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In This Issue

Benefits of Vitamin D Supplementation on Physical Function in Chronic Kidney Disease (CKD) Patients

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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. In addition, this CPE offering is available to current RPG members only and the expiration date is April 15, 2011.

Introduction

The CKD population is at an especially high risk for vitamin D deficiency. In one study, 78% of hemodialysis (HD) patients were found to be vitamin D deficient and 18% were severely deficient (1). Serum 25(OH) vitamin D levels of 16-30 ng/mL, 5-15 ng/mL, and <5 ng/mL are considered insufficient, mildly deficient, and severely deficient, respectively (2). As people age, CKD and vitamin D deficiency becomes more common. In older adults, low serum vitamin D levels have been associated with muscle weakness, poor physical performance, balance problems, and falls (3,4).

Vitamin D deficiency causes renal osteodystrophy, which encompasses many metabolic and morphologic abnormalities of the bone (5). These abnormalities include fractures, tendon ruptures, soft-tissue calcifications, calciphylaxis and bone pain (6-8). Further abnormalities include bone deformities, bone cysts, osteopenia, resistance to erythropoietin caused by marrow fibrosis, intractable pruritis, prearthritis, and myopathy (9). In addition, vitamin D deficiency triggers an increase in parathyroid hormone (PTH) secretion. PTH is the major regulator of bone remodeling and skeletal turnover. It promotes the development of osteoblasts and osteoclasts. As PTH levels increase, the rate of bone formation and resorption also increases. These effects result in weak bone and high-turnover skeletal lesions due to immature and structurally inferior bone (10). This condition is called secondary hyperparathyroidism and is a major component of renal osteodystrophy. Secondary hyperparathyroidism not only impairs bone function, but also has deleterious effects on lymphocytes, erythrocytes, the brain, heart, smooth muscles, and adrenal glands (11). Secondary hyperparathyroidism in HD patients is treated with intravenous active vitamin D (1,25-OH_2D_3) compounds, which reduce serum PTH levels.

R P G

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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.

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From the Editor's Desk

Stacey C. Phillips, RD
Editor

The often used expression, "Time flies when you are having fun!" seems very applicable to my term as editor, as it seems like only recently did I take over this role within the Renal Dietitians Dietetics Practice Group (RPG). Within the last year, I have had the chance to meet many new people through the recruiting of authors, work on the Forum and being involved with RPG. It is through these new connections that I have learned a great deal not only about renal nutrition, but also about the dedication and volunteerism involved in continuing to strengthen the area of nephrology nutrition.

The beginning of June marks a new calendar year with the American Dietetic Association. With tough economical times, it can be difficult to part with membership dues. At this point, I would like to highly encourage you to renew your membership with RPG. Past Forum issues have highlighted numerous membership benefits and it is an ongoing goal of the RPG Executive Committee to provide as many valuable opportunities to our members as possible. Three specific areas to be highlighted within the last year are the inclusion of webinars, the addition of an e-supplement, and also more CPEUs offered through the Forum. Each of these has come at no additional cost to members.

As we transition into a new year with RPG, you will also notice some changes within the Executive Committee. We welcome Kathy Madigan, MS, MBA, RD, CSR, LD as the RPG chair, Rachael Majorowicz, RD, LD as incoming Chair-Elect, Jane Louis, RD, CSR, LD as Secretary, Therese Shumaker, MS, RD, LD as Nominating Member and Megan Sliwa, RD, LDN will make the transition from Assistant Editor to Forum Editor.

Several different articles, each approved for 2 CPEUs, provide the content of the Spring Forum. Recently graduated Master's student Josefine Lampasona, MS, RD, along with Jack Logomarsino, PhD, RD, LDN have authored a review article detailing the effects of vitamin D and benefits on physical function in renal patients. The feature article focuses on trials completed in this area and highlights the possibilities and potential for patients within our own realm of practice.

Our Advances in Practice Article, written by Cynthia Terrill, RD, CSR, CD, covers the extensive topic of nutritional care within our pediatric renal patient population. All aspects of care for these patients from early kidney disease to dialysis and nutrition support are covered. Supporting this article is a reprint, originally published by the Pediatric Nutrition Practice Group, which reflects a case study and the medical nutrition therapy provided to the young renal patient.

Upon completion of this issue of the Forum, I officially pass on the duties of Forum Editor to Megan Sliwa, RD, LDN. It has been a pleasure serving as editor of the Forum and I sincerely appreciate all those who were supportive as I made the switch from Assistant Editor last spring. I strongly encourage anyone wishing to become more involved with RPG to contact membership chair, Danielle Frazer, RD or any member of the Executive Committee about opportunities available. As always, the chance to publish an article within the Forum is an ongoing prospect for authors of all levels. Over the past year, the Forum has been filled with articles from first time and previously published authors-each of which has provided readers with cutting edge and valuable information. It can not be said too often, that without support from RPG members the Forum would not be a success! ◆

Stacey C. Phillips, RD

Loss of skeletal muscle mass, strength, and a decrease in type II muscle fiber circumferences are associated with the frail elderly population. These are important independent predictors of disability in population-based studies linked to functional impairment, increased need for assistance in activities of daily living, risk of falls, fractures, and mortality (12). Ninety-seven percent of patients with vitamin D deficiency have muscular weakness (3). This relationship is due to the fact that a vitamin D receptor that specifically binds to 1,25(OH) vitamin D_3 exists in muscle cells (3,12). The absence of vitamin D receptors is associated with decreased muscular development in mice, suggesting that vitamin D is required for the growth and development of muscle (13).

This paper reviews current research on the benefits of vitamin D supplementation on physical function in the elderly population and discusses the potential for benefits in the CKD population.

Research Review Methods

Medline and PubMed searches were limited to articles published between 1998 through 2008. Search terms used were vitamin D, cholecalciferol, alphacalcidol, ergocalciferol, calcitriol, muscle mass, muscle strength, physical performance and elderly. The search was confined to English reports on human subjects. Length and dose of vitamin D therapy varied, as well as baseline vitamin D status, and age of patients. Review articles were also included in this report.

Studies Supporting Improved Physical Function in Elderly Subjects Supplemented with Vitamin D

Most of the current research on vitamin D supplementation related to physical function in the elderly indicates beneficial effects. Refer to Table 1 for a summary of the studies presented in this section.

In a study with ergocalciferol (vitamin D_2) supplementation, 96 elderly women with poststroke hemiplegia were randomly assigned to receive either 1000 IU ergocalciferol daily or a placebo and were followed for two years. The frequency of falls, the incidence of hip fractures, and the number, size, and strength of muscle fibers were compared. The group treated with ergocalciferol had improved serum vitamin D levels, a 59% reduction in falls ($p=0.003$), an increase in number and size of type II muscle fibers, and improved muscle strength (14). A similar study with ergocalciferol supplementation was conducted in men with advanced hormone refractory prostate cancer. Sixteen men, with a mean age of 67.5 years, were supplemented with 2,000 IU ergocalciferol/day and 500 mg calcium for 12 weeks. Seven of 16 men had decreased levels of serum vitamin D. Strength improvement was assessed by timed chair rises (testing muscle strength) and a timed ten meter walk (testing gait speed). Overall, six subjects showed consistent improvements in strength parameters (15).

Studies were conducted using supplementation of alphacalcidol, a synthetic analog of calcitriol ($1,25\text{-}OH_2D_3$). Supplementation improved muscle strength, functional mobility, and muscle mass (3,16). In one study, ten vitamin D-deficient elderly women and thirteen elderly women with normal vitamin D serum levels were treated with 0.5 mcg alphacalcidol for six months. Assessments of muscle strength and functional mobility were taken at baseline and compared with results after the 6-month intervention period. Knee extensor strength was measured as force was applied at the ankle with the subject seated in a chair, the lower leg unsupported, and the knee flexed at a 90-degree angle. The force was measured with a strain gauge, recorded with a strain meter, and the best of three attempts was documented. The walking test measured the time taken by an individual to stand up from a standard arm chair, walk a distance of three meters, turn, and walk back to the chair and sit down again. Treatment led to improvement in isometric knee extensor strength in the vitamin D-deficient group (left leg: $p= 0.03$; right leg: $p= 0.02$), as well as an increase in the walking distance over two minutes ($p= 0.03$) (3).

In another study, researchers observed the treatment effects of anabolic steroids, calcium and vitamin D supplementation after a hip fracture (16). Sixty-three women who had surgery due to a hip fracture were randomly assigned to receive treatment for one year with anabolic steroids. They were supplemented with vitamin D and calcium, or calcium only. Vitamin D (alphacalcidol 0.25 mcg) and calcium (500 mg) were administered daily. Parameters were measured by bone mineral density (BMD) and thigh muscle volume, which was measured after surgery and after 6 and 12 months; quantitative CT; and quantitative ultrasound. The group supplemented with vitamin D and calcium (anabolic group) did not lose muscle volume within the first 12 months after surgery, whereas the control group did ($p< 0.01$). The anabolic group also had a significant increase in muscle volume in the non-surgical side, and had improved BMD scores in all sites. Hip fractures commonly lead to a catabolic state and are associated with a high mortality rate. The results from this study showed that an increase in muscle volume and BMD will reduce the risk of falls, further fractures, functional dependency, generalized weakness, and mortality (16).

A study using cholecalciferol as the vitamin D supplement showed effects of increased musculoskeletal function and reduced frequency of falls (17). In a double-blind randomized control trial, 122 vitamin D-deficient women, ages 63-99 years, residing in long-stay geriatric care centers were supplemented with vitamin D and calcium. Participants received 1200 mg calcium per day in

Table 1
Studies that Support Improved Physical Function in Elderly Subjects Supplemented with Vitamin D

Author	Subjects	Vitamin D Status	Groups	Supplement	Duration	Outcome Measures	Findings	Study Limitations
Sato and colleagues (14)	96 Women	Deficient		1000 IU ergocalciferol /day	2 years	fall rate, hip fracture incidence, muscle fiber number and size, strength	59% decrease in falls (p=0.003)	
vanVeldhuizen and colleagues (15)	16 Men	Deficient=7 Not Deficient=9		2000 IU ergocalciferol/day 500 mg Ca^{2+}/day	12 weeks	muscle strength, gait speed	improved strength in 6 subjects	small sample size, short duration
Verhaar and colleagues (3)	23 Women	Deficient=10 Not Deficient=13		0.5 mcg alphacalcidol /day	6 months	muscle strength, functional mobility	improved knee extensor strength (left leg p= 0.03, right leg p=0.02), walking speed (p=0.03)	not placebo controlled, small sample size
Hedstrom and colleagues (16)	63 Women		vitamin D and Ca^{2+} vitamin D and anabolic steroids Ca^{2+} only	0.25 mcg alphacalcidol /day 500 mg Ca^{2+}/day	1 year	muscle mass, clinical function	vitamin D group did not lose muscle volume ($p<0.01$), increase in muscle volume on non-surgical side	
Bischoff and colleagues (17)	122 Women	Deficient	vitamin D and Ca^{2+} Ca^{2+} only	800 IU cholecalciferol/day 1200 mg Ca^{2+}/day	3 months	fall rate, gait speed, muscle strength	49% decrease in falls (p=0.01), improved muscle function (p=0.0094)	not generalizable
Gallagher and colleagues (18)	489 Women	Not Deficient	supplement placebo	0.25 mcg calcitriol BID $Ca^{2+} \leq 1000$ mg/day	3 years	fall rate	38% decrease in falls (p=0.0015)	

addition to 800 IU cholecalciferol, or 1200 mg calcium alone for three months during the winter to determine the effects of these supplements on musculoskeletal function and falls. Outcomes were measured by the number of falls during the treatment period, a timed up and go test, knee flexor strength, knee extensor strength, and grip strength. Assessments were performed at baseline and after a three-month follow-up. The vitamin D group accounted for a 49% reduction in falls (p= 0.01) and a significant improvement of musculoskeletal function in 62 women (p= 0.0094) (17).

Vitamin D supplementation appears to improve physical function even in elderly who present with adequate serum levels of vitamin D. A group of 489 vitamin D-sufficient elderly women were randomly assigned to receive 0.25 mcg calcitriol twice a day or a placebo for three years. Data on frequency of falls was collected at 6-month intervals. A 38% decrease (p= 0.0015) in fall rate was seen in the calcitriol-supplemented group at the end of the intervention period (18).

Studies Not Supporting Improved Physical Function in Elderly Subjects Supplemented with Vitamin D

Several studies showed no benefits on physical performance from vitamin D supplementation. However, it is likely that these studies did not demonstrate positive results due to limitations on study designs and methods. Refer to Table 2 for a summary of the studies presented in this section.

A randomized, double-blind, placebo-controlled study was conducted to determine if vitamin D supplementation improves neuromuscular function in older adults with fall histories. A group of 139 people, ages 65 years and older, with a history of falls and 25(OH) vitamin D deficiency were randomized to receive either a single intramuscular injection of 600,000 IU ergocalciferol or a placebo. Measurements were taken at baseline and six months after the intervention. Improvements were seen in functional performance ($p< 0.01$), choice reaction time ($p= 0.01$), and postural stability ($p= 0.02$), although both the intervention and placebo groups showed a loss of strength over the trial period. Although the number of falls may be reduced due to improved neuromuscular function, vitamin D supplementation did not improve muscle strength in this population (19).

To determine the effects of vitamin D supplementation on a healthy population, 65 men, ages 65 years or older, were randomized to receive 1000 IU cholecalciferol per day or a placebo for six months. Both groups were administered 500 mg per day of calcium. In the treatment group, serum levels of 25(OH) vitamin D increased and PTH decreased. No significant difference in strength or physical function was found between the treatment and control

Table 2
Studies that Do Not Support Improved Physical Function in Elderly Subjects Supplemented with Vitamin D

Author	Subjects	Vitamin D Status	Groups	Supplement	Duration	Outcome Measure	Findings	Limitations
Dhesi and colleagues (17)	139 Men and Women	deficient	supplement placebo	600,000 IU ergocalciferol	single dose	strength, functional performance, reaction time, stability, fall rate	decreased strength and fall rate, improved functional performance ($p<0.01$), improved reaction time ($p=0.01$), improved stability ($p=0.02$)	single, large supplement dose
Kenny and colleagues (20)	65 Men	not deficient	supplement placebo	1000 IU cholecalciferol/day 500 mg Ca^{2+}/day	6 months		increased 25(OH) vitamin D levels	did not account for seasonal change in vitamin D, not generalizable, subjects not vitamin D deficient
Faulkner and colleagues (21)	389 Women			Not stated	4 years	muscle function, fall rate	no improvement on fall rate	dose and falls self-reported, multivitamins were included as acceptable vitamin D supplements
Latham and colleagues (22)	183 Men and Women		supplement placebo	300,000 IU calciferol	single dose	fall rate	no improvement	single, large supplement dose

groups (20). A four-year randomized prospective cohort examining the relationship between vitamin D supplementation and calcitropic hormones with neuromuscular function and falls found no association with vitamin D supplementation and fall risk. This study included 389 older community-dwelling Caucasian women from multiple cities within the United States. Supplementation was self-reported and included the use of vitamin D supplements or multivitamins. Neuromuscular function was measured by grip strength, chair-stand time, gait speed, and balance-walk (21).

A randomized, controlled trial using calciferol was conducted to determine the effectiveness of vitamin D and quadriceps resistance exercise on the reduction of falls and improvement of physical health. The subjects of this study consisted of 243 frail people ages 65 and older. Participants received either a single dose of 300,000 IU calciferol or a placebo, along with 10 weeks of high-intensity quadriceps resistance exercises. There were no significant effects on physical health or number of falls in the intervention group or control group (22).

Discussion

There is potential for vitamin D supplementation to improve physical function in CKD patients, but more research is needed within this population. The high prevalence of vitamin D deficiency in the CKD population and the negative effects of deficiency are similar in the elderly, allowing the assumption of comparable benefits in both populations. Several studies have been performed to determine the effects of vitamin D supplementation on muscle function in elderly people although current research is inconsistent (23,24).

Studies that support vitamin D supplementation confirmed various benefits on muscle function in subjects with and without vitamin D deficiency. These benefits include increased muscle strength and muscle mass, improved gait speed, and decreased frequency of falls. Vitamin D supplementation increased muscle strength, as measured by various physical performance assessments (3,14,15,17). Muscle mass also increased, which was seen by reduced atrophy of type II muscle fibers (14,16). Timed up and go tests verified improvement in gait speed (17). The number of falls also decreased (14,17). Beneficial supplement effects were shown in these studies; however, limitations in study designs suggest that results be regarded with caution. One study was limited by a small sample size (3). Another study was limited by the short intervention period, small sample size, and variability in health status due to the cancer diagnosis of the subjects (15). A third study was limited by the lack of generalizability. These subjects were white institutionalized elderly women from Switzerland with low serum vitamin D levels (17).

Studies that did not support a benefit from vitamin D supplementation also had flaws in their study designs. These flaws included the use of subjects who were not vitamin D deficient or a study design in which a single treatment dose of vitamin D was used. Review articles show that muscle function does improve with vitamin D supplementation in subjects who have a vitamin D deficiency (23,24). One study had multiple limitations (20). It did not take into account seasonal change of vitamin D; the men in the study were not typical of the general population, as they were exceptionally strong to begin with; and they were not deficient in 25(OH) vitamin D levels, which would have been required to notice an improvement (20). In another study, fall rates were calculated based on the participants' self-reports, which tends to be subject to error (21). These results must take into consideration that the vitamin D was not supplemented with calcium, which may have limited its absorption (22). The studies that used a single, large dose of a vitamin D supplement should be taken into consideration as a factor that may have greatly affected the study results (19,22). Multiple doses may be necessary to see treatment results and one large, single dose may not be biologically optimal for the human body to absorb.

One mechanism that could support a relation between vitamin D and muscle strength is that an increase in the relative number and cross-sectional area of fast-twitch fibers exists with adequate vitamin D levels. Vitamin D also has an indirect effect on skeletal muscle through the secretion of insulin (25). Higher serum 25(OH) vitamin D concentrations are associated with improved physical performance, muscle strength, and musculoskeletal function (26-28). A study in Japanese elderly women who had low 25(OH) vitamin D levels showed a significantly higher percentage of falls because of inferior physical performance (29).

Recommendations

CKD patients may benefit from early vitamin D supplementation to improve physical function. Current studies show improvement in physical function in vitamin D deficient non-CKD patients. With the high prevalence of vitamin D deficiency in CKD, it is hypothesized that this population is at even greater risk than non-CKD elderly for decreased physical function. If a significant benefit exists, physicians may be more likely to consistently initiate a vitamin D supplement for their patients in the early stages of CKD (Stages 2, 3, and 4). Patients with optimal vitamin D status could maintain their normal muscle strength, muscle mass and physical performance. This has great implications for a population that suffers from frequent falls, hip fractures, hospitalizations, and poor quality of life. Maintaining muscle strength and muscle mass by ensuring adequate vitamin

D levels will likely prevent falls and fractures, decrease hospitalizations, and improve quality of life. In turn, there is potential to improve mortality rates and decrease health care expenses.

Current National Kidney Foundation Kidney Disease Outcome Quality Initiative recommendations encourage initiating vitamin D supplementation in patients with CKD Stages 3 and 4. The recommendation for treatment of vitamin D insufficiency is 50,000 IU/month orally for six months (2). In the mildly deficient population, 50,000 IU/week for four weeks, then 50,000 IU/month orally for six months is recommended. For the severely deficient population, 50,000 IU/week orally for 12 weeks, then monthly for a total duration of six months is recommended (2). Physicians should test serum vitamin D levels earlier and more regularly to monitor vitamin D status and initiate supplementation before patients become deficient.

There is a need for vitamin D research in the CKD population related to physical function. Future studies should be conducted in CKD patients with insufficient or deficient vitamin D status to determine the effects of supplementation on physical function. ◆

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Do you have a provider number and offer Medical Nutrition Therapy to chronic kidney disease patients not on dialysis?

If you are a MNT provider and if you would like to be listed on the RPG Web site, please send an email with your information to pwilliamsrd@gmail.com.

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Thank You...

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Nutrition and the Pediatric Renal Patient

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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. In addition, this CPE offering is available to current RPG members only and the expiration date is April 15, 2011.

Introduction

Caring for the pediatric or adolescent patient with chronic kidney disease (CKD) presents unique and varied challenges for the entire health care team. Balancing the nutritional requirements of these patients in order to promote appropriate growth and development, along with the need to control the biochemical and metabolic consequences associated with the disease state, can be challenging. The pediatric renal dietitian should work closely with the entire healthcare team in order to achieve nutritional goals for each patient.

Causes of Kidney Failure in Children

Unlike adults with CKD, the primary causes of kidney failure in children are congenital disorders. These include: polycystic kidney disease, renal dysplasia and hypoplasia, obstructive uropathy, reflux nephropathy, congenital nephritic syndrome and cystinosis. Other causes of kidney failure in children include acquired disorders such as glomerulonephritis, interstitial nephritis, hemolytic uremic syndrome, cortical and tubular necrosis, renal arterial or venous thrombosis and vasculitis.

Nutritional Goals

The primary nutritional goals for the pediatric renal patient are to promote optimal nutritional status, growth, and development while controlling the biochemical and metabolic consequences associated with the disease state. Barriers in achieving the nutritional goals in this population include: anorexia and associated poor energy intake, metabolic acidosis and hormonal abnormalities, use of corticosteroids in the treatment of certain kidney disorders and as immunosuppressive therapy, and psychosocial and developmental issues. Cultural influences may also make it difficult to meet nutritional needs due to food preferences and religious beliefs. Additionally, depression, family financial concerns, changes in family structure, increased fatigue, changes in mental status, poor concentration, and forgetfulness can all contribute to poor appetite and intake. Finally, oral aversion and gastroesophageal reflux (GERD), frequently associated with CKD in infancy, may make it difficult to meet nutritional needs by mouth. Each of these areas needs to be addressed by the health care team with the appropriate interventions being implemented (1).

Changes in taste due to renal failure, metabolic abnormalities and dietary restrictions often make it difficult for the child with CKD to meet his or her nutritional needs. It is known that anorexia and associated poor energy intake often seen in children with CKD can negatively impact linear growth and weight gain (2). Correction of metabolic acidosis with base supplements such as sodium bicarbonate or sodium citrate, and dialysis therapy can help to promote increased intake and optimize linear growth and weight gain. Additionally, treatment of anemia associated with CKD using erythropoietin and iron supplementation may promote improved oral intake. Finally, a more liberal diet may encourage the patient to meet nutritional needs. However, it is important to monitor laboratory values closely and adjust the diet as appropriate to maintain optimal biochemical control.

Corticosteroids, such as prednisone are often used to treat certain types of kidney disease including glomerulosclerosis and IgA nephropathy. They are also prescribed as part of the immunosuppressive therapy following renal transplantation. While steroids can be part of effective treatment, they have been negatively associated with linear growth in children. Additionally, high dose steroids can contribute to excessive weight gain due to reported stimulation in appetite (3). It is important to monitor linear growth and weight gain closely in children who are on corticosteroids. Ideally, the lowest possible dose of steroids should be used in order to minimize the impact on growth and potential for weight gain.

Linear growth can be negatively impacted by a poor calcium and phosphorus balance. Close attention to serum calcium, phosphorus and parathyroid hormone (PTH) levels is necessary in order to maximize growth. Dietary phosphorus restriction and use of phosphate binders is essential in controlling serum phosphorus levels. Vitamin D metabolites such as calcitriol and paricalcitol are used to prevent and treat hyperparathyroidism and CKD bone and mineral disorders. Despite adequate nutrient intake and good biochemical control, decreased rate of linear growth is common. While adequate nutrient intake may help to promote linear growth, it will not always achieve catch-up growth (4). If linear growth does not improve after ensuring adequate calorie and protein intake with appropriate treatment of metabolic acidosis

and renal osteodystrophy, the use of recombinant growth hormone therapy should be considered. Although pediatric patients with CKD often have normal growth hormone levels in their bodies, growth hormone resistance can be a problem. Giving recombinant growth hormone as a subcutaneous, daily injection can improve linear growth in children with renal failure who still have growth potential or open growth plates (5).

Nutritional Assessment of the Pediatric Renal Patient

The nutritional assessment of the pediatric renal patient is best performed by an experienced pediatric renal dietitian. Interval measurements of growth and nutrition parameters should be obtained on a regular basis and assessed for trends (6). Necessary measurements include height or length (in children less than 2 years of age or for those who are unable to stand without assistance), weight, and head circumference (in children less than 3 years of age). Weight for length and Body Mass Index should be evaluated and plotted on the appropriate growth chart for age. Infants and small children require more frequent assessment to monitor adequacy of intake, tolerance to feedings and growth. The World Health Organization (WHO) Growth Standards should be used as the reference for children from birth to 2 years of age. After age two, it is appropriate to change to the Centers for Disease Control and Prevention (CDC) reference curves (7).

Length measurements should be done on a measuring board by two people in order to get an accurate measurement. One person holds the crown of the head against the headboard while the other person moves the footboard up to the heels of the infant's feet as legs are straightened. When obtaining height measurements, the child should remove his or her shoes and stand on the floor, looking straight ahead. It is preferable that length and height measurements be obtained by the same well-trained person at each assessment. Both length and height measurements should be recorded to the nearest 0.1 cm.

To obtain an accurate weight, an infant should be undressed completely and the weight obtained on an infant scale. Older children may be weighed in light clothing without footwear in a standing position. Weight should be recorded to the nearest 0.1 kg. It is important to consider the fluid status of the patient when evaluating for weight gain. Fluid weight gain may be misinterpreted as actual weight gain and an increase in measured lean body weight. Pediatric dialysis patients should be weighed both before and after a dialysis treatment. Blood pressure measurements, heart rate and clinical appearance may be helpful in assessing whether a patient is at his or her "dry weight" following a dialysis treatment. High blood pressure, which resolves following fluid removal with dialysis, can indicate excess fluid weight. Similarly, low serum sodium and albumin levels may be markers of overhydration. Rapid, unexpected weight gain, in the absence of significantly increased nutrient intake, must be evaluated very carefully when assessing dry weight.

The maximum head circumference should be measured in children up to age 36 months and recorded to the nearest 0.1 cm. Findings should be plotted on the 2007 WHO Growth Standards head circumference-for-age curves (6). Head circumference measurements help in assessing the adequacy of nutrient intake and typically reflect brain growth and development. A sudden acceleration in head growth may signal a change in medical condition such as hydrocephalus. Conversely, a decline in rate of head growth can indicate chronic malnutrition.

In addition to accurate anthropometric measurements, laboratory data is essential in assessing the patient's nutritional status and needs. Albumin is a measure of visceral protein stores and plays an important role in the general evaluation of patients with CKD (6). There are a number of reasons for decreased albumin levels including: inadequate calorie and protein intake, urinary protein losses, nephrotic syndrome, recent surgery, liver disease, peritonitis, volume overload, and other inflammatory processes. Patients on peritoneal dialysis will experience increased protein loss in their dialysate solution, which may lead to hypoalbuminemia (3). These patients require an even higher protein intake than patients on hemodialysis. Measurement of blood urea nitrogen (BUN) can be helpful in assessing the protein intake of the pediatric renal patient. A low BUN in relation to serum creatinine frequently reflects poor protein intake while an excessively high BUN may suggest dehydration, excess protein intake or catabolism. Other laboratory data that needs to be evaluated includes: serum sodium, potassium, calcium, phosphorus, intact or bio-intact PTH, hemoglobin, iron studies (iron, % saturation, ferritin), and CO2 levels. These labs can help to identify patients who are not adequately meeting nutritional needs and also help to assess and monitor for development of anemia or bone and mineral disorders. There is limited data on the use of protein catabolic rate (PCR) in helping to assess dietary protein intake in the pediatric population. However, regularly obtaining PCR in adolescent patients on hemodialysis has been correlated with prediction of weight loss or gain. Dietary modifications must be made frequently, based on laboratory values. Assessing dietary intake with food records can assist with this task. It is particularly important to individualize the diet plan for the pediatric patient. **Dietary restrictions should only be initiated when indicated necessary by laboratory values, medical condition and medical therapy.** Modifications in

calories, protein, sodium, potassium, phosphorus, and fluid intake may be necessary depending on the patient's medical condition and therapy, dialysis modality, medications, blood pressure, fluid balance and urine output, laboratory values, nutritional status, growth, weight gain, and age.

Gastrointestinal (GI) disturbances such as nausea, vomiting, diarrhea, constipation, delayed gastric emptying, and early satiety are frequently seen in children with CKD. Each should be considered when evaluating the pediatric renal patient's nutritional status and dietary needs. These can all negatively impact the patient's ability to meet nutritional needs and may necessitate medical nutrition therapy modifications and adjustments in medications. The renal dietitian can be particularly helpful in alerting the rest of the medical team of these conditions to be addressed and treated appropriately. Proton-pump inhibitors, H-2 antagonists, motility agents, anti-diarrheal agents, antimicrobial agents and probiotic therapy may be useful in treating these problems, although dosages need to be adjusted for renal failure (8).

Nutritional Recommendations for Children with CKD

Calorie and protein needs for children are based on age, gender, medical condition, treatment modality, nutritional status, and response to therapy. Specific nutritional recommendations for children with CKD can be found in Table 1 (3). The 2008 KDOQI Clinical Practice Guideline for Nutrition in Children with CKD is also an excellent reference. Calorie needs are initially based on the estimated energy requirements (EER) for chronological age, but may be adjusted depending on nutritional status, growth, medical complications, inter-current illnesses, activity level, and other factors that could impact calorie needs. As previously stated, dietary restrictions are only initiated when indicated necessary by laboratory values, progression of renal insufficiency, or presence of hypertension or edema. Protein intake changes depending on the stage of CKD and treatment modality. Patients on dialysis should be encouraged to choose high quality protein foods such as beef, chicken, fish, pork, and eggs on a daily basis. Protein powders and liquids may also be necessary to help meet protein needs. Powerpacking, using calorically dense foods such as simple carbohydrates and fats/oils, may help to increase calorie intake and meet nutritional needs while staying within dietary limitations.

Additional Nutritional Recommendations for Children on Dialysis

For children on hemodialysis, interdialytic weight gain should be between 3% -5% of body weight. Fluid restriction is based on achieving this goal. Generally, patients on peritoneal dialysis will have a more liberal fluid allowance than those on hemodialysis. Total fluid intake allowed considers insensible losses, urine output, ultrafiltration capacity, and other losses. Insensible losses will vary depending on the size of the child. They will also increase with fever, phototherapy, open warmers, or tachypnea and decrease in patients who are ventilated with humidified air. Therefore, total fluid intake allowed may change depending on the medical condition of the child.

Dietary restriction of sodium, potassium, and phosphorus for children on dialysis is only implemented when warranted, based on laboratory values. Sodium restriction is necessary for patients who are oliguric or anuric, edematous, or hypertensive. Potassium restriction is needed for patients with hyperkalemia. Phosphorus restriction is recommended with the presence of hyperphosphatemia and/or hyperparathyroidism. Phosphate binders, either calcium or non-calcium based, and vitamin D metabolites are used to prevent and treat hyperparathyroidism and renal osteodystrophy. Vitamin intake may be supplemented to meet 100% of the Dietary Reference Intakes (DRI). Typically a water soluble, renal multivitamin is used. Iron supplementation, frequently necessary for those patients on erythropoietin therapy, is usually given intravenously for patients on hemodialysis and orally for patients on peritoneal dialysis (3). The age, size, stage of development, and preference of the child and parent will determine which type of preparation is used.

For patients on peritoneal dialysis, it is necessary to include calories absorbed from the dialysate solution in the total nutrient intake. Protein needs are increased above the DRI for chronological age due to increased protein losses associated with the peritoneal dialysis process. Sodium restriction is usually not necessary unless the patient is edematous or hypertensive. Infants on peritoneal dialysis may actually require sodium supplementation as they are predisposed to substantial sodium losses, even when anuric. Additionally, infants with renal dysplasia can have increased urinary sodium losses. High ultrafiltration requirements per kilogram body weight can further contribute to sodium loss. Potassium restriction is usually not necessary if dialysis is adequate, although this also depends on transporter type used when on peritoneal dialysis.

Nutritional Recommendations for Children with a Renal Transplant

The nutritional goals following a successful renal transplant are to promote wound healing and anabolism, prevent infection, obtain optimal growth, minimize medication side effects, maintain electrolytes and minerals within normal limits, and stabalize blood pressure within normal limits. It is important to continue

Table 1
Daily Nutrient Recommendations for Children with Chronic Kidney Disease

Note: Restrictions should be implemented only where warranted and kept as liberal as possible to optimize energy intake and prevent malnutrition.

Pediatric dietary restrictions usually take the form of a "low-nutrient X diet" with education about avoiding or limiting foods high in that nutrient. Depending on the response in the parameter relevant to that nutrient (eg, blood pressure; biochemical value) the restriction can be liberalized or tightened.

Prescriptions for specific amounts of a nutrient (eg, 3 mEq nutrient X/kg) are rarely used in pediatrics. Amounts provided in the table can be used as references for assessment of daily intake obtained from food records.

Nutrient	Infant, birth to 1 y	Toddler, 1-2 y	Child, 3-8 y	Adolescent	
Energy (kcal/kg/d)*					
Boys	Birth to 6 mo: 95 7-12 mo: 82	87	87	63	52
Girls	Birth to 6 mo: 87 7-12 mo: 75	82	82	60	44
Protein (g/kg/d)	Birth to 6 mo: 1.52† 7-12 mo: 1.1-1.5‡	0.88-1.10‡	0.76-0.95‡	0.76-0.95‡	Boys: 0.73-0.85‡ Girls: 0.71-0.85‡
Sodium (Recommendations for patients with edema or hypertension)	• No salt shaker and avoid salty foods (≥ 200 mg sodium/serving). • Infants and toddlers: restrict to 1-3 mEq/kg/d.§ • Children and adolescents: restrict to 87-174 mEq/d§ (2-4 g/d).				
Potassium (Recommendations for patients with hyperkalemia)	• Avoid foods with high potassium levels, such as bananas, chocolate, and orange juice. • Infants and toddlers: restrict to 1-3 mEq/kg/d.§ • Children and adolescents: restrict to 51-103 mEq/d§ (2-4 g/d).				
Calcium	• 100% of the DRI. • Monitor total calcium load, including calcium from phosphate binders.				
Phosphorus (mg/d) (Recommendations for patients with hyperphosphatemia)	Restrict to low-phosphorus formula and foods.	≤ 400-600		≤600-800	
Vitamins	• If needed, supplement to 100% of the DRI. • Supplement with vitamin D metabolite to prevent hyperparathyroidism and renal osteodystrophy.				
Trace Minerals	• If needed, supplement to 100% of the DRI. • Iron supplementation is usually needed with erythropoietin therapy.				
Fluids	• Unrestricted unless warranted for fluid management (indications would be decreased urine output, edema, or hypertension). • If restriction is needed: Total Fluid Intake (TFI) = Insensible losses + Urine output + Other losses.				

* Energy recommendations are the estimated energy requirements (EERs). They are based on physical activity levels (PAL) as the level recommended to maintain health and decrease risk of chronic disease and disability. EERs are presented in kcal/kg as determined by dividing the active PAL EER (total kcal/day) by the reference weight for each respective age.
†Protein recommendations are the adequate intake (AI) for ages birth to 6 months.
‡Protein recommendations are the range of estimated average requirement (EAR) to recommended dietary allowance (RDA) for ages 7 months to 18 years.
§For sodium and potassium, mEq = mmol.
Source: Data are from selected *Dietary Reference Intakes* publications (38-42).

to monitor nutritional status and growth closely. Acceleration in rate of linear growth may occur, particularly in younger children. The use of recombinant growth hormone following transplant is controversial due to the potential for deterioration in renal function. Excess weight gain may occur due to increased appetite and intake, a more liberal diet, immunosuppressive medications, and decreased physical activity. Calorie needs are based on EERs for age. They also take into consideration physical activity levels and the level recommended to maintain health and decrease risk of chronic disease and disability. A low saturated fat diet may be necessary for patients with hyperlipidemia. Hyperlipidemia in transplant patients is generally related to immunosuppressant medications. A limited calorie diet may be ordered to combat excessive weight gain following transplantion. Protein needs are initially increased after transplant (1.2-1.5 g/kg/protein x DRI) and return to the DRI for age after three months. Moderate sodium intake is recommended for patients with edema or hypertension. Hyperkalemia may occur in the immediate post-transplant period, often as a result of immunosuppressive drug toxicity, the use of ACE inhibitors, or impaired renal function in the allograft kidney. If hyperkalemia is present, it is usually necessary to temporarily limit intake of high potassium foods until potassium decreases to within normal range. Calcium intake should meet 100% of the DRI for age as these patients are at an increased risk of decreased bone mineral density. If the patient is unable to meet calcium needs with diet alone, a calcium supplement can be provided to ensure adequate calcium intake. Phosphorus supplementation may be necessary initially due to previous hyperparathyroidism and resultant hypophosphatemia associated with immunosuppressant therapy. Magnesium supplementation may also be indicated if hypomagnesemia occurs due to immunosuppressive medications. Vitamin supplementation is generally not necessary, except for the possible exception of vitamin D, unless the child has a poor diet or poor oral intake. If the diet is inadequate, vitamins and trace minerals are supplemented up to 100% of the DRI for age. With stable renal function, high fluid intake should be encouraged to avoid dehydration and volume depletion. Herbals and botanicals are currently contraindicated as they may interact with immunosuppressive medications and potentially contribute to renal dysfunction (3).

Nutritional Support for the Pediatric Renal Patient

If oral intake is inadequate to achieve and maintain optimal nutritional status, enteral nutrition may be necessary to avoid malnutrition. Nasogastric or nasojejunal enteral feedings can be used temporarily. If enteral feedings will be needed long-term, gastrostomy tubes may be placed either surgically or non-surgically. Because the placement of a gastrostomy tube in a patient on peritoneal dialysis has been associated with an increased risk of infectious complications, it may be prudent to place a gastrostomy tube before dialysis is initiated. It is important to consider the risks and benefits of placing a feeding tube on an individual basis. Enteral feedings can be given as either a bolus feeding or as a continuous feeding using a feeding pump depending on feeding tolerance and oral intake. Bolus feedings can supplement oral intake during the day with continuous feedings given overnight to meet goal formula volumes. Continuous enteral feedings may also be given overnight to encourage oral intake during the day. They are usually started at 1 to 3 mL/kg/day and increased as tolerated. Feeding schedules may need to be adjusted for patients on dialysis. The choice of formula is based on age, nutritional requirements, fluid requirements, laboratory values, and concurrent medical problems.

Parenteral nutrition may be necessary if the GI tract is non-functioning or non-accessible, or if enteral feedings are insufficient to meet nutritional needs. Fluid limitations, dialysis modality and route of infusion, either peripheral or central, may impair the ability to fully meet nutritional needs using parenteral nutrition. The most concentrated forms of dextrose, amino acid, and lipid solutions available should be utilized to limit fluid intake in dialysis patients if parenteral nutrition is necessary. There is no scientific evidence to support the use of essential amino acid solutions in the renal patient. Electrolytes should be individualized to meet the patient needs. Standard dosages of multivitamins for parenteral nutrition, as established by the American Medical Association Nutrition Advisory Committee are recommended. Monitoring for potential vitamin A toxicity in patients on long-term parenteral nutrition is necessary (6). Interdialytic parenteral nutrition (IDPN), the provision of macronutrients through the venous drip chamber of the hemodialysis machine may be used in pediatric hemodialysis patients to help meet nutritional needs. Although it will not fully meet nutritional requirements, it may be used in supplementing enteral intake. Strict criteria must be met in order to justify use of IDPN. Intraperitoneal parenteral nutrition (IPN), which substitutes an amino acid solution for one or two glucose exchanges per day when on peritoneal dialysis, may be utilized for pediatric peritoneal dialysis patients who are not able to fully meet their protein requirements. IPN may be indicated in patients with malnutrition who have inadequate calorie and protein intake and are unable to tolerate oral or enteral supplementation. KDOQI guidelines for use should be followed (6).

Infant Nutrition in Pediatric Renal Disease

Meeting the nutritional needs of infants with CKD can be

especially challenging since inadequate nutrient intake is common in this population. Decreased appetite, GERD and oral aversion are frequently observed with the infant refusing most or all oral liquids and solids. Texture aversions are also very common. Enteral feedings may be necessary to meet 100% of nutritional needs (9).

Since breast milk has a very low renal solute load in comparison to infant formulas, it is the ideal choice for feeding infants with CKD. However, because it is difficult to assess adequacy of intake in a breast-fed infant, it may be necessary for the mother to pump her breast milk and give in a bottle or as enteral feedings. Using expressed breast milk facilitates accurate assessment of intake and also allows for addition of modular components as necessary to increase caloric density. Specialized infant formulas designed for children with CKD are lower in sodium, potassium, and phosphorus and have a lower renal solute load than standard infant formulas. It may be necessary to use these formulas to meet nutritional needs and maintain optimal biochemical control. Modular components of protein, carbohydrate, and fat can be added to increase the caloric density and protein content of the formula when necessary without increasing mineral and electrolyte content. Formulas should not typically be concentrated due to increased electrolyte and mineral content. Cost, shelf stability and availability should be considered when choosing formulas and modular components. Table 2 outlines several different formulas and modular components used for children with CKD.

Adult renal formulas, which are calorically dense, high or low in protein, low in electrolytes and phosphorus, and designed for adults with CKD are not usually recommended for children less than 2 years of age due to increased osmolality and inappropriate vitamin and mineral content. With use, it may be necessary to dilute these formulas to ¼ or ½ strength to achieve tolerance. Serum magnesium levels should be monitored closely as magnesium content is significantly higher in adult renal formulas in comparison with infant formulas and may contribute to hypermagnesemia (3). Sodium polysterene sulfonate (Kayexalate) can be effectively used to precipitate potassium from infant formula prior to feeding when hyperkalemia occurs despite use of a low potassium formula (12). However, pretreatment of formula

Table 2
Common Formulas and Modular Components Used for Children with CKD (10,11)

Product	Description	Calories	Protein (g)	Comments
Human Breast Milk	Low renal solute load	20 kcal/mL	1.1 g/100 mL	Low renal solute load and low mineral content
Similac PM 60/40	Low renal solute load	20 kcal/30 mL	1.6 g/100 mL	Minerals comparable to human milk. Not generally available off the shelf
Suplena CHO Steady	Calorically dense, lower protein	1.8 kcal/mL	4.5 g/100 mL	Adult renal formula; may need to dilute
Renalcal	Calorically dense, low protein	2.0 kcal/mL	3.4 g/100 mL	Adult renal formula; may need to dilute
Nepro CHO Steady	Calorically dense, high protein	1.8 kcal/mL	8.1 g/100 mL	Adult renal formula; may need to dilute
Novasource Renal	Calorically dense, high protein	2.0 kcal/mL	7.3 g/100 mL	Adult renal formula; may need to dilute
ProMod	Protein liquid modular	3.3 kcal/mL	3 g/TBSP	Used to increase protein in formula
Resource Beneprotein	Protein modular	3.6 kcal/g	4 g/TBSP	Used to increase protein in formula
Polycose powder	Glucose polymer	3.8 kcal/g	2 g/tsp (8 kcal/tsp)	Used to increase calories with low osmolality, low minerals and electrolytes
Microlipid	50% fat emulsion	7.5 kcal/g	0g	Mixes easily, used to increase calories without minerals or electrolytes
Vegetable oil	Safflower or canola oil	8.4 kcal/g	0g	Non-emulsified; does not stay mixed. Used to increase calories without minerals or electrolytes

can result in an increase in sodium content while decreasing formula levels of calcium and magnesium. Close attention to possible complications from these minerals is necessary.

Fluid needs in infants with non-oliguric CKD, usually due to congenital renal dysplasia, may be significantly increased due to the infants inability to concentrate urine. There also may be increased urinary sodium losses, necessitating sodium supplementation to achieve optimal growth and weight gain (13). Calorie and protein dense formulas, using modular components, are frequently necessary to meet calorie and protein needs without compromising biochemical control. However, these formulas may exacerbate GI disturbances such as vomiting and diarrhea. Frequent adjustments in the formula, feeding modality, and nutritional plan by the pediatric renal dietitian, in conjunction with the pediatric renal team, is often necessary to achieve optimal nutrient intake and promote appropriate growth and weight gain. Introduction of solids should be done on a normal schedule when the patient is developmentally appropriate. The infant may benefit from occupational and speech therapy involvement to promote oral intake and avoid or limit oral aversion.

Nutritional Concerns for School-Aged Children and Adolescents with CKD

Children and adolescents with CKD who are short in stature, may experience increased social difficulties as they grow older. It is important for caregivers and medical staff to treat the child in an age-appropriate manner and not view them as younger than their chronological age based on height. Children who are short may also have increased problems with peers as they grow older, resulting in behavioral changes such as anger or withdrawal. The medical team needs to provide emotional support to the child when such difficulties occur and consider changes in, or additions to, the medical and dietary management of the patient in order to optimize growth potential. As previously discussed, optimal biochemical control and nutrient intake is essential in maximizing growth in children with CKD.

As the child becomes older, dietary and medication adherence may be adversely impacted due to an increased need to assert independence. Additionally, food choices at school may not be ideal for children with CKD. There may be more irregular eating patterns with skipped meals and increased peer pressure to eat foods that are typically limited in the diet. Parents are frequently reluctant to allow their child more independence in making appropriate food choices and taking medications as scheduled. Conversely, some parents may allow their child more independence in these areas than they are emotionally and intellectually ready to handle, which can adversely impact their nutritional status, growth, and medical condition. The renal dietitian and other health care professionals can work closely with parents and patients in achieving the appropriate balance of autonomy and independence related to medical and dietary therapy. Nutritional counseling should be individualized based on the nutritional assessment and plan of care. The child with CKD should be included in discussions related to diet, nutrition, growth, laboratory data, and medications between medical staff and parents/caregivers (when developmentally appropriate). It also may be helpful for health care professionals to contact the child's school and provide education to peers, teachers, school nurses, and school food service workers regarding the child's medical condition and dietary and health needs. School breakfast and lunch programs may need to be modified to accommodate the diet limitations of the child.

Conclusion

Providing care to the pediatric patient with CKD is complicated and requires the cooperation and coordination of the entire health care team, including nurses, social workers, dietitians, physicians, technicians, child life specialists, and the patient and family. Optimizing nutritional status and growth, and maintaining good biochemical control is essential in achieving a good outcome medically, physically, and emotionally for these patients. Nutritional status and needs should be assessed frequently and dietary modifications made as needed to meet these goals.

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"They will rise highest who strive for the highest place."
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Before you start, stop.

Because the benefits should accumulate. Not the risks.

Renvela® (sevelamer carbonate) tablets or for oral suspension is an effective first-line monotherapy for controlling serum phosphorus in dialysis patients — without calcium or metal[1] accumulation. Renvela is the ***only*** phosphate binder available in both tablet and powder dosing options.

Learn more about Renvela powder at renvela.com.

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

Important Treatment Considerations

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.

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See package insert for full prescribing information.

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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: pruritus, 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 exsiccated 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 overdosage 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, diacetylated 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, sucralose, 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)

STORAGE
Store at 25°C (77°F): excursions permitted to 15-30°C (59-86°F).
[See USP controlled room temperature]
Protect from moisture.

Distributed by:

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Genzyme Corporation
500 Kendall Street
Cambridge, MA 02142 USA

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Case Study Using the Nutrition Care Process

A Child with Kidney Failure

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The Nutrition Care Process leads to a consistent yet individualized care for a patient or client in which improved nutrition care and predictable outcomes are intended. Nutrition care is not meant to be standardized, but the process for providing the care may be established. Following along with the case study, the four steps of the process should be identifiable. The four steps are Nutrition Assessment, Nutrition Diagnosis, Nutrition Intervention, and Nutrition Monitoring and Evaluation. **Please note the standardized language appears in bold face throughout.**

Patient Background:
JW is a 6–year–old boy who presented to the hospital with chief complaint of short stature, abnormal gait, and elevated BUN and creatinine. Past medical history is significant for von Willebrand disease and poor growth. A consult with the registered dietitian occurred secondary to initiation of peritoneal dialysis.
Teaching Point: *While performing a Nutrition Assessment, it is important to cluster pertinent data to get a "clear picture of the patient's nutritional health." This is established from reviewing Food/Nutrition Related History, Anthropometric Measurements, Biochemical Data, Medical Tests and Procedures, Nutrition Focused Physical Findings and Client Hx. Although all parameters are reviewed, not all parameters need to be documented. The documentation included should support the current nutrition diagnosis and planned interventions. Nutrition Monitoring and Evaluation refers to the desired outcomes or results that are identified which are measurable, as compared to established criteria or reference standards.*

Nutrition Assessment
Personal data: 6–year–old boy admitted two days ago.
Patient medical/health history:
History of von Willebrand disease and poor growth.
Food and nutrient intake: Prior to admission JW consumed a regular diet, consisting of typical age-preferred foods including peanut butter and jelly, macaroni and cheese, hot dogs, etc. Since admission and initiation of renal diet, his intake seems limited. Parents have questions and concerns about the renal diet.
Diet order: renal diet
Anthropometric measurements:
Weight: 17.1 kg (5th%tile)
Height: 104.5 cm (<5th%tile)
BMI-for-age: 15.7 kg/m^2 (50-75th%tile)
Estimated energy needs: 1377-1590 kcal (REE x 1.2 x 1.3-1.5)
Estimated protein needs: 34 grams protein (2 grams/kg)
Estimated fluid needs: 1400 mL or per balance (results are normal unless noted otherwise)
Electrolyte and renal profile: Creat 4.5 ↑, K 3.5 ↓, Phos 7.5 ↑
Acid-base balance: CO2 18 ↓

Nutrition Diagnoses:
Inadequate oral food/beverage intake *related* to poor appetite and depressed mood *as evidenced by* patient's refusal to eat or drink.
Decreased nutrient needs (phosphorus) *related* to kidney disease *as evidenced by* serum phosphorus of 7.5 mg/dL.
Food- and nutrition-related knowledge deficit *related* to new initiation of peritoneal dialysis and no previous exposure *as evidenced by* parents asking questions about the renal diet.
Teaching Point: *Saying "inadequate oral food/beverage" intake would be strengthened greatly by specifying the "amount of food" taken so you could later measure and report a change in the amount eaten. Knowing the amount of food and helping the client improve the amount of food taken is the hallmark of this diagnosis.*

Timeline	Pertinent Information	Nutrition Therapy
2/12	Patient admitted to the Pediatric Intensive Care Unit with suspicion of kidney failure.	Diet order: renal diet
2/13	Social work consulted for adjustment issues/counseling	10 mcg
2/14	Peritoneal dialysis initiated	Nutrition Assessment completed

Intervention
1. Meals and snacks:
- Continue renal diet; may liberalize if JW continues to avoid oral intake due to limited choices. Oral intake encouraged by RD.
- Initiate three-day calorie count.
- Snacks ordered upon agreeable choices made by JW.

2. Vitamin and mineral supplements:
- Start Nephrovite; Strovite liquid MVI is also available if JW refuses to take tablet.

3. Nutrition-related medication management:

- Start Tums orally three times daily with meals for phosphate binding.

4. Initial/brief nutrition education:

- Met with JW and his parents to discuss the renal diet for peritoneal dialysis. Provided instruction on sodium, potassium, phosphorus, and protein. Emphasized low-phosphorus and high-protein foods at this time. Discussed the importance of taking phosphate binder (Tums) with meals. Parents were very receptive and asked questions appropriately. Expected compliance is fair to good as parents are somewhat overwhelmed. Handouts provided including *PD Nutrition Guide* as well as cookbooks. Contact information for RD was provided for additional questions or concerns.

Teaching Point: *Consider the Nutrition Diagnosis the critical link between the assessment and the intervention. Remember a Nutrition Diagnosis is not a medical diagnosis. The Nutrition Diagnosis is written in the Problem, Etiology, Signs & Symptoms format also known as PES. For example there is a Nutrition Diagnostic Label (problem), related to (etiology), as evidenced by (signs and symptoms). When faced with equally good choices from the three different domains (intake, clinical or behavioral/environmental), choose Intake. It is more likely for the Intake domain to have a nutritional etiology and thus a nutrition-directed intervention.*

Monitoring and Evaluation

Food intake: JW will order three meals daily with the help of his parents and try the snacks in between his meals.

Energy intake: JW will meet his estimated nutrient needs from adequate oral intake prior to discharge.

Knowledge: by next encounter parents will be able to verbalize appropriate foods within the renal diet.

Phosphorus: achieve serum phosphorus within normal limits.

Desired growth pattern: maintain current BMI-for-age while inpatient.

Teaching Point: *It will likely be difficult to measure "verbalize appropriate foods." How would you know if you have made a difference with your intervention? It is recommended to use a specific measurement –examples include querying of certain foods or planning of 2 meals accurately.*

Nutrition Reassessment

Patient history: 6–year–old boy presented to hospital with chief complaint of short stature, abnormal gait with elevated BUN and creatinine. Past medical history is significant for von Willebrand disease and poor growth. He has kidney failure and is being maintained on peritoneal dialysis. Parents state "he is more like himself today" and have several questions.

Diet Order: Peds general diet, 60 mEq K+

Food and nutrient intake: parents report improved oral intake.

Weight: 16.3 kg (down 0.8 kg since admit)

Estimated energy needs: 1377-1590 kcal (REE x 1.2 x 1.3-1.5) calorie count is 1390 kcal and 30 grams protein. (results are normal unless noted otherwise)

Electrolyte and renal profile: Creat 3.7 ↑, K+ 4.0, Phos 5.5

Acid-base balance: CO_2 24

Nutrition Diagnoses

Inadequate oral food/beverage intake has improved *as evidenced by* patient requesting meals now and resulting in improved calorie count.

Decreased nutrient needs has been addressed and has resolved *as evidenced by* phosphate binders in place and serum phosphorus has improved to WNL.

Food- and nutrition-related knowledge deficit has been addressed and improves *as evidenced by* completion of thorough education and parents being able to repeat major concepts of the renal diet.

Teaching Point: *These could be strengthened by more specific outcomes.*

Timeline	Nutrition Therapy
2/15	Diet order changed to peds general diet, 60 mEq K+
2/15-2/17	Three-day calorie count
2/18	Nutrition Reassessment completed

Interventions

1. Meals and snacks:

- provided more encouragement for JW to continue to consume snacks in between all three meals
- encouraged intake of high-protein foods while maintaining a low-phosphorus diet

2. Vitamin/mineral supplement:

- JW willing to take Nephrovite (MVI tablet) versus liquid version.

Teaching Point: *You'll notice that, in the Nutrition Assessment and Nutrition Reassessment, the Nutrition Interventions describe what the registered dietitian does to fix the nutrition problem, identified by the Nutrition Diagnosis and corresponding PES statement. The Interventions also enable goals to be met. Three actions by you as a practitioner are part of the Nutrition Monitoring & Evaluation:*

monitor, measure, and evaluate nutrition indicators or parameters to determine the patient's progress. Notice Energy Intake, where it was clearly stated that JW would meet his nutrient needs from adequate oral intake which was measured/evaluated per results of a three-day calorie count.

Monitoring and Evaluation

Food intake: JW oral intake is improving; he is consuming three small meals and snacks daily.

Knowledge: Parents repeat major diet concepts correctly.

Desired growth pattern: BMI-for-age is stable; JW will continue to meet age-appropriate growth standards with average gain of 5-8 grams/day for weight and 0.5 cm/month for height.

Summary

JW admitted in November for a scheduled living-related kidney transplant. He was hospitalized for nearly one week and discharged home without complications. He initially visited the kidney transplant clinic weekly for three months. He returned to school and is pleased to have a less restricted diet which allows him to eat lunch from the School Lunch Program along with his friends. ◆

Timeline	Pertinent Information	Nutrition Therapy
2/20	Patient discharged home	Same as previous
2/29	Patient attended first monthly dialysis clinic	Nutrition Reassessment completed
6/3	Patient attended kidney transplant clinic for evaluation	Received nutrition education for nutrition-related expectations following a kidney transplant.

House of Delegates (HOD) Fact Sheet

Why Management and Leadership?

Management skills offer Registered Dietitians (RD) and Dietetic Technicians, Registered (DTR) an avenue for professional development and opportunity for career ladder advancement with increasing years of experience. Management and leadership abilities ultimately benefit the entire profession of dietetics, as RDs and DTRs become more highly valued employees in our institutions and organizations. Some of the positive benefits of management and leadership include:

- increased remuneration,
- increased authority,
- increased value,
- increased job satisfaction,
- a sense of accomplishment, and
- the positioning of RDs or DTRs in key decision making roles.

The four items rated as challenges by the greatest numbers of RDs echo a persistent theme:

- recognition of the value delivered by the profession of dietetics to the larger society,
- public awareness of our field,
- reimbursement for services, and
- compensation.

Big Question

What is needed to influence and encourage RDs/DTRs to hold, aspire to hold, or function in a leadership or executive role in all environments?

Practitioners need to understand and value that management and leadership skills are essential components used in all areas of practice. The education and training of dietetics practitioners already includes curriculum and competencies in management and leadership; however, RD/DTRs do not always adopt a mindset or promote themselves as managers or leaders; other professionals whose academic training in management may be minimal are promoted to positions of leadership more readily.

Why Does Management and Leadership Matter?

RDs and DTRs may perceive that management is focused on positions in foodservice or industry. But the skills needed to prepare for a secure future within many organizations will be tied to the ability to successfully demonstrate the application of management within all areas of dietetics practice.

The core trends in the 1995/2000 CDR employer studies reveal a focus on the need for organizations to do more and better with less as they face rising costs, increased competition, and higher customer expectations. Organizations will downsize, reorganize, outsource and automate.

And, they will rely on multi-disciplinary teams of cross trained, flexible, versatile, creative, proactive professionals who know how to focus their efforts on the organization's outcomes and bottom line – and who know how to show professional and public audiences that they are doing so.

We also know that advanced-level managers who assume risk and high-level decision making receive higher salary levels in every area of dietetics practice. Management and leadership matter!

How Will This Impact Us?

The quality of leadership and management provided within the health care industry will be pivotal to its success over the next five years.

Barker, Arensberg, and Schiller noted, "The cry for dietetics leadership has been heard for decades" and described the need for dietitians to serve as leader-managers, integrating both the role of leader and manager into one.

When surveyed, employers of dietetics professionals indicate that they are seeking entry-level practitioners who can:

- take on leadership roles more quickly,
- use an entrepreneurial approach from practitioners to achieve needed results,
- put a premium on efficiency, prioritizing, and decision-making, and
- consider marketing, sales, product development, and grant writing.

Discussion Activity – Talk with Your Delegate

Think of a leader (outside of dietetics) you admire. What are the skills and attributes that make that leader successful and admirable?

Think of a leader specifically in the profession of dietetics that you admire. What are the skills and attributes that make that leader successful and admirable?

Looking at the list of skills and attributes you identified for these leaders. Which skills and attributes are reflected in your colleagues within the profession of dietetics and which are missing?

Talk with your delegate(s) about the skills and attributes you identified and your ideas regarding this mega issue. Delegates will be discussing this issue at the Spring 2010 HOD Meeting (May 1 and 2). Delegate contact information is available at www.eatright.org/leaderdirectory.

To obtain the full backgrounder "Management and Leadership Across Practice," visit www.eatright.org/HODMegaIssues. ◆

Renal Dietitians Chair Message

Patricia Williams, RD, CSR, LDN
RPG Chair

I would like to take this opportunity to thank you for allowing me to serve you as the Renal Dietitians Practice Group (RPG) Chair. I have been reflecting on my year and a few events especially stand out to me. We had the honor of helping host the American Dietetic Association (ADA) President's reception for Jessie Pavlinac, MS, RD, CSR, along with the Oregon State Affiliate and Clinical Nutrition Management Practice Group. RPG sponsored its first webinar, the Nutrition Care Process and Standardized Language in Nephrology Nutrition, with over one thousand dietitians registering to take part. And, to meet member requests to have a Certified Renal Specialist (CSR) Review offered in more areas, we offered the first CSR Review course as a webinar.

I am excited about some changes that are taking place in ADA and RPG. Starting in 2011, RPG will appoint a member to be our DPG representative in the House of Delegates for ADA. In the past we have been assigned a Professional Issues Delegate to represent us, but in the future we will have a representative who works in renal and represents the interests and concerns of the renal dietitian.

RPG was asked to consider offering a list of renal dietitians who have a provider number and offer Medical Nutrition Therapy to chronic kidney disease patients not on dialysis on our Web site, so patients can find a provider in their area. The executive committee of RPG felt this would be a good service to offer. In order to do this, we need to know if you are a MNT provider and if you would like to be listed on the RPG Web site. If you would like to participate, please send an email with your information to pwilliamsrd@gmail.com.

One of RPG's Strategic Plan Goals is to impact regulatory and legislative issues related to nephrology nutrition. We greatly appreciate Karen Basinger, MS, RD, LDN, as Legislative Chair, with her work this year representing RPG's views on Early CKD Education and Bundling. However, having Karen represent our interests is not enough. We need you to be involved as well. On The Pulse is sent to ADA members weekly to keep us informed about issues which impact us as dietitians. As I have been involved as chair of RPG, I have come to understand how important it is for us to take action and make our voice known to our representatives and senators. Please take the time to read about the issues and send emails and letters when asked to respond to Call to Actions.

I also want to encourage you to take part in the surveys that are posted on the RPG Web site on a regular basis. The surveys let us know where your interests are and what you would like to see RPG offer to help you advance in your career. Your executive committee uses these surveys to help develop the new year's plan of work and upcoming events. RPG wants to continue to work for you. ◆

CALENDAR OF EVENTS

May

American Transplant Congress 2010
May 1 - 5, 2010
San Diego Convention Center in San Diego, CA
Visit www.atcmeeting.org/2010

June

ILTS 16th Annual International Congress
June 16 - 19, 2010
Hong Kong Convention & Exhibition Centre in Hong Kong, China
Visit www.ilts.org

Introductory Education Course for the New Transplant & Procurement Professional
June 25 - 29, 2010
Tempe Mission Palms Hotel & Conference Center in Tempe, AZ
Visit www.natco1.org

August

NATCO 35th Annual Meeting
August 1 - 4, 2010
Westin Diplomat Resort & Spa in Hollywood, FL
Visit www.natco1.org

CST Annual Scientific Conference
August 13 - 14, 2010
Vancouver Convention & Exhibition Centre in Vancouver, BC, Canada
Visit www.cst-transplant.ca

XXIII International Congress of TTS
August 15 - 19, 2010
Vancouver, Canada
Visit www.transplantation2010.org

September

The 1st World Congress on Controversies in Gastroenterology & Liver Diseases (C-GOLD)
September 23 - 26, 2010
Prague, Czech Republic
Visit www.comtecmed.com/cgold/2010/

CRN Chairperson Message

Karen Wiesen, MS, RD, LD
CRN Chair

Kidney Disease Patient Education Service

The Kidney Disease Patient Education (KDE) Services Final Rule (Section 152b) (410.48) went into effect January 1, 2010. These services are part of the Medicare Improvements Patient and Provider Act (MIPPA). During the comment period last fall, the Council on Renal Nutrition and the National Kidney Foundation submitted comments and suggestions regarding the role of the dietitian in this area. Unfortunately, these were not accepted by the Centers for Medicare and Medicaid Services (CMS) and the final rule was issued in December 2009. While disappointing, it is important to remember that Medical Nutrition Therapy (MNT) for chronic kidney disease (CKD) Stage 3-4 is covered by Medicare Part B. We should continue to focus our efforts on promoting MNT to nephrologists and primary care physicians. Following is a brief summary of the final rule on KDE Services and highlights of questions and the CMS response.

KDE Services are to be provided to beneficiaries with Stage 4 CKD. Services are to be provided by a "qualified person" who CMS defined as either a physician, physician assistant, nurse practitioner or clinical nurse specialist. The content of the six, 60-minute, face-to-face classes should include the following: (1) "the management of co-morbidities including for the purpose of delaying the need for dialysis" which includes management of bone and mineral disorders; (2) "the prevention of uremic complications" which includes diet, fluid restriction and medication management; (3) "therapeutic options, treatment modalities and settings;" (4) "opportunities for beneficiaries to actively participate in the choice of therapy and for therapy to meet their individual needs" which would include exercise, the right to refuse therapy and psychological impact; (5) "qualified persons must develop outcomes assessments designed to measure the beneficiary's knowledge about CKD and its treatment."

NKF and CRN asked that other healthcare professionals be added to the definition of qualified providers including the registered dietitian. The CMS response was: "*Since Congress did not specifically authorize the Secretary to approve additional healthcare providers within the defined term, no comments to expand the definition of provider were accepted."*

It was also suggested that the physician managing the KDE program initiate a referral for MNT. The CMS response was: "*We recognize that MNT can be an important benefit. Since referral of a patient for MNT services under 42 CFR 410 Subpart G is left to the discretion of the physician, CMS did not think it was appropriate to include a requirement for referral to MNT services as part of the referral process or part of the standards for content under KDE services. Physicians are encouraged to discuss with the beneficiary whether a referral for MNT would be appropriate."*

You can read the transcripts from both comment sessions along with the CMS response at http://www.cms.hhs.gov/CoverageGenInfo/08_CKD.asp. At the top of the page you can search for KDE services. ◆

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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 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.