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In This Issue:

Feature Article:

The Impact of Alternative Medicine Therapies on the Nutrition and Well-being of the Chronic Kidney Disease (CKD) Stage 5 Patient

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This article has been approved for 2 CPE units and the CPEU insert can be accessed in the Members Only Section of the website from the CPEU Inserts link.

Introduction

There are limited studies available on the use of alternative medicine therapies in CKD stage 5 patients, and little known about the effects of botanical medicines in this population. In these patients, malnutrition has been linked with both depression and cardiovascular disease. The purpose of this article is to examine how depression and cardiovascular disease may have ties to the malnutrition in this population, and review possible alternative medicine therapy options.

Depression in the CKD Stage 5 Population

Depression is the most common psychological problem in dialysis patients, and is associated with increased mortality in this group (1-3). Studies have evaluated quality of life scores from patient self assessments, and have found them to be lower than those of healthy populations (1-3).

Kalender et al. studied quality of life in CKD patients, and found that when compared to control subjects, patients on dialysis had lower scores on all dimensions of quality of life (2). Twenty-four percent of patients had depression (2). The researchers concluded that lower quality of life scores were associated with higher serum C-reactive protein (CRP, an inflammatory marker); specifically, serum CRP levels were 1.52 +/- 2.72 for patients with depression compared to 0.62 +/- 1.29 in patients that did not have depression. Patients with depression also had lower albumin levels with a mean albumin of 3.48 +/- 0.56 versus 3.75 +/- 0.51 in non-depressed patients (2).

Micozkadioglu studied the relationship between a depressive affect and the Malnutrition Inflammation Complex Syndrome (MICS) in hemodialysis patients (3). He found that patients with a depressive affect had higher malnutrition-inflammation scores, and surmised that the cytokine response may lead to depression. Cytokines may also stimulate an inflammatory response and increase protein catabolism, thereby exacerbating malnutrition (3).

Alternative Medicine Therapies in the Treatment of Depression

Many alternative medicine treatments including the use of botanical medicines have been explored for the treatment of depression. Two botanical medicines that have been researched extensively in the treatment of depression are S-adenosyl-L-methionine (SAMe) and St. John's Wort (SJW). While these botanical medicines have

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From the Editor's Desk

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I recently visited my home state of Rhode Island and attended a reading and signing featuring the New York Times bestselling author Jodi Picoult. Some of her best known novels include "My Sister's Keeper," "Nineteen Minutes," and her latest release "Change of Heart." As a medical professional, I appreciated her remarks regarding the amount of research that she completes prior to writing each of her novels. She interviews experts in pertinent fields that pertain to the subject matter of a given book including physicians and other medical professionals. For example, one character, Lucius in "Change of Heart,"describes his CD4 count and viral load as he battles AIDS. In "My Sister's Keeper," Kate suffers from leukemia, and must undergo countless surgeries, transfusions, and bone marrow transplants. As a fictional author, Picoult creates realistic characters without sacrificing the accuracy of the medical content.

At the event, Picoult invited audience members to engage in a question and answer forum. Countless questions from loyal fans were related to the controversial themes and the realistic tone of her books. It became obvious that her novels touch people in very powerful ways. Picoult's eloquent responses enlightened the audience that as an author, she feels that it is important to challenge readers to step outside of the norm. She feels it is important to challenge the thinking of her readers on current events and issues such as the death penalty, school shooting, and sexual abuse. In fact, when asked if there are any topics that are "off limits," she responded that she would write about anything except an issue that she was personally affected by at the time. She also stressed that she carefully crafts her characters in an effort to illustrate multiple perspectives on an issue. This allows readers an opportunity to change their viewpoint during the course of the story.

This author reminded me that sometimes we need to consider "stepping out of the norm." In the field of nephrology nutrition, we may fail to consider the efficacy and benefit of alternative and botanical therapies. Lack of knowledge, unfamiliarity and unavailability of resources, lack of research with chronic kidney disease patients, and lack of FDA regulation may be some reasons for clinical professionals to be wary of recommending alternative and botanical therapies. In this issue, the feature article by Mona Soucy, RD, CSR explores the use of alternative and botanical therapies in the treatment of depression and cardiovascular disease in the chronic kidney disease population. The Advances in Practice article by Philippa Norton Feiertag MEd, RD, LD, discusses considerations regarding cardiovascular disease in the treatment of post renal transplant patients. We are pleased to offer these two articles that have been approved for a total of 3 continuing professional education units.

June 1st marks the beginning of a new year with ADA. I encourage you to renew your RPG membership during the month of May, and be sure to refer to our chair's message in this issue to take a closer look at all of the RPG member benefits. As we enter a new year, let us be open to the possibilities that new research and advancements bring to the field of nephrology nutrition and our respective clinical practices.

Jodi Picoult encourages her readers to remain receptive in considering new perspectives. Let us embrace and follow this prolific author's lead in keeping our minds open to unchartered transformations, whether large or small, personal or professional.

Aimee Zajc, RD LD

not been studied specifically in CKD stage 5 patients, they have shown positive results in the general population.

S-adenosyl-L-methionine (SAMe)

Brown and Gerbarg reviewed 16 open, uncontrolled trials, 13 randomized, double-blind, placebo-controlled trials and 19 double-blind trials comparing SAMe to other antidepressants such as imipramine, amitriptyline, chlorimipramine, nomifensine, minaprine,and desipramine (4). All but one study showed SAMe to be more effective than placebo and equivalent to the comparison antidepressant in treating major depression (4). Pancheri et al. found that SAMe exhibited similar potency to the use of imipramine in treating depression, but SAMe had fewer side-effects (5). Delle Chiaie et al. reported the results of two large multicenter trials comparing SAMe to imipramine, and found similar results (6). In a study by Alpert et al., SAMe was used as an adjunct therapy for resistant depressive disorder (7). In 30 patients treated with selective serotonin reuptake inhibitors (SSRIs) or venlafaxine who were given 800 to 1600 mg of SAMe over 6 weeks, the researchers found that patients treated with SAMe had a response rate of 50% and a remission rate of 43% (7).

It has been suggested that there may be a link between depression and folate deficiency. Fugh-Berman and Cott reviewed several studies on depressed patients and found that up to 35% of these patients had a folate deficiency (8). Folate is necessary for the synthesis of SAMe. The most serious side effect of SAMe is the reported appearance of manic symptoms in some bipolar patients (8). Other side effects are mild and may include headaches, anxiety, insomnia, diarrhea, and nausea (4). Some studies suggest SAMe helps lower levels of homocysteine (4), which is an independent risk factor for cardiovascular disease. Research on the use of SAMe in chronic kidney disease patients is scant, and the maximum safe dosage in CKD stage 5 patients is unknown.

St. John's Wort (SJW)

St. John's Wort (Hypericum perforatum) holds great promise in the treatment of mild to moderate depression. Kasper et al. conducted a double-blind, randomized placebo controlled multi-center clinical trial to assess the efficacy of SJW extract, using 600 mg and 1200 mg doses (9). Using the Hamilton Rating Scale, SJW extract was determined to be more effective than placebo in treating mild to moderate depressive disorder after 6 weeks of treatment (9). Similarly, Szegedi et al. conducted a double-blind, randomized study comparing the effectiveness of SJW to paroxetine (10). Fugh-Berman and Cott reviewed the data from 23 clinical trials and found that SJW improved depressive symptoms, and was significantly more effective than placebo (8).

The side-effect profile of SJW appears to be better than that of standard anti-depressants such as SSRIs. Insomnia, weight gain and sexual dysfunction have been reported in patients taking SSRIs. In patients taking tricyclic antidepressants, increased heart rate, blurred vision, and urinary difficulties have been reported (11). In their review of clinical trials, Fugh-Berman and Cott reported that 19.8% of patients randomized to treatment with SJW reported side effects compared to 52.8% of those on tricyclic antidepressants (8). Common side effects from SJW include nausea, heartburn, diarrhea, insomnia, fatigue and jitteriness (4). There are a few SJW-drug interactions that may be particularly relevant for dialysis patients. SJW may affect cyclosporine levels by lowering them by up to 50%. Cyclosporine is an immunosuppressive drug, which many kidney transplant patients may be prescribed. SJW may also interfere with warfarin, commonly prescribed to dialysis patients, which may lead to inadequate anticoagulation or bleeding problems (4). Lastly, the active ingredient in SJW, hypericin, is primarily excreted by the kidney. SJW should be used with caution in patients with kidney failure since they may not be able to clear its active ingredients (12).

Cardiovascular Disease in the Dialysis Population

CKD stage 5 patients are at extremely high risk for cardiovascular disease, and cardiovascular complications are the leading cause of death in patients with kidney failure (13). According to the United States Renal Data System, mortality rates due to heart disease, in CKD stage 5 patients between 45 to 64 years of age are more than three times greater than rates in the general population. The mortality rate for dialysis patients are 180.8 per 1000 patient years compared to 49.8 per 1000 patient years in the general population (14). Survival probability in the first year after a diagnosis of heart

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disease in dialysis patients is significantly lower than in the general population. After five years, dialysis patients have only approximately a quarter of the survival probability of the general population (14).

Known risk factors for cardiovascular disease include high serum lipids, elevated coagulation factors and increased platelet activation. Studies have also linked oxidative stress with cardiovascular disease (15).

Vascular calcification may be a major contributor to cardiovascular disease in dialysis patients. Calcification is an early feature of atherosclerotic plaque formation in the general population; however, it is speculated that because of calcium and phosphorus imbalances, dialysis patients experience calcification at a much earlier age and much more frequently than healthy counterparts (13).
In recent years, malnutrition and inflammation have been linked to what is now referred to as malnutrition-inflammation syndrome. This syndrome is specific to the dialysis population and largely involves the process of atherosclerotic complications.

Malnutrition-inflammation complex syndrome has been associated with decreased quality of life, and higher rates of morbidity and mortality (3,16). There are many causes of inflammation in dialysis patients, some of them specific to dialysis including vascular access infections. Other causes of inflammation include chronic heart failure and coronary artery disease (16). The inflammatory state in dialysis patients may lead to a loss of appetite and lead to catabolism of lean body mass (16).

Alternative Medicine Therapies in the Treatment of Cardiovascular Disease

There have been many studies on the use of alternative medicine therapies in the prevention and treatment of cardiovascular disease. Some of these studies have been specific to the CKD stage 5 population, and provide healthcare practitioners with information which can be applied directly to these patients.

Omega-3 Fatty Acids (n-3 fatty acids)

The use of n-3 fatty acids may have a positive affect on albumin, cardiovascular events and mortality. Kutner et al. examined the eating habits of 216 dialysis patients for three years, and found that those who consumed fish at least once per three day period were less likely to die compared to those patients who were not fish eaters (17). It was also found that individuals who consumed fish on a regular basis had higher albumin levels (17).

Svensson et al. studied n-3 fatty acid intake and incidence of cardiovascular events in 206 hemodialysis patients (18). The results indicated that n-3 fatty acids had no significant effect on all cause mortality and total cardiovascular events. However, n-3 fatty acids decreased the rate of myocardial infarction (MI) in the study population after a two year period. The reduction in MI was explained as a possible “antithrombotic, anti-inflammatory or antioxidative effect” of n-3 fatty acids (18).

Risks and side effects of fish oil intake in hemodialysis patients may include mild gastrointestinal episodes, adverse interactions with hypertensive medications, potentiated effect in combination with aspirin and other anti-coagulation problems. This is especially concerning if patients are concomitantly taking warfarin, aspirin, garlic or gingko biloba. The FDA states that the use of eicosahentaenoic (EPA) and docosahexaenoicacid (DHA) n-3 fatty acids as dietary supplements is safe as long as the amount of 3 g per day is not exceeded, but this dosage recommendation is not specific for the CKD stage 5 population (19).

Flaxseed is another rich source of long-chain n-3 polyunsaturated fatty acids. Plant derived n-3 fatty acids have been shown to reduce atherosclerotic lesions in animal models (20). It is recommended that flaxseed be taken with fairly large amounts of fluid; this may be problematic for dialysis patients who have fluid limitations (12). No studies to date have been done on flaxseed supplementation in dialysis patients.

Garlic

Garlic is another botanical medicine that may be helpful in the treatment of cardiovascular disease; unfortunately no studies have been done in the CKD stage 5 population at this time.

Budoff studied the effect of aged garlic extract on the atherosclerotic plaque burden from calcification (21). The results indicated that the plaque burden in the study group increased by only 7.5% in one year compared to 22.2% in the control group. In this study, both groups were already on statin therapy, suggesting a possible potentiated benefit of garlic (21). This is a significant study not only because it revealed the positive effect of garlic in reducing coronary calcification, but also because it demonstrated a trend in the reduction of homocysteine levels. Both

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coronary calcification and elevated homocysteine levels are known risk factors for coronary artery disease in dialysis patients. In a four year, double-blind, placebo controlled study, Koscielny et al. showed that 900 mg per day of garlic powder significantly decreased the rate of development of atherosclerosis (22). The reduced rate of plaque development ranged from 5% to 18% (22). Garlic is not recommended for patients with diabetes who have widely fluctuating blood glucose levels, as it might elicit a hypoglycemic effect (23). Garlic should also be used with caution in patients taking warfarin since garlic may increase bleeding time (12). Patients on dialysis also receive heparin during dialysis treatments, so the addition of garlic supplements can be of concern.

Soy Protein

Hyperlipidemia contributes to the high rates of cardiovascular disease in patients with CKD stage 5. The U.S. Food and Drug Administration has approved the statement that 25 grams per day of soy protein, as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease (19).

Studies have shown positive results in lowering cholesterol associated with soy protein intake in dialysis patients. One study evaluated the effect of soy protein on serum lipid profiles in hyperlipidemic and normolipidemic patients on dialysis. Researchers administered either 30 grams of isolated soy protein or milk protein to dialysis patients daily for 12 weeks. The soy protein intake was found to significantly lower total cholesterol by 18.6%, triglycerides by 43.1%, LDLs by 25.8% and increased HDLs by 17% (24). Similarly, a short-term study by Siefker and DiSilvestro showed that providing 25 grams of soy protein, four times per week for four weeks to 17 hemodialysis patients produced no harmful effects (25). In addition it was suggested that soy protein may potentially be beneficial as an antioxidant and anti-inflammatory agent (25). The results also indicated that soy protein intake was associated with reduced plasma values for oxidized low-density lipoprotein, a known risk factor for cardiovascular disease (25). They recommended further studies in this group with longer therapy intervention periods. Finally, a study by Fanti et al. demonstrated that soy protein could reduce serum CRP levels, thereby reducing the risk of the inflammatory response in hemodialysis patients (26).

However, because soy foods tend to be high in both potassium and phosphorus, adjustments may need to be made in the prescribed nutrition plans of dialysis patients who consume large amounts of soy foods.

Green Tea

Research has shown that intake of green tea may lower cholesterol and triglycerides (27). Catechin, the antioxidant present in green tea, may have a protective effect against atherosclerosis by reducing smooth muscle cell plaque proliferation (27). In dialysis patients, atherosclerosis is a prominent feature of the malnutrition-inflammation complex syndrome. Green tea may hold some promise in the hemodialysis population; however, the recommended dosage of green tea necessary to exert the cardiovascular protective effects has usually been five to six cups per day (28). This would usually exceed the recommended the fluid limitation prescribed for hemodialysis patients. The extract of green tea may be a more reasonable approach in this population. Although green tea extract may have possible drug interactions with anti-coagulants such as warfarin, therefore caution with tea extract and anti-coagulants needs to be exercised (12). In addition, a high dose of the extract for extended periods has been found to be unsafe. This can be problematic for individuals who adhere to the adage “if a little is good then more is better.”

Special Issues with Alternative Medicine Therapies in CKD Stage 5 Patients.

The use of alternative medicine therapies has not been well studied with dialysis patients. Most dialysis patients usually have a long list of prescribed medications, and it may be challenging to identify all the potential botanical medicine-drug interactions. Dialytic clearance of botanical medicines is largely unknown (29). Dahl reports that the “unpredictable pharmacokinetics” of botanical medicines in patients with kidney failure is of great concern (30). Additionally, since botanical medicines lack standardization, they pose a special problem for dietitians and other clinicians in determining safe dosages for kidney failure (30). Some botanical medicines may be adulterated with toxic levels of lead, cadmium, mercury, and even arsenic or additives such as aluminum and magnesium. Other adulterated products that have been found in botanical medicines include hormonal and glandular extracts which may negate any potential benefits of a given

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botanical. These may be extremely dangerous due to the lack of clearance by the kidney. For most of the botanical medicines and several dietary supplements discussed in this review, the safe dosage for CKD stage 5 patients is unknown since most of the research has been conducted in the general population. Many of these studies have been conducted with relatively small populations, making the statistical significance and extrapolation of the research findings to the dialysis patient challenging and difficult.

Conclusion

This article has provided a review of the relationship between alternative medicine therapies and malnutrition as it relates to the treatment of depression and cardiovascular disease in the CKD stage 5 patient. Specific concerns associated with alternative medicine therapy use in dialysis patients have also been discussed. After reviewing the clinical studies, there may be indications for the use of alternative medicine therapies in the treatment of depression. Depression has been shown to be the most common psychological problem of patients with kidney failure. There is strong evidence for the use of SJW and SAMe in the treatment of mild to moderate depression. No clinical trials on SJW and SAMe have been conducted in the CKD stage 5 population, but there have been many successful clinical trials in the general population. Dialysis patients on warfarin and transplant patients on cyclosporine should exercise caution due to possible drug-botanical medicine interactions. The side effects of SAMe and SJW have been reported as mild, therefore these two botanical medicines show promise in the dialysis population. Further studies should be conducted specifically with CKD stage 5 patients and the associated potential renal clearance concerns.

With regards to cardiovascular disease, this is a very significant problem and poses a high risk for mortality in the dialysis population. This review focused on the potential benefits of fish oils, flaxseed, garlic, soy protein and green tea in the treatment of various cardiovascular disease risks. There have been some studies done with dialysis patients on fish oils and soy in particular. Most of these studies demonstrated positive results on cardiovascular risk factors in the dialysis population but with certain limitations. It has been suggested that both can probably be safely recommended in dialysis patients as an adjunct therapy in the treatment of cardiovascular disease. Garlic, flaxeed and green tea have not been tested in clinical trials in the dialysis population; however, clinical trials in the general population have shown positive results in the treatment of cardiovascular disease. These dietary supplements and botanical medicines could possibly be used in dialysis patients.

Finally, more research needs to be done on the topic of alternative medicine therapies such as botanical medicines in the CKD stage 5 population. Some botanical medicines may have promise in the improvement of nutritional status and well-being in the dialysis population. More research in this area and expanded use of botanical medicines could lead to an improved life expectancy and a better quality of life for those patients debilitated by malnutrition.

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Nutritional Strategies for Managing Cardiovascular Disease in Adult Patients with Kidney Transplants

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This article has been approved for 1 CPE unit and the CPEU insert can be accessed in the Members Only Section of the website from the CPEU Inserts link.

Introduction

In 2006, over 17,000 kidney transplants were performed in the U.S. (1). Compared with dialysis, kidney transplantation improves patient survival and quality of life, and is the preferred treatment modality for suitable candidates with chronic kidney disease (CKD) Stage 5 (2).

Some of the benefits that follow a successful kidney transplant include correction or improvement of disturbances in carbohydrate, protein and lipid metabolism that negatively impact nutritional status in patients undergoing maintenance dialysis therapy (3). However, despite modest increases in graft survival rates during the last decade of the 20th century, kidney transplantation is not without risk (4). Increase in body weight of transplant recipients changes lipid metabolism and can contribute to development of post-transplant diabetes mellitus (5,6). Prevalence of hyperlipidemia in kidney transplant recipients is estimated at 80% to 90% and, together with obesity and post-transplant diabetes mellitus, increases the risk for cardiovascular disease and graft loss (7-9).

While immunosuppressive drugs have been linked with diabetes mellitus and hyperlipidemia in kidney transplant recipients, dietary intervention can play an important role in improving health outcomes in this population (6-8). This article will review nutritional strategies for managing cardiovascular disease in adult patients with kidney transplants.

Relationship of Obesity and Cardiovascular Disease in Kidney Transplant Recipients

Increase in energy intake following kidney transplant, resulting in weight gain of up to 10 kg within the first year post-transplant has been reported (5,10). However, overweight (body mass index or BMI 25-29.9 kg/m^2) and obesity (BMI >30 kg/ m^2) are also common at the time of kidney transplantation, with the proportion of obese transplant recipients rising by 116% between 1987 and 2001 (11).

When kidney transplantation outcomes were compared in overweight patients and patients with BMI <25 kg/m^2, the overweight group had higher total cholesterol and triglyceride levels and lower overall survival rates (12). Furthermore, obesity in kidney transplant recipients has been identified as an important modifiable variable in predicting the incidence of cardiovascular events, including myocardial infarction, peripheral vascular disease and cerebrovascular accident (13).

Effects of Dietary Intervention on Body Mass Index and Hyperlipidemia in Kidney Transplant Recipients

The increasing incidence of obesity in kidney transplant recipients and the impact of overweight and obesity on cardiovascular events have resulted in interventions directed to improve patient outcomes in this population. Treatment of 68 obese kidney transplant recipients with modified immunosuppression, statins and an individualized hypocaloric-hypolipidemic meal plan over a 24-month period resulted in a significant decrease in BMI and improvement in lipid parameters (14).

In another study, 36 stable patients were followed for 5 years after kidney transplantation (15). Patients were instructed to consume 30-35 kcal/kg/day with lipids limited to ≤30% of total energy intake and polyunsaturated to saturated fat ratio >1. Cholesterol was limited to 300 mg/day, simple sugars were eliminated and patients were encouraged to exercise daily. After 5 years, mean cholesterol and triglycerides were normalized in most patients. Females had a significant increase in body weight over the first 2 years, followed by stabilization over

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the remaining 3 years. In males, body weight decreased during the first 3 months, increased to initial values at the sixth month and subsequently remained unchanged. Weight gain in females was attributed to dramatic increase in fat mass, while body composition in males remained close to baseline values. Limitations of this study included lack of systematic dietary assessment or consultation after the first year, and failure to measure patients' activity levels.

In a study designed to determine the effects of dietary intervention on obesity rates and cardiovascular risk factors in 86 kidney transplant recipients, outcomes were compared in patients who adhered to the dietary prescription (compliant group) and those who did not (control group) (16). The prescribed diet was based on 30 kcal/kg/day with 0.7 to 0.8 g protein/kg/day, salt intake less than 5 g/day and lipids limited to ≤30% of total energy intake. Patients kept a 2-day diet diary every 2 months. Patients in the compliant group maintained or achieved adequate nutritional status, and avoided weight gain and changes in body composition. Most patients in the control group became overweight or obese. Findings from this study also indicated that controlling calorie, protein and lipid intake and encouraging physical activity had beneficial effects on lipid levels and lowered cardiovascular events.

In the general population, there is evidence that the Mediterranean diet decreases risk of death from cardiovascular disease (17,18). A modified version of the Mediterranean diet has also been found to improve lipid profiles in kidney transplant recipients without serious

Table 1
Summary of clinical studies investigating the effect of dietary intervention on body mass index (BMI) and hyperlipidemia in kidney transplant recipients.

Study Subjects	Study duration	Interventions	Study Outcomes
68 obese kidney transplant recipients	2 years	• Individualized hypocaloric-hypolipidemic meal plan • Modified immunosuppression • Statins	Significant decrease in BMI and improvement in lipid profile (14)
36 stable kidney transplant recipients	5 years	• 30-35 kcal/kg/day • Lipids ≤30% total energy intake • Polyunsaturated to saturated fat ratio >1 • ≤300mg cholesterol/day	Mean cholesterol and triglycerides normalized in most subjects. Femal subject experienced increased fat mass and initial weight gain (15)
86 kidney transplant patients with stable graft function	12 years	• 30 kcal/kg/day • Lipids ≤30% total energy intake • 0.7-0.8g protein/kg/day • Salt <5g/day	Compliant patients showed: • absence of weight gain and changes in body composition • decrease in cardiovascular events (16)
21 kidney transplant recipients following a modified Mediterranean diet and 16 on a low-fat diet isocaloric with the study diet	6 months	• Daily energy intake: 47% low glycemic index carbohydrates; 15% protein; 38% fat (10% saturated, 22% monounsaturated, 6%polyunsaturated) • Cholesterol 165±17 mg/day • Animal protein representing one-third total protein	Patients following the modified Mediterranean diet showed: • Continuous decline in total cholesterol and triglyceride levels • Significant decrease in LDL levels after 6 months (19,20)

pathologic dyslipidemia (19,20). This diet consisted of carbohydrates with low glycemic index (including cereals, rye bread, vegetables and noodles); olive oil and rapeseed oil; grains, flaxseed and nuts. Animal protein represented one-third of total protein. Carbohydrate accounted for 47% and protein comprised 15% of daily energy intake. The remaining 38% of energy intake was contributed by fatty acids (10% saturated, 22% monounsaturated and 6% polyunsaturated), and cholesterol was limited to 165±17 mg/day. Weekly menus were provided and dietary compliance was assessed monthly with 24-hour food diaries. When compared with patients in a control group consuming a low-lipid diet that was isocaloric with the study diet, patients consuming the modified Mediterranean diet showed a continuous decline in total cholesterol and triglyceride levels, and significantly lower low-density lipoprotein (LDL) levels after 6 months. No significant differences in body weight, body fat or BMI were noted in either group.

Recommendations for Managing Dyslipidemias and Cardiovascular Disease in Kidney Transplant Recipients

Clinical research studies on dietary interventions in kidney transplant recipients indicate that total cholesterol, LDL and triglyceride levels, and in some cases body weight, can be modified by limiting calorie intake and manipulating the amounts and types of carbohydrates, proteins and fatty acids consumed (14-16,19,20). Findings from these studies are summarized in Table 1. There is also evidence to suggest that incorporating exercise into the post-transplantation medical regimen can reduce hyperlipidemia and facilitate weight loss in patients who have received a kidney transplant (21).

In 2004, the Managing Dyslipidemias in Chronic Kidney Disease Work Group of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative published recommendations for the management of dyslipidemias in kidney transplant patients (22). These clinical practice guidelines recommend the implementation of therapeutic lifestyle changes including diet, weight reduction and increased physical activity to treat triglycerides ≥500 mg/dL (≥ 5.65 mmol/L) and/or LDL 100-129 mg/dL (2.59-3.34 mmol/L). Recommendations include consulting with a dietitian with expertise in chronic kidney disease for dietary management. Table 2 summarizes therapeutic lifestyle changes for adult kidney transplant recipients.

Table 2
Overview of therapeutic lifestyle modifications for adult kidney transplant recipients (22)

Diet:
Total fat: 22-35% of total calories
Saturated fat: <7% of total calories
Polyunsaturated fat: ≤10% of total calories
Monounsaturated fat: ≤20% of total calories
Cholesterol: <200 mg per day
Carbohydrate: 50-60% of total calories
Improve blood sugar control
Focus on total calories; strive to maintain standard body weight
Balance overall caloric intake with energy needs
Body mass index 25-28 kg/m^2
Physical activity:
Moderate activities of daily living
Moderate & routine physical activity:
• 3-4 times weekly; 20-30 minute intervals
• Important to Include 5 minute warm-up and cool-down
• Walking, swimming, supervised exercise; exercise within ability
• Include resistance exercise training
Habits:
Moderate alcohol intake; limit one drink per day with physician approval
Cease smoking

For the most part, treatment paradigms formulated by this Work Group reflect interventions that have promoted favorable outcomes in the clinical research studies described in this article. The Work Group also emphasized the need for controlled studies to define the importance of weight reduction and exercise in kidney transplant patients with dyslipidemias.

Conclusion

The high incidence of hyperlipidemia and resulting risk for cardiovascular disease require aggressive interventions to improve outcomes in the kidney transplant population. Renal nutrition professionals can play a key role in this process by providing medical nutrition therapy, as

➡

outlined in the NKF-K/DOQI clinical practice guidelines for managing dyslipidemias in kidney transplant patients (22). Studies directed to evaluate effects of nutrition intervention on patient outcomes have focused on the post-transplant phase. However, dialysis staff members can prepare kidney transplant candidates prior to the transplant event by providing education and behavior modification to address heart-healthy eating and weight management (23).

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    4. Hydration
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    6. Childhood Overweight
    7. Chronic Kidney Disease and Nutrition
    8. Chronic Obstructive Pulmonary Disease and Nutrition
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There is also a Chronic Kidney Disease workgroup in the initial stages of adding content to the EAL®. Questions can be directed to eal@adaevidencelibrary.com.

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Start Sensipar® before your secondary HPT patients get in too deep

iPTH 1100 pg/mL

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For a better chance of success:

Start Sensipar® at iPTH > 300 pg/mL in all appropriate patients with secondary HPT on dialysis[1]

Starting Sensipar® at iPTH levels of 300-500 pg/mL enabled more patients to simultaneously achieve the 4 key NKF-KDOQI™ secondary HPT goals[1,2*†‡]

- PTH goal[†]: 81% with Sensipar® vs 21% with control therapy ($P < 0.0001$)[1-3]
- Ca x P goal[‡]: 70% with Sensipar® vs 51% with control therapy ($P = 0.0005$)[1-3]

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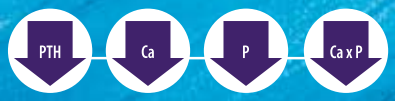

Sensipar®
(cinacalcet) Tablets
30mg · 60mg · 90mg

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

Important Safety Information: Sensipar® lowers serum calcium; therefore, it is important that patients have a serum calcium ≥ 8.4 mg/dL when initiating therapy. Significant reductions in calcium may lower the threshold for seizures. Secondary 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 and/or worsening heart failure 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.

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

Please see brief summary of Full Prescribing Information on following page.

*NKF-KDOQI™ Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease (Stage 5). †Mean iPTH ≤ 300 pg/mL. ‡Mean Ca x P < 55 mg^2/dL^2.
KDOQI™ is a trademark of the National Kidney Foundation, Inc.

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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 and/or worsening heart failure have been reported in patients with impaired cardiac function, in which a causal relationship to Sensipar® could not be completely excluded and may be mediated by reductions in serum calcium levels. Clinical trial data showed hypotension occurred in 7% of Sensipar®-treated patients, 12% of placebo-treated patients, and heart failure occurred in 2% of patients receiving Sensipar® or placebo.

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)[1] 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 $AUC_{(0\text{-}inf)}$ 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 and have a narrow therapeutic index (e.g., flecainide, 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 nortriptyline (active metabolite) exposure by approximately 20% in CYP2D6 extensive metabolizers. 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 (periparturient 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 (%)
Nausea	19	31
Vomiting	15	27
Diarrhea	20	21
Myalgia	14	15
Dizziness	8	10
Hypertension	5	7
Asthenia	4	7
Anorexia	4	6
Pain Chest, Non-Cardiac	4	6
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-six 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 and/or worsening heart failure 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 $AUC_{(0\text{-}inf)}$, 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 25ºC (77ºF); excursions permitted to 15-30ºC (59-86ºF). [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.

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Nephrology Nutrition and the Nutrition Care Process (NCP)

A Renal Nutrition Forum Series with Practice-Based Examples of the NCP

Maureen McCarthy, MPH, RD, CSR, LD and Nancy Duhaime, MS, RD, LD

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This article will introduce a series of case studies from nephrology nutrition practices. Each case study will be presented in the framework of the Nutrition Care Process (NCP) model and will be documented with standardized language (SL). The goal of the series will be to support nephrology dietitians in implementing NCP and SL.

Without some preparation prior to implementing NCP, such as Kotter's eight-step model of change described in some of the NCP resources listed on the American Dietetic Association's (ADA) web site, it is easy to be overwhelmed by barriers to change that exist in every work place (1). Laying the proper foundation for the process of change can be as important as an intellectual grasp of the proposed change.

Since the NCP was introduced, the ADA has published three manuals on an annual basis to help guide practitioners in the implementation of SL as a major component of operationalizing the NCP (2, 3-5). The latest edition, the International Dietetics and Nutrition Terminology (IDNT) Reference Manual, includes SL for nutrition diagnosis, intervention, and monitoring and evaluation (5). The specific terminology for nutrition assessment should be available later this year, and will be added to these case studies when it is introduced. Until then, assessment data will be presented as it might be written in a progress note.

There is already a strong foundation for the application of NCP in nephrology nutrition. Over 30 years ago, Kight and others developed and tested a system of nutrition diagnostic terms (6). Kelly reported her application of Kight's terminology with chronic kidney disease (CKD) stage five patients at many meetings and in numerous articles, including a report of the terms most frequently used in her practice at that time (7). This history is not offered to suggest an equivalency between Kight's terminology and ADA's SL. It demonstrates why nephrology dietitians may find the idea of nutrition diagnosis and a system of terms to consistently describe it, to be a familiar concept. Theoretically, if dietitians have access to the same information in the same context and setting, they should make similar decisions about a patient's problem, how to intervene, and what to monitor.

To support adoption of the NCP and its components, ADA has developed tutorials with narration, which explain each component of the NCP in detail for ADA members. These include practical case studies. Go to www.eatright.org and log in with user identification and password; Next:

- Select "Nutrition Care Process" in the left column
- Select "Learn More" under Practitioners
- Select "Are You Ready For Change?" for more information about managing change
- Select "How Are You Going To Get There?" for more information about NCP
  - ADA members can purchase the IDNT manual or download it as a pdf file
  - Under "Presentations", members can select the menu item for tutorials to view slide-audio files which explain NCP in general, the 4 components of the NCP and the associated terminology that is being developed to support them.

The case study that follows describes an intake assessment for a patient who has CKD stage 5 secondary to hypertension (HTN) and is just starting hemodialysis (HD). He presents with some apparent misinformation about his dietary protein requirements.

Future topics in this RNF series will include practical tips for writing nutrition diagnostic statements (problem—etiology—signs and symptoms or PES), review of the tools available on the ADA website to support implementation of NCP and related terminology, and discussions of each component of the NCP and its terminology.

CASE STUDY – New HD Patient

Lab	Results	Lab Norm	Lab	Results	Lab Norm
Potassium	4.6 mEq/L	3.5-5.5	Calcium	8.8 mg/dl	8.5-10.5
CO2	21.0 mmol/L	23-29	ADJ Calcium	9.3 mg/dL	NA
BUN	95 mg/dL	6-20	Phosphorus	5.3 mEq/L	2.5-4.5
Creatinine	9.2 mg/dL	0.7-1.5	URR*	77.0%	≥70%
Glucose	154 mg/dL	70-110	Kt/V*	0.98	NA
Albumin	3.1 g/dL	3.5-4.7	nPCR*	1.03	NA

Assessment

53 year old male with CKD stage 5 due to HTN
Dialysis Prescription: HD – 4.5 hours, 3x/week; 2 K*, 2.5 Ca* bath; access: AV* fistula
Anthropometrics: Height 157 cm; large frame; target weight 107 kg; UBW* 107 kg (pt is 100% of UBW)
SBW* 82 kg (pt is 130% of SBW); adj SBW* 101 kg
Clinical Data: History of gastro-esophageal reflux disease (GERD); no chewing or swallowing problems; independent in activities of daily living. Urine output decreasing. Pt believes low protein diet is still important for him (thinks he consumes ~45 g/day).
Usual Diet: 3 meals plus 1 snack/day, no nutrition supplements; avoids salt and salt substitutes; no appetite for several weeks prior to starting HD, significantly less oral intake than usual.
Diet before HD: low protein, low potassium, low phosphorus
Meds: 1000 mg lanthanum carbonate/meal; erythropoietin and heparin at dialysis unit; 125 mg IV iron every HD treatment; 2.5 mg glyburide/day; multivitamin every day
(*K=potassium; Ca=calcium; AV=arterio-venous; UBW-usual body weight; SBW=standard body weight; adj SBW=adjusted standard body weight; URR=urea reduction ratio; Kt/V=a measure of dialysis adequacy; nPCR=normalized protein catabolic ratio. See reference 8 for further information about anthropometric and biochemical terms in the case study.)

Diagnosis
(Problem-Etiology-Signs and Symptoms or PES)

Problem (or Diagnosis): Inadequate protein intake related to
Etiology: food and nutrition-related knowledge deficit and to recent poor appetite, as evidenced by
Signs and Symptoms: patient history and by 24-hour recall showing 50 g protein/day (compared to estimated needs = 100 g protein/day). (8)

Intervention

Nutrition Prescription: 1.2 g pro/kg adj SBW or 100 g pro/day (8); 2 g Na, 2 g K, low phosphorus
Intervention 1: Nutrition education regarding protein needs
Goal: Patient will understand the rationale of higher protein intake and know how to select foods to meet the nutrition prescription of 100 g protein/day: 70-85 g/day from meals/snacks 15-30 g/day from supplement (see goal 2)
Intervention 2: Food or nutrition delivery – recommend appropriate high protein bar/powder
Goal 2: Patient will consume appropriate supplement to add 15-30 g dietary protein/day.

Monitoring and evaluation

Indicator	Criteria
Total Protein intake	100 g protein per day (8)
Serum albumin and nPCR	Stabilize and/or increase to serum goals
Food intake	Identify and use daily acceptable protein supplement (protein bar, powder, beverage)

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Member Spotlight

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I recently attended the 28th Annual Dialysis Conference March 2 – 4 in Orlando, Florida. I had a wonderful time! This was the first national dialysis conference that I ever attended. I *wholeheartedly* recommend attending a conference like this, and if you are considering it, you will not regret it.

There were many sessions to choose from each day. The majority of sessions were excellent. There were two speakers who really stood out for me, and this was during a 4-hour session on bone and mineral metabolism. The speakers were nephrologists Daniel Coyne and Charles Nolan. Hearing Dr. Coyne and Dr. Nolan speak has forever changed the way that I will critique studies that are presented to me.

Dr Nolan's talk was titled "Revisiting the K/DOQI Clinical Practice Guidelines for Bone Metabolism in CKD." He essentially challenged the current thinking regarding the K/DOQI guidelines. Specifically, he referred to the fact that the majority of the K/DOQI guidelines are *opinion* based, and we may have accepted this information as *evidence* based.

Consider the K/DOQI calcium guideline. It's based on opinion, yet, many of us have accepted this information as evidence and included the 8.4 – 9.5 target range into our protocols. We may have switched our patients to non-calcium based phosphate binders, and added calcimetic medication to our patient's regime all based on the premise that this will result in a decreased risk of systemic calcification. The point is that we did all this based on opinion-based guidelines, as well as some recent research studies that has been suggested by numerous experts to have study design limitations which are being scrutinized. There *appears* to be a survival benefit in maintaining serum calcium between 8.4 and 10.5, but this is only association data and not prospective data.

Dr. Nolan warned us that the pharmaceutical sales force may focus on *association* data, rather than data from well-designed randomized clinical trials. Furthermore, he thought that some of the recent phosphate binder research may have design limitations that he felt were significant enough to disagree with the conclusions (Treat To Goal, RIND, DCOR). He made recommendations for future research with improved study design. I sensed that Dr Nolan is seeking sound scientific information, and is passionate about caring for patients. He tackled some tough issues head on. Dr Nolan received the most applause of any speaker I had the pleasure of listening to during the entire conference.

Final Thoughts

What's the solution to remain on the cutting edge of our clinical practice? I think we have to remember not to solely rely on the pharmaceutical sales force to educate us about caring for our patients. I believe that attending dialysis conferences routinely and having access to presentations from nephrology *experts* is critical to our success in improving outcomes. I believe that obtaining knowledge about the latest well-designed randomized controlled clinical trials is important to both the clinical practitioner and the patient.

From this point forward I will be a regular attendee of national dialysis conferences, whether it is this one again, or the National Kidney Foundation's Spring Clinical Meetings.

Education, Practice, and Research: Shaping Advanced-Level Practice

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Introduction

The primary role of the renal dietitian has evolved over the last several decades. Prior to the advent of renal replacement therapies, the renal dietitian was predominantly responsible for the procurement of specialized diets and food products in the management of kidney failure. Presently, the renal dietitian, who is an integral member of the interprofessional health care team, is critically involved in the prevention as well as the treatment of disease. Seemingly the 21st Century has moved the role of the renal dietitian away from prescribing "butter balls" towards dosing vitamin D (1). Advances in medicine and technology, and shifts in health care delivery systems, have greatly shaped the opportunities for role expansion in renal dietetics. As such, this article will briefly describe the major trends that affect renal dietetics practice, discuss the relationship of such trends with the establishment of a "scope of practice" in renal nutrition, and explore how education, practice, and research can best prepare the renal dietitian for the future.

Environmental Trends

What are the factors that shape renal dietetics practice? The American Dietetic Association, on a routine basis, conducts environmental scans that "identify, prioritize, and evaluate the trends affecting the profession of dietetics and the Association" (2). Such surveillance systems are needed in order to "identify threats and opportunities that lie ahead and develop a vision for the future" (3). The most recent environmental scan was completed by the House of Delegates from March through May of 2006 (1). This process clustered a myriad of trends around 11 common themes ranging from aging, convenience foods, obesity, information systems and communication networks, cultural diversity, economic disparities, environmental issues, alternative care, health and wellness, and science and technology advancements (4).

The practicing renal dietitian already recognizes the impact of such trends on his/her duties and responsibilities. For example, according to the latest statistics from the United States Renal Data System (USRDS), the median age for those individuals on dialysis is 64.6 years (5). Estimates project that the elderly population will have doubled by 2030 to over 70 million (6). Thus, to practice competently as a renal dietitian, it will be imperative that s/he understand the issues concerning the older adult on dialysis. Likewise, the burgeoning diversity within the United States also requires that the renal dietitian utilize culturally appropriate interventions. Lastly, not only has obesity been identified as a risk factor for disease progression, but the obese dialysis patient demands significant resources in order to be managed successfully (7, 8). Thus, future trends highlight the necessity for competent, highly skilled practitioners; this underscores the need for a scope of practice in nephrology care.

Scope of Dietetics Practice

The ADA has formulated its Scope of Dietetics Practice Framework (SODPF) Framework as a "flexible decision-making structure, empowering practitioners to provide safe, effective, timely healthcare services" (9). Essentially, the intent of the Framework is to provide a standardized process whereby the practitioner may identify the foundational knowledge s/he must possess to gain entry into the field, use evaluative tools necessary for determining competency in the selected area of practice; e.g., Standards of Practice (SOP) and Standards of Professional Performance (SOPP), and employ decision aids that define whether performing a particular act is within his/her scope (9). Additional references may be consulted that more fully explain the SODPF (9, 10).

The Future of Renal Dietetics

A number of dietetic practice groups (DPGs) have developed their own SOPs and SOPPs which outline the competencies required to practice at either the generalist, specialty, or advanced levels within the area specified (11-13). SOPs and SOPPs in nephrology care are being developed through a collaborative effort among the leadership of the Renal Dietitians Dietetic Practice Group of the ADA and the National Kidney Foundation Council on Renal Nutrition. These evaluative tools are anticipated to be published in 2008.

Given the current structure of the SODPF, renal dietitians may choose to operate at any one of these levels relative to their competency within the practice area. Typical classifications for the three levels of practice are as follows (13):

- Generalist (Novice Stage): is "new" to renal dietetics;
- Specialist (Proficient Stage): develops a deeper understanding of renal dietetics practice and is able to apply these principles and modify practice accordingly;
- Advanced (Expert Stage): attains a far more intuitive understanding of renal dietetics and his/her practice reflects a range of highly developed skills and judgments acquired through a combination of experience and education.

Regardless of how such levels are defined, clinical practice needs are dictated by environmental trends. Thus, the renal dietitian must examine ways of preparing for the future.

What's the Future?

Completing additional education and training, redefining practice, and participating in research are key elements that will expand the roles for renal dietitians. The current proposed changes in dietetics education identify the need for advancement in practice (14). Some of the key recommendations that impact renal dietetics practice include: a) flexibility concerning educational models and experiential routes to entry-level practice,; b) alternate routes of entry into the profession; c) restructuring of the Registration Examination for Dietitians; d) more formal education after five years of professional practice to expand scope of practice competently beyond entry-level or novice level; e) continued support and definition of specialty and advanced-level practice in dietetics; and f) the full integration of the dietetic technician, registered (DTR) as a valuable member of the Association. Regardless of what changes are accepted and implemented, renal dietitians must identify routes for education and training that will adequately prepare them to meet environmental trends previously described. Such preparation may or may not mean formal academic education, but may also include completing a board certification exam and/or incorporating a supervised training experience into the Professional Development Portfolio. Nonetheless, education is often tied to clinical practice. Advanced degrees, such as practice doctorates which prepare dietitians with "expert knowledge and skills, critical thinking proficiency, and aptitude in scientific inquiry to foster the development of innovative, autonomous advanced dietetics practitioners and researchers" (15), not only provide didactic learning, but also mentored clinical experiences and residencies. Practice doctorates are different from traditional PhD programs. The former trains the student to become an advanced-level practitioner in dietetics; the latter mentors the student to become an independent researcher.

Obtaining research skills by renal dietitians are critical so that changes in practice lead to improve patient outcomes. Research drives the best practices, and identifies benchmarks and outcome indicators that serve to document effectiveness. Some research topics of keen interest in nutrition and kidney disease that would further the knowledge and practice of renal nutrition include and are not limited to dialysis adequacy, novel treatment approaches, malnutrition and inflammation, and preventive nutrition in chronic kidney disease. The mortality rate among dialysis patients in the United States is higher than other European and Asian countries, despite controlling for the typical case-mix variables such as age and specific comorbidities (16). Therefore, improving the health status and outcome among patients diagnosed with chronic kidney disease is paramount.

Conclusion

The next decade in renal dietetics practice will be a dynamic one. Employment opportunities will abound, job roles will continue to expand, and advanced education and

➡

training will be required. The renal dietitian of tomorrow does not just prepare for the future but creates it!

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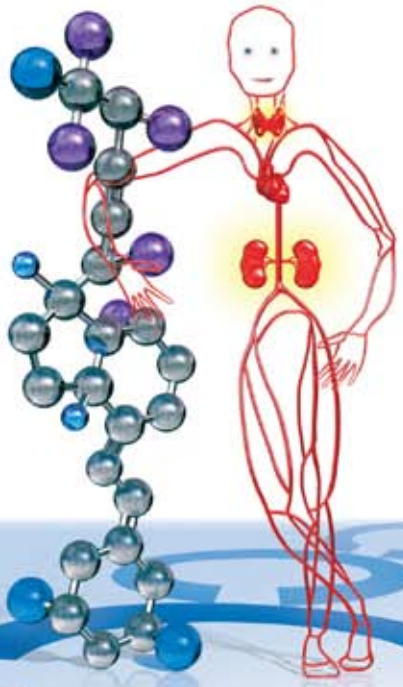

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Renal Dietitians Dietetic Practice Group 2007 - 2008 Year in Review

Lois Hill, MS, RD, CSR
RPG Chair

As I complete my term as Chair of the American Dietetic Association Renal Dietitians Dietetic Practice Group (RPG), the practice group is 2190 members strong. RPG celebrated its 30th anniversary milestone in 2007! In my final report, I will provide a brief annual report for the 2007 – 2008 activities, and review some of RPG's future endeavors.

Members are RPG's greatest resource. Walt Disney said, "You can dream, create, design and build the most wonderful place in the world…but it requires people to make the dream a reality." You can dream, create, design and build the most wonderful practice group…but it requires members, including dedicated board members with the support of an ADA Practice Team Manager to make that dream a reality. The efforts of RPG could not have been accomplished without the dedication and devotion of the entire board, and I would like to thank them.

RPG will continue to engage members in projects that benefit the entire nephrology nutrition community. RPG is committed to enhancing the value of membership, and increasing member involvement and retention.

Member Benefits Include:

➢ Quarterly subscription to the *Renal Nutrition Forum* (RNF), the peer-reviewed publication of RPG.

➢ E-blasts for RPG members regarding local/national event updates, time sensitive issues that impact out profession and a recent member survey

➢ Website – www.renalnutrition.org benefits include:

- ❖ Access to Continuing Professional Education Units (CPEUs) offered in every issue of the RNF. RPG is a recognized provider of CPEUs by the Commission on Dietetic Registration. In this membership year, members had the opportunity to earn a minimum of 2 CPEUs per issue
- ❖ Current and archived files of the RNF issues
- ❖ Compiled list of ADA's Renal related publications
- ❖ Calendar and meetings list nation-wide
- ❖ Recommended Internet links for patients and professionals
- ❖ Kidney Friendly Facts column with patient handouts and practical tips
- ❖ RPG educational materials for purchase (plans are underway for materials to be reviewed.)

➢ Educational grants and scholarships, including meeting stipends for attending approved conferences, are a member benefit. See Awards – Grants -- Scholarships at www.renalnutrition.org for details. The grants and scholarships range from $500 - $2000, and to apply one must be an RPG member for at least one year.

➢ A networking RPG membership and industry recognition breakfast is held annually at the American Dietetic Association Food & Nutrition Conference & Expo (FNCE). The Outstanding Service Award recipient and industry sponsors are recognized at this event. This past year in Philadelphia, the Outstanding Service Award winner, Cathi Martin, RD, CSR, LDN presented "Volunteering is Magic" about the rewards of volunteering.

2007-2008 Key RPG Projects

Co-planned priority session with the Medical Nutrition Practice Group at FNCE 2007: "The Nutritional and Inflammatory Evaluation in Dialysis Patients (NIED Study): What You Need to Know" was presented by Kamyar Kalantar-Zadeh, MD, PhD, MPH and Sara Coleman, RD, CSR, CDE.

➡

Renal Dietitians Chair Message

Professional Development Project:
The Second Annual CSR Review Workshop was held April 1, 2008, and will be offered again in the future.

Public Policy and Reimbursement: Advocating for nephrology nutrition and reimbursement for early CKD. RPG was represented at the Centers for Medicaid & Medicare and National Kidney Disease Education Program Meetings by Karen Basinger, MS, RD, LD, RPG, RPG Legislative and Reimbursement Chair.

RPG members collaborated with the National Kidney Disease Education Program Director, Andrew S. Narva, MD, FACP and a group of renal dietitians about how to increase early nutrition intervention with CKD patients. The roundtable discussion was the feature article in the Renal Nutrition Forum, Fall 2007.

Standard of Practice (SOP)/ Standards of Professional Practice (SOPP): Watch for an upcoming report on these projects in the Journal of the American Dietetic Association and the Journal of Renal Nutrition.

RPG collaborated with the American Dietetic Association Foundation with support and sponsorship from Abbott Nutrition to set up initial funding for a grant in the amount of $50,000 for renal disease research. The goal would be to develop some type of nutritional screening and assessment tool to identify people with chronic kidney disease (stages 1 – 5) who are at nutritional risk. See visit www.renalnutrition.org for upcoming information about the recipient of this grant and other opportunities.

Looking Ahead: RPG Strategic Plan

- Promote and increase an engaged, diverse membership that is actively involved with nephrology nutrition initiatives.
- Encourage quality nutrition care in chronic kidney disease by providing opportunities for professional education and development of effective patient education materials. Continue to collaborate with NKF CRN on implementation of the Nutrition Care Process into nephrology nutrition practice.
- Ongoing definition of the standard of practice (SOP) and standards of professional performance (SOPP) for dietitians in nephrology nutrition practice. Support of the SOP/SOPP marketing to members via the Journal of the American Dietetic Association and the Journal of Renal Nutrition. This has been a joint project with NKF CRN.
- Stimulate, support, encourage and disseminate nephrology nutrition-related research.
- Impact regulatory and legislative issues related to nephrology nutrition via attendance and representation at the Public Policy Workshop & ADA Reimbursement Workshop. Continue to collaborate with ADA Legislative & Public Policy and NKF CRN on important nutritional labeling issues related to nephrology practice.

To discover more about the RPG please visit the RPG Web Site at www.renalnutrition.org. Don't forget to renew your membership to RPG for 2008-2009!

Website Extras

Visit RPG's web site www.renalnutrition.org for:

WE NEED YOU-OUR Members!
Don't Forget to Renew your ADA and RPG Membership by May 31, 2008
www.renalnutrition.org/about/renew.php

A list of RPG members being honored by ADA for 50 yr & 50 yr plus membership:
www.renalnutrition.org/about/awards.php

Calendar/Meetings section for an extensive list of conferences & add'l CPEU opportunities:
www.renalnutrition.org/calendar/index.php

Evidence Analysis Library (EAL) information and tips for using this valuable resource:
www.renalnutrition.org/members_only/resources.php

Current & archived PDF files of the Renal Nutrition Forum (RNF) Issues & RNF CPEU Inserts
www.renalnutrition.org/members_only/forum.php

For more information about the Certification Specialty Exam in Renal (CSR)
www.renalnutrition.org/faq/index.php

To access a copy of the ADA/CDR code of ethics and reference list updates:
http://www.renalnutrition.org/resources/index.php

Member input and suggestions are a vital part of improving our member resources such as the website. Please submit your ideas and suggestions to Cathy M. Goeddeke-Merickel, Web Editor via **cmgmerickel@gmail.com**

"To give anything less than your best is to sacrifice the gift." Steve Prefontaine

FDA Food Labeling Petition – An Update from ADA and NKF

Maria Karalis, MBA, RD, LDN
CRN Chair

The American Dietetic Association (ADA) and the National Kidney Foundation (NKF) have been working together to ask the Food and Drug Administration (FDA) to mandate potassium on the Nutrition Facts (NF) label. They have also requested that potassium and calcium amounts in a serving of food be included, as well as the percent of Daily Value (%DV). ADA and NKF have also spoken with the FDA about the possibility of mandating phosphorus on the NF label.

The Nutrition Labeling and Education Act of 1990 mandated the labeling of foods with serving sizes and certain nutrients to assist "consumers in maintaining healthy dietary practices," aimed at the general public, and not at specific disease populations. Consequently, it is highly likely that the FDA will be amenable to including potassium on the NF label because the most recent edition of the Dietary Reference Intakes (DRI) and the Dietary Guidelines for Americans emphasized the need for Americans to increase potassium intake to 4700 mg per day. However, the same scientific documents did not identify a public health concern for the general population for phosphorus, and thus FDA has discouraged a mandate for it on the NF label.

In November, the FDA published an advance notice for proposed rulemaking to update the information on the NF label (based on the new DRIs). NKF and ADA spoke with FDA, and learned that their requests for mandatory labeling for potassium and including the absolute amounts of potassium and calcium would be more expeditiously reviewed if it were submitted during the public comment period. This closed on April 30, 2008.

FDA also said that decisions to list specific nutrients on the NF panel are based on scientific evidence, and not upon popular vote. It cannot take into account form letters that lack such evidence.

At the NKF Clinical Meeting in 2007, and again in 2008, Mary Hager presented the data from the patient survey that was conducted in preparation for this petition. 83% of all CKD patients surveyed stated that they read the food label for the first time before deciding to purchase that product.

A sample list of some of the phosphorus food additives and their purposes

Additive	Food Status	Purpose
Ammonium phosphate, monobasic and dibasic	GRAS/FS	Buffer & neutralizing agent
Calcium phosphate (mono-, di-) and pyrophosphate	GRAS/FS	Nutrient & misc use in cereal flours and other standardized foods
Ferric phosphate	GRAS	Nutrient/Dietary Supplement
Ferric pyrophosphate	GRAS	Nutrient/Dietary Supplement
Ferric sodium pyrophosphate	GRAS	Nutrient/Dietary Supplement
Magnesium phosphate	GRAS	Nutrient/Dietary Supplement
Sodium acid phosphate	GRAS	Sequestrant
Sodium aluminum phosphate	GRAS/FS	Miscellaneous (self-rising flours and meals; cheeses)
Sodium hypophosphite	GRAS	Emulsifier/stabilizer

GRAS: generally recognized as safe
FS: Substances permitted as optional ingredient in a standardized food

Sodium, fat and calories were the top three nutrients that patients looked for when reading the nutrition facts panel. Not surprisingly, 89% and 84% stated that potassium and phosphorus respectively, would be useful if listed.

In the meantime, what can we do to better educate CKD patients? Our educational efforts should continue to focus on teaching patients how to read a food label, particularly ingredient lists in regards to phosphorus. For example, meats that are packaged as shelf-ready contain a wide variety of additives, including phosphate salts. Sample labels of various food products can help you teach patients how to find added phosphorus sources.

Here are some additional "*phosphorus factoids*" for you and your patients, provided by Mary Hager:

Foods Naturally Rich in Phosphorus

Nearly all foods contain phosphorus, but certain foods are naturally richer sources than others. These include dairy-based foods, meats, fish, dried peas, nuts, beans and cereals. Foods derived from plant seeds (e.g., beans, peas, cereals, and nuts) contain phytic acid (also called phytate), a storage form of phosphorus that is poorly absorbed in humans (1).

Added Sources of Food Phosphorus

Any phosphate salt or other phosphorus-containing ingredient added to a food must be listed on the label. The U.S. Food and Drug Administration published an organized list of additives found in Title 21 of the Code of Federal Regulations into a single alphabetized list (2). The list also includes selected pesticide chemicals from Title 40 of the Code of Federal Regulations, Section 180, for which the Environmental Protection Agency has set tolerances in food. High intakes of polyphosphates found in additives may interfere with the absorption of iron, copper, and zinc. However, further research is necessary in this area (1).

Phosphorus in the Nutrition Fact Panel

While listing of phosphorus ingredient additions is not optional for food manufacturers, the listing of the phosphorus content of foods in the nutrition facts panel is optional. Many manufacturers have chosen to list phosphorus. For example, one international manufacturer lists 4 ounces of their yogurt product as providing 10% of the Daily Value for phosphorus. The Daily Value for phosphorus is currently 1000 mg, so the yogurt contains 100 mg of phosphorus.

When phosphorus levels are reported on the label, they would include the sum of both naturally occurring and added phosphorus.

References:

1. Institute of Medicine. *Dietary Reference Intakes*. Washington, DC.: National Academies Press; 2007.
2. U.S. Food and Drug Administration. Food additive status list. Available at http://www.cfsan.fda.gov/~dms/opa-appa.html. Accessed July 27, 2007.

AN ADA UPDATE:

The Centers for Medicare & Medicaid Services has released new rules specific for dialysis centers. These are the first major revisions made since the rules were introduced in 1976. The rules feature important updates to the minimum standards that dialysis facilities must meet in order to participate in the Medicare program. The new rules also require a renal dialysis center to have a credentialed RD who has a minimum of one year professional work experience in clinical nutrition. **For more information, visit www.cms.hhs.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf.**

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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, D.C.: 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. Accessed Feb. 3, 2004.
Author information: List author with first name, middle initial (if any), last name, professional suffix and affiliation (all in italics) 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.

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