 5: 2 g N in only 100 mL urine
- BUN 1 (collected postdialysis on day 5): 40 mg/dL (0.4 g/L)
- BUN 2 (collected predialysis on day 6): 50 mg/dL (0.5 g/L)
- BW1 (postdialysis weight on day 5): 80.2 kg
- BW2 (predialysis weight on day 6): 81.0 kg

On day 6, the dietitian calculated the patient's UNA:

$$\begin{aligned} UNA (\text{g/day}) &= UUN (\text{g}/24 \text{ hr}) + \\ &[(\text{BUN}_2 - \text{BUN}_1) \times 0.6 \times \text{BW}_1] + [(\text{BW}_2 - \text{BW}_1) \times \text{BUN}_2] \\ &= 2 \text{ g} + [(0.5 - 0.4) \times 0.6 \times 80.2] + \\ &[(81.0 - 80.2) \times 0.5] = 7.2 \text{ g/day} \end{aligned}$$

This UNA result of 7.2 indicates that Patient X has a moderate degree of hypercatabolism and fits into Group II as described previously. According to the guidelines by Valencia et al, this patient should have a protein intake goal between 0.8-1.2 g/kg/day (1). The patient is currently receiving approximately 1 g/kg protein/day based on the dietitian's earlier calculations. Since the patient was started on dialysis, it may be reasonable to increase his protein intake toward the upper limit of this guideline, 1.2 g/kg/day.

## Future Research

Review of the RIFLE and AKIN classification systems for AKI reveal that both systems are useful in defining and monitoring various stages of AKI and can be useful in correlating AKI with clinical outcomes. The physician authors of *UpToDate's* "Definition of acute kidney injury" state that both the RIFLE and AKIN criteria may have the greatest utility in epidemiologic studies rather than clinical bedside use, and may eventually be replaced by sensitive, specific biomarkers of renal tubular injury (11). Further information on the popularity of using these AKI classification systems, as well as developing more detailed nutrition therapy guidelines for each level of AKI is needed.

In addition, since UNA calculations are time-consuming and not a part of many dietetic clinicians' practice, studies on the UNA levels of commonly seen AKI patients may be helpful in determining what scenarios of AKI require the most protein replacement. ◆

# Feature Article....

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# Advances in Practice

## Oral Nutrition Supplements and Outcomes in Patients on Maintenance Dialysis

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Epidemiological studies show that protein-energy malnutrition is a strong predictor of morbidity and mortality in patients with chronic kidney disease (CKD) undergoing maintenance dialysis therapy (1-3). Low serum albumin and body mass index have been identified as key contributors to increased mortality, and many patients starting dialysis have energy and protein intake below the National Kidney Foundation's Kidney Dialysis Outcome Quality Improvement guidelines (2,4).

Projections based on data from more than 77,000 maintenance hemodialysis (HD) patients suggest that nutritional interventions that increase serum albumin by  $\geq 0.2$  g/dL may lead to improved outcomes, including reduction in death rate, hospitalizations and related costs (5). Nutrition counseling, often the first step in treating malnutrition, has been used in conjunction with oral nutrition supplements in attempt to improve nutritional intake and functional outcomes (6,7). However, research published in the late 1990's found little evidence that nutrition supplements definitively improve nutritional status in patients undergoing maintenance dialysis therapy (8,9). Furthermore, few of the studies reviewed explored the impact of nutrition supplements on morbidity and mortality rates in this population.

Since reimbursement for nutrition supplementation is difficult to secure and requires that stringent criteria are met, efficacy and cost effectiveness of oral nutrition supplements deserves greater attention (10). This article will summarize findings from studies conducted since 2000 and directed to determine the effect of oral

nutrition supplements on patient outcomes.

A number of studies investigating benefits of oral nutrition supplements in patients with CKD undergoing maintenance dialysis have shown positive effects on biochemical and nutritional measures. A systematic review of 18 studies suggested that both standard and renal disease specific oral supplements increase total energy and protein intake, and serum albumin levels (11).

Research has also been conducted to investigate the impact on nutritional measures of oral supplements in combination with, or in place of, nutrition counseling. One small study compared the standard practice of providing nutrition counseling alone with therapy combining both nutrition counseling and oral supplementation, when serum albumin begins to drop (3.5-3.7 g/dL) in maintenance HD patients (10). Fourteen patients in a control group were counseled to liberalize calorie and protein intake. Eighteen patients in an experimental group received nutrition counseling and one or two cans of NuBasics supplement (Nestle Clinical Nutrition, Deerfield, IL) free of charge to increase protein intake to 1.2 g/kg daily. During a six month treatment phase, nutritional repletion (defined as serum albumin  $\geq 3.8$  g/dL for 2 consecutive months) occurred more quickly ( $3.2 \pm 1.7$  months) and in a larger number of patients in the experimental group than in the control group ( $3.5 \pm 1.2$  months). During a three month follow-up, patients in the experimental group were more likely to maintain or improve their nutritional status than those in the control group. Findings from this study indicate that early intervention with oral nutrition supplements may allow more rapid and sustained nutritional repletion.

Another study compared rates of change in serum albumin level in 41 malnourished HD patients randomly assigned to receive either intensive dietary counseling or oral nutrition supplementation for 14 months (12). Patients in the supplementation group received 1 or 2 cans of Nepro daily (Abbott Nutrition, Abbott Park, IL) while those in the nonsupplement group received dietary counseling designed to promote daily intake of 30-35 kcal/kg and 1.2 g protein/kg ideal body weight. Patients in both groups had serum albumin  $\leq 3.5$  g/dL prior to the study. Rate of change in serum albumin was significantly greater in patients who received dietary counseling than in those receiving oral supplements, suggesting that in patients who are already malnourished, intensive dietary counseling may be of greater benefit than nutritional supplements.

Research in the non-CKD population has demonstrated variable adherence to oral nutrition supplements and several more recent studies have investigated the effects on patient outcomes of providing nutrition supplements during dialysis treatments (13-17). One such study assigned hemodialysis patients to a supplement

# Advances in Practice....

or comparison group based on patient preference (13). Forty-four patients in the supplement group (mean baseline serum albumin  $3.68 \pm 0.33$  g/dL) received 8 ounces Nepro before or immediately after each hemodialysis treatment in addition to standard nutrition care. Forty-four patients in the comparison group (mean baseline serum albumin  $3.93 \pm 0.34$  g/dL) received standard care without oral nutrition supplementation. Changes in quality of life were also monitored using the Kidney Disease Quality of Life – Short Form. Nepro was well accepted by patients in the supplement group and successfully maintained serum albumin concentration and role physical domain scores in the quality of life survey. In contrast, patients in the comparison group experienced a significant drop in serum albumin to  $3.81 \pm 0.37$  g/dL and in role physical domain scores during the course of the study.

In a smaller randomized study, 26 patients received a high-calorie, high-protein milkshake (500 kcal and 15 g protein) administered under supervision post-HD for one month in addition to standard nutrition counseling (14). Ten patients in a control group received nutrition counseling only. While both groups showed significant improvements in dry weight and body mass index, the supplement group also showed a significant increase in serum albumin and functional status, as measured by the Karnofsky score. Intradialytic oral supplementation has also been associated with persistent anabolic effects for muscle protein metabolism and increase in subjective global assessment scores in maintenance HD patients (15,16).

There is little published research addressing the impact of nutrition supplements on morbidity and mortality in this population. However, a recent study evaluated the impact on hospitalizations of oral protein supplements administered during HD and peritoneal dialysis (17). Patients were randomly assigned to treatment or control groups and all patients received counseling from dietitians throughout the study to maintain dietary protein intake at goal levels. HD patients in the treatment group received 15 g Proteinex protein supplement (Llorens Pharmaceutical Corporation, Miami, FL) three times a week after dialysis. Peritoneal dialysis patients in the treatment group received 15 g protein supplement daily. The control group did not receive protein supplementation. At the end of an initial 6-month period, patients crossed over to the opposite group for 6 months. For patients receiving protein supplementation during the first 6 months, normalized protein catabolic rate (nPCR) increased significantly by month 4 of treatment; serum albumin also increased, but not significantly. For patients receiving protein supplements during the second 6 months, nPCR and serum albumin trended upward but did not increase significantly. Serum albumin and nPCR both declined when protein supplementation

was discontinued. Trends towards a decrease in both hospital admissions and length of stay were seen in both crossover treatment groups. During the first 6 months, 50% of the control group was hospitalized, versus 42% of patients receiving protein supplements. During the second 6 months, 45% of the control group versus 39% of the protein group was hospitalized.

In summary, nutrition supplements increase energy and protein intake, and maintain or improve nutritional status (10,11,13-16). According to one study, outcomes appear to be better when nutrition supplementation is initiated prior to onset of malnutrition (10). There is limited evidence that nutrition supplements reduce hospitalization in this population and larger studies are needed to confirm trends observed (17). The success of nutrition supplementation is strongly dependent on patient compliance and outcomes are improved when supplements are administered under supervision during or immediately after dialysis (13-17). Patient preferences regarding taste, texture, flavor ranges, phosphate binder requirements and fluid contribution of nutrition supplements have also been investigated (18,19). Findings from these studies indicate good acceptance rates for renal-specific liquid supplements and selected high-protein supplement bars.

The impact of nutrition supplementation on nutrition outcomes in patients undergoing maintenance dialysis therapy remains an important topic for additional research. Results from existing research need to be confirmed and extended through larger studies so that standards can be developed for effective use of nutrition supplements in this patient population. ◆

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#### Important Treatment Considerations

Renvela® (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis • Renvela is contraindicated in patients with bowel obstruction • Caution should be exercised in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery • Uncommon cases of bowel obstruction and perforation have been reported • Serum bicarbonate and chloride levels should be monitored • Vitamins D, E, K (coagulation parameters), and folic acid levels should be monitored • The most frequently occurring adverse reactions in a short-term study with sevelamer carbonate tablets were nausea and vomiting • In a short-term study of sevelamer carbonate powder dosed three times daily, adverse events were similar to those reported for sevelamer carbonate tablets • In long-term studies with sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, the most common adverse events included: vomiting, nausea, diarrhea, dyspepsia, abdominal pain, flatulence, and constipation • Cases of fecal impaction and, less commonly, ileus, bowel obstruction, and bowel perforation have been reported • Drug-drug interactions may occur with some medications and should be taken into consideration when instructing patients how to take Renvela • Patients should be informed to take Renvela with meals and to adhere to their prescribed diets

Please see Brief Summary of Prescribing Information on adjacent page.

Reference: 1. Renvela [package insert]. Cambridge, MA: Genzyme Corp; 2009.



sevelamer carbonate

[se vel' a mer]

See package insert for full prescribing information.

#### BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

##### INDICATIONS AND USAGE

Renvela® (sevelamer carbonate) is indicated for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis.

##### DOSAGE AND ADMINISTRATION

Because of the rapid reaction with the hydrochloric acid in the stomach, the dosing of Renvela powder or tablet is anticipated to be similar to that of the sevelamer hydrochloride salt or tablet.

##### General Dosing Information

*Patients Not Taking a Phosphate Binder:* The recommended starting dose of Renvela is 0.8 to 1.6 g, with meals based on serum phosphorus level. Table 1 provides recommended starting doses of Renvela for patients not taking a phosphate binder.

Table 1. Starting Dose for Dialysis Patients Not Taking a Phosphate Binder

SERUM PHOSPHORUS	RENVELA® 800 MG	RENVELA POWDER
> 5.5 and < 7.5 mg/dL	1 tablet three times daily with meals	0.8 g three times daily with meals
> 7.5 mg/dL	2 tablets three times daily with meals	1.6 g three times daily with meals

*Switching from Sevelamer Hydrochloride Tablets:* For patients switching from sevelamer hydrochloride tablets to sevelamer carbonate tablets or powder, use the same dose in grams. Further titration may be necessary to achieve desired phosphorus levels. The highest daily dose of sevelamer carbonate studied was 14 grams in CKD patients on dialysis.

*Switching between Sevelamer Carbonate Tablets and Powder:* Use the same dose in grams. Further titration may be necessary to achieve desired phosphorus levels.

*Switching from Calcium Acetate:* In a study in 84 CKD patients on hemodialysis, a similar reduction in serum phosphorus was seen with equivalent doses (approximately mg for mg) of sevelamer hydrochloride and calcium acetate. Table 2 gives recommended starting doses of Renvela based on a patient's current calcium acetate dose.

Table 2. Starting Dose for Dialysis Patients Switching From Calcium Acetate to Renvela

CALCIUM ACETATE 667 MG (TABLETS PER MEAL)	RENVELA® 800 MG (TABLETS PER MEAL)	RENVELA POWDER
1 tablet	1 tablet	0.8 g
2 tablets	2 tablets	1.6 g
3 tablets	3 tablets	2.4 g

*Dose Titration for All Patients Taking Renvela:* Titrate the Renvela dose by 0.8 g TID with meals at two-week intervals as necessary with the goal of controlling serum phosphorus within the target range.

##### Sevelamer Carbonate Powder Preparation Instructions

The entire contents of each 0.8 or 2.4 g packet should be placed in a cup and mixed thoroughly with the amount of water described in Table 3.

Table 3. Sevelamer Carbonate Powder Preparation Instructions

RENVELA POWDER PACKET STRENGTH	MINIMUM AMOUNT OF WATER FOR DOSE PREPARATION (EITHER OUNCES, mL, OR TEASPOON/TABLESPOON)		
	ounces	mL	tsp/tbsp
0.8 g	1	30	6 teaspoons/2 tablespoons
2.4 g	2	60	4 tablespoons

Multiple packets may be mixed together with the appropriate amount of water. Patients should be instructed to stir the mixture vigorously (it does not dissolve) and drink the entire preparation within 30 minutes or resuspend the preparation right before drinking.

Based on clinical studies, the average prescribed daily dose of sevelamer carbonate is approximately 7.2 g per day.

##### DOSAGE FORMS AND STRENGTHS

Tablets: 800 mg white oval, film-coated, compressed tablets imprinted with "RENVELA 800".

Powder: 0.8 g and 2.4 g pale yellow powder packaged in an opaque, foil lined, heat sealed packet.

##### CONTRAINDICATIONS

Renvela is contraindicated in patients with bowel obstruction.

##### WARNINGS AND PRECAUTIONS

**Use Caution in Patients with Gastrointestinal Disorders.** The safety of Renvela has not been established in patients with dysphagia, swallowing disorders, severe gastrointestinal (GI) motility disorders including severe constipation, or major GI tract surgery. Uncommon cases of bowel obstruction and perforation have been reported.

**Monitor Serum Chemistries:** Bicarbonate and chloride levels should be monitored.

**Monitor for Reduced Vitamins D, E, K (clotting factors) and Folic Acid Levels.** In preclinical studies in rats and dogs, sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, reduced vitamins D, E, and K (coagulation parameters) and folic acid levels at doses of 6–10 times the recommended human dose. In short-term clinical trials, there was no evidence of reduction in serum levels of vitamins. However, in a one-year clinical trial, 25-hydroxyvitamin D (normal range 10 to 55 ng/mL) fell from 39 ± 22 ng/mL to 34 ± 22 ng/mL ( $p<0.01$ ) with sevelamer hydrochloride treatment. Most (approximately 75%) patients in sevelamer hydrochloride clinical trials received vitamin supplements, which is typical of patients on dialysis.

##### ADVERSE REACTIONS

**Clinical Trials Experience:** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

There are limited data on the safety of Renvela. However, based on the fact that it contains the same active ingredient as the hydrochloride salt, the adverse event profiles of the two salts should be similar. In a cross-over study in hemodialysis patients with treatment durations of eight weeks each and no washout the adverse reactions on sevelamer carbonate tablets were similar to those reported for sevelamer hydrochloride. In another cross-over study in hemodialysis patients, with treatment durations of four weeks each and no washout between treatment periods, the adverse reactions on sevelamer carbonate powder were similar to those reported for sevelamer hydrochloride.

In a parallel design study of sevelamer hydrochloride with treatment duration of 52 weeks, adverse reactions reported for sevelamer hydrochloride ( $n=99$ ) were similar to those reported for the active-comparator group ( $n=101$ ). Overall adverse reactions among those treated with sevelamer hydrochloride occurring in > 5% of patients included: vomiting (22%), nausea (20%), diarrhea (19%), dyspepsia (16%), abdominal pain (9%), flatulence (8%), and constipation (8%). A total of 27 patients treated with sevelamer and 10 patients treated with comparator withdrew from the study due to adverse reactions.

Based on studies of 8–52 weeks, the most common reason for withdrawal from sevelamer hydrochloride was gastrointestinal adverse reactions (3–16%).

In one hundred and forty-three peritoneal dialysis patients studied for 12 weeks using sevelamer hydrochloride, most adverse reactions were similar to adverse reactions observed in hemodialysis patients. The most frequently occurring treatment emergent serious adverse reaction was peritonitis (8 reactions in 8 patients [8%] in the sevelamer group and 2 reactions in 2 patients [4%] on active-control). Thirteen patients (14%) in the sevelamer group and 9 patients (20%) in the active-control group discontinued, mostly for gastrointestinal adverse reactions. Patients on peritoneal dialysis 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.

**Postmarketing Experience:** Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure.

The following adverse reactions have been identified during post-approval use of sevelamer hydrochloride, which has the same active moiety as sevelamer carbonate: pruritis, rash, abdominal pain, fecal impaction, and uncommon cases of ileus, intestinal obstruction, and intestinal perforation. Appropriate medical management should be given to patients who develop constipation or have worsening of existing constipation to avoid severe complications.

##### DRUG INTERACTIONS

Sevelamer carbonate has been studied in human drug-drug interaction studies with warfarin and digoxin. Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been studied in human drug-drug interaction studies with ciprofloxacin, digoxin, warfarin, enalapril, metoprolol, and iron.

**Ciprofloxacin:** In a study of 15 healthy subjects, a co-administered single dose of 2.8 grams of sevelamer hydrochloride decreased the bioavailability of ciprofloxacin by approximately 50%.

**Digoxin:** In 19 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals for 2 days, sevelamer did not alter the pharmacokinetics of a single dose of digoxin. In 18 healthy subjects receiving 9.6 grams of sevelamer carbonate once daily, sevelamer did not alter the pharmacokinetics of a single dose of digoxin.

**Warfarin:** In 14 healthy subjects receiving 2.4 grams of sevelamer hydrochloride three times a day with meals, sevelamer did not alter the pharmacokinetics of a single dose of warfarin. In 14 healthy subjects receiving 9.6 grams of sevelamer carbonate once daily with meal, sevelamer did not alter the pharmacokinetics of a single dose of warfarin.

**Enalapril:** In 28 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of enalapril.

**Metoprolol:** In 31 healthy subjects a single 2.4 gram dose of sevelamer hydrochloride did not alter the pharmacokinetics of a single dose of metoprolol.

**Iron:** In 23 healthy subjects, a single 2.8 gram dose of sevelamer hydrochloride did not alter the absorption of a single oral dose of iron as 200 mg excipient ferrous sulfate tablet.

**Other Concomitant Drug Therapy:** There are no empirical data on avoiding drug interactions between Renvela and most concomitant drugs. During postmarketing experience, very rare cases of increased thyroid stimulating hormone (TSH) levels have been reported in patients co-administered sevelamer hydrochloride and levothyroxine. Monitor TSH levels and signs of hypothyroidism in patients receiving both medications.

When administering an oral medication where a reduction in the bioavailability of that medication would have a clinically significant effect on its safety or efficacy, there is no information suggesting a dosing regimen that would be universally appropriate for all drugs. One may, however, administer the drug one hour before or three hours after Renvela, and when important, monitor blood levels of the drug. Patients taking anti-arrhythmic medications for the control of arrhythmias and anti-seizure medications for the control of seizure disorders were excluded from the clinical trials.

##### USE IN SPECIFIC POPULATIONS

**Pregnancy: Pregnancy Category C:** There are no adequate and well-controlled studies in pregnant women. Sevelamer products should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The effect of sevelamer hydrochloride on the absorption of vitamins and other nutrients has not been studied in pregnant women. Requirements for vitamins and other nutrients are increased in pregnancy. In pregnant rats given doses of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred at a dose approximately equal to the maximum clinical trial dose of 13 g on a body surface area basis. In pregnant rabbits given oral doses of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred at a dose approximately twice the maximum clinical trial dose on a body surface area basis. (See *NONCLINICAL TOXICOLOGY* (13.2)).

**Labor and Delivery:** No sevelamer hydrochloride treatment-related effects on labor and delivery were seen in animal studies. (See *NONCLINICAL TOXICOLOGY* (13)). The effects of sevelamer carbonate on labor and delivery in humans is unknown.

**Pediatric use:** The safety and efficacy of Renvela has not been established in pediatric patients.

**Geriatric use:** Clinical studies of Renvela did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range.

##### OVERDOSAGE

Sevelamer hydrochloride, which contains the same active moiety as sevelamer carbonate, has been given to normal healthy volunteers in doses of up to 14 grams per day for eight days with no adverse effects. In CKD patients on dialysis, the maximum dose studied was 14 grams of sevelamer carbonate and 13 grams of sevelamer hydrochloride. There are no reports of overdose with sevelamer carbonate or sevelamer hydrochloride in patients. Since sevelamer is not absorbed, the risk of systemic toxicity is low.

##### NONCLINICAL TOXICOLOGY

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Standard lifetime carcinogenicity bioassays were conducted in mice and rats. Rats were given sevelamer hydrochloride by diet at 0.3, 1, or 3 g/kg/day. There was an increased incidence of urinary bladder transitional cell papilloma in male rats of the high dose group (human equivalent dose twice the maximum clinical trial dose of 13 g). Mice received dietary administration of sevelamer hydrochloride at doses of up to 9 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose). There was no increased incidence of tumors observed in mice.

In an *in vitro* mammalian cytogenetic test with metabolic activation, sevelamer hydrochloride caused a statistically significant increase in the number of structural chromosome aberrations. Sevelamer hydrochloride was not mutagenic in the Ames bacterial mutation assay.

Sevelamer hydrochloride did not impair the fertility of male or female rats in a dietary administration study in which the females were treated from 14 days prior to mating through gestation and the males were treated for 28 days prior to mating. The highest dose in this study was 4.5 g/kg/day (human equivalent dose 3 times the maximum clinical trial dose of 13 g).

**Developmental Toxicity:** In pregnant rats given dietary doses of 0.5, 1.5, or 4.5 g/kg/day of sevelamer hydrochloride during organogenesis, reduced or irregular ossification of fetal bones, probably due to a reduced absorption of fat-soluble vitamin D, occurred in mid- and high-dose groups (human equivalent doses approximately equal to and 3.4 times the maximum clinical trial dose of 13 g). In pregnant rabbits given oral doses of 100, 500, or 1000 mg/kg/day of sevelamer hydrochloride by gavage during organogenesis, an increase of early resorptions occurred in the high-dose group (human equivalent dose twice the maximum clinical trial dose).

##### HOW SUPPLIED/STORAGE AND HANDLING

**Tablets:** Renvela® 800 mg Tablets are supplied as white oval, film-coated, compressed tablets, imprinted with "RENVELA 800", containing 800 mg of sevelamer carbonate on an anhydrous basis, microcrystalline cellulose, hypromellose, diacylated monoglycerides, sodium chloride, and zinc stearate.

1 Bottle of 30 ct 800 mg Tablets (NDC 58468-0130-2)

1 Bottle of 270 ct 800 mg Tablets (NDC 58468-0130-1)

**Powder:** Renvela® for Oral Suspension is supplied as opaque, foil lined, heat sealed, packets containing 0.8 g or 2.4 g of sevelamer carbonate on an anhydrous basis, natural and artificial citrus cream flavor, propylene glycol alginate, sodium chloride, sucrose, and ferric oxide (yellow).

1 Box (NDC 58468-0131-2) of 90 ct 2.4 g packets (NDC 58468-0131-1)

1 Box (NDC 58468-0132-2) of 90 ct 0.8 g packets (NDC 58468-0132-1)

1 Sample Box (NDC 58468-0131-4) of 90 ct 2.4 g packets (NDC 58468-0131-3)

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# Nephrology Nutrition and the Nutrition Care Process

## A Renal Nutrition Forum Series with Practice-Based Examples of the Nutrition Care Process (NCP): What's Happening Among Dialysis Providers?

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**This article has been approved for 1 CPE unit. The online CPEU quiz and certificate of completion can be accessed in the Members Only section of the RPG web site via the My CPEU link. In addition, this CPE offering is available to current RPG members only and the expiration date is January 20, 2011.**

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### Introduction

This article, the eighth and final column in this series, will provide a brief report on efforts to prepare for implementation of the Nutrition Care Process (NCP) and standardized language (SL) by dialysis providers.

Readers may recall that the Commission on Accreditation for Dietetics Education mandates that the NCP model be part of curricula for accredited undergraduate and dietetic internship programs (1). For registered dietitians in clinical settings, the American Dietetic Association (ADA) has developed and published standards of practice (SOP) and standards of professional performance (SOPP) which are built around the NCP model (2). Fall 2009 saw joint publication in the *Journal of the American Dietetic Association* and in the *Journal of Renal Nutrition* of SOP and SOPP for nephrology dietitians (3). The structure of these standards is based on the NCP model. In this manner, the NCP and its major tool, SL, are becoming standards of practice for our profession. *The International Dietetics and Nutrition Terminology Reference Manual, 2<sup>nd</sup> edition*, provides a comprehensive overview of the model and SL at this time (4). The NCP model fulfills the requirement of regulatory agencies such as the Centers for Medicare & Medicaid Services for practice protocols which are research-based and which are nationally recognized (2).

### Electronic Health Records, NCP, and Conditions for Coverage

The development of the NCP and SL just as the movement towards electronic health records (EHR) gains momentum is fortuitous. The EHR simplifies the process of gathering data for quality improvement, for research, and for other purposes. Templates that are developed to follow the steps of the NCP can also meet mandates from the Conditions for Coverage (CfCs) published in the fall of 2008 (5). The NCP terminology for Step 3 can be used to describe nutrition interventions, which the CfCs refer to as "services." Also the terminology for monitoring and evaluation is well suited to document outcomes, as required by the CfCs, which can then be followed over time.

### NCP Implementation by Dialysis Providers

Nephrology dietitians are at various points in following the NCP model and using its terminology today, four years after the publication of the first reference manual for the NCP (6). An informal survey generated reports of some activities related to NCP implementation by larger dialysis entities. One large provider reports action to include the NCP and problem-etiology-signs and symptoms statements in nutrition documentation in the EHR. Another dialysis provider indicates that there have been preliminary activities toward adopting the NCP into their nutrition care documentation but no details are available at this time. Some dietitians affiliated with a third major provider are working to identify resources to support eventual implementation of the NCP and its terminology in their region.

There are several reasons why nephrology nutrition is well-suited to active use of the NCP and SL. These include:

- 1) Patients present with complex nutrition problems and are assessed and re-assessed over time.
- 2) The NCP and SL match very well with the mandates in the CfCs which require that the dialysis care team complete an assessment and describe a plan of care with services (intervention) and with stated outcomes (4,5).
- 3) The standardized terminology of the NCP will advance clear descriptions and clear evaluation of services provided and outcomes achieved in this population. Years from now this could support diagnostic and procedural coding for nutrition care in ESRD (4).
- 4) ESRD patients represent a large patient population that could be studied carefully to determine the effectiveness of MNT if care were documented in a standard manner from one center to another and from one provider to another across the nation.

# Nutrition Care Process....

## The NCP and the Future in Nephrology Nutrition

In addition to the introduction of the NCP and standardized terminology in recent years, renal dietitians have seen major developments which are shaping the future:

- the publication of the new CfCs (5);
- the introduction of and continuing updates of EHRs;
- a Kidney Disease Outcomes Quality Initiative (KDOQI) update of nutrition guidelines for children with chronic kidney disease (CKD) (7); and
- the publication of SOP and SOPP for Renal Dietitians (3).

While these significant developments may seem wide-ranging and disparate, each one of them offers an opportunity for excellence in practice which can be enhanced by the standardization that NCP and SL provide.

For example, how might NCP relate to KDOQI nutrition guidelines? The fact is that updates to the KDOQI nutrition guidelines for adults with CKD, originally published in 2000 (8), have been stymied by a serious lack of new evidence to support updated guideline recommendations (9). The fact that clinicians have not employed a common language to describe the problems they diagnose, the interventions they manage, or the outcomes that are observed makes it difficult to combine results of nutrition care from various clinics across the nation into one study with sufficient sample size to achieve significance. The potential for multi-center studies, with enough subjects to demonstrate significance, will be realized more readily with standardized documentation of care in nephrology nutrition.

## Summary

Some helpful and readily available resources, including NCP tutorials with continuing education credit posted on the ADA web page, were identified in the first article in this series (10). Another new tool, the NCP In-Depth Sponsored Independent Learning Toolkit, has been approved by the Commission on Dietetics Registration for five or more continuing education units (11). An individual clinician, working with a mentor, completes defined learning activities and a client-based case study to improve understanding and implementation of the NCP and its terminology.

Moving forward with the NCP and SL is important for the future of nephrology nutrition practice and research. The time and energy each individual invests into mastering the NCP will bring benefits to all of us practicing nephrology nutrition. ◆

*Thank You...*

**Maureen McCarthy**, and your numerous co-authors, for the series on the NCP. These two years of articles are a testament to your professionalism and dedication to the betterment of renal nutrition.

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# Member Spotlight

## Christine Dobmeier, RD, CSR, LDN

Recipient of an RPG educational stipend for the 2009 Mayo Clinic Conference on Nutrition and Wellness in Rochester, MN  
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I recently attended the 9<sup>th</sup> Annual Mayo Clinic Conference on Nutrition and Wellness in Health and Disease. This conference had a lot to offer. There were multiple sessions on working with obese patients, as well as lectures on web-based resources for nutrition, nutrition support, a vitamin D update, evaluation of electrolytes and replacing mineral deficiencies.

As a dietitian whose primary practice focuses on working with transplant patients, both pre and post-operatively, I was looking forward to many of these sessions as they confronted issues that I deal with daily. Obesity is an issue that I see in a majority of my patients being worked up for transplants, as well as those post-transplant.

One of the talks that I found very interesting was given by Dr. Michael Jensen, titled "Energy Metabolism Myths and Obesity." The first myth he tackled was, "I gain weight if I eat more than 1000 calories!" We all have patients that insist they barely eat, yet are gaining weight. First, assess your patients' actual intake; most people under-estimate their caloric intake by at least 30%. Dr. Jensen stated that it is possible for people to gain weight on a 1000 calorie diet, briefly after following a very low calorie ketogenic diet, or fasting. Encouraging a more balanced weight loss plan is vital.

Myth #2, "Dieting will lower my metabolism so I can't lose weight." Reduced calorie intake can decrease the metabolic rate, but it does not have to, and is not a permanent change. The main determinant of basal metabolic rate is lean tissue; adipose tissue uses very few calories. During weight loss, the goal is to maintain lean tissue so the metabolic rate is not decreased. Gradual weight loss affects the metabolic rate much less than following a very low calorie diet with rapid weight loss.

The third myth was, "Exercise is a good way to lose weight." With my patients, I encourage exercise and activity to help with weight loss; my average "active patient" may walk three days a week for 20-30 minutes. In a 100 kg individual, walking at a slow pace for 30 minutes burns about 100 calories. While exercise is important to help with maintaining lean tissue, it is important to show our patients how small changes in the diet can greatly affect caloric deficit more than exercise. Dr. Jensen highlighted how one could eliminate two ounces of potato chips; or substitute two diet sodas for two regular sodas in order to save 300 calories.

Alternatively, the patient could run three miles in 30 minutes, or bicycle eight miles in 30 minutes. Diet modifications can be easier to make; this is an important point to focus on with patients. Looking at their typical day and trying to identify places to save a few hundred calories can make a world of difference. While exercise isn't the single most effective tool in weight loss, maintaining an active lifestyle can help preserve lean tissue, which helps to stabilize basal metabolic rate while losing weight.

Overall, the conference was an excellent overview of many different facets of nutrition and wellness, and how it affects chronic disease in our patients. ◆

## Do you have an educational handout that you have created and would like to share with others?

The editorial team is seeking professional resources to compile in a second "electronic only" supplement to the *Renal Nutrition Forum*.

We are looking for handouts such as holiday eating ideas, fluid restrictions, pediatric renal nutrition and vegetarian renal nutrition.

If you are interested, please contact assistant editor:  
Megan Sliwa, RD, LDN at [megansliwa@aol.com](mailto:megansliwa@aol.com)  
by March 1, 2010.

## WANT TO GET INVOLVED? Let us know!

Contact Membership Chair:  
**Danielle Frazer, RD**  
[rd813303@gmail.com](mailto:rd813303@gmail.com)

ZEMPLAR is indicated for the prevention and treatment of secondary hyperparathyroidism (SHPT) associated with chronic kidney disease (CKD) stage 3 and 4 (ZEMPLAR Capsules) and stage 5 (ZEMPLAR Injection)<sup>1,2</sup>

# HELP FIGHT A COMPLICATION OF CKD

## Important Safety Information<sup>1,2</sup>

- ZEMPLAR Capsules and Injection are contraindicated in patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any product ingredient.
- Excessive administration of vitamin D compounds can cause over suppression of parathyroid hormone (PTH), hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. High intake of calcium and phosphate concomitant with vitamin D compounds may lead to similar abnormalities, and patient monitoring and individualized dose titration is required. Progressive hypercalcemia due to overdosage of vitamin D may require emergency medical attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis. Use caution when digitalis compounds are prescribed concomitantly with ZEMPLAR. Chronic hypercalcemia can lead to vascular and soft-tissue calcifications. Chronic administration of ZEMPLAR Injection may place patients at risk for hypercalcemia, elevated Ca x P product, and metastatic calcification.

- ZEMPLAR is partially metabolized by CYP3A. Care should be taken while dosing ZEMPLAR with ketoconazole and other strong cytochrome P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.
- During ZEMPLAR Capsules therapy withhold pharmacologic doses of vitamin D compounds. PTH, calcium and phosphorus levels should be monitored at least every 2 weeks for 3 months after initiation or following dose adjustments, then monthly for 3 months, and every 3 months thereafter. Patient monitoring and individualized dose titration are required to maintain physiologic targets and optimum reduction/levels of PTH. The dose of ZEMPLAR Capsules should be reduced or interrupted if hypercalcemia or elevated Ca x P is observed.
- During ZEMPLAR Injection therapy withhold phosphate or vitamin D related compounds. PTH should be monitored at least every 3 months and more frequently at initiation and dosage changes. Calcium and phosphorus should be measured at least monthly and

more frequently at initiation or following dosage changes. If clinically significant hypercalcemia develops or an elevated Ca x P product greater than 75 mg<sup>2</sup>/dL<sup>2</sup> is noted, the dose should be immediately reduced or interrupted.

- Patients should be informed to adhere to their diet and phosphorus restriction, to take prescribed phosphate binders, and should be knowledgeable about the symptoms of hypercalcemia. While taking ZEMPLAR Capsules patients should be informed to comply with dosage instructions.
- Adverse events reported by at least 5% and at a frequency of at least twice that of placebo were allergic reaction, rash, arthritis, and vertigo for the ZEMPLAR Capsules Stage 3 and 4 treated patients and chills, fever, sepsis, gastrointestinal bleeding, vomiting, edema, light-headedness, and pneumonia for the ZEMPLAR Injection Stage 5 treated patients.



Goal achievement across the treatment continuum

[www.zemplar.com](http://www.zemplar.com)



## Please see brief summary of Prescribing Information for ZEMPLAR Injection and ZEMPLAR Capsules on following pages.

**References:** 1. ZEMPLAR (paricalcitol) Capsules [package insert]. North Chicago, IL; Abbott Laboratories. 2. ZEMPLAR (paricalcitol) Injection [package insert]. Lake Forest, IL; Abbott Laboratories.

ZEMPLAR is a trademark of Abbott Laboratories.

**PROFESSIONAL BRIEF SUMMARY**  
**CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

# Zemplar®

(paricalcitol) Capsules

Rx only

## INDICATIONS AND USAGE

Zemplar Capsules are indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 3 and 4.

## CONTRAINDICATIONS

Zemplar Capsules should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any ingredient in this product (see **WARNINGS**).

## WARNINGS

Excessive administration of vitamin D compounds, including Zemplar Capsules, can cause over suppression of PTH, hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. Progressive hypercalcemia due to overdose of vitamin D and its metabolites may be so severe as to require emergency attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. High intake of calcium and phosphate concomitant with vitamin D compounds may lead to similar abnormalities and patient monitoring and individualized dose titration is required.

Pharmacologic doses of vitamin D and its derivatives should be withheld during Zemplar treatment to avoid hypercalcemia.

## PRECAUTIONS

### General

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar Capsules.

### Information for Patients

The patient or guardian should be informed about compliance with dosage instructions, adherence to instructions about diet and phosphorus restriction, and avoidance of the use of unapproved nonprescription drugs. Phosphate-binding agents may be needed to control serum phosphorus levels in patients, but excessive use of aluminum containing compounds should be avoided. Patients also should be informed about the symptoms of elevated calcium (see **ADVERSE REACTIONS**).

### Laboratory Tests

During the initial dosing or following any dose adjustment of medication, serum calcium, serum phosphorus, and serum or plasma iPTH should be monitored at least every two weeks for 3 months after initiation of Zemplar therapy or following dose-adjustments in Zemplar therapy, then monthly for 3 months, and every 3 months thereafter.

### Drug Interactions

Paricalcitol is not expected to inhibit the clearance of drugs metabolized by cytochrome P450 enzymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1 or CYP3A nor induce the clearance of drugs metabolized by CYP2B6, CYP2C9 or CYP3A.

A multiple dose drug-drug interaction study demonstrated that ketoconazole approximately doubled paricalcitol AUC<sub>0-∞</sub>. Since paricalcitol is partially metabolized by CYP3A and ketoconazole is known to be a strong inhibitor of cytochrome P450 3A enzyme, care should be taken while dosing paricalcitol with ketoconazole and other strong P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, neflavir, ritonavir, saquinavir, telithromycin or voriconazole. Dose adjustment of Zemplar Capsules may be required, and iPTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor such as ketoconazole.

Drugs that impair intestinal absorption of fat-soluble vitamins, such as cholestyramine, may interfere with the absorption of Zemplar Capsules.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, an increased incidence of uterine leiomyoma and leiomyosarcoma was observed at subcutaneous doses of 1, 3, 10 mcg/kg given three times weekly (2 to 15 times the AUC at a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The incidence rate of uterine leiomyoma was significantly different than the control group at the highest dose of 10 mcg/kg. In a 104-week carcinogenicity study in rats, there was an increased incidence of benign adrenal pheochromocytoma at subcutaneous doses of 0.15, 0.5, 1.5 mcg/kg (< 1 to 7 times the exposure following a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The increased incidence of pheochromocytomas in rats may be related to the alteration of calcium homeostasis by paricalcitol. Paricalcitol did not exhibit genetic toxicity *in vitro* with or without metabolic activation in the microbial mutagenesis assay (Ames Assay), mouse lymphoma mutagenesis assay (L5178Y), or a human lymphocyte cell chromosomal aberration assay. There was also no evidence of genetic toxicity in an *in vivo* mouse micronucleus assay. Paricalcitol had no effect on fertility (male or female) in rats at intravenous doses up to 20 mcg/kg/dose (equivalent to 13 times a human dose of 14 mcg based on surface area, mcg/m<sup>2</sup>).

## Pregnancy

### Pregnancy category C

Paricalcitol has been shown to cause minimal decreases in fetal viability (5%) when administered daily to rabbits at a dose 0.5 times a human dose of 14 mcg or 0.24 mcg/kg (based on body surface area, mcg/m<sup>2</sup>), and when administered to rats at a dose two times the 0.24 mcg/kg human dose (based on body surface area, mcg/m<sup>2</sup>). At the highest dose tested, 20 mcg/kg administered three times per week in rats (13 times the 14 mcg human dose based on surface area, mcg/m<sup>2</sup>), there was a significant increase in the mortality of newborn rats at doses that were maternally toxic and are known to produce hypercalcemia in rats. No other effects on offspring development were observed. Paricalcitol was not teratogenic at the doses tested. Paricalcitol (20 mcg/kg) has been shown to cross the placental barrier in rats.

There are no adequate and well-controlled clinical studies in pregnant women. Zemplar Capsules should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

### Nursing Mothers

Studies in rats have shown that paricalcitol is present in the milk. It is not known whether paricalcitol is excreted in human milk. In the nursing patient, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Geriatric Use

Of the total number (n = 220) of patients in clinical studies of Zemplar Capsules, 49% were 65 and over, while 17% were 75 and over. No overall differences in safety and effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

### Pediatric Use

Safety and efficacy of Zemplar Capsules in pediatric patients have not been established.

### ADVERSE REACTIONS

The safety of Zemplar Capsules has been evaluated in three 24-week (approximately six-month), double-blind, placebo-controlled, multicenter clinical studies involving 220 CKD Stage 3 and 4 patients. Six percent (6%) of Zemplar Capsules treated patients and 4% of placebo treated patients discontinued from clinical studies due to an adverse event. All reported adverse events occurring in at least 2% in either treatment group are presented in Table 3.

**Table 3. Treatment - Emergent Adverse Events by Body System Occurring in ≥ 2% of Subjects in the Zemplar-Treated Group of Three, Double-Blind, Placebo-Controlled, Phase 3, CKD Stage 3 and 4 Studies; All Treated Patients**

Body System <sup>a</sup> COSTART V Term	Number (%) of Subjects	
	Zemplar Capsules (n = 107)	Placebo (n = 113)
<b>Overall</b>	<b>88 (82%)</b>	<b>86 (76%)</b>
<b>Body as a Whole</b>		
Accidental Injury	49 (46%)	40 (35%)
Pain	10 (9%)	8 (7%)
Viral Infection	8 (7%)	7 (6%)
Allergic Reaction	6 (6%)	2 (2%)
Headache	5 (5%)	5 (4%)
Abdominal Pain	4 (4%)	2 (2%)
Back Pain	4 (4%)	1 (1%)
Infection	4 (4%)	4 (4%)
Asthenia	3 (3%)	2 (2%)
Chest Pain	3 (3%)	1 (1%)
Fever	3 (3%)	1 (1%)
Infection Fungal	3 (3%)	0 (0%)
Cyst	2 (2%)	0 (0%)
Flu Syndrome	2 (2%)	1 (1%)
Infection Bacterial	2 (2%)	1 (1%)
<b>Cardiovascular</b>		
Hypertension	27 (25%)	19 (17%)
Hypotension	7 (7%)	4 (4%)
Syncope	5 (5%)	3 (3%)
Cardiomyopathy	3 (3%)	1 (1%)
Congestive Heart Failure	2 (2%)	5 (4%)
Myocardial Infarct	2 (2%)	0 (0%)
Postural Hypotension	2 (2%)	0 (0%)
<b>Digestive</b>		
Diarrhea	29 (27%)	31 (27%)
Nausea	7 (7%)	5 (4%)
Vomiting	6 (6%)	4 (4%)
Constipation	6 (6%)	5 (4%)
Gastroenteritis	4 (4%)	4 (4%)
Dyspepsia	3 (3%)	3 (3%)
Gastritis	2 (2%)	2 (2%)
Rectal Disorder	2 (2%)	4 (4%)
<b>Hemic and Lymphatic System</b>		
Hemolytic Anemia	4 (4%)	10 (9%)
Hypervolemia	2 (2%)	4 (4%)
Ecchymosis	2 (2%)	4 (4%)

## (Continued..)

Body System <sup>a</sup> COSTART V Term	Number (%) of Subjects	
	Zemplar Capsules (n = 107)	Placebo (n = 113)
<b>Overall</b>	<b>88 (82%)</b>	<b>86 (76%)</b>
<b>Metabolic and Nutritional Disorders</b>		
Edema	24 (22%)	34 (30%)
Uremia	7 (7%)	5 (4%)
Gout	4 (4%)	6 (5%)
Dehydration	3 (3%)	1 (1%)
Acidosis	2 (2%)	1 (1%)
Hyperkalemia	2 (2%)	3 (3%)
Hyperphosphatemia	2 (2%)	4 (4%)
Hypoglycemia	2 (2%)	4 (4%)
Hypokalemia	2 (2%)	1 (1%)
<b>Musculoskeletal</b>		
Arthritis	12 (11%)	9 (8%)
Leg Cramps	5 (5%)	1 (1%)
Myalgia	2 (2%)	5 (4%)
<b>Nervous</b>		
Dizziness	18 (17%)	12 (11%)
Vertigo	5 (5%)	4 (4%)
Depression	5 (5%)	0 (0%)
Insomnia	3 (3%)	2 (2%)
Neuropathy	2 (2%)	1 (1%)
<b>Respiratory</b>		
Pharyngitis	26 (24%)	25 (22%)
Rhinitis	11 (10%)	12 (11%)
Bronchitis	5 (5%)	4 (4%)
Cough Increased	3 (3%)	2 (2%)
Sinusitis	3 (3%)	1 (1%)
Epistaxis	2 (2%)	1 (1%)
Pneumonia	2 (2%)	0 (0%)
<b>Skin and Appendages</b>		
Rash	17 (16%)	10 (9%)
Pruritus	6 (6%)	3 (3%)
Skin Ulcer	3 (3%)	0 (0%)
Skin Hypertrophy	2 (2%)	0 (0%)
Vesiculobullous Rash	2 (2%)	1 (1%)
<b>Special Senses</b>		
Amblyopia	9 (8%)	11 (10%)
Retinal Disorder	2 (2%)	0 (0%)
<b>Urogenital System</b>		
Urinary Tract Infection	10 (9%)	10 (9%)
Kidney Function Abnormal	3 (3%)	1 (1%)

a. Includes all patients with events in that body system.

Potential adverse effects of Zemplar Capsules are, in general, similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms of hypercalcemia associated with vitamin D overdoses include:

**Early:** Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, and metallic taste.

**Late:** Anorexia, weight loss, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, puritus, hyperthermia, decreased libido, elevated BUN, hypercholesterolemia, elevated AST and ALT, ectopic calcification, hypertension, cardiac arrhythmias, somnolence, death, and, rarely, overt psychosis.

## OVERDOSE

Excessive administration of Zemplar Capsules can cause hypercalcemia, hypercalciuria, and hyperphosphatemia, and over suppression of PTH (see **WARNINGS**).

### Treatment of Overdosage

The treatment of acute overdosage of Zemplar Capsules should consist of general supportive measures. If drug ingestion is discovered within a relatively short time, induction of emesis or gastric lavage may be of benefit in preventing further absorption. If the drug has passed through the stomach, the administration of mineral oil may promote its fecal elimination. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low-calcium diet are also indicated in accidental overdosage. Due to the relatively short duration of the pharmacological action of paricalcitol, further measures are probably unnecessary. If persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives that may be considered depending on the patient's underlying condition. These include the use of drugs such as phosphates and corticosteroids, as well as measures to induce an appropriate forced diuresis.

Ref: 03-5368-R1

Revised: May, 2005

05E-131-J612-2 MASTER

**PROFESSIONAL BRIEF SUMMARY**  
**CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

# Zemplar®

(paricalcitol) Injection

Fliptop Vial

Rx only

## INDICATIONS AND USAGE

Zemplar is indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease Stage 5.

## CONTRAINDICATIONS

Zemplar should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any ingredient in this product (see **WARNINGS**).

## WARNINGS

Acute overdose of Zemplar may cause hypercalcemia, and require emergency attention. During dose adjustment, serum calcium and phosphorus levels should be monitored closely (e.g., twice weekly). If clinically significant hypercalcemia develops, the dose should be reduced or interrupted. Chronic administration of Zemplar may place patients at risk of hypercalcemia, elevated Ca x P product, and metastatic calcification.

Treatment of patients with clinically significant hypercalcemia consists of immediate dose reduction or interruption of Zemplar therapy and includes a low calcium diet, withdrawal of calcium supplements, patient mobilization, attention to fluid and electrolyte imbalances, assessment of electrocardiographic abnormalities (critical in patients receiving digitalis), hemodialysis or peritoneal dialysis against a calcium-free dialysate, as warranted. Serum calcium levels should be monitored frequently until normocalcemia ensues.

Phosphate or vitamin D-related compounds should not be taken concomitantly with Zemplar.

## PRECAUTIONS

### General

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar. A dynamic bone lesions may develop if PTH levels are suppressed to abnormal levels.

### Information for the Patient

The patient should be instructed that, to ensure effectiveness of Zemplar therapy, it is important to adhere to a dietary regimen of calcium supplementation and phosphorus restriction. Appropriate types of phosphate-binding compounds may be needed to control serum phosphorus levels in patients with chronic kidney disease (CKD) Stage 5, but excessive use of aluminum containing compounds should be avoided. Patients should also be carefully informed about the symptoms of elevated calcium (see **ADVERSE REACTIONS**).

### Laboratory Tests

During the initial phase of medication, serum calcium and phosphorus should be determined frequently (e.g., twice weekly). Once dosage has been established, serum calcium and phosphorus should be measured at least monthly. Measurements of serum or plasma PTH are recommended every 3 months. An intact PTH (iPTH) assay is recommended for reliable detection of biologically active PTH in patients with CKD Stage 5. During dose adjustment of Zemplar, laboratory tests may be required more frequently.

### Drug Interactions

Paricalcitol is not expected to inhibit the clearance of drugs metabolized by cytochrome P450 enzymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1, or CYP3A nor induce the clearance of drug metabolized by CYP2B6, CYP2C9 or CYP3A.

Specific interaction studies were not performed with Zemplar Injection.

A multiple dose drug-drug interaction study with ketoconazole and paricalcitol capsule demonstrated that ketoconazole approximately doubled paricalcitol AUC<sub>0-∞</sub>. Since paricalcitol is partially metabolized by CYP3A and ketoconazole is known to be a strong inhibitor of cytochrome P450 3A enzyme, care should be taken while dosing paricalcitol with ketoconazole and other strong P450 3A inhibitors including azatazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole.

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar.

### Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, an increased incidence of uterine leiomyoma and leiomyosarcoma was observed at subcutaneous doses of 1, 3, 10 mcg/kg (2 to 15 times the AUC at a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The incidence rate of uterine leiomyoma was significantly different than the control group at the highest dose of 10 mcg/kg.

In a 104-week carcinogenicity study in rats, there was an increased incidence of benign adrenal pheochromocytoma at subcutaneous doses of 0.15, 0.5, 1.5 mcg/kg (<1 to 7 times the exposure following a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The increased incidence of pheochromocytomas in rats may be related to the alteration of calcium homeostasis by paricalcitol.

Paricalcitol did not exhibit genetic toxicity *in vitro* with or without metabolic activation in the microbial mutagenesis assay (Ames Assay), mouse lymphoma mutagenesis assay (L5178Y), or a human lymphocyte cell chromosomal aberration assay. There was also no evidence of genetic toxicity in an *in vivo* mouse micronucleus assay. Zemplar had no effect on fertility (male or female) in rats at intravenous doses up to 20 mcg/kg/dose [equivalent to 13 times the highest recommended human dose (0.24 mcg/kg) based on surface area, mg/m<sup>2</sup>].

### Pregnancy

Pregnancy Category C.

Paricalcitol has been shown to cause minimal decreases in fetal viability (5%) when administered daily to rabbits at a dose 0.5 times the 0.24 mcg/kg human dose (based on surface area, mg/m<sup>2</sup>) and when administered to rats at a dose 2 times the 0.24 mcg/kg human dose (based on plasma levels of exposure). At the highest dose tested (20 mcg/kg 3 times per week in rats, 13 times the 0.24 mcg/kg human dose based on surface area), there was a significant increase of the mortality of newborn rats at doses that were maternally toxic (hypercalcemia). No other effects on offspring development were observed. Paricalcitol was not teratogenic at the doses tested.

There are no adequate and well-controlled studies in pregnant women. Zemplar should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

### Nursing Mothers

Studies in rats have shown that paricalcitol is present in the milk. It is not known whether paricalcitol is excreted in human milk. In the nursing patient, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

### Pediatric Use

The safety and effectiveness of Zemplar were examined in a 12-week randomized, double-blind, placebo-controlled study of 29 pediatric patients, aged 5-19 years, with end-stage renal disease on hemodialysis and nearly all had received some form of vitamin D prior to the study. Seventy-six percent of the patients were male, 52% were Caucasian and 45% were African-American. The initial dose of Zemplar was 0.04 mcg/kg 3 times per week, based on baseline iPTH level of

less than 500 pg/mL, or 0.08 mcg/kg 3 times a week based on baseline iPTH level of ≥ 500 pg/mL, respectively. The dose of Zemplar was adjusted in 0.04 mcg/kg increments based on the levels of serum iPTH, calcium, and Ca x P. The mean baseline levels of iPTH were 841 pg/mL for the 15 Zemplar-treated patients and 740 pg/mL for the 14 placebo-treated subjects. The mean dose of Zemplar administered was 4.6 mcg (range: 0.8 mcg – 9.6 mcg). Ten of the 15 (67%) Zemplar-treated patients and 2 of the 14 (14%) placebo-treated patients completed the trial. Ten of the placebo patients (71%) were discontinued due to excessive elevations in iPTH levels as defined by 2 consecutive iPTH levels > 700 pg/mL and greater than baseline after 4 weeks of treatment.

In the primary efficacy analysis, 9 of 15 (60%) subjects in the Zemplar group had 2 consecutive 30% decreases from baseline iPTH compared with 3 of 14 (21%) patients in the placebo group (95% CI for the difference between groups –1%, 63%). Twenty-three percent of Zemplar vs. 31% of placebo patients had at least one serum calcium level > 10.3 mg/dL, and 40% vs. 14% of Zemplar vs. placebo subjects had at least one Ca x P ion product > 72 (mg/dL)<sup>2</sup>. The overall percentage of serum calcium measurements > 10.3 mg/dL was 7% in the Zemplar group and 7% in the placebo group; the overall percentage of patients with Ca x P product > 72 (mg/dL)<sup>2</sup> was 8% in the Zemplar group and 7% in the placebo group. No subjects in either the Zemplar group or placebo group developed hypercalcemia (defined as at least one calcium value > 11.2 mg/dL) during the study.

### Geriatric Use

Of the 40 patients receiving Zemplar in the three phase 3 placebo-controlled CKD Stage 5 studies, 10 patients were 65 years or over. In these studies, no overall differences in efficacy or safety were observed between patients 65 years or older and younger patients.

### ADVERSE REACTIONS

Zemplar has been evaluated for safety in clinical studies in 454 CKD Stage 5 patients. In four, placebo-controlled, double-blind, multicenter studies, discontinuation of therapy due to any adverse event occurred in 6.5% of 62 patients treated with Zemplar (dosage titrated as tolerated) and 2.0% of 51 patients treated with placebo for 1 to 3 months. Adverse events occurring with greater frequency in the Zemplar group at a frequency of 2% or greater, regardless of causality, are presented in the following table:

Adverse Event Incidence Rates For All Treated Patients In All Placebo-Controlled Studies		
Adverse Event	Zemplar (n=62) %	Placebo (n=51) %
<b>Overall</b>	71	78
<b>Body as a Whole</b>		
Chills	5	0
Feeling unwell	3	0
Fever	5	2
Flu	5	4
Sepsis	5	2
<b>Cardiovascular</b>		
Palpitation	3	0
<b>Digestive System</b>		
Dry mouth	3	2
Gastrointestinal bleeding	5	2
Nausea	13	8
Vomiting	8	4
<b>Metabolic and Nutritional Disorders</b>		
Edema	7	0
<b>Nervous System</b>		
Light-headedness	5	2
<b>Respiratory System</b>		
Pneumonia	5	0

A patient who reported the same medical term more than once was counted only once for that medical term.

Safety parameters (changes in mean Ca, P, Ca x P) in an open-label safety study up to 13 months in duration support the long-term safety of Zemplar in this patient population.

Potential adverse events of Zemplar Injection are, in general, similar to those encountered with excessive vitamin D intake. Signs and symptoms of vitamin D intoxication associated with hypercalcemia include:

**Early**  
Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, and metallic taste.

**Late**  
Anorexia, weight loss, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, hypercholesterolemia, elevated AST and ALT, ectopic calcification, hypertension, cardiac arrhythmias, somnolence, death, and rarely, overt psychosis.

**Adverse events during post-marketing experience:** Taste perversion, such as metallic taste, and allergic reactions, such as rash, urticaria, pruritus, facial and oral edema rarely have been reported.

### OVERDOSE

Overdosage of Zemplar may lead to hypercalcemia, hypercalciuria, hyperphosphatemia, and/or suppression of PTH. (see **WARNINGS**).

### Treatment of Overdosage and Hypercalcemia

The treatment of acute overdosage should consist of general supportive measures. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low calcium diet are also indicated in acute overdosage.

General treatment of hypercalcemia due to overdosage consists of immediate suspension of Zemplar therapy, institution of a low calcium diet, and withdrawal of calcium supplements. Serum calcium levels should be determined at least weekly until normocalcemia ensues. When serum calcium levels have returned to within normal limits, Zemplar may be reinitiated at a lower dose. If persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives that may be considered. These include the use of drugs such as phosphates and corticosteroids as well as measures to induce diuresis. Also, one may consider dialysis against a calcium-free dialysate.

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# 2008 – 2009 Annual Report

## Renal Dietitians Dietetic Practice Group (RPG)

**MISSION:** RPG members are a valued source of expertise in nephrology nutrition.

**VISION:** RPG is leading the future of dietetics by promoting and supporting ADA members working in nephrology practice.

### STRATEGIC PLAN:

- Promote and increase an engaged, diverse membership that is actively involved with renal nutrition
- Encourage quality nutrition care in Chronic Kidney Disease by providing opportunities for professional education and development of effective patient educational materials
- Define scope of practice and standards of professional performance for dietitians in nephrology practice
- Stimulate, support, encourage and disseminate nephrology nutrition-related research
- Impact regulatory and legislative issues related to nephrology nutrition

### Member Benefits Include

- Subscription to the *Renal Nutrition Forum* (RNF), a quarterly peer reviewed publication
- Access to the members only section of the Renal Dietitians Web site: [www.renalnutrition.org](http://www.renalnutrition.org), which features archived issues of the RNF, downloadable forms and applications, CPEU tracking, and other topics of interest to renal dietitians
- Access to the Lending Library which enables members to check out current texts and other materials free of charge, except for shipping costs. The library contains texts that are recommended for review for the Certified Specialist in Renal Nutrition (CSR) exam
- Educational scholarships for advanced degrees and stipends for attending professional conferences. See Awards-Grants-Scholarships at [www.renalnutrition.org](http://www.renalnutrition.org) for details

- Networking opportunities through the Area Coordinators, RPG events at the Food & Nutrition Conference & Expo (FNCE) and collaboration on projects within the RPG and with the National Kidney Foundation Council on Renal Nutrition
- Opportunities for involvement in RPG projects such as writing articles or as a peer reviewer for the RNF, providing technical expertise on projects or suggestions for new projects

### 2008-2009 Key RPG Projects

**Awards:** 2008 Outstanding Service Award recipient – Karen Basinger MS, RD, LD, for her significant efforts and representation of renal dietitians as RPG's Legislative/Reimbursement Chair

### Media

- Quarterly RNF
- Through our peer reviewed publication, the RNF, and the Web site, [www.renalnutrition.org](http://www.renalnutrition.org), members can receive free professional development and continuing professional education units (CPEU)
- RPG is a recognized provider of CPEU by the Commission on Dietetic Registration. In the 2008 - 09 membership year, members had the opportunity to earn **10 CPEUs**

### Electronic Communications

- The RPG Web site, [www.renalnutrition.org](http://www.renalnutrition.org) features a variety of professional resources, including the opportunity to receive RNF continuing professional education hours online
- Member eblasts on RPG timely topics
- Member eblasts that provide a preview of the upcoming issue of RNF
- Online Membership Survey
- Web site with free CPEUs

### Meetings with RPG Representation

- RPG Transitional Leadership Meeting
- ADA Leadership Institute
- ADA House of Delegates

# RPG Annual Report...

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- Priority session at FNCE, 2008 – “Nutritional Management of the Patient with Acute Kidney Injury and Chronic Kidney Disease” was presented by Marcia Kalista Richards, MPH, RD, CNSC, LDN
- Pre-FNCE 2008 Workshop on MNT: Train for the Chronic Kidney Disease Medical Nutrition Therapy Triathlon

## Public Policy & Reimbursement

- ADA Public Policy Workshop
- Centers for Medicaid & Medicare (CMS) Stakeholder meetings
- National Kidney Disease Education (NKDEP) focus groups
- ADA Reimbursement Workshop
- Roundtable discussion conducted with NKDEP and renal dietitians on how to increase early nutrition intervention with CKD patients

## Networking Membership Reception

This networking event was held at the American Dietetic Association FNCE in Chicago, 2008. The keynote speaker was Karen Basinger, Outstanding Service Award recipient, who provided an update on legislative activities. Industry partners were also recognized.

## Professional Development Project

- **CSR Review Pre-Conference Workshop** – March 25, 2009, Nashville, held prior to the National Kidney Foundation Spring Clinical Meeting.
- **Nutrition Care Process** – Published a series of articles in the RNF on the Nutrition Care Process in Nephrology Nutrition Practice and provided a webinar on the Nutrition Care Process in October 2009.

## Joint Projects with the National Kidney Foundation/ Council of Renal Nutrition

Standards of Practice / Standards of Professional Performance published in the Journal of the American Dietetic Association, September 2009

*A Clinical Guide to Nutrition Care in Kidney Disease, 2<sup>nd</sup> Edition*, undergoing revision

Collaborated with National Kidney Foundation Council on Renal Nutrition on implementation of the Nutrition Care Process into Nephrology Practice. Published a series of articles in the RNF on the Nutrition Care Process in Nephrology Nutrition Practice.

## Industry Sponsors

- Abbott Nutrition
- Abbott Renal Care
- Amgen
- National Nutrition
- Nephrotech

## Collaborations

- National Kidney Foundation Council on Renal Nutrition
- National Kidney Disease Education Program

## Financial Outcomes

- Revenues totaled: \$100,112.00
- Expenses totaled: \$129,991.00

RPG ended the year with net assets of \$186,677.00.

**Join more than 2,000 kidney health care professionals at the beautiful Walt Disney World Swan & Dolphin Hotels in Orlando, Florida.**

At the National Kidney Foundation 2010 Spring Clinical Meetings, April 13–17, you'll be part of information-filled courses, practical workshops, well-argued debates and thought-provoking symposia. Engage in stimulating activities for new, non-renal and advanced practice dietitians. You'll take home insights you can apply in your practice right away!

**Don't miss these informative sessions:**

- Inflammation and Wasting Syndrome in Nutrition and CKD and HD
- Regulations and Oversight: Protecting Nephrology RD Practice
- Standards of Performance and the New CMS Guidelines
- Cutting Edge Research in Nephrology Nutrition
- Beyond KDOQI Nutrition 2000 - Where Does the Evidence Take Us?
- Top Chef: CKD/Vegetarian Challenge
- Phosphorus and Cardiovascular Disease in Non-ESRD Populations
- Diabetes and Dialysis, Round Table Controversies, including:  
Gastropathy in Patients with DM and CKD, IDPN & IPN & Managing Reimbursement for CKD Education
- Diabesity, GI Issues and the Bariatric CKD Patient
- Ethical Issues Affecting the Dietitian
- And so MUCH MORE!!!

For additional program information or to register, visit [www.nkfclinicalmeetings.org](http://www.nkfclinicalmeetings.org)  
or call 212.889.2210. Email questions to [clinicalmeetings@kidney.org](mailto:clinicalmeetings@kidney.org).



RPG is pleased to announce  
the 2009 Outstanding Service Award recipient  
**Catherine (Cathy) Goeddeke-Merickel, MS, RD, LD**

Cathy's dedication to the RPG has spanned over numerous years and multiple positions including: Chair, Secretary, Renal Nutrition Forum Editor and Web site Editor. Cathy served as one of the members representing RPG on the joint ADA-RPG/NKF-CRN project of the Standards of Practice (SOP) & Standards of Professional Practice (SOPP) which was published in both JREN and JADA in September of 2009. Her work with the RPG Web site has been extensive. Cathy helped secure the [www.renalnutrition.org](http://www.renalnutrition.org) URL and has been instrumental in the relaunch of the new web site format, design, and content. She continues to help expand and improve the web site. One of the new member benefits now offered is CPEUs that can be completed and recorded online as a result of Cathy's vision, dedication and hard work with the web site.

Congratulations Cathy!



Adding Sensipar® now?  
**Good thinking.**

**81%**  
of dialysis patients achieved PTH treatment goal when starting Sensipar® at  
**iPTH 300–500 pg/mL<sup>1</sup>**

Waiting until now?  
**Think again.**

**22%**  
of dialysis patients achieved PTH treatment goal when starting Sensipar® at  
**iPTH > 800 pg/mL<sup>1</sup>**

Sensipar® simultaneously lowers<sup>2</sup>  
  
**Sensipar®**  
(cinacalcet) Tablets  
30mg-60mg-90mg

**Sensipar® is indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease (CKD) on dialysis.**

**Important Safety Information**

Significant reductions in calcium may lower the threshold for seizures. Secondary hyperparathyroidism (HPT) patients, particularly those with a history of seizure disorder, should be carefully monitored for the occurrence of low serum calcium or symptoms of hypocalcemia.

In Sensipar® postmarketing use, isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia were reported in patients with impaired cardiac function. The causal relationship to Sensipar® therapy could not be completely excluded and may be mediated by reductions in serum calcium levels.

Sensipar® lowers serum calcium; therefore, it is important that patients have a serum calcium  $\geq 8.4$  mg/dL when initiating therapy.

Adynamic bone disease may develop if intact parathyroid hormone (iPTH) levels are suppressed below 100 pg/mL.

Patients with moderate to severe hepatic impairment should be monitored throughout treatment with Sensipar®, as cinacalcet exposure assessed by area under the curve (AUC) was higher than in patients with normal hepatic function.

Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months.

The most commonly reported side effects were nausea, vomiting, and diarrhea.

**References:** 1. Moe SM, Chertow GM, Coburn JW, et al. Achieving NKF-K/DOQI™ bone metabolism and disease treatment goals with cinacalcet HCl. *Kidney Int.* 2005;67:760-771. 2. Sensipar® (cinacalcet) prescribing information, Amgen.

**Please see brief summary of prescribing information on next page.**

**Brief Summary****See package insert for full prescribing information****SENSIPAR® (cinacalcet) Tablets****INDICATIONS AND USAGE**

Sensipar® is indicated for the treatment of secondary hyperparathyroidism in patients with Chronic Kidney Disease on dialysis.

**CONTRAINDICATIONS**

Sensipar® is contraindicated in patients with hypersensitivity to any component(s) of this product.

**WARNINGS**

**Seizures:** In three clinical studies of CKD patients on dialysis, 5% of the patients in both the Sensipar® and placebo groups reported a history of seizure disorder at baseline. During the trials, seizures (primarily generalized or tonic-clonic) were observed in 1.4% (9/656) of Sensipar®-treated patients and 0.4% (2/470) of placebo-treated patients. Five of the nine Sensipar®-treated patients had a history of a seizure disorder and two were receiving anti-seizure medication at the time of their seizure. Both placebo-treated patients had a history of seizure disorder and were receiving anti-seizure medication at the time of their seizure. While the basis for the reported difference in seizure rate is not clear, the threshold for seizures is lowered by significant reductions in serum calcium levels. Therefore, serum calcium levels should be closely monitored in patients receiving Sensipar®, particularly in patients with a history of a seizure disorder (see PRECAUTIONS, Hypocalcemia).

**Hypotension and/or Worsening Heart Failure:** In postmarketing safety surveillance, isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia have been reported in patients with impaired cardiac function, in which a causal relationship to Sensipar® could not be completely excluded and which may be mediated by reductions in serum calcium levels. Clinical trial data showed hypotension occurred in 7% of Sensipar®-treated patients and 12% of placebo-treated patients, heart failure occurred in 2% of both Sensipar®- and placebo-treated patients.

**PRECAUTIONS****General**

**Hypocalcemia:** Sensipar® lowers serum calcium, and therefore patients should be carefully monitored for the occurrence of hypocalcemia. Potential manifestations of hypocalcemia include paresthesias, myalgias, cramping, tetany, and convulsions. Sensipar® treatment should not be initiated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL). Serum calcium should be measured within 1 week after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium should be measured approximately monthly (see DOSAGE AND ADMINISTRATION). If serum calcium falls below 8.4 mg/dL but remains above 7.5 mg/dL, or if symptoms of hypocalcemia occur, calcium-containing phosphate binders and/or vitamin D sterols can be used to raise serum calcium. If serum calcium falls below 7.5 mg/dL, or if symptoms of hypocalcemia persist and the dose of vitamin D cannot be increased, withhold administration of Sensipar® until serum calcium levels reach 8.0 mg/dL, and/or symptoms of hypocalcemia have resolved. Treatment should be re-initiated using the next lowest dose of Sensipar® (see DOSAGE AND ADMINISTRATION). In the 26-week studies of patients with CKD on dialysis, 66% of patients receiving Sensipar® compared with 25% of patients receiving placebo developed at least one serum calcium value < 8.4 mg/dL. Less than 1% of patients in each group permanently discontinued study drug due to hypocalcemia. Sensipar® is not indicated for CKD patients not on dialysis. In CKD patients with secondary HPT not on dialysis, the long-term safety and efficacy of Sensipar® have not been established. Clinical studies indicate that Sensipar®-treated CKD patients not on dialysis have an increased risk for hypocalcemia compared to Sensipar®-treated CKD patients on dialysis, which may be due to lower baseline calcium levels. In a phase 3 study of 32 weeks duration and including 404 subjects (302 cinacalcet, 102 placebo), in which the median dose for cinacalcet was 60 mg at the completion of the study, 80% of Sensipar®-treated patients experienced at least one serum calcium value < 8.4 mg/dL compared to 5% of patients receiving placebo.

**Adynamic Bone Disease:** Adynamic bone disease may develop if iPTH levels are suppressed below 100 pg/mL. One clinical study evaluated bone histomorphometry in patients treated with Sensipar® for one year. Three patients with mild hyperparathyroid bone disease at the beginning of the study developed adynamic bone disease during treatment with Sensipar®. Two of these patients had iPTH levels below 100 pg/mL at multiple time points during the study. In the three 6-month, phase 3 studies conducted in CKD patients on dialysis, 11% of patients treated with Sensipar® had mean iPTH values below 100 pg/mL during the efficacy-assessment phase. If iPTH levels decrease below the NKF-K/DOQI recommended target range (150–300 pg/mL)\* in patients treated with Sensipar®, the dose of Sensipar® and/or vitamin D sterols should be reduced or therapy discontinued. **Hepatic Insufficiency:** Cinacalcet exposure as assessed by AUC<sub>0-48h</sub> in patients with moderate and severe hepatic impairment (as indicated by the Child-Pugh method) were 2.4 and 4.2 times higher, respectively, than that in normals. Patients with moderate and severe hepatic impairment should be monitored throughout treatment with Sensipar® (see CLINICAL PHARMACOLOGY, Pharmacokinetics and DOSAGE AND ADMINISTRATION). **Information for Patients:** It is recommended that Sensipar® be taken with food or shortly after a meal. Tablets should be taken whole and should not be divided. **Laboratory Tests: Patients with CKD on Dialysis with Secondary Hyperparathyroidism:** Serum calcium and serum phosphorus should be measured within 1 week and iPTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months (see DOSAGE AND ADMINISTRATION). All iPTH measurements during the Sensipar® trials were obtained using the Nichols IRMA. In patients with end-stage renal disease, testosterone levels are often below the normal range. In a placebo-controlled trial in patients with CKD on dialysis, there were reductions in total and free testosterone in male patients following six months of treatment with Sensipar®. Levels of total testosterone decreased by a median of 15.8% in the Sensipar®-treated patients and by 0.6% in the placebo-treated patients. Levels of free testosterone decreased by a median of 31.3% in the Sensipar®-treated patients and by 16.3% in the placebo-treated patients. The clinical significance of these reductions in serum testosterone is unknown. **Drug Interactions and/or Drug/Laboratory Test Interactions:** See CLINICAL PHARMACOLOGY, Pharmacokinetics and Drug Interactions. Effect of Sensipar® on other drugs: Drugs metabolized by cytochrome P450 2D6 (CYP2D6): Sensipar® is a strong in vitro, as well as in vivo, inhibitor of CYP2D6. Therefore, dose adjustments of concomitant medications that are predominantly metabolized by CYP2D6 (e.g., metoprolol and carvedilol) and particularly those with a narrow therapeutic index (e.g., flecaïnide, vinblastine, thioridazine and most tricyclic antidepressants) may be required. Desipramine: Concurrent administration of cinacalcet (90 mg) with desipramine (50 mg) increased the exposure of desipramine by 3.6 fold in CYP2D6 extensive metabolizers. Amitriptyline: Concurrent administration of 25 mg or 100 mg cinacalcet with 50 mg amitriptyline increased amitriptyline exposure and noramitriptyline (active metabolite) exposure by approximately 20% in CYP2D6 extensive metabolizers. Midazolam: There were no significant differences in the pharmacokinetics of midazolam, a CYP3A4 and CYP3A5 substrate, in subjects receiving 90 mg cinacalcet once daily for 5 days and a single dose of 2 mg midazolam on day 5 as compared to those of subjects receiving 2 mg midazolam alone. This suggests that cinacalcet would not affect the pharmacokinetics of drugs predominantly metabolized by CYP3A4 and CYP3A5. Effect of other drugs on Sensipar®: Sensipar® is metabolized by multiple cytochrome P450 enzymes, primarily CYP3A4, CYP2D6, and CYP1A2. Ketoconazole: Sensipar® is metabolized in part by CYP3A4. Co-administration of ketoconazole, a strong inhibitor of CYP3A4, increased cinacalcet exposure following a single 90 mg dose of Sensipar® by 2.3 fold. Dose adjustment of Sensipar® may be required and PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, erythromycin, itraconazole; see DOSAGE AND ADMINISTRATION).

**Carcinogenesis, Mutagenesis, and Impairment of Fertility: Carcinogenicity:** Standard lifetime dietary carcinogenicity bioassays were conducted in mice and rats. Mice were given dietary doses of 15, 50, 125 mg/kg/day in males and 30, 70, 200 mg/kg/day in females (exposures up to 2 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). Rats were given dietary doses of 5, 15, 35 mg/kg/day in males and 5, 20, 35 mg/kg/day in females (exposures up to 2 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). No increased incidence of tumors was observed following treatment with cinacalcet. **Mutagenicity:** Cinacalcet was not genotoxic in the Ames bacterial mutagenicity assay or in the Chinese Hamster Ovary (CHO) cell HGPRT forward mutation assay and CHO cell chromosomal aberration assay, with and without metabolic activation or in the *in vivo* mouse micronucleus assay. **Impairment of Fertility:** Female rats were given oral gavage doses of 5, 25, 75 mg/kg/day beginning 2 weeks before mating and continuing through gestation day 7. Male rats were given oral doses 4 weeks prior to mating, during mating (3 weeks) and 2 weeks post-mating. No effects were observed in male or female fertility at 5 and 25 mg/kg/day (exposures up to 3 times

those resulting with a human oral dose of 180 mg/day based on AUC comparison). At 75 mg/kg/day, there were slight adverse effects (slight decreases in body weight and food consumption) in males and females. **Pregnancy Category C:** In pregnant female rats given oral gavage doses of 2, 25, 50 mg/kg/day during gestation no teratogenicity was observed at doses up to 50 mg/kg/day (exposure 4 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). Decreased fetal body weights were observed at all doses (less than 1 to 4 times a human oral dose of 180 mg/day based on AUC comparison) in conjunction with maternal toxicity (decreased food consumption and body weight gain). In pregnant female rabbits given oral gavage doses of 2, 12, 25 mg/kg/day during gestation no adverse fetal effects were observed (exposures less than with a human oral dose of 180 mg/day based on AUC comparisons). Reductions in maternal food consumption and body weight gain were seen at doses of 12 and 25 mg/kg/day. In pregnant rats given oral gavage doses of 5, 15, 25 mg/kg/day during gestation through lactation no adverse fetal or pup (post-weaning) effects were observed at 5 mg/kg/day (exposures less than with a human therapeutic dose of 180 mg/day based on AUC comparisons). Higher doses of 15 and 25 mg/kg/day (exposures 2-3 times a human oral dose of 180 mg/day based on AUC comparisons) were accompanied by maternal signs of hypocalcemia (peri-parturient mortality and early postnatal pup loss), and reductions in postnatal maternal and pup body-weight gain. Sensipar® has been shown to cross the placental barrier in rabbits. There are no adequate and well-controlled studies in pregnant women. Sensipar® should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Lactating Women:** Studies in rats have shown that Sensipar® is excreted in the milk with a high milk-to-plasma ratio. It is not known whether this drug is excreted in human milk. Considering these data in rats and because many drugs are excreted in human milk and because of the potential for clinically significant adverse reactions in infants from Sensipar®, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the lactating woman. **Pediatric Use:** The safety and efficacy of Sensipar® in pediatric patients have not been established. **Geriatric Use:** Of the 1136 patients enrolled in the Sensipar® phase 3 clinical program, 26% were ≥ 65 years old, and 9% were ≥ 75 years old. No differences in the safety and efficacy of Sensipar® were observed in patients greater or less than 65 years of age (see DOSAGE AND ADMINISTRATION, Geriatric Patients).

**ADVERSE EVENTS**

**Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease on Dialysis:** In 3 double-blind placebo-controlled clinical trials, 1126 CKD patients on dialysis received study drug (656 Sensipar®, 470 placebo) for up to 6 months. The most frequently reported adverse events (incidence of at least 5% in the Sensipar® group and greater than placebo) are provided in Table 1. The most frequently reported events in the Sensipar® group were nausea, vomiting, and diarrhea.

**Table 1. Adverse Event Incidence (≥ 5%) in Patients On Dialysis**

Event*	Placebo n=470 (%)	Sensipar® n=656 (%)	Event*	Placebo n=470 (%)	Sensipar® n=656 (%)
Nausea	19	31	Hypertension	5	7
Vomiting	15	27	Asthenia	4	7
Diarrhea	20	21	Anorexia	4	6
Myalgia	14	15	Pain Chest, Non-Cardiac	4	6
Dizziness	8	10	Access Infection	4	5

\*Included are events that were reported at a greater incidence in the Sensipar® group than in the placebo group.

The incidence of serious adverse events (29% vs. 31%) was similar in the Sensipar® and placebo groups, respectively. **12-Month Experience with Sensipar®:** Two hundred and sixty-three patients from 2 phase 3 studies continued to receive Sensipar® or placebo treatment in a 6-month double-blind extension study (12-month total treatment duration). The incidence and nature of adverse events in this study were similar in the two treatment groups, and comparable to those observed in the phase 3 studies. **Postmarketing Experience with Sensipar®:** Rash, hypersensitivity, diarrhea and myalgia have been identified as adverse reactions during post-approval use of Sensipar®. Isolated, idiosyncratic cases of hypotension, worsening heart failure, and/or arrhythmia have been reported in Sensipar®-treated patients with impaired cardiac function in postmarketing safety surveillance. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. **Laboratory Values:** Serum calcium levels should be closely monitored in patients receiving Sensipar® (see PRECAUTIONS and DOSAGE AND ADMINISTRATION).

**OVERDOSAGE**

Doses titrated up to 300 mg once daily have been safely administered to patients on dialysis. Overdosage of Sensipar® may lead to hypocalcemia. In the event of overdosage, patients should be monitored for signs and symptoms of hypocalcemia and appropriate measures taken to correct serum calcium levels (see PRECAUTIONS). Since Sensipar® is highly protein bound, hemodialysis is not an effective treatment for overdosage of Sensipar®.

**DOSAGE AND ADMINISTRATION**

Sensipar® tablets should be taken whole and should not be divided. Sensipar® should be taken with food or shortly after a meal. Dosage must be individualized. **Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease on Dialysis:** The recommended starting oral dose of Sensipar® is 30 mg once daily. Serum calcium and serum phosphorus should be measured within 1 week and PTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Sensipar® should be titrated no more frequently than every 2 to 4 weeks through sequential doses of 60, 90, 120, and 180 mg once daily to target iPTH consistent with the NKF-K/DOQI recommendation for CKD patients on dialysis of 150–300 pg/mL. PTH levels should be assessed no earlier than 12 hours after dosing with Sensipar®. Sensipar® can be used alone or in combination with vitamin D sterols and/or phosphate binders. During dose titration, serum calcium levels should be monitored frequently and if levels decrease below the normal range, appropriate steps should be taken to increase serum calcium levels, such as by providing supplemental calcium, initiating or increasing the dose of calcium-based phosphate binder, initiating or increasing the dose of vitamin D sterols, or temporarily withholding treatment with Sensipar® (see PRECAUTIONS).

**Special Populations: Geriatric patients:** Age does not alter the pharmacokinetics of Sensipar®; no dosage adjustment is required for geriatric patients. **Patients with renal impairment:** Renal impairment does not alter the pharmacokinetics of Sensipar®; no dosage adjustment is necessary for renal impairment. **Patients with hepatic impairment:** Cinacalcet exposures, as assessed by AUC<sub>0-48h</sub>, in patients with moderate and severe hepatic impairment (as indicated by the Child-Pugh method) were 2.4 and 4.2 times higher, respectively, than in normals. In patients with moderate and severe hepatic impairment, PTH and serum calcium concentrations should be closely monitored throughout treatment with Sensipar® (see CLINICAL PHARMACOLOGY, Pharmacokinetics and PRECAUTIONS). **Drug Interactions:** Sensipar® is metabolized in part by the enzyme CYP3A4. Co-administration of ketoconazole, a strong inhibitor of CYP3A4, caused an approximate 2-fold increase in cinacalcet exposure. Dose adjustment of Sensipar® may be required and PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, erythromycin, itraconazole; see CLINICAL PHARMACOLOGY, Pharmacokinetics and PRECAUTIONS).

**Storage:** Store at 25°C (77°F); excursions permitted to 15–30°C (59–86°F). [See USP controlled room temperature]. Rx Only: This product, or its use, may be covered by one or more US Patents including US Patent Nos. 6313146, 6211244, 6031003 and 6011068, in addition to others, including patents pending.

**References:** 1. National Kidney Foundation: K/DOQI clinical practice guidelines: bone metabolism and disease in chronic kidney disease. American Journal of Kidney Disease 42:S1-S201, 2003



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MC43218-B-1

# Article Review

## Oral Protein Supplementation Alone Improves Anabolism in a Dose-Dependent Manner in Chronic Hemodialysis Patients.

Sundell MB, Cavanaugh KL, Wu P,  
Shintani A, Hakim RM, Ikzler TA.

*Journal of Renal Nutrition.*

2009;19(5)412-421.

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A positive net protein anabolic effect, reversing protein wasting associated with chronic hemodialysis (HD), was shown in six Vanderbilt HD patients with either 60-mL and 30-mL doses of Pro-Stat\* administered one time in conjunction with HD. The higher dose resulted in a more robust net protein anabolic response both in whole-body and skeletal muscle compartments.

Supplementation with Pro-Stat significantly decreased acute protein breakdown with some concurrent improvement in acute protein synthesis without reported side-effects. This is in contrast to other studies based on combination protein, carbohydrate and fat ("mixed diet") supplementation, which also decreased protein wasting but often with patient intolerance due to symptoms of bloating and diarrhea. The improved tolerance with the use of amino acids alone is thought to be due to significantly lower volume and absence of high carbohydrate and fat content (of common oral supplements). However, authors point out that theirs was a one-time administration and repetitive administrations may lead to some inconvenience.

The primary outcome of this study was NET PROTEIN BALANCE (protein synthesis minus protein breakdown). Both whole-body protein and skeletal muscle turnover were measured, with amino acids grouped into branched chain, essential, non-essential and total for statistical comparisons. Pre-HD, during HD and post-HD periods were also compared.

The three protocols were no supplement (control), two 30-mL doses or two 60-mL doses administered in a random, prospective, crossover design. The first dose was given at the initiation of HD

and the second dose 30 minutes after HD was initiated. The six patients participated in all three protocols with at least 4 weeks between treatments for isotope clearance. Changes in the amino-acid and protein results along with insulin concentration and plasma glucose concentration were compared statistically among protocols.

The control protocol resulted in a substantial release of amino acids from the forearm (catabolic state), which was greatly reduced by both Pro-Stat protocols and was to some extent reversed to a positive state during the 60-mL protocol. Whole-body protein metabolism showed differences during the different time periods and three protocols but a stronger anabolic response for the 60-mL supplementation was observed.

These one-time acute results are interesting and certainly could improve nutritional status of many HD patients if they are shown to be applicable longer term, to larger populations of patients and in patients with co-morbidities such as inflammation, congestive heart failure, coronary artery disease or diabetes mellitus, which are common in the HD population. ◆

\* Pro-Stat (Medical Nutrition USA, Inc, Englewood, NJ) is a high-nitrogen containing, enzyme-hydrolyzed, tryptophan-fortified, collagen protein supplement.

In the spirit of "thinking green"  
the *Renal Nutrition Forum*  
will be offered in an  
electronic only version  
for the Spring 2010 issue.

If you do not have computer access  
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425 North Front St.  
Apartment #424  
Columbus, OH 43215

# What is Quality Dietetics?

## Do RDs Practice It? How Do Dietetics Practitioners Know the Activities They Are Authorized to Perform?

**Sharon McCauley, MS, MBA, RD, LDN, FADA and Cecily Byrne, MS, RD, LDN**

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*Reprinted with permission from the Fall 2009 Dep-Line; Dietetic Educators of Practitioners (DEP) DPG*

Quality is about providing safe, effective, patient/resident/client-centered, timely, efficient, and equitable dietetics care. These six dimensions of quality are outlined in a report by the committee on the Quality of Health Care in America (1). Overall, the report makes an urgent call for fundamental change to close the quality gap, recommends a redesign of the American health care system, and provides overarching principles for specific direction for policymakers, health care leaders, clinicians, regulators, purchasers, and others. The report urges these health care constituencies to commit to a national statement of purpose for the health care system as a whole. In making this commitment, the parties would accept as their explicit purpose “to continually reduce the burden of illness, injury, and disability, and to improve the health and functioning of the people of the United States (1).

### What Steps Must Be Taken to Provide Quality Dietetics Care?

RDs in all practice settings must review and understand federal and state regulations, accreditation standards (if applicable to their facility or service), their facility policies and procedures, and their individual scope of practice. RDs must read the regulations and interpretive guidelines of the Centers for Medicare & Medicaid Services (CMS) - Conditions of Participation for their respective practice setting. RDs must know the federal and state licensure requirements for food and dietetics service personnel, the food and dietetics service standards, laws and regulations, and their

state practice acts to locate what, if any, legal scope of practice is defined within the state where they are employed.

RDs must also note their accreditation standards (if applicable) that their facility or practice setting utilizes to ensure they are providing quality care. These accreditation standards are aligned with the CMS Services - Conditions of Participation and its regulations for food and dietetic services. Accreditation organizations are: The Joint Commission, Healthcare Facilities Accreditation Program of the American Osteopathic Association, DNV-National Integrated Accreditation for Healthcare Organizations, and the Public Health Accreditation Board.

Next, RDs must know their facility policies and procedures in order to perform effectively within medical executive approved disease and condition specific protocols that outline standing nutrition orders. RDs must determine and approve, along with the Medical Executive Director or Board, their formulary of therapeutic diet orders for the patients/residents/clients under their nutrition care. RDs who demonstrate competency at the advanced practice level may then apply to obtain clinical privileging in their facilities to perform medical level tasks.

### How Do RDs Know That They Are Able to Apply for Privileges within Their Facility?

According to CMS, clinical privileging “is a process by which the governance of the hospital, specifically the governing body and the medical staff, develop and implement a process to ensure safe and quality patient care” (2). Practitioners, including RDs, must demonstrate competence of medical level tasks (e.g., ordering therapeutic diets, ordering parenteral nutrition) to obtain and maintain clinical privileges. Obtaining clinical privileges for RDs depends on the RD’s legal scope of practice, medical staff bylaws in the facility, culture of the facility, and the RD’s competency level (2).

### How is Scope of Practice Defined?

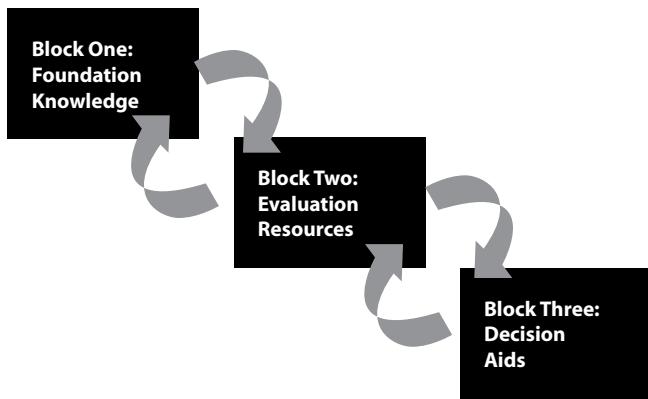
Scope of practice is defined by The University of California at San Francisco’s Center for the Health Professions as, “legal scopes of practice for the health care professions establish which professionals may provide which health care services, in which settings, and under which guidelines or parameters. With a few exceptions, determining scopes of practice is a state-based activity. State legislatures consider and pass practice acts, which are referred to as statute, law, or code. State regulatory agencies, such as medical or other health professions’ boards, implement laws by writing and enforcing rules and regulations detailing the acts” (3).

# What is Quality Dietetics?

Each RD must know his/her individual scope of practice and should be performing at his/her highest level to provide best quality care. How does an RD determine this level? By using the ADA Scope of Dietetics Practice Framework to determine his/her own individual scope of practice and verify if he/she is qualified to do what he/she has been hired to do. What competencies has the RD obtained? Does the RD accept responsibility and accountability for his/her own nutrition care actions? Bottom-line –**Quality begins with competency.**

The ADA Scope of Dietetics Practice Framework is designed to assist the RD with determining whether a service is within his/her own scope of practice. RDs will not find a laundry list of services and skills a dietetics practitioner can do. Lists tend to limit practice. Scope of practice is a fluid concept. It changes as knowledge, the healthcare environment, and technology expand. Dietetics practitioners must possess the knowledge, skills, and competencies to perform their duties; therefore, scope of practice comes down to the competency of the individual dietetics practitioner and his/her particular practice setting (4).

The Framework is divided into three blocks: foundation knowledge, evaluation resources, and decision aids.



Block Two – Evaluation Resources – comprises the Standards of Practice (SOP) in Nutrition Care and Standards of Professional Performance (SOPP) for RDs and DTRs which are a guide for self-evaluation (5). The SOP in Nutrition Care and SOPP for RDs and DTRs are minimum competence levels for RDs and DTRs in all practice settings. Practice specific SOP and SOPP identify generalist, specialty, and advanced levels of practice within a particular practice area (e.g., education, pediatrics, management, sports dietetics, etc). RDs and DTRs can use the SOP and SOPP to determine their individual competency level, determine areas where skills need to be developed, and devise a professional development plan to advance their level of practice.

RDs must provide evidence-based, quality dietetics practice. An RD's practice must be measured, documented, and reported as

part of their performance improvement program to verify quality services and demonstrate value through outcome, process, and structural measures. How involved are RDs in their quality team or quality and safety committee at their facility or practice setting? Quality is not going away – it is being taken to the next level as demonstrated in our future federal and state health care reform (6). Be prepared to measure your performance, be patient/resident/client-centered driven! RDs must decide on how to be included in measurement, as measurement will predict quality and quality will receive compensation for nutrition care services. **Do It Right the First Time: Quality Dietetics Practice is the RD and DTR.** ◆

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3. Dower C, Christian S, O'Neil E. Promising scope of practice models for the health professions. The Center for the Health Professions at University of California San Francisco Web site. Available at [http://futurehealth.ucsf.edu/Content/29/2007-12\\_Promising\\_Scope\\_of\\_Practice\\_Models\\_for\\_the\\_Health\\_Professions.pdf](http://futurehealth.ucsf.edu/Content/29/2007-12_Promising_Scope_of_Practice_Models_for_the_Health_Professions.pdf). Accessed September 1, 2009.
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# RPG Awards, Grants and Scholarships

Are you aware of the awards, grants and scholarships available to you as a member of the Renal Dietitians Dietetics Practice Group (RPG)? The following two individuals are past winners of the Outstanding Service award (OSA). Volunteering has been an important part of their careers in dietetics. As you read through their stories, take some time and think how you could use your skills and talents to become more involved. Consider volunteering, and you will reap benefits that you never dreamed of! Contact one of your RPG officers to see how you can get involved or consider nominating an RPG member for the OSA. Complete the form found in the Award/Stipend section of the RPG web site and submit it with a current resume or curriculum vitae and a one-page biographical sketch to the RPG Award chairperson. All applications must be received by April.

## **Maureen McCarthy, MPH, RD, CSR, LD OSA Recipient 2001**

Volunteerism is most definitely a 2-way street. The volunteer gives and the volunteer gets. Or maybe it is a superhighway, because there are many intersections with other givers and other recipients. It is impossible to overstate the richness of interactions that are possible, especially when one considers the options at local, regional and national levels—the people one will meet and the places one will go, both literally and figuratively. And, every one of those interactions brings rewards as described.

## **Pathway to Volunteerism**

At each step of a career—finishing one's internship, starting a new job, changing directions with a second degree or a job change—it is particularly helpful to look around and identify an organization with which to volunteer. My first volunteer experience was with the Interagency Nutrition Council (INC) of Santa Clara County, after finishing a master's in public health in the mid-seventies. The contacts I made within the INC gave me a great introduction to the public health nutrition community, which was new to me at that time in my career. Later, after another move, I became involved as a legislative liaison with the district dietetic association in my new community. In both of these situations, I gained skills and professional contacts that enriched my commitment to my profession and increased my productivity at work.

## **Benefits for the Volunteer**

Advantages to the volunteer include:

- New skills, improved skills—These skills enrich your personal life and your workplace abilities.
- Networking—at this point, it is breathtaking and humbling to contemplate the multitude of friends that volunteer activities have given me.

- Peer review—No matter what the project, one has opportunities to offer constructive peer review and to receive the benefits of the same.
- Praise—It is not uncommon to receive praise from peers for accomplishments in the work setting that might not be recognized there!
- Meeting our leaders—This adds a rich human element to the professional association within which one volunteers.
- Participating in change—Rather than be the target of change “from above,” volunteers can help to direct change, making it more likely to meet the diversity of needs within the profession.
- Knowledge—Knowledge is power, and volunteerism brings one to the front lines of cutting edge developments in the field.

## **Benefits for Others**

The profession, professional associations, and the public all gain from volunteerism. A diverse volunteer base can only strengthen an organization. It is wonderful to realize that some of my volunteer colleagues over the decades are today's leaders. In addition, I have been able to participate in breaking developments in nephrology nutrition and in related public policy. That in itself is highly motivating to continue working to give back to our profession!

## **Laura Byham-Gray, PhD, RD OSA Recipient 2000 and 2006**

I became active in RPG after submitting a few articles for the *Renal Nutrition Forum* in 1991-1992. I was then asked to consider stepping into the role of Assistant Editor, and the mentorship I gained by the RPG Executive Board at that time empowered me to continue serving the RPG for nearly a decade as Editor, Membership Chair, Chair-Elect, Chair, and Past-Chair. I can honestly tell you that such volunteer service not only impacted my dietetics practice but also made an incredible influence on me personally. Over the course of these many years, I have built and have continued to build wonderful friendships and expansive professional networks. I cannot emphasize the importance of giving to your professional organizations as it will come-back to you 100-fold!

I was fortunate enough to earn the Outstanding Service Award granted by the RPG twice; once in 2000 and again in 2006. I am and continue to be humbled to receive such national recognition, and I never take these accolades lightly. These awards are confirmation that I am making a difference for our profession and field of renal nutrition. I am hopeful that my contributions will positively impact future practice for renal dietitians. ◆

# Renal Dietitians Chair Message

**Patricia Williams, RD, CSR, LDN**

RPG Chair



Having just finished reading the latest issue of the Forum, I am reminded how many outstanding dietitians we have in the nephrology community. I am impressed with the willingness to share knowledge and expertise. I am also reminded of what it felt like to be a new nephrology dietitian. I missed the camaraderie of having a group of dietitians in the hospital to sit down with each morning before work to discuss ideas, problem cases, and solutions. Although at that time there were about six other dietitians in our company, I felt like I was alone being the only dietitian in two dialysis clinics. I was a sponge soaking up all the information I could find and one of the first things I did was join the Renal Dietitians Dietetic Practice Group (RPG) and the Council of Renal Nutrition (CRN). I found that being a member of the RPG was a great choice and a bargain. I began to read the articles in the *Renal Nutrition Forum* and at that time we didn't get as many opportunities for CPEUs, but I gained lots of valuable information. I learned that I got back more from my membership than I paid and began to see the benefit of being a member of a professional organization. I was no longer a lone dietitian in a clinic as I had years of experience and knowledgeable fellow members to help me grow. You are one of 2200 plus members

this year. It is hard to imagine the amount of talent and expertise we have in our organization. I know today, many nephrology dietitians are employed by large corporations and have a great support system. However, the membership in RPG gives dietitians the opportunity to work together for the common good of all patients and for our profession.

A good example is the new Standards of Practice and Standards of Professional Performance (SOP/SOPP), a joint effort between RPG and CRN. The committee of dietitians who worked on this project represented different areas of renal nutrition and several corporations. As a result of the many hours of hard work by these outstanding nephrology dietitians, we have an excellent set of standards available. The SOP/SOPP will be useful in determining career level, developing a plan for advancement, and demonstrating the value of the nephrology dietitian to employers. A copy of the SOP/SOPP can be found on the RPG or ADA Web sites.

Political action is another area where being a member of a larger group is important. Health reform is constantly in the news. It is great to know that while I am working, ADA employees in policy, advocacy, and government relations are busy keeping abreast of important issues. Issues that need action are posted on the ADA Web site. I can make my voice known by contacting my elected officials. As an ADA member, I can make a difference. As a member of ADA and RPG, you can make a difference as well. ◆

# CRN Chairperson Message

**Karen Wiesen, MS, RD, LD**

CRN Chair

Learning is a lifelong process, whether it is for personal or professional reasons. Working in medicine requires us to constantly stay abreast of new research and changes in the field. The role of the renal dietitian continues to expand to meet the needs of the renal community. With the September 2009 publication of the *Standards of Practice and Standards of Professional Performance for Dietitians in Nephrology Care* we now have a framework to help us evaluate ourselves and our practice. It also guides us in deciding the next step in our professional development.

Are you a generalist dietitian motivated to move into the specialty realm? Are you ready to practice at an advanced level? Whatever direction you choose, you will be able to find lectures that will stimulate and inform at the National Kidney Foundation Spring Clinical Meeting to be held at Walt Disney World April 14-17, 2010.

Two pre-conference workshops are planned. "Foundations of Nutrition Practice for Kidney Disease (Strategies I)" is for the generalist or new renal dietitian who wishes to strengthen their basic knowledge. The "Advanced Practice in Renal Nutrition Update" is designed to integrate new research into clinical practice and foster critical thinking strategies with the goal being to improve patients outcomes. This workshop will include presentations on: phosphate additives in the food supply, the relationship of micronutrients, uric acid and the metabolic syndrome, high fructose corn syrup, and the nutrition interventions.

The regular program will include a Diabetes Track, Round Table Controversies, a session on Chronic Kidney Disease and the Vegetarian Challenge, Ethical Issues for the RD, Vitamin and Micronutrient Deficiencies in Chronic Kidney Disease and many more diverse topics.

When you are done learning, remember that play and laughter are also just as important in keeping your mind and spirit healthy. What better place to bring out the child in you than Disney World? I'm going to Disney World. Are you? ◆

# 2009-2010 RPG Executive Committee

**Mission:** Renal dietitians dietetic practice group is leading the future of dietetics by promoting and supporting its members working in nephrology nutrition.

**Vision:** RPG members are a valued source of expertise in nephrology nutrition.

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## RNF Guidelines for Authors

**Article length:** Article length is determined by the Editor for each specific issue. The feature article (including abstract) is approximately 3000 words (not including tables/graphs). Other articles are usually 1000-1500 words; member highlights and reports are approximately 400-500 words.

**Text format:** Times New Roman font, 12 point, double space.

**Tables/illustrations:** Tables should be self-explanatory. All diagrams, charts and figures should be camera-ready. Each should be accompanied by a title and brief caption that clearly explains the table, chart, diagram, figure, illustration, etc.

**References:** References should be cited in the text in consecutive order parenthetically. At the end of the text, each reference should be listed in order of citation. The format should be the same as the *Journal of the American Dietetic Association*.

### Reference citation examples:

#### Article in periodical:

Knower WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Eng J Med*. 2002;346:393–403.

#### Book:

Institute of Medicine. *Dietary Reference Intakes: Applications for Dietary Assessment*. Washington, DC.: National Academy Press; 2001.

#### Chapter in a book:

Walsh J. Which insulin to use and how to start. In: *Using Insulin*. San Diego, Calif.: Torry Pines Press; 2003.

#### Web site:

Medscape drug info. Available at [www.medscape.com/druginfo](http://www.medscape.com/druginfo). Accessed Feb. 3, 2004.

**Author information:** List author with first name, middle initial (if any), last name, professional suffix and affiliation below the title of the article. Also include the primary author's complete contact information including affiliation, phone, fax and email address.

*All submissions for publication should be submitted to the editor as an email attachment (MS Word file). The feature articles from the Renal Nutrition Forum will be posted on the Members Only Section of the RPG website (password protected). Thus, please include a brief abstract along with feature article submissions.*

Stacey C. Phillips, RD  
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