



RENALIFE

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Caregiver Profile

Food is Good

Does My Child Need
a Support Group?

Influencer Interview

A Publication of the American Association of Kidney Patients

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Understanding kidney disease is a critical first step to improving your health. The American Association of Kidney Patients is the leader in kidney patient centered education. For nearly 50 years, AAKP has provided patients and families the educational tools they need to understand kidney disease and take a more active and informed role in their health care.

Our efforts across the country to speak on behalf of patients and their families have improved their lives and well-being - benefiting all of America's kidney patients. Building communities among kidney patients and their families, health care professionals, and other support groups is an important goal of AAKP.

Education • Community • Advocacy

AAKP promotes education and encourages conversations that help improve patients' everyday lives.

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The Independent Voice of Kidney Patients Since 1969™

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By AAKP Staff Writer

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Food is Good

By Jennifer Rose Parker, RDN, CSR, LDN

Do you think that food is good? Are you still able to eat the food you most enjoy? This nutrition article is a must read for anyone living with kidney disease. The article explores food groups to choose, estimated proportions and food group facts. After reading it we hope you believe that food is good and can improve your health.

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Does My Child Need a Support Group?

By Michael Schwing MSW, LCSW

Pediatric patients who have been diagnosed with End Stage Renal Disease often need help coping. A support group can be a great resource for both the patient and their family. This article describes what a support group is about, as well as its benefits. It also gives advice on how to find a support group.

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Influencer Interview: Elena K. Balovlenkov, MS, RN, CHN, Centers For Medicare & Medicaid Services

For many, the choice of where to go for dialysis care may not feel like a choice at all, particularly when the need to start dialysis is sudden. So how do you know if you made the right decision? And even if you are not looking to change facilities, how can you make sure you are getting the best care? This interview discusses the Dialysis Facility Compare website, the official Centers for Medicare & Medicaid Services source for information about the quality of dialysis centers.

MESSAGE FROM AAKP

I hope this issue of *aakpRENALIFE* finds you well, busy living life, working hard and enjoying your family and friends!

As AAKP heads into Fall 2017, our team is aggressively working to advance AAKP as a national organization engaged in substantive efforts to improve your access to timely information and to create even more opportunities for you to become involved in the fight against kidney disease.

This issue will find many of you in attendance at our National Patient Meeting on September 8-10 in St. Petersburg, Florida at the Vinoy Renaissance Resort. An even greater number of you will be attending the conference via livestream in real time or watching the conference after it has concluded. One of the reasons why we invest in livestream for our conferences is because it allows patients and families to access our stunning lineup of speakers and panelists and their valuable information for months and years to come. Many of our speakers come to the AAKP National Patient Meeting because it is so unique - they know AAKP is the nation's oldest and largest patient-lead and fully independent kidney organization and that the

perspectives they offer will be unfiltered and warmly received. So thank you for the respect that you extend to them!

As AAKP grows, so does our relevance on the national stage and the number of invitations that AAKP leadership, the Board of Directors and the Medical Advisory Board receive to become even more involved at the national level to impact kidney health policy, innovation and scientific breakthroughs.

Since our last issue of *aakpRENALIFE*, we achieved the following as an extension of our national strategy to raise the impact of AAKP and awareness among the national policy-makers and influencers who ultimately impact the future of the fight against kidney disease:

- In July, the Food and Drug Administration (FDA), announced the launch of an exciting new effort, the Patient Engagement and Advisory Committee (PEAC) to more formally involve the patient's voice in efforts to advise the FDA on the multiple complex issues related to medical devices and their impact on patients. The PEAC is the first FDA committee that is wholly focused on patients. The goal of the PEAC, as stated by the FDA, is to help the FDA "to better understand and integrate patient perspectives into our oversight, to improve communications with patients about benefits, risks, and clinical outcomes related

to medical devices, and to identify new approaches, unforeseen risks or barriers, and unintended consequences from the use of medical devices." I was honored to be asked by the FDA to serve as the first Chair of the PEAC and I look forward to working with patients across every community to provide the FDA with candid insights in support of their mission to aid all those who suffer from disease and illness. You can learn more about the FDA PEAC here: <https://blogs.fda.gov/fdavoices/index.php/2017/07/fda-sets-inaugural-meeting-of-first-ever-patient-engagement-advisory-committee/>

The first meeting of the PEAC will be conducted October 11-12, 2017 at the Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy, Gaithersburg, MD 20877. For those interested in attending or offering testimony, please find more information via this link: <https://www.fda.gov/AdvisoryCommittees/Calendar/ucm568511.htm>

- In August, Vice President Richard Knight and I had the opportunity to participate, along with over fifteen other patients, in the launch of the Kidney Precision Medicine Project (KPMP), a strategic initiative of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH).

Based on the mission outline, the KPMP hopes to make precision medicine possible for kidney diseases. KPMP will help scientists understand the kidney at a very detailed level. KPMP scientists will make a map of the kidney to show important cells, regions, and disease pathways. Ultimately, KPMP research will find new markers and treatment targets that make personalized, effective, and safe treatments possible for kidney diseases. Vice President Richard Knight was asked by NIDDK to serve on the formal Steering Committee for the KPMP and AAKP is honored to once again play a key role on this pioneering effort.

But well beyond these opportunities, the AAKP team continues their efforts to expand AAKP at the national and local level in order to improve patient access to timely information about kidney disease and to help you “plug-in” to a more active role for the kidney community. Here are the top three things you can do today with just a small amount of your time to help AAKP and your fellow patients by sharing information and taking action to fight kidney disease:

1. Encourage others to join AAKP and utilize our free membership to gain valuable access to information at no cost! Send your friends, fellow patients and personal network this link to sign up: <https://aakp.org/patientfamily-membership-registration/>
2. Follow us on Twitter and Facebook, share our posts and give us your comments! Tell us what you are up to as a patient and how you manage the balance of life, family, work and health! On Twitter, find us at: @kidneypatients and on Facebook find us at: <https://www.facebook.com/kidneypatient>
3. Become an AAKP Ambassador! This is a new program AAKP has launched under the direction of our new team member, Erin Kahle, Director, Stakeholder Operations for the AAKP Center for Patient Engagement & Advocacy. Ambassadors are some of the most activated kidney patients in the AAKP membership –

these are fellow patients who engage their own networks into our activities, attend events, travel to Washington, D.C. to help us on Capitol Hill and at other major events. For more information email: ekahle@aakp.org

Enjoy this issue of aakpRENALIFE and remember – AAKP draws its ultimate strength and relevance from patients like you. We have worked very hard to raise the funds necessary to offer free membership, tremendous educational programs and highly impactful advocacy training and tools. Our entire team does this to help patients like you become more active in your own care. We need your help. Please become more active today – we have made it easy – the rest is up to you!



Paul T. Conway
President of AAKP

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An interview with **BRENDA VASSER-TAYLOR,** founder of **ESRD Rockstars**

By Deborah Pelaez, AAKP Staff Writer



Brenda Vasser - Taylor knows what it feels like to be “in the trenches”. She spent seven years caring for both her husband and daughter with end stage renal disease (ESRD) with no supports in place for herself. She often felt stressed, and had no outlet to recharge from the demands of work and running a household. She promised herself and her husband that one day, if she had the opportunity, she would devote her time to help ESRD caregivers.

Brenda’s husband, Eddie, was diagnosed with kidney disease over 30 years ago, when they had only been married a year. The doctor told the couple if they

wanted kids, they did not have much time. Their daughter, Quin, was born one year later. And, Eddie received a much needed kidney transplant.

It was when Quin turned 20 years old and she started experiencing symptoms, they learned she too had kidney disease. She inherited Focal Segmental Glomerulosclerosis (FSGS) and faced dialysis and needing a transplant. During this same time, Eddie’s transplant failed. Both father and daughter were on dialysis.

Brenda says, “They do not have a manual for the caregiver when someone goes on dialysis.” Brenda desperately looked for resources and help. She said that she was so overwhelmed that when someone would ask her what kind of help she needed she did not know how to answer. She asked herself often, “How do people get through this?”

After almost six years on dialysis, Quin received a kidney transplant. Shortly after, Eddie passed away and Brenda founded ESRD Rockstars, the non-profit that she and her husband had talked about many times, to support caregivers.

The mission of ESRD Rockstars states, “Here at ESRD Rockstars, we encourage caregivers to make themselves a priority, so that they can continue caring for the ones that they love.” ESRD Rockstars

currently has a website, a blog, a local support group in Chicago, IL and Treasure Chest program for caregivers.

- The ESRD Rockstars website and the blog have educational stories and resources for caregivers. Some of the articles you will find there include: *The 5 Most Unexpected Challenges of Caregiving* and *Caregiver Stress: Tips for Taking Care of Yourself*.
- The ESRD Rockstars support group takes place at the University of Chicago. Anyone at the hospital going on dialysis gets information on the ESRD Rockstars support group for caregivers. Brenda works in hospital administration and has personally volunteered to talk to any caregiver who is scared about their loved one going on dialysis.
- The ESRD Rockstars Treasure Chest program awards gifts to caregivers. Caregivers can nominate themselves or someone else can nominate them. Depending on the number of requests and incoming donations, Brenda awards spa days, weekend trips, bath & body items and much more to caregivers in need of a little support, time off, or just the knowledge of knowing someone is thinking of them. 🌸



For more information on ESRD Rockstars or to contact Brenda Vasser-Taylor, please visit the ESRD Rockstars website at www.esdrockstars.com.

You can also meet Brenda at these upcoming events!

- **AAKP's 43rd National Patient Meeting**, Sept. 8-10, 2017 in St. Petersburg, FL. For more information, contact AAKP!
- **Living with Kidney Disease and Transplantation -** Chicago Central educational seminar, Sept. 16, 2017. For more information, visit NKF of Illinois online.

AAKP gratefully acknowledges our In Memoriam and anonymous gifts received by mail and online.

Your donation helps AAKP continue to be the independent voice of kidney patients through education, advocacy and the fostering of patient communities!

Donations and memorials are accepted online at: <https://donatenow.networkforgood.org/aakphelps>

Do you have SHPT with stage 3 or 4 CKD and a

GET YOUR CON



What is SHPT?

In patients with chronic kidney disease (CKD), when the parathyroid glands make too much parathyroid hormone (PTH), it is called secondary hyperparathyroidism (SHPT). Some patients with SHPT also have low levels of vitamin D. People with CKD, SHPT, and low vitamin D levels have a greater risk of bone disease and fractures.

Indication and Limitations of Use

Royaldee® (calcifediol) extended-release 30 mcg capsules is a treatment for secondary hyperparathyroidism (SHPT) in adults with stage 3 or 4 chronic kidney disease (CKD) and low vitamin D blood levels (25-hydroxyvitamin D less than 30 ng/mL). It is not for patients with stage 5 CKD or on dialysis.

Important Safety Information

- Before starting Royaldee, the level of calcium in your blood should be in the normal range (below 9.8 mg/dL). Your doctor can tell you if your calcium level is right for starting Royaldee.
- Royaldee can cause hypercalcemia and hypercalciuria (high levels of calcium in your blood and urine, respectively). You should tell your doctor if you are taking any other medications, including other vitamin D medications (prescription or over-the-counter vitamin D supplements). Your doctor may tell you to stop taking them while you are taking Royaldee, as very high calcium levels due to high vitamin D levels could cause severe changes to your heart rhythm or seizures and require emergency treatment.
- Tell your doctor about any and all medications you may be taking. While you are taking Royaldee, tell your doctor if you receive any new prescriptions or start any new over-the-counter medications.
- Tell your doctor immediately if you experience any of the following symptoms of very high calcium: feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss.

low vitamin D level?

SHPT UNDER TROL

What is Rayaldee?

RAYALDEE® is a treatment for SHPT in adults with stage 3 or 4 CKD and low vitamin D blood levels (25-hydroxyvitamin D less than 30 ng/mL). RAYALDEE can help increase the vitamin D level in your body and decrease PTH.

Rayaldee may not work the same for everyone.

Ask your doctor if Rayaldee is right for you!

For more information, visit Rayaldee.com.

- While you are taking Rayaldee, your doctor will order laboratory tests to see how your CKD is doing. These lab tests will also examine your blood for levels of calcium, phosphorus, 25-hydroxyvitamin D, and PTH. Based on your test results, your dose of Rayaldee may be changed or stopped until your lab results improve.
- The most common side effects of Rayaldee reported by patients in clinical trials were anemia (low levels of red blood cells or hemoglobin), infection in the nose and/or throat, high levels of blood creatinine (a lab test for measuring kidney function), shortness of breath, cough, congestive heart failure, and constipation.
- Take your Rayaldee at bedtime and swallow your capsules whole; do not bite into or chew them.
- If you miss a dose, take Rayaldee at your next scheduled time. Do not take an extra dose to make up for the dose you missed.
- Be sure to follow your doctor's orders, including getting your laboratory tests done on time.

You are encouraged to report negative side effects of prescription drugs to the U.S. Food and Drug Administration (FDA).

Visit www.fda.gov/medwatch, or call
1-800-FDA-1088 (1-800-332-1088).

Please see Brief Summary of Prescribing Information on following page, and Full Prescribing Information at Rayaldee.com.



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30 mcg

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FULL PRESCRIBING INFORMATION**

RAYALDEE® (calcifediol) extended-release capsules, for oral use



INDICATIONS AND USAGE:

RAYALDEE® is a vitamin D₃ analog indicated for the treatment of secondary hyperparathyroidism in adult patients with stage 3 or 4 chronic kidney disease and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. RAYALDEE is not indicated for the treatment of secondary hyperparathyroidism in patients with stage 5 chronic kidney disease or in patients with end-stage renal disease on dialysis.

CONTRAINDICATIONS:

None

WARNINGS AND PRECAUTIONS

Hypercalcemia may occur during RAYALDEE treatment. Acute hypercalcemia may increase the risk of cardiac arrhythmias and seizures and may potentiate the effect of digitalis on the heart. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. Severe hypercalcemia may require emergency attention.

Hypercalcemia may be exacerbated by concomitant administration of high doses of calcium containing preparations, thiazide diuretics, or other vitamin D compounds. In addition, high intake of calcium and phosphate concomitantly with vitamin D compounds may lead to hypercalcemia and hyperphosphatemia. In these circumstances, frequent serum calcium monitoring and RAYALDEE dose adjustments may be required. Patients with a history of hypercalcemia prior to initiating therapy with RAYALDEE should be monitored more frequently for possible hypercalcemia during therapy.

Patients should be informed about the symptoms of elevated serum calcium, which include feeling tired, difficulty thinking clearly, loss of appetite, nausea, vomiting, constipation, increased thirst, increased urination, and weight loss. Hypercalcemia of any cause, including RAYALDEE, increases the risk of digitalis toxicity. In patients using RAYALDEE concomitantly with digitalis compounds, monitor both serum calcium and patients for signs and symptoms of digitalis toxicity and increase the frequency of monitoring when initiating or adjusting the dose of RAYALDEE.

Adynamic bone disease with subsequent increased risk of fractures may develop if intact PTH levels are suppressed by RAYALDEE to abnormally low levels. Monitor intact PTH levels and adjust RAYALDEE dose, if needed.

DOSAGE AND ADMINISTRATION

Important Dosage and Administration Information

- Ensure serum calcium is below 9.8 mg/dL before initiating treatment.
- Instruct patients to swallow RAYALDEE capsules whole.
- Instruct patients to skip a missed dose and to resume taking the medicine at the next regularly scheduled time. Do not administer an extra dose.

Starting Dose and Dose Titration

- The initial dose of RAYALDEE is 30 mg administered orally once daily at bedtime.
- The maintenance dose of RAYALDEE should target serum total 25-hydroxyvitamin D levels between 30 and 100 ng/mL, intact parathyroid hormone (PTH) levels within the desired therapeutic range, serum calcium (corrected for low albumin) within the normal range and serum phosphorus below 5.5 mg/dL.
- Monitor serum calcium, serum phosphorus, serum total 25-hydroxyvitamin D and intact PTH levels at a minimum of 3 months after initiation of therapy or dose adjustment, and subsequently at least every 6 to 12 months.
- Increase the dose to 60 mg orally once daily at bedtime after approximately 3 months, if intact PTH remains above the desired therapeutic range. Prior to raising the dose, ensure serum calcium is below 9.8 mg/dL, serum phosphorus is below 5.5 mg/dL and serum total 25-hydroxyvitamin D is below 100 ng/mL.
- Suspend dosing if intact PTH is persistently and abnormally low to reduce the risk of adynamic bone disease (see Warnings and Precautions), if serum calcium is consistently above the normal range to reduce the risk of hypercalcemia (see Warnings and Precautions), or if serum total 25-hydroxyvitamin D is consistently above 100 ng/mL. Restart at a reduced dose after these laboratory values have normalized.

USE IN SPECIFIC POPULATIONS

Teratogenic Effects - Pregnancy Category C: Calcifediol has been shown to be teratogenic in rabbits when given in doses of 8 to 16 times the human dose of 60 mg/day, based on body surface area. There are no adequate and well-controlled studies in pregnant women. RAYALDEE should be used during pregnancy only if the potential benefit justifies potential risk to the fetus. When calcifediol was given orally to pregnant rabbits on the 6th through the 18th day of gestation, gross visceral and skeletal examination of pups indicated that the

compound was teratogenic at doses of 25 and 50 mg/kg/day. A dose of 5 mg/kg/day was not teratogenic. In a similar study in rats, calcifediol was not teratogenic at doses up to and including 60 mg/kg/day.

Carcinogenesis, Mutagenesis, Impairment of Fertility

No neoplastic changes attributable to calcifediol were observed at subcutaneous doses of 3, 10 and 33 mg/kg/day in a 26-week non-H2 transgenic mouse study. In vitro or in vivo mutagenicity studies have not been performed with RAYALDEE. No genotoxic or mutagenic effects have been reported with calcifediol. Calcifediol has not been shown to have significant effects on fertility in rats.

Labor and Delivery: The effect of this drug on the mother and fetus during labor and delivery is not known.

Nursing Mothers: Limited available evidence indicates that calcifediol is poorly excreted in human milk. Caution should be exercised when RAYALDEE is administered to a nursing woman.

Pediatric Use: The safety and efficacy of RAYALDEE have not been established in pediatric patients.

Geriatric Use: Of the total number of subjects in phase 3 placebo-controlled clinical studies of RAYALDEE, 63% were ≥65 years of age and 22% were ≥75 years of age. No overall differences in the safety or efficacy of RAYALDEE were observed between subjects older than 65 years and younger subjects.

Renal Impairment

No difference in efficacy was observed between patients with stage 3 chronic kidney disease or those with stage 4 disease in subgroup analysis. Safety outcomes were similar in these subgroups. The safety and efficacy of RAYALDEE in the treatment of secondary hyperparathyroidism in patients with stage 2 or stage 5 chronic kidney disease and patients with end-stage renal disease on dialysis have not been established (see Indications and Usage).

Overdosage

Excessive administration of RAYALDEE can cause hypercalcemia, hyperphosphatemia, or over-suppression of intact PTH. Common symptoms of vitamin D overdosage may include constipation, decreased appetite, dehydration, fatigue, irritability, muscle weakness, or vomiting.

Treatment of acute accidental overdosage with RAYALDEE should consist of general supportive measures. If the overdosage is discovered within a short time, induce emesis or perform gastric lavage to prevent further absorption. Obtain serial serum and urine calcium measurements, and assess any electrocardiographic abnormalities due to hypercalcemia. Discontinue supplemental calcium. Treat with standard medical care if persistent and markedly elevated serum calcium levels occur.

Calcifediol is not significantly removed by dialysis.

ADVERSE REACTIONS

The data in Table 1 are derived from two pivotal studies described below. These data reflect exposure of 285 subjects to RAYALDEE 30 or 60 mg daily for up to 6 months (mean 24 weeks, range 1 to 31 weeks). The mean age of the study population was 66 years old (range 25-85 years). Half of the subjects were male, 65% were White, and 32% were African-American or Black. At baseline, subjects had secondary hyperparathyroidism, stage 3 (52%) or 4 (48%) chronic kidney disease without monoclonal gammopathy and serum total 25-hydroxyvitamin D levels less than 30 ng/mL. The most common causes of chronic kidney disease were diabetes and hypertension and the mean estimated GFR at baseline was 31 mL/min/1.73 m². At baseline, mean plasma intact PTH was 148 pg/mL, mean serum calcium was 9.2 mg/dL, mean serum phosphorus was 3.7 mg/dL and mean serum 25-hydroxyvitamin D was 20 ng/mL.

Table 1 shows common adverse reactions associated with the use of RAYALDEE in the pooled placebo-controlled trials. These adverse reactions were not present at baseline, occurred more commonly on RAYALDEE than on placebo, and occurred in at least 1.4% of patients treated with RAYALDEE.

Table 1. Common Adverse Reactions in Placebo-controlled Trials Reported in ≥1.4% of RAYALDEE-Treated Subjects

Adverse Reaction	Placebo N=144	RAYALDEE N=285
	%	%
Anemia	3.5	4.9
Nasopharyngitis	2.8	4.9
Blood creatinine increased	1.4	4.9
Dyspnea	2.8	4.2
Cough	2.1	3.5
Cardiac failure congestive	0.7	3.5
Constipation	2.8	3.2
Bradycardia	0.7	2.8
Hyperkalemia	0.7	2.5
Osteoarthritis	0.7	2.1
Hypotension	0.7	1.8
Confusion	0.0	1.8
Pneumonia	0.7	1.4
Chronic obstructive pulmonary disease	0.0	1.4

Increase in Serum Calcium: Patients randomized to RAYALDEE experienced a greater mean (SE) increase in serum calcium (P<0.001) than patients randomized to placebo [i.e., 0.2 (0.02) mg/dL on RAYALDEE versus 0.1 (0.03) mg/dL on placebo from baseline to trial end]. Six subjects (2%) in the RAYALDEE treatment group and no subjects (0%) in the placebo group required dose reductions for protocol-defined hypercalcemia (two consecutive serum calcium values greater than 10.3 mg/dL). A total of 4.2% of RAYALDEE-treated subjects and 2.1% of placebo-treated subjects experienced at least 1 elevation in serum calcium above the upper limit of normal (10.5 mg/dL).

Increase in Serum Phosphorus: Patients randomized to RAYALDEE experienced a greater mean (SE) increase in serum phosphorus than patients randomized to placebo [i.e., 0.2 (0.03) mg/dL on RAYALDEE versus 0.1 (0.04) mg/dL on placebo from baseline to trial end]. One subject (0.4%) in the RAYALDEE treatment group met protocol-defined hyperphosphatemia (two consecutive serum phosphorus values >5.5 mg/dL deemed to be study drug related) compared to no subjects in the placebo group. A total of 45% of RAYALDEE-treated subjects and 44% of placebo-treated subjects experienced at least one elevation in serum phosphorus above the upper limit of normal (4.5 mg/dL).

To report SUSPECTED ADVERSE REACTIONS, contact OPKO Pharmaceuticals, LLC at 1-844-729-2539 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

CYP3A4 Inhibitors

Cytchrome P450 inhibitors, such as ketoconazole, itraconazole, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, trimethoprim or voriconazole, may inhibit enzymes involved in vitamin D metabolism (CYP24A1 and CYP27B1), and may alter serum levels of calcifediol. Dose adjustment of RAYALDEE may be required, and serum 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor.

Thiazides

Thiazides are known to induce hypercalcemia by reducing excretion of calcium in the urine. Concomitant administration of thiazides with RAYALDEE may cause hypercalcemia. Patients may require more frequent serum calcium monitoring in this setting.

Cholestyramine

Cholestyramine has been reported to reduce intestinal absorption of fat-soluble vitamins and may impair the absorption of calcifediol, the active ingredient in RAYALDEE. Dose adjustment of RAYALDEE may be required, and serum total 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with cholestyramine.

Other Agents

Phenobarbital or other anticonvulsants or other compounds that stimulate microsomal hydroxylation reduce the half-life of calcifediol, the active ingredient in RAYALDEE. Dose adjustment of RAYALDEE may be required, and serum total 25-hydroxyvitamin D, intact PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with phenobarbital or other anticonvulsants.

HOW SUPPLIED

RAYALDEE is supplied as 30 mg calcifediol in blue, oval extended-release capsules, imprinted O.

Bottles of 30 [NDC 70301-1001-1]

Bottles of 60 [NDC 70301-1001-2]

STORAGE AND HANDLING

Store at 20-25°C (68-77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

RAYALDEE is a registered trademark of OPKO Inland Global Holdings Ltd.

Patent: <http://www.opko.com/products/patents/>

Rac. 06/2016

OPKO RENAL

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FOOD IS GOOD

By Jennifer Rose Parker, RDN, CSR, LDN

Nestled in historic Charleston, South Carolina, on the corner of Hasell and Meeting Street, sits a restaurant named, “F.I.G.” which stands for, “Food is Good”. That got me to thinking, as a clinical dietitian, working with people on special diets, do my patients still believe that food is good? For most, the “renal diet” is considered a challenge. Mashed potatoes or beans and rice have been cultural staples they have enjoyed until they are told to follow a renal diet and “limit” their potassium. But perhaps there’s more good food than they once thought—and just maybe, mashed potatoes and beans and rice can fit into the renal diet and also be seen as healthy choices for all stages of chronic kidney disease? My message to anyone living with CKD is that food is good and can improve your health. When you find what you and your body can enjoy, you’ll look forward to eating again.

So where do we start? We will begin with healthy choices for all stages of CKD and then customize from there. If you also have diabetes, hypertension, or cardiac disease, take heart—there is harmony amongst these special diets too.

Food Groups to Choose

- Whole Grains (like breads, cereals, oats, pasta, rice, quinoa)
- Lean Proteins (like legumes, peas, meats, poultry, fish, game)
- Fruits

- Vegetables
- Dairy
- Nuts and Seeds
- Healthy Oils

The human body, even with chronic kidney disease, diabetes, or hypertension needs a well-balanced diet that includes carbs, protein, fat, fiber, vitamins, minerals and water to thrive. These important nutrients will improve blood pressure, decrease inflammation, help you build and maintain strong muscles, and protect your heart and bones.



Estimating Portions

For all stages of chronic kidney disease (CKD 1-5, Dialysis, and Transplant), you can estimate

Nutritional Article continued on next page

portions for each meal using your own hand. A good rule of thumb is to have a fist full of carbs, a cupped handful of fruit and vegetables, and a palm-sized portion of protein.

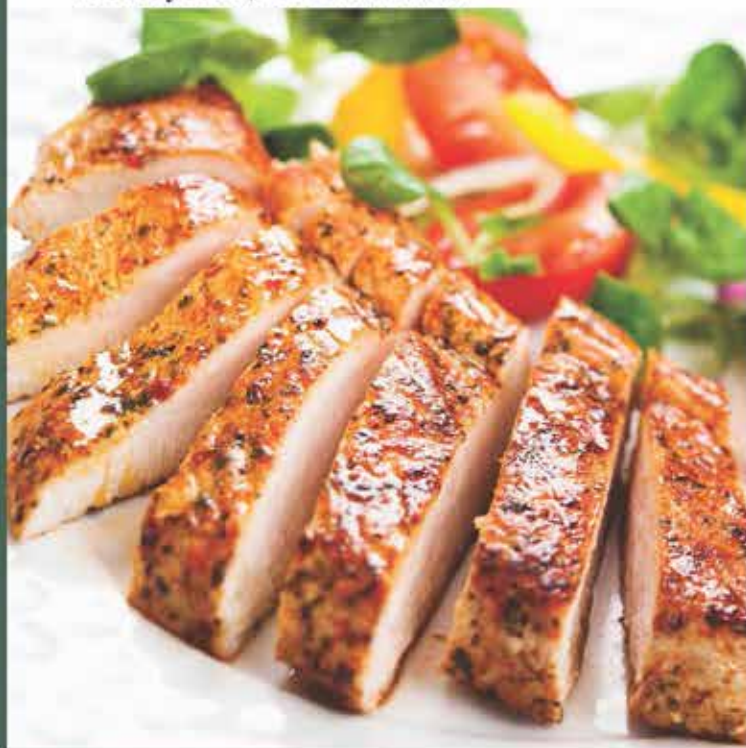
Food Group Facts for Kidney Patients

Whole Grains

- Aim for 2-3 servings of bread/cereal/grains for each meal, three times a day.
- Choose whole grains for at least 3 of all your servings in one day.
- Whole grains contain a good amount of fiber which helps control blood sugar, lower cholesterol and blood pressure, and can help you feel fuller, longer.

Lean Protein

- Aim for protein at every meal, three times a day. It can be plant-based, like beans or lentils, or lean animal meat from beef, chicken, eggs, fish, pork, or wild game.
- All protein foods, plant and animal sources, contain a good amount of potassium, protein and phosphorus to help your body build and maintain strong muscles (including the heart), healthy skin, hair and nails.



- If you have CKD stages 3-5 with no dialysis, you'll follow a lower protein diet—using half the size of your palm for each meal.
- If you have CKD stage 5 with dialysis or have just received a transplant, you'll follow a higher protein diet—using your whole palm for each meal.

Fruits and Vegetables

- Aim for 1-2 fruits and 1-2 vegetables at each meal, three times a day.
- Fruits and vegetables contain a good amount of fiber, potassium, vitamins and minerals and help fight infections, lower blood pressure and can improve your overall health.
- If you have CKD stage 5 with no dialysis or stage 5 with traditional in center dialysis you'll likely follow a "lower potassium diet" and choose fruits and veggies lower in potassium.
- If you have CKD stage 3, 4, PD, Nocturnal, Home Hemodialysis or short-daily hemodialysis, you'll likely follow a "higher potassium diet" and therefore choose mostly higher potassium fruits and vegetables.

Dairy

- Aim for the amount your renal dietitian recommends for you, specifically.
- Dairy contains a good amount of potassium, protein, phosphorus, and some vitamins like Calcium and Vitamin D. These vitamins help maintain bone and heart health.
- Depending on your unique needs, you may be able to choose milk, cheese, and other dairy products every day.

Putting it all Together

The best thing you can do is to meet with a registered dietitian nutritionist (RDN) who specializes in kidney disease. You can share what foods you most enjoy and your dietitian can help you build them into a balanced eating plan. No

matter the stage of your chronic kidney disease, food is good and good for you, so let's eat! 🌱



Jennifer Rose Parker, RDN, CSR, LDN is a Lead Dietitian with Fresenius Kidney Care (FKC) and has enjoyed helping patients, managing dietitians and participating in company-wide campaigns focused on eating well with CKD since 2010. She completed her B.S. at Florida State University

and Dietetic Internship at Barnes-Jewish College at Washington University and has been working in nephrology and diabetes management since 2005. She has presented to NKF's Renal Professional Forums, the ANNA and AAKP and other corporate wellness programs on the bioavailability of phosphorus and dangers of phosphate additives. She is an active member of the Academy's Renal Practice Group and the NKF's Council on Renal Nutrition. In her free time, she and her husband love traveling and investing in their community through their local church.



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The *Delicious!* third edition recipe cards includes eighteen recipes total including Chicken Pot Pie, Steak Fajita Salad, Summer Berry Semifredo, and Ginger Pork Lettuce Wraps. Check out our store to order your set now.

<https://aakp.org/product/aakp-delicious-recipe-card-series-3rd-edition-complete-set/>





EDUCATION ARTICLE

Does My Child Need a Support Group?

By Michael Schwing MSW, LCSW

Pediatric patients who have been diagnosed with End Stage Renal Disease often have difficulty coping and adjusting to a lifelong chronic illness.

Depression and anxiety are extremely common in this population. Patients express feelings of loneliness, isolation and being different. They often feel as though no one understands what they are going through, and even they don't know what they are going through or what to expect in the future. They express feelings of grief from losing the

freedom they once enjoyed and the carefree attitude they once had. Whether it is depression, anxiety, or an adjustment disorder, these mental health concerns become enormous barriers to care and require intervention by the clinical social worker.

The thoughts and feelings expressed by these teens are expected. The issue becomes how to help them and their families cope and adjust, connect to resources, and realize they are NOT alone. Therapists could have all of the training in the world

but could never feel what these kids are feeling or understand what these kids are experiencing. When intervening with these challenging emotional barriers to care, a support group can be a great resource.

What is a support group and how does it help?

A support group is simply a group of people with common experiences or concerns who provide each other with encouragement, comfort and advice.

The three main goals of a support group are to:

1. Encourage patients and families to develop healthy coping skills
2. Help them connect with vital resources
3. Facilitate unique friendships within the group

The most important function of a good support group is to provide the opportunity for kids to connect and share with others dealing with similar circumstances. It helps to talk or just listen to others who are also trying to find ways to cope.

Support groups are not designed to replace medical or individual counseling. However, sometimes just telling your story will encourage other members to offer coping skills. Patients and parents are eager to share with others in the group the resources they have located that could benefit others.

Support groups are typically facilitated by licensed clinical social workers who work in the dialysis unit. The therapists have access to local and national resources. Speakers are often invited to address the group on local services that are available and helpful.

Benefits of support groups

Regardless of their diagnosis, support groups help teens and parents find people with concerns similar to theirs. Members of a support group share personal experiences and offer one another emotional comfort and moral support.



Benefits include:

- Reducing distress, depression, anxiety or fatigue
- Feeling less lonely, isolated or judged
- Gaining self-esteem, a sense of empowerment and control
- Improving coping skills and sense of adjustment
- Talking openly and honestly about your feelings
- Developing a clearer understanding of what to expect with your situation
- Getting practical advice or information about treatment options
- Comparing notes about resources, such as doctors and alternative options

Parents and caretakers also find camaraderie and support through mutual experiences. They assist others in locating support services and referral services. Interaction with other parents and caretakers can reinforce their own self-health skills.

Education Article continued on next page

HOW TO FIND A SUPPORT GROUP

- Ask the Clinical Social Worker.
- Search the Internet.
- Contact local community centers.
- Ask people you know with the condition.
- Contact organizations like AAKP. 🌐



Michael Schwing is an LCSW with a MSW degree from the University of Central Florida's School of Social Work. He works specifically with pediatric nephrology patients in the Hewell Kid's Kidney Center at Arnold Palmer Hospital for Children, part of Orlando Health.

Michael has presented nationally as a distinguished faculty member of the National Kidney Foundation Spring Clinical Meeting 2016, in Boston, on the topic *Transition of Care: Teen to Adult*, and again in 2017, in Orlando, on the topic *Just Don't Call it a Support Group*. Two clinical abstracts written and co-written by Michael were published in the peer reviewed journal *Hemodialysis International*, January 2016, and presented nationally via poster at The Annual Dialysis Conference 2016, in Seattle. In 2017 a clinical abstract written by Michael was published in the same peer reviewed journal, *Hemodialysis International*, March 2017, and presented via poster at the ADC 2017, in Long Beach, CA.

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EDUCATION ARTICLE

AAKP Healthline: Advancements in Telemedicine

By AAKP Staff, reviewed by Dr. Rebecca Schmidt, DO, FACP

Rebecca Schmidt, DO, FACP, Professor and Chief of the Section of Nephrology at the West Virginia School of Medicine led an AAKP Healthline webinar on how telemedicine is being used to revolutionize patient care on July 19, 2017. The webinar also featured a patient perspective: Bill Murray, kidney home hemodialysis patient. This educational webinar was proudly supported by an educational donation by Baxter.

Here are a few takeaways from the webinar.

Telemedicine is a medical service: Telemedicine differs from Telehealth. Telemedicine is an actual clinical service, whereas Telehealth can be a public health app or a webinar.

Telemedicine is not just for rural areas: Telemedicine is used for many reasons these days. Many people use it for convenience, to have more frequent interactions with physicians and better coordinated care.

Many specialties use Telemedicine: Depending

where you live, many specialists are available to do Telemedicine. In fact, in the state of West Virginia, where Dr. Schmidt works, patients can “see” a variety of specialists including nephrologists, psychiatrists, dermatologists and neurologists.

Telemedicine does have some disadvantages: Telemedicine requires technical training and special equipment and is not available everywhere or for every patient. Services may not be covered by Medicaid (it depends on the state) and Medicare has restrictions on the use of Telemedicine.

Telemedicine laws vary by state: Laws governing how telemedicine can be used vary greatly from state to state. As with national policy, state health care laws related to Telemedicine are rapidly changing. To stay on top of your state laws on Telemedicine, you can go to: <http://www.cchpca.org/>.

The full webinar is available for you to listen to at www.aakp.org/aakp-healthline and click on the “Past Webinar” button.

A Second Chance At A Healthy Life

At 18 months, Taylor Kroeger received a life-saving kidney transplant from his father. But by age 21, his kidney was failing.

Taylor's mother stepped up and offered to donate. But doctors found Deanna wasn't an ideal match.

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Learn more at MiamiTransplant.org or call 305-355-5000.



INFLUENCER INTERVIEW:

Elena K. Balovlenkov, MS, RN, CHN,
Centers For Medicare & Medicaid Services

AAKP has the distinct honor to work very closely with some of the finest U.S. Civil Servants in the Federal Government whose responsibilities include working on your behalf to serve and protect the best interests of patients and their families. Recently, AAKP had the distinct privilege to talk with Elena Balovlenkov of the Centers for Medicare & Medicaid Services about dialysis care and patient choice. On the national stage, Elena is an important "influencer" and we thought you would find her comments helpful and insightful. I am sure you will agree that having professionals of her caliber and candor working as public servants for America is a source of pride.

- Paul T. Conway, President of AAKP



For many, the choice of where to go for dialysis care may not feel like a choice at all, particularly when the need to start dialysis is sudden. So how do you know if you made the right decision? And even if you are not looking to change facilities, how can you make sure you are getting the best care?

"It matters where you go for care," says Elena Balovlenkov, the Dialysis Facility Compare lead at the Centers for Medicare & Medicaid Services. "My job is to make it easier for patients to make an informed decision, and to educate patients on how

to start a conversation with their dialysis facility to ensure they are getting the best care."

The Dialysis Facility Compare website, <https://www.medicare.gov/dialysisfacilitycompare>, is the official Centers for Medicare & Medicaid Services source for information about the quality of dialysis centers. Medicare collects information from thousands of certified dialysis centers across the country to measure how well they provide dialysis care to their patients. In the questions and answers below, Balovlenkov discusses the website and what it can offer kidney patients.

AAKP: Elena, tell us more about your background and how you came to work on the Dialysis Facility Compare website?

ELENA BALOVLENKOV (EB): I started working as a nurse in 1975, and I've spent most of my career focused on kidney patients. I've worked not just as a caregiver but in many other roles as well. I've worked in or managed hospital-based dialysis centers, large dialysis organizations, nursing homes offering dialysis, pre- and post-transplant centers, and as a Joint Commission Surveyor for Centers of Excellence. I actually credentialed the first Chronic Kidney Disease Center in California.

Seven years ago I came to CMS to work on the Medicare kidney disease programs. I wanted to be able to help patients on a larger scale. I believed that working with the Medicare program would give me that opportunity.

AAKP: We understand that Dialysis Facility Compare is a website with information about dialysis centers and their quality of care. How do you think the website helps patients?

EB: If you want to find the best possible dialysis care to fit your needs, Dialysis Facility Compare is the place to go. It lets you search for and compare dialysis centers side by side. And you can see that not all dialysis centers provide the same quality.

For example, some centers are better at preventing bloodstream infections than others. Not all centers offer the same set of services, for example, not all offer Home Hemodialysis Training. It's helpful for patients to understand those differences, because it makes a difference in the care you receive.

AAKP: What kinds of information can you find on DFC?

EB: Dialysis Facility Compare shows you the basics, including hours of operation, location, services, and an overall star rating. You can select up to three dialysis centers to compare. This helps you see which center can best meet your needs. You can also find detailed quality information, such as which centers have the lowest rates of hospitalization.

Even when patients are getting dialysis treatments regularly, patients with kidney failure often get sick and have to go to the hospital because of infections or other problems. In some cases, these problems may be related to the dialysis treatment itself. Dialysis centers whose patients have lower rates of hospitalizations may be better at helping their patients avoid serious problems. Working to keep you out of the hospital is very important, not just in managing your kidney disease, but also in staying healthy in general.

AAKP: So, who should use DFC?

EB: Whether you're just starting dialysis, you've been going to the same dialysis center for a long time, or are caring for a kidney patient, I truly believe there is something for everyone on Dialysis Facility Compare. I would encourage everyone to check it out. Even if you're not looking to make a change, knowing how your center is doing helps you to take an active role in your health.

You can also see if there's a center out there that can better fit your needs or your lifestyle. For example, if one center does not have shifts after 5 p.m., you can check Dialysis Facility Compare to see if there are any other local facilities that do. Dialysis Facility Compare is also a great resource to use when you are traveling and need to find a place to dialyze.

AAKP: With so many kidney disease sites out there, what makes DFC special?

EB: There are a lot of good kidney websites out there. Dialysis Facility Compare is designed to help patients find and compare dialysis centers, so you can choose the right center for you. It's the only site backed by the Medicare program and it uses government data about quality of care, so you can trust the information. We built Dialysis Facility Compare with patients in mind, and patients have given us a lot of feedback about what matters to them. We're using that to make it even better.

AAKP: What should patients do if they have concerns about their care?

EB: Patients who take an active role in their care have better outcomes. If you have a concern about your care, you can use the information on Dialysis Facility Compare to start the conversation with your dialysis center about how you can work together to improve outcomes for yourself and for others. If you find your dialysis center is no longer a good fit for you, Dialysis Facility Compare can help you find other options.

AAKP: What about the star ratings? Many patients and their families have heard of them and but many are not quite certain what they mean.

EB: Before the star ratings, the information on Dialysis Facility Compare was presented as percentages, rates and ratios. But we heard over and over from patients and caregivers that it was too difficult to understand all of those numbers and what they meant for their center. So, we added the star ratings to improve the usefulness of quality information. Star ratings can help patients quickly see differences in the quality between different dialysis centers. Besides summarizing performance, star ratings can help dialysis centers identify areas for improvement.

The star rating is based on a summary of different indicators of quality of patient care. Five stars is the highest rating. Dialysis Facility Compare also includes results of a survey that asks dialysis patients about their experience with their dialysis center—it asks things such as how clean the center is and how well the staff listen. The patient survey results are not currently part of the star ratings.

AAKP: What should a patient do if his or her dialysis center has one star?

EB: You should look at the other information on Dialysis Facility Compare that is not part of the Star Ratings, like the information on patient experience



and infection. You can also talk to your doctor and to the staff at your center. You may want to ask about steps your center is taking to improve the quality of care, or how you can get involved in working together with your center's staff to make positive changes.

AAKP: What do you want patients to know about DFC?

EB: The Medicare program is constantly working to improve Dialysis Facility Compare. We regularly speak with patients and ask them for their honest feedback on the site, because we want to make sure it really meets patients' needs. Although there's still more to do, I think feedback we've received has gone a long way to help us improve the site.

AAKP: How do you decide how to make changes or add new information to the website?

EB: Whenever we make major changes to the site, we typically go to the kidney community. We've worked closely with AAKP to receive invaluable feedback from leadership and members who we have volunteered their time to tell us how to improve the website. This past spring I joined a Patient Summit with members of AAKP and other major

Education Article continued on next page

national kidney patient organizations to hear about patients' information needs and how they like to get information. We also have "Technical Expert Panels" that help make important decisions about Dialysis Facility Compare. These panels include patient members in addition to science and medical experts to make sure the patient voice is represented.

We also pay close attention to the feedback we receive from people who submit emails on the website, and we have a "pop up" survey that website visitors can take, too. All of this feedback is taken into consideration.

AAKP: What have you heard from patients in the past and how has patient feedback led to changes on Dialysis Facility Compare?

EB: In response to feedback from dialysis patients and experts in kidney care, we've recently added the results of the survey of patients about their experiences with dialysis centers that I mentioned before. We also added star ratings because of feedback from patients. In recent years, we improved the user experience on the website to make it easier to find the information you're looking for, and make complex quality information easier to understand.

At the recent patient summit, it was great to hear that patients generally trust the information on Dialysis Facility Compare because they know it's backed by Medicare. We also received constructive feedback from Kidney patients and caregivers that the website could do a better job of providing information for their specific point in their care journey. We also heard that patients want to see positive images of

patients who are living with Kidney disease and that reflect the diversity of kidney patients.

AAKP: What's next from DFC?

EB: We are committed to making information about dialysis centers easy to access and understand for patients and their loved ones – the goal is to give you the information you need to make the best possible decision for you. We are looking at adding new information that can give patients an even better picture of dialysis centers, such as survey results on patient experiences. We're also adding more resources to help kidney patients in other areas besides choosing a dialysis center, such as providing links to treatment information, checklists to help in their dialysis center search, and educational materials. With the help of the kidney community, I know we will continue to improve the site to help even more people get the care they need.

AAKP: As a final comment Elena – we thank you for this interview and for both your public service to America and your work on behalf of kidney patients. We are very pleased that you will be a speaker at our annual National Patient Meeting and our patient members will look forward to speaking with you directly.

Visit Dialysis Facility Compare at:
<https://www.medicare.gov/dialysisfacilitycompare> 🌐





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As dialysis patients, we all are familiar with low energy, fatigue and weakness – the kind of anemia that saps us of our strength, making it difficult to get through each day. This occurs mostly because we lose iron at every hemodialysis treatment. Dialysis patients lose 5-7 milligrams of iron every time they get hemodialysis, from needle sticks, blood trapped in the blood lines and dialyzer and lab draws, among other things. This iron loss that occurs equals about 1 gram of iron every year, and it is the primary driver of the type of anemia dialysis patients suffer from.

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we don't get enough oxygen and we lose energy", says Flo Lewis, RN and Unit Director at the Maple Avenue Kidney Center.

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-- Charlene B. Westbury, NY

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About AAKP

The American Association of Kidney Patients (AAKP) is a national non-profit organization founded by kidney patients for kidney patients. We are dedicated to improving the quality of life of kidney patients through education, advocacy and through fostering patient communities.

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