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Vitamin and Mineral Recommendations for Older People with Chronic Kidney Disease

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Introduction

The number of people aged 65 and older in the US is currently more than 36 million and will increase to 86 million by 2050 (1). At age 65, life expectancy is an additional 18.2 years (1). The prevalence of chronic diseases, including chronic kidney disease (CKD), is high, and chronic diseases are responsible for almost half of all disabilities among older adults (2). Four out of five older Americans experience limitations as a result of chronic disease (2).

It is important for health professionals to consider that 80% of people newly diagnosed with CKD are 65 or older (3). Both age and CKD can influence nutrient requirements. Generally, the Dietary Reference Intakes (DRI) should be used as the basis for nutrient recommendations (Recommended Dietary Allowances (RDA) and Adequate Intakes (AI))(4)(Table 1). The Dietary Guidelines for Americans should also be used because they recently increased the amount of vitamin D

recommended for older adults (5) (Table 1). The DRIs recommend that compared to people aged 50 or younger, those 51 and older need less iron (women only), more calcium and vitamin D, and should consume vitamin B12 in the crystalline form. The DRIs also provide Tolerable Upper Intake Levels (UL) that can help health professionals and their patients avoid excess amounts of some vitamins and minerals (Table 1). The most authoritative source of nutrient recommendations specifically for CKD are the guidelines established by the National Kidney Foundation (NKF) Kidney Disease Outcome Quality Initiative (K/DOQI) (6), which in some cases differ markedly from the DRIs (e.g., for iron). There are several other sources of vitamin and mineral recommendations that are cited in the CKD literature (7,8). The purpose of this article is to: 1) identify authoritative vitamin and mineral recommendations for older people with CKD and 2) provide practical advice regarding inconsistencies in recommendations and supplement formulations.

Iron

Iron is often depleted in CKD and anemia is common (7,9,10). The RDA for iron is 8 mg/day for older adults (Table 1). However, for those with CKD, especially those receiving dialysis or erythropoietin therapy, iron needs far exceed the RDA and the UL (6). Most references support K/DOQI recommendations of 200 mg/day and suggest oral supplementation (7,10), but a daily dose of 200 mg of elemental iron may not maintain iron stores and intravenous administration is often necessary (9,10). Problems such as poor bioavailability and lack of patient compliance accompany the use of oral supplements. Multivitamins do not provide sufficient

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FROM THE EDITOR'S DESK

Renal Nutrition Forum is published quarterly (winter, spring, summer, fall) as a publication of the Renal Dietitians Dietetic Practice Group of the American Dietetic Association.

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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 sent to the editor by the next deadline.

Future Deadlines:
June 1, 2007
September 1, 2007
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March 1, 2008

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Remember to update your profile electronically in the 'members only' section of ADA's website. You will need your registration number and web password. Keeping ADA informed of your name and contact information will help avoid delayed issues of your Renal Nutrition Forum.

Would you believe that this is a quote from one of the most beloved children's books? "You're braver than you believe, and stronger than you seem, and smarter than you think" Christopher Robin to Pooh. I think this characterizes the common dilemma that we may sometimes fall into by not giving ourselves or others enough credit for their strengths.

Peter Drucker stated that, "Most Americans do not know what their strengths are. When you ask them, they look at you with a blank stare, or they respond in terms of subject knowledge, which is the wrong answer."

In a revolutionary book about discovering your strengths, Marcus Buckingham and Donald O. Clifton, PhD detail the obsession and vicious cycle we fall into becoming experts in our weaknesses and failing to utilize our strengths! This book, "Now, Discover Your Strengths", is well worth the investment and you will be amazed at the results of the online assessment, the strength finder, that assesses the strengths and attributes of individuals. I think you will find this book and the results of the strength finder assessment to be extremely valuable in both your professional and personal life too!

So many dietitians fail to acknowledge the skill and expertise that they possess. Thus, at times this can work against us especially when we have worked hard to achieve a goal but fail to make the road

easier for those that follow. No one ever made it mandatory for those that come afterward to encounter more barriers than the groundbreakers. If we are confident in our abilities and expertise we are more likely to provide opportunities to the up and coming dietitians and those new to the field of renal nutrition. MaryAnn Johnson, PhD, Professor and Graduate Coordinator of Foods and Nutrition, is a great example of one of these individuals. She offered guidance and mentorship to the three authors of the vitamin and mineral article mentioned below. She is a wonderful example of an individual who utilizes her strengths to lead and guide students to excel in their field and chosen careers in nutrition. I was fortunate enough to have her as a role model and mentor during my undergraduate and graduate studies. Open a new door, find your strengths and gain an entirely new perspective to excel, lead and mentor others!

This issue, I am pleased to introduce a trio of new authors to our publication, Tiffany Sellars, MS, RD, Melinda Bell, BS, and Elizabeth M. Speer, BS, from the University of Georgia. The Vitamin and Mineral Recommendations for Older People with Chronic Kidney Disease article has been approved for 1.5 CPE credits. You will also find the final article of an excellent 2 part series about dietitians in research by Alison Steiber. Phillipa Norton-Feirtag provides members with an excellent overview of botanical supplement use and CKD.

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Thank you to the following peer reviewers for this issue:

Sharon Griff Maria Karalis Lynn Munson
Susan Salmi Mary Sundell

A Nutrition Therapy Reimbursement Guide has been reprinted to provide you with a useful and valuable reference. Please take the opportunity to get to know one of our newest Board Members, Lesley Wujastyk, in her FNCE First Attendee article, and our DPG Practice Team Manager, Susan Dupraw, in the RPG Spotlight.

Please take note of the RPG Workshop Announcement on page 28. This workshop will be held on April 9, 2007 in Orlando, FL. One of the featured speakers will be the 2006 RPG Outstanding Service Award recipient, Laura Byham-Gray, PhD, RD, CNSD.

Finally, it is with much sadness that we say good-bye to two RPG Board Members, Susan Knapp, the former Nominations Chair and Cindy Mervis, the incoming Legislative Chair. We will miss these dedicated colleagues and thank them for the contributions great and small that they have made to our profession and patients too! Those that go before us help to remind us to make every moment count in our professional and personal lives!

Please feel free to contact me and offer your ideas, suggestions and comments at cmgmerickel@comcast.net.

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Important Notice for All RPG Members:

It has come to our attention that some of the 2006 fall issue Forums arrived without the CPE questions and self-mailer included. The fall issue offered 1.0 CPE units for the feature article by Roxanne Poole, et al. If you did not receive the CPE insert, please visit the RPG website to obtain a copy of the insert.

www.renalnutrition.org

Please contact the Asst Editor, Lesley Wujastyk at lesleyrockcity@hotmail.com for additional questions.

IN MEMORY

Hope is the thing with feathers, that perches in the soul, and sings the tune without the words, and never stops at all. - Emily Dickenson

Susan C Knapp, MS, RD, CSR LD

A colleague, friend, wife, mom, daughter, sister - you will always be remembered. Susan was a person that was committed to her family, profession and patients. We will all feel the void of her absence in our lives and remember her dedication in all that she did professionally and personally. She was a member of the RPG and served most recently in an elected position as the Nominations Chair. She was eager to be involved in our professional organization and had the desire to make a difference in her chosen profession of renal nutrition. She focused on improving the quality of life for her patients and going the extra mile with her many volunteer activities. Although she has left us, the difference that she made for her patients will always be remembered.

Susan's family indicated that Susan would have wanted donations to be made to the National Kidney Foundation on her behalf. Please access <http://www.kidney.org/support/>, "You Can Help/Make a Gift", through this secure link to donate online. If you would like her family to know about the donation, please complete the "notification" part of the form as follows: Ken Knapp, 125 Charlotte St. Broken Arrow, OK 74011

Cindy Mervis, MS, RD, LDN

A kind and caring colleague, friend, wife, and mother passed away unexpectedly recently. She will not be forgotten. Cindy was committed to her family, profession and most of all her patients. Cindy cared deeply about her patients and was always looking for new ways to improve the quality of life for them. She was a RPG member and the incoming Legislative Chair. The RPG Board Members were anxious to work and collaborate with her. She made a difference by her willingness to become involved and stretching her boundaries. She will be missed by family, friends, colleagues, and loved ones!

The ADA-Renal Dietitians DPG Executive Committee and Board Members are grateful and appreciative for the dedicated service of both Susan and Cindy to our professional organization. They will be remembered with a memorial contribution made in their honor to the ADA Foundation.

Please visit www.renalnutrition.org for an additional tribute to Susan submitted by her employer, Davita.

oral iron for the CKD patient (Table 1). IV iron sources include iron dextran, gluconate, and sucrose and side effects of IV iron tend to be mild and transient for most people. Patients receiving IV iron should be monitored for iron overload at least every 3 months by evaluating serum ferritin levels (6,10).

Calcium

The AI for calcium in older people is 1,200 mg/day (Table 1). The maximum amount of calcium recommended for CKD is generally lower than the UL of 2,500 mg/day (Table 1). For example, K/DOQI recommends that the total elemental calcium (including dietary calcium and calcium-based phosphate binders) should not exceed 2,000 mg/day (6). Others recommend that when calcium-based binders are used, the total elemental calcium should not exceed 1,500 mg/day (8). These recommendations reflect the concern about calcium homeostasis in those with CKD and the need for close dietary management of calcium intake as an effective strategy for maintaining calcium levels within normal limits and preventing calcification of body tissue and vasculature (11,12). Although calcium intake may be restricted in CKD, an adequate intake is needed for maintenance of bone health. Hypercalcemia is common in those receiving calcium-based phosphate binders; therefore, a reduced dosage or alternative non-calcium containing binder may be recommended. Multivitamin/mineral supplements for the general population of older adults can be a source of calcium (Table 1), so their use should be considered in calculating total calcium intake in CKD.

Vitamin D

Vitamin D is best known for its roles in calcium homeostasis and bone health, and poor vitamin D status is associated with high PTH. Because diminished skin synthesis of vitamin D occurs with aging (13), the Dietary Guidelines for Americans recommends that older people consume 1,000 IU of vitamin D daily from foods and supplements (5). 25-hydroxyvitamin D is a biomarker for the nutritional status of vitamin D and reflects the contributions of sunlight, diet, and dietary supplements (13). The Dietary Guidelines (5) and K/DOQI (6) have similar recommendations for optimal serum 25-hydroxyvitamin D concentrations of 75 nmol/L to 80 nmol/L.

Unless otherwise contraindicated by the physician and the stage of CKD, it may be reasonable to consider that older people with CKD should consume the new recommendation for vitamin D of 1,000 IU/day. Supplements would be needed, because there are few rich dietary sources (e.g., one cup of milk has 100 IU vitamin D, 13). Multivitamin/mineral supplements for the general population typically have 400 IU vitamin D, but those for CKD do not contain vitamin D (Table 1).

K/DOQI (6) provides guidelines for treating vitamin D deficiency and insufficiency (Table 2). For those with severe deficiency, supplementation would average about 7,000 IU/day. Although this is well above the UL of 2000 IU/day, it reflects the body's high need for vitamin D to correct deficiency (14). K/DOQI (6) also provide guidelines for reducing PTH, with active oral vitamin D sterols (calcitriol, alfacalcidol, paracalcitol or doxercalciferol) when serum levels of 25 (OH)D are greater than 30 ng/ml (75 nmol/L) and plasma levels of intact PTH are above the target range for the CKD stage.

Vitamin A

It seems reasonable to recommend that older people with CKD consume the RDA for vitamin A from foods (7,15,16), such as vitamin A-rich vegetables, and avoid exceeding the UL of 3,000 µg of pre-formed retinol/day (Table 1). Others note the need for vitamin A for wound healing and recommend that intake not exceed 1000 µg/day from all sources (17). It is difficult to compare the amount of vitamin A in foods and supplements with the DRIs, because the DRI units are µg/day, while dietary supplements use units of "IU" (additional information can be found at reference 18). Also, some supplements may have only pre-formed retinol, while others may have the less bioavailable beta-carotene. One CKD supplement was reported to contain vitamin A and provided 3000 IU (19), which is similar to most multivitamin/mineral supplements for the general older adult population (Table 1). With a decline in kidney function, vitamin A has the potential to accumulate in serum. However, both high and low serum vitamin A concentrations have been found in those with CKD (15) and the increase in serum vitamin A often seen in CKD parallels the increase in retinol-binding

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Table 1

Vitamin and Mineral Recommendations for Older People with CKD

	Males ^a 51-70 y >70 y	Females ^a 51-70 y >70 y	UL ^a	MVM CKD ^c	MVM Older Adults ^d
Vitamin A, retinol (µg/d)	900	700	3000	0 or 3000 IU	2500-3500 IU
Vitamin C (mg/d)	90	75	2000	40-100	60-120
Vitamin D (µg/d) ^b	25	25	50	-	400 IU
Vitamin E (mg/d)	15	15	1000	30-100 IU	33-45 IU
Vitamin K (µg/d)	120	90	NE	-	10-20
Thiamin (mg/d)	1.2	1.1	NE	1.5-3.0	1.5-4.5
Riboflavin (mg/d)	1.3	1.1	NE	1.5-2.0	1.7-3.4
Niacin (mg/d)	16	14	35	20	20
Vitamin B ₆ (mg/d)	1.7	1.5	100	10-50	3-6
Folate (µg/d)	400	400	1000	800-5000	400
Vitamin B ₁₂ , crystalline (µg/d)	2.4	2.4	NE	6-2000	25
Panthenic (mg/d)	5	5	NE	5-10	10-15
Biotin (µg/d)	30	30	NE	150-300	30
Choline (mg/d)	550	425	3.5g	-	-
Calcium (mg/d)	1200	1200	2500	-	120-200
Chromium (µg/d)	30	20	NE	-	150-180
Copper (µg/d)	900	900	10000	-	2 mg
Fluoride (mg/d)	4	3	10	-	-
Iodine (µg/d)	150	150	1100	-	150
Iron (mg/d)	8	8	45	-	-
Magnesium (mg/d)	420	320	350	-	100
Manganese (mg/d)	2.3	1.8	11	-	2-4
Molybdenum (µg/d)	45	45	2000	-	75-90
Phosphorus (mg/d)	700	700	4000 (19-70 yrs) 3000 (>70 yrs)	-	0-48
Selenium (µg/d)	55	55	400	0-70	20-105
Zinc (mg/d)	11	8	40	12.5-50	15-22.5

Abbreviations: MVM is multivitamin/mineral supplement; NE is Not Established; UL is Tolerable Upper Intake Level

^aFrom Food and Nutrition Board, Institute of Medicine, National Academies. *Dietary Reference Intakes (DRIs): Recommended Intakes for Individuals, Vitamins, Elements*. National Academy of Sciences. Washington DC, National Academy Press, 2004. (41)

^bFrom USDHHS & USDA, 2005. *2005 Dietary Guidelines for Americans*; ref #); the recommendation for vitamin D is for "older adults", but age is not defined; 40 IU - 1 µg. (5)

^cFrom Feiertag PN. Dietary supplement use in patients with chronic kidney disease. *Ren Nutr Forum*. 2006;25:11-20. (19)

^dFrom Centrum® Silver® and One-A-Day® 50+ daily multivitamin supplements.

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Table 2

Recommended Supplementation for Vitamin D Deficiency/Insufficiency in Patients with CKD Stage 3 and 4

Serum 25(OH)D	Definition	Ergocalciferol Dose (Vitamin D2)	Average Daily Dose	Duration (months)	Comment
< 5 ng/ml, <12.5 nmol/L	Severe vitamin D deficiency	50,000 IU/wk orally x 12 wks: then monthly 500,000 IU as single I.M. dose	7143 IU/day	6 months	Measure 25(OH)D levels after 6 months Assure patient adherence: measure at 6 months
5-15 ng/ml 12.5-37.5 nmol/L	Mild vitamin D deficiency	50,000 IU/wk x 4 wks then 50,000 IU/month orally	7143 IU/day	6 months	Measure 25(OH)D levels after 6 months
16-30 ng/ml 40-75 nmol/L	Vitamin D insufficiency	50,000 IU/monthly orally	1667 IU/day	6 months	

K/DOQI (6). 25(OH)D is 25-hydroxy vitamin D. 1 IU of vitamin D = 0.25 µg.

protein (20). It has been noted that elevated levels of vitamin A can contribute to anemia and abnormalities of lipid and calcium metabolism (21).

Vitamin E

Vitamin E is an antioxidant vitamin and vitamin E supplements may enhance the immune system of older people (22,23), but the benefits for cardiovascular health are disappointing (7). Studies reviewed by K/DOQI suggest that oral supplements of vitamin E reduced oxidative stress for some with CKD. For example, the Secondary Prevention with Antioxidants of Cardiovascular Disease (SPACE) trial showed a significant benefit from vitamin E (800 IU/day) supplementation in hemodialysis patients with pre-existing CVD. In contrast, another study found that supplements did not reduce oxidative stress in those undergoing hemodialysis (400 mg, 888 IU/day, 24).

Similar to vitamin A, the units for vitamin E can be confusing because there are different chemical forms in foods (tocopherols and tocotrienols), different stereoisomers ("d" and "l") in supplements, and "IU" is defined differently by the DRI and on supplement labels (for more information see reference 25). The DRI defines one IU as 1 mg d-alpha-tocopherol; thus, for a supplement of dl-alpha-tocopherol label as 400 IU, only about half of this would be in the "d" form. It may be reasonable to consider that people with CKD consume at least the RDA (15 mg/day as alpha-tocopherol) and avoid exceeding the UL of 1,000 mg/day

(Table 1). This UL is for supplements only, because of concern that very high intakes of vitamin E (> 1,000 mg/day) can become antagonistic to vitamin K, putting individuals at risk for hemorrhage, particularly those using oral anticoagulants (7,25).

Recommendations for CKD include 15 IU of vitamin E daily for older adults undergoing hemodialysis (8) and meeting the vitamin E requirement through diet (16), but the US diet generally provides only half of the RDA (25). Supplements for CKD and for the general population of older adults contain similar amounts of vitamin E (Table 1), but do not contain the amount that has been shown to enhance immune function in older people (about 200 IU, 22).

Vitamin K

Vitamin K is required for synthesis of proteins needed for blood coagulation and bone metabolism (18). There is concern that the current AI for vitamin K may be too low (26), but because vitamin K might interfere with certain mediations (e.g, anticoagulants), vitamin K is added in only low amounts to general multivitamin/mineral supplements and apparently is not added to supplements for CKD (Table 1). Intake may be low in people advised to limit green leafy vegetables because of anticoagulation therapy (27). Supplements for vitamin K are not typically recommended for people with CKD and it has been suggested that needs

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are usually met with diet (16). No UL has been established for vitamin K and single supplements are normally not taken by the general population (18). More research is needed about vitamin K and CKD, especially regarding the role of vitamin K in bone metabolism.

Folate

Folate is involved in the prevention of megaloblastic anemia and the regulation of homocysteine levels. The RDA for older adults is 400 µg/day and the UL is 1,000 µg/day and pertains to supplements only (28). For CKD, folate supplements in the range of 1,000 to 5,000 µg/day have been recommended (7,29), which may be of concern because these levels exceed the UL of 1,000 µg/day (Table 1). The rationale for the UL for folate includes potential masking of vitamin B12 deficiency.

The rationale for high supplemental intakes of folate in CKD is for homocysteine lowering, with homocysteine being a risk factor for cardiovascular disease. Menon et al. (30) showed a reduction in elevated homocysteine levels for half of the participants that were supplemented with 1,000 µg of folic acid in combination with 10 mg of vitamin B6 and 6 µg of vitamin B12/day. Wrone et al. (31) showed that dosages of 5,000 µg, 10,000 µg, and 15,000 µg/day reduced homocysteine levels, but the study failed to support doses over 1,000 µg/day for reduction of CVD or other outcomes. Other studies indicate that folic acid supplementation is not effective for lowering homocysteine levels in those undergoing dialysis (32) and there is limited support for supplementation for all stages of CKD (30).

Vitamin B12

Vitamin B12 is needed for the nervous system and red cell synthesis (28). Vitamin B12 presents unique concerns for the older adult population, often attributable to malabsorption problems associated with atrophic gastritis or *Helicobacter pylori* infection (28,33,34). Between 5% and 40% of the older adult population may have vitamin B12 deficiency, depending on the population and the criteria used for assessment of deficiency (35).

The RDA for vitamin B12 is 2.4 µg/day for older adults and should be in the crystalline form found in dietary supplements or fortified foods for enhanced absorption

(5,28). For CKD, others recommend consuming 100% of the RDA (7), 3 µg/day (8), and 6 µg/day for those with CKD receiving renal replacement therapy (36,37). Also, Menon et al. (30) noted that supplementation with 6 µg of vitamin B12, along with supplements of folic acid and vitamin B6, were effective in reducing homocysteine. Vitamin B12 absorption in CKD was much lower than that of healthy controls, perhaps suggesting that requirements are higher in CKD than the non-CKD population (36,38). Obeid et al. (38) has proposed that elevations in homocysteine seen in CKD may be related to "vitamin B12 resistance," because of impaired cellular uptake of vitamin B12. There is a large range of vitamin B12 in multivitamin/mineral supplements for CKD and for older adults, but most provide at least 6 µg (Table 1).

Vitamin B6

Vitamin B6 is involved in hemoglobin synthesis and hence is important in the prevention of anemia, especially for those with CKD. The RDA for vitamin B6 is just under 2 mg/day for older men and women (Table 1). Others recommend that those with CKD receiving renal replacement therapy should obtain 100% of the RDA (7) compared to the older segment of CKD patients receiving renal replacement therapy that should consume 2 mg of vitamin B6 (8).

Vitamin B6 deficiency may occur in CKD, and approximately 10 mg daily is recommended for treatment of deficiency (30,37,39). This does not exceed the UL of 100 mg/day. This UL is based on concern that excessive vitamin B6 can lead to peripheral neuropathy (28). Therefore, attention should also be given for the prevention of toxicity (39). Vitamin B6 in multivitamin/mineral supplements is many fold higher in formulations for those with CKD compared to the general older adult population (Table 1), but is less than the UL. However, animal studies show that renal insufficiency increases vitamin B6 toxicity (39), so the high level found in CKD supplements is potentially of concern.

Comparison of Multivitamin/mineral Supplements

Those with CKD may be advised not to take any over-the-counter dietary supplements (40). However, several formulations specifically for people with CKD provide only a few of the vitamins and minerals known to be essential,

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provide some nutrients at high levels (e.g., folate and vitamin B6), and do not contain any vitamin D which is of particular concern for older adults (Table 1). Perhaps improvements could be made in multivitamin/mineral supplements that might provide additional nutritional support for the CKD patient.

Recommendations for the Renal Dietitian

1. Assist patients in meeting their vitamin and mineral needs for their prescribed nutrition plan.
2. Encourage patients to consult their dietitian and physician before taking dietary supplements.
3. Recognize that the current formulations of multivitamin/mineral supplements for CKD vary considerably, typically contain fewer nutrients compared to general multivitamin/mineral, and contain some nutrients in excess of the UL.
4. Understand that current formulations multivitamin/mineral supplements for the general older adult population may contain some vitamins and minerals contraindicated in some patients with CKD.

Acknowledgements

The authors wish to thank Mary Ann Johnson, PhD, for reviewing and editing this article.

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Dietitians in Research: Part 2

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Encouraging renal dietitians' participation in research is of the utmost importance for the field of renal nutrition and for the discipline of dietetics. In this two part series on Dietitians in Research, the benefits, barriers and concepts necessary for renal dietitians to do research are explored. In part 1, the current status of participation, potential barriers, and pieces of the puzzle needed to encourage dietitians' participation were discussed. The emphasis of part 2 focuses on the components of research and how dietitians can acquire the skills and knowledge needed to conduct research.

Conducting research requires energy, dedication, support, and some knowledge of the process. There are many ways in which dietitians can get the knowledge they need to incorporate research into their practice. Taking courses, attending seminars, reading books or articles on research methods and collaborating with other more experienced researchers are all ways to acquire expertise and skills in research methodologies and processes. Each of these techniques has its own merits; but perhaps reading and collaboration are the most feasible methods for the majority of clinicians. Some books and journal articles on research with an emphasis in nutrition are listed in Table 1.

Familiarity with terms and concepts of research can aid renal dietitians in feeling comfortable when discussing potential projects with collaborators and other health care team members, thus breaking down a possible barrier to conducting research. Collaboration has been shown to be a conduit into the world of research. In fact, Gardner et al [1] suggested a potential reason for dietitians not participating in research was a lack of multidisciplinary collaborations. In her research study, there was a 50% response rate resulting in a sample of 153 dietitians. Of those, 27% had participated in some sort of research project and within that 27%, 88% had collaborated with another dietitian within their facility and 48% collaborated with a non-dietitian within their facility [1]. Basically only about an eighth

Table 1
Research References

Books:

- E. Koh and W. Owen, *Introduction to Nutrition and Health Research*. Kluwer Academic Publishers, 2000
- C. Ireton-Jones, M. Gottschlich, and S. Bell, *Practice-Oriented Nutrition Research, An Outcomes Measurement Approach*. ASPEN Publishers, Inc., 1998
- E. Monsen, Editor, *Research, Successful Approaches*, 2nd ed, The American Dietetic Association, 2003
- B. Dennis, A. Ershow, E. Obarzanek, and B. Clevidence, Editors, *Well-Controlled Diet Studies in Humans: A Practical Guide to Design and Management*. The American Dietetic Association, 1999
- *Self-Assessment Series: Research in Practice: From Planning to Presenting*, The American Dietetic Association

Journal Articles:

- Boushey C, Harris J, Bruemmer B, Archer SL, Van Horn L., Publishing nutrition research: a review of study design, statistical analyses, and other key elements of manuscript preparation, Part 1., *J Am Diet Assoc*. 2006 Jan;106(1):89-96.
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Continued on page 11

of the dietitians surveyed were forming multidisciplinary collaborations. Per Gardner "...the collaborators acted as mentors, encouraging and motivating dietitians to become confident researchers[1]." This type of training is not often discussed but can certainly be a cost-effective way to guide renal dietitians through the research process.

Outcomes Research

In a clinical setting, outcomes research is the most common type conducted and in our profession the most important type of research. It has been suggested that outcomes research can validate the "value and worth of the nutrition care provided" (2, 3). Outcomes research is the study of inputs, processes and outcomes. Using this type of research, interventions can be monitored to determine whether or not they result in outcomes, which improve patient's care and/or medical status. Outcomes research can begin with an idea such as, "I think I can do this differently with better results" or a question, "Why do we do this process this way? Would another way result in improved patient nutritional status?" These types of thoughts beg for outcomes research projects. Once an idea has been formulated, a careful review of the literature is warranted. Access to the internet is now universally available and as such performing a literature review is no longer the daunting task it was in the past.

Literature Review

A literature review serves many purposes, including determining whether others have already tested your idea or question, how they went about testing the question and what results were found. It may be that a similar idea was examined but in a different group of patients (e.g. oncology patients versus renal patients). Or it may be that a similar idea was examined but the study conducted used a less than ideal method; therefore the results may differ from what would be found with better methods. Also, you may determine the benefit of taking the research further. For instance, a lot of research may have been done on low protein diets in chronic kidney disease (CKD) patients stages 1-4 but perhaps very little research has been done on the type of dietary fat CKD patients are consuming and its effect on serum very low density lipoproteins (VLDL) concentrations. Reviewing the literature should be

a systematic and reproducible search. Databases such as Pubmed are extremely useful and can be accessed online; Pubmed can be found at: www.pubmed.com. An additional resource would be research librarians at universities and medical centers.

Hypothesis Statement and Specific Aims

After completing a literature review, the dietitian will begin to draft a statement describing what the researcher proposes will happen in the study. This statement is the hypothesis and according to Boushey et al [4] a good hypothesis should be based on the research questions and be the basis of what will be tested in the study. In other words if the question is: "In CKD patients stages 3 and 4, will a diet high in monosaturated fat decrease serum VLDL concentrations?" a compatible hypothesis might be: "Adult CKD patients stages 3 and 4 fed a diet with 11% of total kilocalories (kcal) from monounsaturated fats will have lower serum VLDL concentrations than patients fed a diet with <11% of total kcal from monounsaturated fats." This type of statement indicates what data (e.g. serum VLDL concentrations) will be collected and what type of intervention will be done (i.e. patients will consume different amounts of monounsaturated fat diets).

The hypothesis also provides information on the group (or sample) of patients that the study will include. The planning of the study will then be directed by the research question and the hypothesis. A well developed hypothesis is essential; it strengthens the study and the results found. It is therefore imperative to revisit the hypothesis frequently during the planning phases of the study. The hypothesis may evolve as more facts are discovered about what has been done previously and what is truly feasible in the current setting. Additionally, refining the hypothesis will keep the study directed and focused on the original target.

Specific aims should be created from the hypothesis once it has been reasonably established. Specific aims are the clear and detailed objectives that will be accomplished during the study. They are directly derived from the hypothesis. An example of a specific aim from the previous example on VLDL concentrations would be:

1. To determine whether there are differences in serum

Continued on page 12

VLDL concentrations before and after adult CKD patients stages 3 and 4 consume either a diet with >11% or <11% of total kcals from monounsaturated fat for 12 weeks. Typically, no more than 3 specific aims for a hypothesis are needed; however, the number of aims is really driven by the depth of the hypothesis.

Careful consideration for the wording of the aims is warranted. The example above has the potential to be carried out in a couple of ways depending on the dietitian's capabilities. The most rigorous method would be a feeding study where the patients were provided all their food for 12 weeks so the exact amount of monounsaturated fat would be known. This type of study is very time consuming and costly but provides excellent data. Another way the aim could be met would be to have the dietitian use a dietary intake instrument to measure the current monounsaturated fat intake in the patients' diets and simultaneously document the serum VLDL. Then for the patients with <11% instruct them on a diet of > or equal to 11% monounsaturated fat and have them keep food records to provide documentation of the actual foods consumed. A follow up serum VLDL would be needed to determine effectiveness. This method is less labor intensive and far less costly but leaves more room for error. Each dietitian must consider what is feasible in their own setting. In this example, the dietitian may find that instructing the patients can be incorporated into the daily work schedule and is reflective of a real life situation.

Funding Sources

A few items need to be considered prior to diving into the details of a study. The first two are whether the study will need any type of external funding and, if humans are involved, which institutional review board (IRB) should be used. Both funding agencies and IRBs need a formal proposal to be written in order to evaluate the study; in many cases one proposal can serve both purposes. Funding agencies can vary from local diabetes or kidney foundations to national foundations. Additionally, private organizations such as pharmaceutical companies will often help fund studies either with monetary support or free study drug. Table 2 lists some potential funding sources that offer smaller scale grants compared to large scale grants available through agencies such as the National Institutes of Health (NIH).

Table 2

Potential Sources of Funding

Funding Source Website

National Kidney Foundation's Council on Renal Nutrition

<http://www.kidney.org/professionals/research/prof-council.cfm>. Accessed January 2007.

American Society of Enteral and Parenteral Nutrition
<http://www.nutritioncare.org/homelink.asp?Link=www.nutritioncare.org/research/index.html>. Accessed January 2007.

Diabetes Association of America <http://www.diabetes.org/diabetes-research/research-grant-application-forms/ADA-grant-opportunities/ADA-current-grant-opportunities.jsp>. Accessed January 2007.

Dietitians in Nutrition Support, ADA Dietetic Practice Group

Email Jennifer Bowers, PhD, RD, CNSD
for information: drjmbrd@mindspring.com

Institutional Review Board Applications

The IRB application should be completed and turned in immediately after the funding application is submitted. If the study does not require funding then the IRB application should be submitted and approved before any research is initiated. Dietitians affiliated with medical centers or universities should be able to contact the IRB located at their facility. If the dietitian works at a dialysis center in a national chain, typically the chain will have a person who monitors and approves all research done. Examples of this are DaVita and Fresenius, both of which have their own IRB processes. Individuals who work at a free standing facility may want to contact their Medical Director to determine the best way of securing IRB approval.

The purpose of an IRB is to ensure the study is done in an ethical manner that does not endanger the patient in any way. The three primary items involved in the IRB process are informed consent, assessment of risks and benefits to the subjects, and the selection of subjects. The IRB application involves a checklist which is composed of a variety of questions about the study; e.g. will blood be drawn, how many patients are involved, how will the

Continued on page 13

patients be enrolled in the study, and what will the patients be required to do if they chose to participate in the study. The other parts of the application include a copy of the proposal, an informed consent document, any flyers that will be used to recruit, and if a patient is to be interviewed a script of what will be said. The informed consent is a document which details what will be involved if the patient becomes a study subject and agrees to be involved in the study. Table 3 outlines the key aspects of an informed consent document.

Table 3
Key Aspects of an Informed Consent Document

1. Brief background and rationale of the project
2. Purpose of the research study
3. Details of the procedures to be done
4. Duration of patient participation
5. Risks and Benefit analysis
6. Alternative to participation
7. Confidentiality
8. Cost statement and injury compensation
9. Contact persons
10. Statement indicating participation is voluntary

In addition to the informed consent, a Health Insurance Portability and Accountability Act (HIPAA) document may be required by some institutions. Many IRB websites have templates of these documents available for download by potential applicants.

It is very important that IRB approval is secured prior to any patient recruitment or data collection. The IRB process can be very daunting to a new researcher or clinician desiring to try research for the first time. However, most IRBs have people who coordinate and help prepare applications before they are viewed by the official IRB board. The coordinators can be a great resource and should be contacted with questions on the application process.

The proposal portion of the IRB application needs to meet the requirements of the individual institution where it will be submitted. These directions are usually located on the website. However, in those incidences where the IRB does not have a website, the application and instructions can be picked up at the IRB office or often through the mail.

Components of a research proposal that are usually required for the IRB or grant application are:

- Introduction (in a grant this may be called the Specific Aims page)
 - Introduce the topic
 - Present the hypothesis and specific aims
- Background and Significance (for IRB this should be brief)
- Preliminary data (only include if available, usually not required in IRB process)
- Methods section
 - Subjects – who, where from, patient criteria needed to be included in the study e.g., specific gender, presences of co-morbidities, age range, etc...
 - IRB approval will be applied for from...
 - Study design – observational, experimental...
 - Intervention (only needed if one will be done)
 - Procedures – who will do what, when, where, and how
 - What data will be collected, how and by whom
 - Include specific assessment tools to be used in an appendix and reference specific procedures if possible, e.g. Block's food frequency, Multiple Pass Method 24 hour recall, Subjective Global Assessment or Malnutrition Inflammation Score
 - Data analysis
 - How will the data be used to answer the specific aims presented, e.g. the mean VLDL concentrations will be compared between patients on <11% and >11% of Total kcal intake from mono-unsaturated fat.

Details on each of these proposal sections can be found at the IRB website, within the grant instructions, or within the readings outlined above. The initial work put into planning the study can be overwhelming. However, it can be achieved! Collaboration and good resources are helpful in this process. Careful planning will result in a superior study, with fewer complications.

Conducting the Study

Patient recruitment and data collection commence when the IRB approval is obtained. Depending on the location, recruitment can range from extremely easy to incredibly hard. There are several factors that may impact the

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recruitment process: 1. the inclusion and exclusion criteria – how difficult are they to meet; 2. competition with other research projects being conducted simultaneously at the facility – patients may only be able to participate in one at a time and other studies may compensate patients financially; 3. the level of collaboration with patients' physician and other medical staff. If recruitment is expected to be difficult there are a few techniques to help. A rolling recruitment can be done so only a few patients are enrolled at a time; using an outside company to assist with recruitment; and offering incentives to patients who participate (free assessments, oral supplements, additional laboratory work, and money). Each of these options has pros and cons and must be considered fully prior to initiating. While a rolling recruitment can ease the pressure of recruiting it does extend the duration of the study. Outside companies and patient incentives will add cost to the study which may mean external funding is required.

Data collection should be done thoroughly, with great attention to detail. Analysis of the data can be done by a local statistician. Many medical centers and universities have statisticians who can be hired at very low cost or will do the analyses for free. Additionally, experienced collaborators may be helpful in completing or directing data analysis.

Publishing the Results

The final step is getting the work published! Submitting an abstract to a local or national meeting is a great way to let colleagues know what you have accomplished. The National Kidney Foundation, American Society of Nephrology, the International Society of Renal Nutrition and Metabolism, and the American Dietetics Association all have annual or biannual meetings, which encourage dietitians to submit abstracts. Guidelines for writing abstracts can be found on their websites. However, the project is not completed until a manuscript detailing the study results has been written and submitted.

There are a number of journals well suited to publishing the results of outcomes research. The Journal of Renal Nutrition is perhaps the most obvious; however, the Journal of the American Dietetic Association and the Journal of Parenteral and Enteral Nutrition are other good choices. International journals such as the Nephrology, Dialysis and Transplantation, British Journal of Dietetics, Nutrition, or

Clinical Nutrition are other alternatives. Each of these journals has a website with detailed instructions on the format required for manuscript submission.

There are many conceivable barriers to conducting research; however, the results from the hard work and innovative thinking are well worth the effort. Incorporating research into renal dietitians' clinical practice will benefit the individual by advancing and improving their interactions with patients. It may benefit the affiliated facilities by improving overall patient outcomes and will benefit the field of renal nutrition by adding to the existing body of literature.

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Take a moment to view the newest RPG member benefit, the redesigned website that includes many more resources just for you, our members! You can even view pictures of RPG leaders and read their bios. Maybe you will consider becoming more involved with RPG or running for an office sometime in the future, the opportunities are waiting for you. Take a look at the member's only area to access patient education materials and research resources. Remember to use your last name (as listed with ADA) and ADA number (no zeros at the beginning) to gain access to the website. Sit down with a good hot beverage and absorb the many resources available to help you in working with kidney patients.

Botanical supplement use and potential side effects in patients with chronic kidney disease

By Phillipa Norton-Feirtag

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Use of alternative medicine in the U.S. has increased 34% to 42% between 1990 and 1997 (1,2). Therapies increasing the most included herbal medicines, megavitamins, folk remedies and homeopathy. More recently, it was estimated that over 38 million adults in the United States used herbal products in 2002 based on responses to the complementary and alternative medicine (CAM) supplement to the 2002 National Health Interview Survey (NHIS) (3).

The popularity of botanical supplements reflects their availability without a prescription from natural food stores, supermarkets, pharmacies and via the Internet as well as the belief among consumers that these products are important to their health and well-being (3). Although they are used for "medicinal" purposes, botanical products are not regulated in the same way as prescription and over the counter medications (4). The Dietary Supplement Health and Education Act (DSHEA) classifies herbal products as dietary supplements and limits their control by the Food and Drug Administration (FDA). Consequently, these products can be marketed with limited proof of safety or effectiveness. Since quality and consistency of botanical products is affected by harvesting, storage, processing and formulating methods, there is a need for validated quality control techniques to ensure standardization of products (5). These measures would allow comparison of pharmacological, toxicological and clinical studies of botanical supplements.

When botanical supplements are taken in combination with prescribed medications, there is the potential for herb-drug interactions (6). In patients with chronic kidney disease (CKD), possible hazards of botanical supplement use

are not limited to drug interactions but also include negative effects on kidney function, exacerbation of electrolyte abnormalities and alterations in blood pressure (7).

This column will review botanical supplement use in the CKD population and summarize traditional uses and potential adverse effects of more commonly used botanical products.

Botanical supplement use in the CKD population

Since complementary and alternative medicine use is common in the general population, it is likely that patients with CKD are also trying these therapies (1-3,8). Pre-dialysis, maintenance dialysis and post-renal transplant patients may use alternative medicine in the form of botanical supplements when conventional medicine is ineffective or causes adverse side effects (9). However, there are few documented studies of herbal supplement use in this population.

In a cross-sectional survey of 100 Canadian adults (age >18 years) with renal failure (CKD Stages 2 through 5), a detailed questionnaire was used to collect information on dietary supplements used (10). Forty-five percent of respondents used dietary supplements. Garlic and cranberry juice extract were among the most commonly used products. Less commonly used herbal products (<2% of supplement users) were Noni, saw palmetto, bilberry, valerian root, flaxseed, evening primrose oil, ginseng and St. John's wort. Use of supplements was more common in the early stages of kidney disease and decreased as renal failure progressed.

Another study identified botanical product use in a maintenance dialysis population in northwest Ohio by conducting personal interviews with the patients (11). Thirty-one of the 216 peritoneal dialysis and hemodialysis patients surveyed reported taking botanical products. Use of garlic and ginseng was reported most often. Other herbal products used were aloe, alfalfa, belladonna, bilberry, black cohosh, cat's claw, corn silk, cranberry, dandelion, Echinacea, ginkgo, goldenseal, horse chestnut and saw palmetto.

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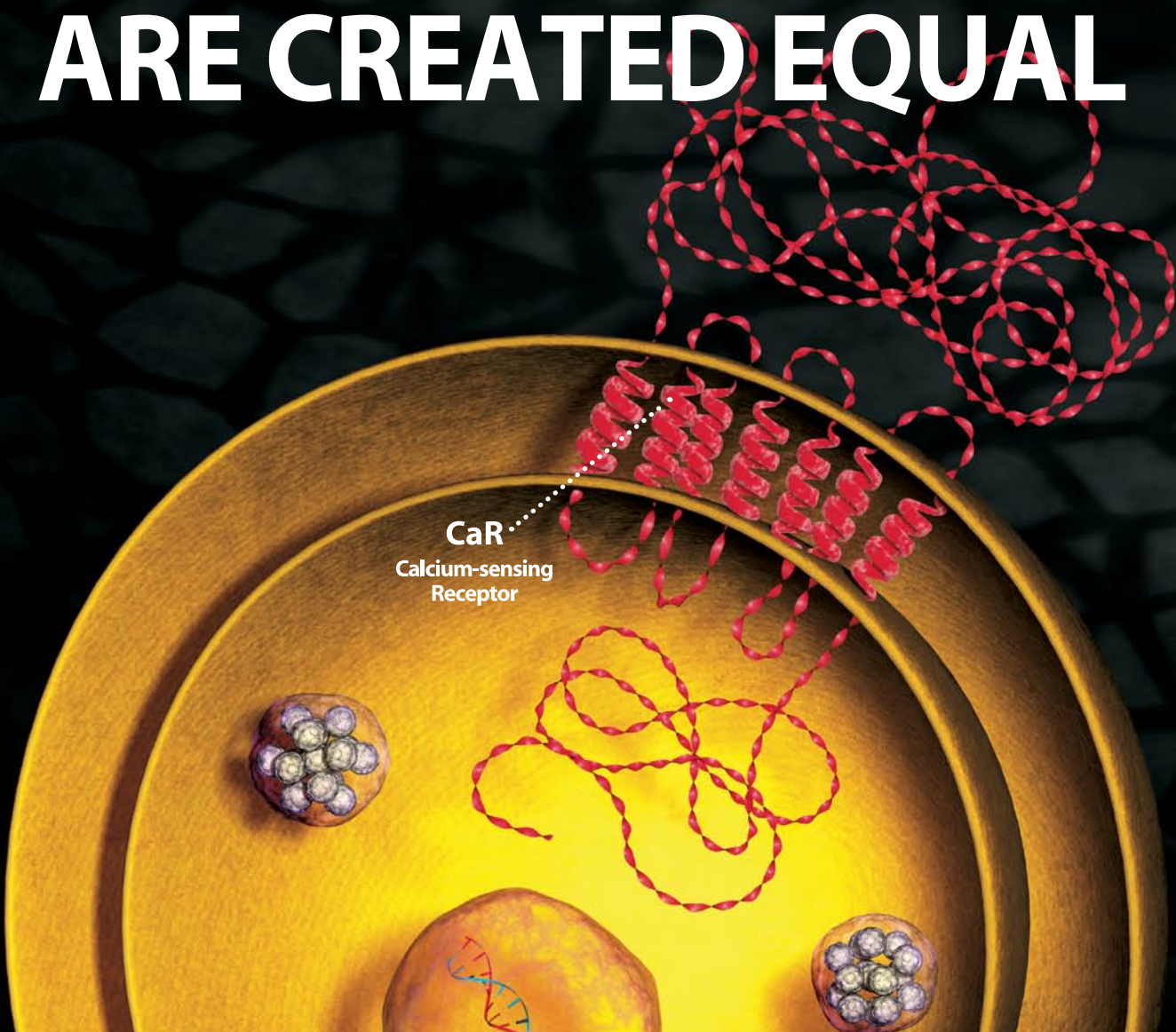


VDR
Vitamin D
Receptor

This diagram shows a cross-section of a cell with a yellow nucleus. Inside the nucleus, there is a DNA double helix and a blue, multi-lobed protein structure labeled 'VDR' (Vitamin D Receptor). Two purple, spherical organelles with internal structures are also visible within the nucleus. The cell is surrounded by a dark, textured background.

In secondary HPT,

NOT ALL RECEPTORS ARE CREATED EQUAL



CaR
Calcium-sensing
Receptor

This diagram shows a cross-section of a cell with a yellow nucleus. A red, multi-lobed protein structure labeled 'CaR' (Calcium-sensing Receptor) is shown on the cell membrane, with a dotted line indicating its location. Inside the nucleus, there is a DNA double helix and a purple, spherical organelle with internal structures. The cell is surrounded by a dark, textured background.

Data show that the vitamin D receptor and the calcium-sensing receptor play independent roles in the pathogenesis of secondary HPT

Secondary hyperparathyroidism (HPT) begins at early stages of chronic kidney disease and becomes increasingly severe over time.^{1,2} Disease progression is characterized by parathyroid gland hyperplasia—defined as cell proliferation—and gland enlargement.^{3,4} It is crucial, therefore, to understand the factors that mediate parathyroid gland hyperplasia and its role in disease progression.³⁻⁷

Calcium, acting through the calcium-sensing receptor (CaR), and vitamin D, acting through the vitamin D receptor (VDR), have diverse effects in a variety of tissues⁸ and independently impact parathyroid gland function.^{4-6,9} Vitamin D directly diminishes parathyroid hormone (PTH) gene expression and hormone synthesis and indirectly reduces PTH synthesis and secretion by raising blood calcium levels.^{7,10} In contrast, calcium signaling through the CaR directly inhibits PTH secretion and reduces PTH gene expression.^{3,6-8}

Moreover, recent evidence suggests that signaling through the CaR is a key determinant of parathyroid gland enlargement and cell proliferation.^{3,6} Findings from preclinical studies by Li et al suggested that calcium-dependent signaling through the CaR was sufficient to prevent parathyroid gland hyperplasia even in mice lacking a functional VDR whose tissues cannot respond to vitamin D.^{6,11}

Research suggests that there are 2 independent pathways involved in the pathogenesis of secondary HPT.^{5,12} Signaling through the VDR inhibits PTH gene expression and hormone synthesis¹² while signaling via the CaR affects PTH secretion, PTH synthesis, and parathyroid cell proliferation^{3,6,12}—the last impacting parathyroid gland hyperplasia.^{3,6,8}

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A few studies have been directed to determine beneficial effects of botanical supplements on specific symptoms in patients with CKD. In one study, 16 hemodialysis patients were randomly assigned to receive either linoleic acid or evening primrose oil rich in gamma-linolenic acid for treatment of uremic skin problems (12). Patients receiving evening primrose oil showed significant improvement in uremic skin symptoms and greater improvement in pruritis scores than those given linoleic acid. These findings suggest that evening primrose oil may be effective for treatment of uremic pruritis in hemodialysis patients.

Adverse effects of botanical supplements on renal function have also been studied. In the early 1990s, a small group of women developed renal failure after using a weight loss regimen based on a formulation of Chinese herbs. When 15 women (mean age 41 ± 10 years) with Chinese herb nephropathy were compared with a control group matched for age, sex and serum creatinine but with interstitial nephropathies of other origins, the study group showed more rapid deterioration in renal function and more severe anemia (13). Toxicological investigation of the herbal supplement revealed that the Chinese herb Fangchi (*Aristolochia fangchi*) had inadvertently been substituted for Fangji (*Stephania tetrandra*) during formulation. Aristolochic acid in Fangchi caused interstitial nephropathy in the women who followed this weight loss regimen. Although treatment with angiotensin-converting enzyme (ACE) inhibitors failed to prevent progression of renal failure in these patients, several were successfully transplanted without recurrence of renal disease. Other cases of Chinese herb nephropathy linked to aristolochic acid have been reported, underscoring the need for standardization of formulation methods and more precise labeling of herbal supplements (14-16).

Traditional uses and adverse effects of botanical supplements

Botanical supplements taken by patients with CKD may interfere with conventional medical treatment and it is important for the renal care team to understand which alternative therapies their patients are using (17). The Table lists botanical supplements that patients with CKD have reported using (10,11). Traditional uses and potential adverse effects are shown for each botanical supplement (18-33).

As shown in Table 1, interactions between botanical supplements and prescribed medications are common, and can result in serious clinical consequences. Patients taking anticoagulants are at high risk for herb-drug interactions, but botanical supplements may also interfere with the actions of other medications including antihypertensives, anticonvulsants, diuretics, immunosuppressants and cholesterol-lowering drugs. Other potential adverse effects of botanical supplements include gastrointestinal disturbances, electrolyte and fluid imbalance, hypoglycemia and hepatotoxicity.

Few consumers of botanical supplements inform conventional health care providers of their use, and 60% of current herbal supplement users in a maintenance dialysis population did not tell their nephrologist that they were taking these products (3,11). It may be difficult for patients to find reliable information on botanical supplements in a timely manner (20,34,35).

Clearly, it is vital for the renal care team to screen patients for use of botanical supplements and to provide education regarding their potential effects. Patients should be encouraged to bring in all products that they are taking for periodic medication reviews so that the care team is informed of botanical supplement use. Patients can also be educated about risks associated with specific herbal supplements. If a patient continues to take these products, some simple guidelines can be provided (18):

1. Use only those supplements that have been standardized to ensure consistency.
2. Supplements that display the United States Pharmacopeia (USP) symbol comply with the five quality criteria listed below:
 - Contain ingredients listed on the product label;
 - Contain declared amounts and concentrations of ingredients;
 - Readily broken down in the gastrointestinal tract for effective nutrient absorption;
 - Screened for harmful contaminants;
 - Manufactured in controlled conditions.
3. Inform health care providers of botanical supplement use;
4. Avoid using supplements in larger than recommended

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Table 1

Uses and potential adverse effects of botanical supplements in patients with chronic kidney disease (CKD)

Botanical Supplement	Traditional Uses (18,19)	Potential adverse effects
Aloe	Anti-inflammatory, wound healing and laxative effects	Diarrhea, hypokalemia, increased toxicity with cardiac glycosides (11,18)
Alfalfa	Alleviation of swelling, fluid retention and kidney stones	Decreased effectiveness of the anticoagulant warfarin; high potassium content may affect electrolyte balance in patients taking potassium-sparing diuretics (11,20)
Belladonna	Relief from headache, peptic ulcer disease, inflammation, menstrual symptoms	Exacerbation of congestive heart failure; tachycardia (11)
Bilberry	Treatment of urinary tract infection, kidney stones, diabetes, diarrhea	Lowers blood glucose; may increase bleeding risk when taken with non-steroidal anti-inflammatory drugs (NSAIDs) (11,21)
Black Cohosh	Relief from menstrual disorders, early menopause	Cramps, dizziness, gastrointestinal discomfort (18)
Cat's Claw	Stimulation of the immune system, anti-inflammatory effects, treatment of gastrointestinal complaints	Reduction in blood pressure and heart rate; interaction with anticoagulants (18) Report of acute kidney injury in systemic lupus erythematosus (SLE) patient (36); Fever, intermittent constipation, diarrhea, and fatigue, avoid use with immunoglobulin therapy, immunosuppressive agents and bovine or porcine insulin (36)
Corn Silk	Treatment of prostate and urinary tract infections; kidney stones	Lowers blood pressure; hypokalemia (11)
Cranberry Juice Extract	Treatment of urinary tract infections	Nephrolithiasis (11)
Dandelion	Alleviation of upset stomach, water retention, urinary tract infections, kidney stones and poor appetite; blood sugar regulation	Enhances diuretics, interferes with antacids (11)
Echinacea	Relief of cold symptoms	Interaction with anti-rejection drugs; exacerbation of autoimmune disease and Type 1 diabetes mellitus. Can cause hepatotoxicity if used for more than 8 weeks and should not be used with other hepatotoxic drugs including anabolic steroids, amiodorone, methotrexate and ketoconazole (18,22)
Evening Primrose Oil	Uremic pruritis, menstrual disorders	May cause nausea, indigestion, soft stools, increased bleeding time; inhibits inflammation; may lower seizure threshold when taken with anticonvulsants (18,22)
Flaxseed	Bulk-forming laxative	Requires increased fluid intake (23)
Garlic	Antioxidant properties; reduction of cholesterol, triglyceride and blood sugar levels; treatment of hypertension and atherosclerosis	Interacts with warfarin, increasing anticoagulant effect (21,24,25)

doses or for long periods of time;

- Avoid wild botanical, which can be misidentified or contaminated.

The safety of botanical supplements for patients with CKD is of significant concern. Further research is needed

to investigate the use of these products in this population, and the safety and effectiveness of products consumed. Efforts should be directed to provide appropriate instructional materials to educate and inform patients about bo-

Continued on page 20

Table 1 (cont.)

Uses and potential adverse effects of botanical supplements in patients with chronic kidney disease (CKD)

Botanical Supplement	Traditional Uses (18,19)	Potential adverse effects
Ginkgo	To maintain or enhance mental function	Interacts with warfarin, increasing anticoagulant effect; may cause hypertension when taken with thiazide diuretics (21,24,25)
Ginseng	Treatment of early menopause, menstrual disorders and digestive problems	Sleep and gastrointestinal disturbances; headaches; may decrease anticoagulant effect of warfarin and decrease plasma digoxin levels; may cause hypoglycemia (24,26,27)
Goldenseal	Treatment of infections and inflammation	Interactions with antihypertensive and anticoagulant medications; gastrointestinal discomfort (28,29)
Horse Chesnut	To reduce pain and inflammation associated with arthritis and rheumatism; cough remedy; fever reduction	Increased risk of bleeding with warfarin (24)
Noni	Immune system enhancement; aid to digestion	Hyperkalemia (30)
Saw Palmetto	Urinary tract ailments including prostatitis and benign prostatic hypertrophy	Minor gastrointestinal problems including nausea, vomiting, constipation and diarrhea; mild pruritis; headache; hypertension; erectile dysfunction (31)
St. John's Wort	Treatment of depression, infection, wounds and burns; relief from anxiety and sleeping disorders	Decreases blood levels of the cholesterol-lowering drug simvastatin; anticoagulant effects; interacts with the immunosuppressants cyclosporine and tacrolimus, increased risk of organ rejection (25,32,33)
Valerian Root	Relief from insomnia, anxiety and pain	Headache, dizziness, upset stomach (19)

tanical and any potential side effects and drug interactions. Most importantly, find a way to maintain an open line of communication and trust with your patients on the topic.

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RENAL DIETITIANS CHAIR MESSAGE

Patricia Weber MS RD CSR CDE

Welcome home! If you ever see someone getting out of a car at the mall, and you notice the bright green, gold and red bumper sticker that identifies them as a Vietnam veteran, try saying that to them. Chances are it will bring a strong smile of appreciation, and perhaps a tear. In the 60's and 70's, when these young people were returning from an unpopular war, too many were greeted with slurs and spit. Thirty or forty years later, many of the same Air-men, Corpsmen, Marines, Sailors and Soldiers have been greeted with another disappointment: diabetes, presumably related to their exposure to Agent Orange, an herbicide used to defoliate the dense jungles of Vietnam. In 2000, the Veterans Administration added type 2 diabetes to the list of "presumptive diseases associated with herbicide exposure."

We in Nephrology know what diabetes can do. Combined with late diagnosis and inadequate control, it can create customers for us, customers that we would rather not have. Diabetes is a progressive disease. It's part of that other insidious "CKD": Cardiovascular, Kidney and Diabetes disorders. Programs like the NKF's Kidney Early Evaluation Program (KEEP) valiantly try to identify at-risk citizens, but too many miss the screenings. We lose many in Stage 4 chronic kidney disease. Those that survive to choose renal replacement therapy face the challenges of accepting a palliative treatment, along with adapting to lifelong dietary changes. Can you count the times that you have been asked this question from a new dialysis patient? "How long will I have to do this?"

To provide the best palliative care possible, we must continually be on a learning curve, seeking out the newest and most reliable evidence-based practices, like the Medical Nutrition Therapy protocols from the American Dietetic Association (ADA) and the K/DOQI Guidelines. We need to form strong multidisciplinary teams, utilizing the best talents of all the clinicians. No one is a "one man show", but if we cross-train with the intent to support the patient care team, we can improve morbidity and mortality. Our roles do overlap, so we should educate our staff about the best nutrition principles.

Since nutrition is key in treating patients with kidney disease, it is critically important to have well-trained and experienced renal dietitians. We should continue to support federal regulations that mandate at least a year of clinical experience before one can work in a dialysis facility. The NKF's Strategies for New and Renal Dietitians, which is offered in conjunction with the Spring Clinical Meetings is invaluable. On April 9, the Renal Dietitians Practice Group (RPG) of the ADA will be offering a workshop prior to the NKF's Spring Clinical Meetings in Orlando. The goal is to prepare renal dietitians to take the ADA's board-certification exam in renal nutrition. RPG members will receive a deep discount on the cost of the workshop, as a member benefit. Ask your dialysis company if they support the certification of registered dietitians, as they do with nurses and technicians.

In closing, it is very likely that you will begin to treat more Vietnam veterans. Make sure you thank them for their service and then partner with them to palliate their chronic kidney disease.

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<http://www.diabetes.org/type-2-diabetes/agent-orange.jsp> (accessed 1/07)

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CRN CHAIRPERSON MESSAGE

European Partners

Deborah Brommage, MS, RD, CSR, CDN

Collaboration allows us to partner with those who have similar interests in an effort to share knowledge, find an innovative approach to a project or to solve a problem. Registered dietitians in nephrology care possess diverse backgrounds, varied experiences and exceptional ideas that enable us to provide the best nutrition care for our patients with kidney disease. It goes without saying that when renal dietitians collaborate, the possibilities are endless.

CRN and RPG are often called upon to collaborate with other organizations that specialize in nephrology care. One such request recently came from the European Dialysis & Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA) Nutrition Interest Group. This unique opportunity is an invitation for us to start thinking globally and to build international professional relationships.

EDTNA/ERCA is a multi-disciplinary renal care association in Europe with 4200 members from 73 countries. Their goal is to promote quality renal care through education, and implementation of standards and research in Europe. The committees are comprised of an Education Board, a Research Board and Interest Groups. The Interest Groups within the organization include Anemia, Hypertension, Nutrition, Pediatric, Social Workers and Technicians, which allow practitioners with shared interests to collaborate on renal treatment trends and resolve shared problems. The Association has published the European Core Curriculum for a Post Basic Course in Renal Nursing, the European Standards for Nephrology Nursing Practice and developed the Collaborative Research Program. The 35th EDTNA/ERCA International Conference, titled Prevention, Care and Management of Renal Disease, was held September 2006 in Madrid, Spain. NKF participated with exhibits and Dr. Mary Sevick represented NKF on a panel to present the NKF USA Guidelines for Management of Diabetes, and

was also a faculty member for a Diabetic Advanced Skills Workshop.

The EDTNA/ERCA Nutrition Interest Group, established in 1986, was formed to promote nutrition and dietetic intervention in renal therapy. The Chair is Lone Ashurst and the Project Leader is Annemarie Viser. One of the projects being initiated by the EDTNA/ERCA Nutrition Interest Group is the development of the European Consensus Statement on Nutrition Support in Adults on Renal Replacement Therapy (RRT). The purpose of this project is to develop guidelines in order to achieve a high level of quality nutrition support for patients on dialysis. A systematic literature review is being conducted on all current methods of nutrition support in adults on RRT to determine evidence-based practice. A survey will also be conducted in a minimum of 6 European Countries and the U.S. to assess nutrition support practices and recommendations for adults on RRT to evaluate current practices. All eligible CRN and RPG members are being asked to participate in this important survey.

The second project is to publish a book on Nutritional Supplement Recommendations in Kidney Failure Patients. The objective is to provide evidence-based information on all vitamins, minerals and trace elements with regard to metabolic changes and recommendations for patients with kidney disease. The publication will also report on the most commonly known alternative supplements including their function, role and implications for patients with kidney disease. The CRN participant for this project is Maureen McCarthy, MPH, RD, CSR, LD, who graciously volunteered to assist with the alternative supplements section. For many years, CRN and RPG have worked collectively on numerous projects giving the membership of both groups the benefits of shared knowledge, talents and creativity. We are now seizing the opportunity for global collaboration with EDTNA/ERCA on these noteworthy activities and hope to forge a long lasting relationship for future endeavors. More information on EDTNA/ERCA can be found on their website www.edtna-erca.org.

**The Renal Dietitians DPG
would like to congratulate the current RPG members
that are being recognized by ADA as 50 year and 50-plus year members.**

These Members will receive a congratulatory letter and certificate, signed by the 2007-08 ADA President, Connie Diekman. They will also receive complimentary registration to attend the 2007 Food & Nutrition Conference & Expo (FNCE) in Philadelphia, PA and be recognized at a special ceremony held during the meeting.
Please take a moment to congratulate these dedicated members of our DPG.

50 year members

Maureen Kachinski, NJ
Joyce Mooty, MI

50-plus year members

Janice Byrd, TX
Janice Cullen, CA
Mary Jane Lee, MI
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Nutrition Therapy Reimbursement Guide

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Determine key players to include in process

Key positions include: reimbursement specialist, payor contract coordinator, credentialing, compliance, reimbursement/billing manager, provider enrollment, provider relations, provider services, medical records, accounting service, information technology service, scheduling, finance and marketing.

Know the payor guidelines for nutrition therapy. Payor guidelines found in third-party payors' policies, manuals and/or the contract between the facility/registered dietitian (RD) practice and the payor determine what nutrition services will be covered by a specific provider's (insurance company) plan.

Investigate credentialing requirements and obtain provider numbers from each payor.

Key departments to include in this process are: compliance, credentialing and/or payor contract coordinator or provider relations.

- The provider number is specific to one person, although RDs' charges may also be billed under a clinic's provider number.
- Submit a credentialing application to each insurance company. This will include demographics, registration, licensure, etc. This can take up to 90 days and must be completed before billing is initiated. It is possible to have several different provider numbers for different payors (Blue Cross/Blue Shield, Medicaid, Medicare, etc). The provider numbers will stay the same if you change employment. Medicare is the only provider number that would change if you were to change employers.
- Beginning May 23, 2007, or May 23, 2008 for small plans, all providers must apply for a national provider identifier (NPI) that will replace the RD's Medicare PIN and other provider numbers from other payors. The NPI is a unique, government-issued, standard identifier mandated by the 1996 Health Insurance Portability and Accountability Act.

Understand the billing and coding process

In my facility the reimbursement specialist (RS) put together a comprehensive scorecard system to determine the appropriate "level of visit" for billing. Our scorecard is used by several disciplines and by both the chemotherapy and the radiotherapy departments. It uses the International Classification of Disease codes (ICD-9 code) to describe the patient's medical condition or diagnosis that is determined by the physician and professional coder.

- Determine appropriate billing form
Different facilities have different billing forms.
 - Hospital-based clinic: utilize form CMS UB92 for inpatient services, while outpatient services are generally billed on the CMS1500 form.
 - Freestanding clinic: utilize form CMS1500
- Determine appropriate procedure code
Current procedural terminology (CPT) codes are a systematic listing of services and procedures. The CPT system provides one universal, uniform language for communication with third-party payors for reimbursement purposes. The American Medical Association publishes an updated CPT code listing yearly.

In addition to the medical nutrition therapy (MNT) CPT codes, a hospital-based clinic visit level for education non-specific to discipline can be utilized if the payor indicates it will accept this code for covered services. The accounting department may be involved in naming the nutrition charges (ex: new patient education visit or established patient education visit). Most commercial payors pay these codes. Additionally, some clinics bill nutrition services incident to physicians' services. Note Medicare Part B does not allow MNT services to be billed incident to physicians' services. At the comprehensive cancer center where I provide nutrition services, we have confirmed that certain physician evaluation and management service codes (99201, 99202, 99211 and 99212) may be used in addition to the MNT CPT codes (97802, 97803). It is imperative to verify with the payor contracting coordinator which codes to use to bill nutrition services, including MNT.

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The patient claim and medical record documentation should include the appropriate diagnosis code (ICD-9 CM) to qualify for payment. One code utilized is V65.3 Dietary Counseling, or confer with the physician or biller to identify an alternative diagnosis that specifically describes the patient's disease or condition.

Determine appropriate charges

Payment for procedures identified by CPT codes varies by payor group. Under Medicare Part B, where MNT services are covered for qualifying beneficiaries with diabetes, renal disease or post-kidney transplants, the payment rate is listed in the 2006 Physician Fee Schedule. CMS posts the fee schedule on its Web page. Other third-party payors will determine a payment schedule that is usually included in their manual or in policies that are shared with the RD provider who is under contract with the payor.

Check with your chemotherapy or radiation nurses to see their process for daily charge tickets. A charge ticket must establish medical necessity (i.e., reason patient was seen).

Track cost-benefit

Work with accounting to help develop a report for nutrition therapy charges. Depending on the caseload, one could request a daily, weekly or monthly report of your charges. The report is helpful when verifying patients seen to charges submitted. It also is a system that is helpful in tracking your own statistics.

Document outcomes

Keep a record of your patient outcomes. It will help quantify an RD's caseload and help establish volumes as they relate to the need for staffing. It is also a method to determine revenue generated (again, to help verify and justify the need for additional staffing).

Know the system

Depending on the CPT code that your facility or practice is allowed to use for the particular third-party payor, you may be able to use a modifier when billing for nutrition services. For example, if the plan allows the RD to use an evaluation and management CPT code, an extended time or same-day service modifier may apply. Since the MNT CPT codes are time-based codes, instead of using a time extender modifier, the RD should use additional units of

the MNT code. Also, since MNT services can be provided on the same day as physician services, modifier 25 is not needed. Modifier-25 from the CPT 2006 definition is "significant, separately identifiable evaluation and management service on the same day of the procedure or other service." If other CPT codes are used, the billing department can help determine whether a modifier is needed.

Track your payments

The accounting department can review your NT charges on a monthly or quarterly basis to determine if there are payor issues preventing you from getting reimbursed for submitted claims. It will also help you determine what percentage you are being reimbursed and help spot any trends that are developing along the charging process. I find this very valuable and interesting information!

CRN Tribute

Susan C. Knapp, MS, RD, CSR, LD

The Renal Community was saddened by the loss of Susan Knapp who passed away January 8, 2007, after a short battle with cancer. Susan was not only an experienced renal dietitian, but also a patient advocate, supporter, educator, and friend to many.

Susan's professional affiliation included the National Kidney Foundation Council on Renal Nutrition (CRN). She served as Secretary/Treasurer for five years, and was on the Nominating and Membership Committees. Susan's enthusiastic approach to everything she did made her a great asset to the CRN Executive Committee. One of her notable education projects was a video to help dialysis patients shop at the supermarket and make smart choices to fit their renal diet. She was also a chapter author for the *Clinical Guide to Nutrition Care in Kidney Disease*. Susan also did volunteer work for the ESRD Network 13 Medical Review Board and the Oklahoma Council on Renal Nutrition. Susan had numerous publications to her credit and eagerly participated in research.

Susan inspired an interest in renal nutrition for many interns and young dietitians. CRN will commemorate the achievement the the Susan Knapp Recognized Young Renal Dietitian in her honor. The 2007 award will be presented to Susan's husband, Ken Knapp.

Susan will be missed by all who had the good fortune to know her!

■ 2006 ADA Food and Nutrition Conference

As Experienced by a First Time Attendee

by Lesley Wujastyk, RD, LD

As a renal dietitian at an outpatient hemodialysis clinic, I find myself focusing on anemia and bone management, phosphorus and mineral control and dialysis adequacy most of my days. The patient population where I work is not as varied as other nutrition professionals may encounter and staying updated on other aspects of nutrition is sometimes not a priority. Thus, I have made it a priority to expand my clinical knowledge beyond chronic kidney disease for myself and my patients too!

I recently attended my first ADA Food & Nutrition Conference & Expo as a member of the Renal Dietitians (RPG) Editorial Board. The conference was held in Honolulu, Hawaii this year which made the trip even more special since I had never been there.

Attending this conference is a great way to remain current on emerging trends in nutrition, meet professionals from all over the United States and network with others who are passionate about nutrition. I was also curious to see what my ADA membership was doing for me!

In keeping with my priority to expand my knowledge beyond chronic kidney disease, I decided to attend a few seminars dedicated to non-renal topics. I was able to attend seminars including "Nutrition, Physical Activity and Cancer: What You Need to Know Now", presented by: Michael Thun MD, MS and Colleen Doyle MS, RD and "Omega-3 Fats in Health and Disease: Implications for Education and Practice", presented by Barbara Lohse, PhD, RD and Nancy M. Lewis PhD, RD, FADA. These were just two of many seminars that I attended over the four day conference. Can you believe that there were between 20-40 different topics each day! These seminars seemed unlike any I had seen at renal conferences, yet the information was pertinent enough to bring back to the clinic.

I had the privilege of meeting many people from around the country at the conference. I found the best way to meet people was at the planned events such as the Dietetic Practice Group (DPG) showcase and the Expo. At

the DPG showcase each DPG had the opportunity to host an informational booth to showcase their group's activities and publications. I worked at the DPG booth, which provide a great opportunity to meet members of the DPG from around the country. I also had the chance to visit the 28 other DPG booths and meet dietitians in different specialties from all over the country.

Another great networking opportunity was the Expo hall, where new products were introduced. Representatives from each company were on hand to answer questions, and it was easy to request additional information and samples with a simple swipe of your conference registration card.

The opportunity to attend the ADA FNCE conference was a first-hand experience that validated that my ADA membership is a professional choice that I feel good about making. It was an overwhelming feeling to walk into the Hawaii conference center and see over 6000 nutrition professionals on the first day of the conference! It was great to see so many individuals in one place who were passionate about nutrition. I felt grateful to be involved.

If you too are passionate about nutrition and making a difference, join the ADA and your DPG now—don't wait! Volunteer for a committee, present a poster or develop educational materials. The sky is the limit to your ideas; the ADA offers dietitians and nutrition professionals a recognizable forum to present them.

***Eating Simply with
Renal Disease:
Simple overview of the
renal nutrition plan for
patients with CKD Stage 5***

Spanish Version

NOW AVAILABLE

See page 29 for ordering information

RPG WORKSHOP

First time offered!

A Board Certified Specialist in Renal Nutrition (CSR)
Review Course
sponsored by the Renal Dietitians Practice Group

Monday, April 9th 2007

1:00 pm-9:00pm

Walt Disney World Swan & Dolphin Hotel
Orlando, FL

Dinner is included in registration fee.

The course will offer a comprehensive review of renal nutrition, hands-on practice test questions for the CSR exam, and breakout sessions on kinetics, transplant and pediatrics.

Approval pending for 8 CPE units through ADA/CDR

The cost is \$25 for Renal Dietitians Practice Group members and \$50 for non-members.

Deadline to register is Friday, March 23rd

For questions or more information,
please contact Cathi Martin at cathim@bellsouth.net

ADA's DPG Practice Team Manager:

Susan DuPraw, MPH, RD

As an ADA staff person who works with five dietetic practice groups including Renal Dietitians (RPG), everyday provides interesting and sometimes challenging issues for me. For eight years I have been coordinating DPG activities including reviewing newsletters and publications, analyzing budgets, participating in strategic planning, approving business contracts, training and guiding DPG volunteer leaders, and fielding member calls regarding practice related questions.

My past positions as a clinical dietitian at a large teaching hospital, and marketing coordinator for Dairy Council of Wisconsin have provided me with a wealth of experience including media relations, public speaking, and working with a variety of health and business professionals.

I have been an active volunteer on several committees with Chicago Dietetic Association, and more recently with

West Suburban Dietetic Association as their newsletter co-editor. I do feel that volunteering at the local level provides an opportunity for individuals to network and share the same interests outside their immediate work environment.

Renal Dietitians (RPG) is a dynamic group with many volunteer leaders from around the country. I have seen this practice group grow and provide more member services over the years. Calls that I field in the area of renal nutrition are from members who are interested in RPG publications, questions regarding the RPG Web site www.renalnutrition.org, and members who are interested in networking with other registered dietitians in the renal arena. One of the more unusual questions I received was from a registered dietitian who was seeking advice on feeding a gorilla at a local zoo with renal insufficiency!

ADA appreciates your support and membership in our national organization and in RPG.

Please consider volunteering for a leadership position with RPG. This experience will enhance your skills, and provide networks and pathways to even greater success.

Renal Practice Group: Educational Materials

<u>Title/Description</u>	<u>RPG Member Price</u>
Eating Simply with Renal Disease: (25 per pkg) Simple overview of the renal nutrition plan for patients with CKD Stage 5	\$15.50 per pkg \$20.15- non-RPG member
Eating Simply with Renal Disease: (25 per pkg) Spanish version of the renal nutrition plan overview for patients with CKD Stage 5	\$15.50 per pkg \$20.15- non-RPG member
Bone Store Kit: Patient education module focusing on calcium and phosphorus to improve mineral metabolism imbalances	\$10.00 each \$13.00- non-RPG member
Dietitian's Manual: Camera-ready, single-page patient education compiled from previous Renal Nutrition Forum Issues	\$10.00 each \$13.00- non-RPG member

Please Note:

Shipping and Handling Fees: 1 – 3 items: \$5.00 4 – 13 items: \$10.00 (pkg of 25 = 1 item)

To order materials:

Please download order form from RPG website at www.renalnutrition.org under Member Resources.

Make checks payable to: ADA/DPG#21

Mail form and check to: Pam Kent – RPG Treasurer, 114 Infantry Road, Vermillion, OH 44089

For additional information: Please contact Pat Williams at gpatwill@comcast.net



More than 25 years of dedicated service in the Renal community.

Abbott has provided more than 25 years of service to the Renal community. As an active member of the community, Abbott is dedicated to providing continuing education programs to help improve the lives of patients with chronic kidney disease.

**Abbott is proud to sponsor the
Renal Nutrition Forum.**



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■ 2006-2007 RPG Executive Committee

Mission: Renal dietitians dietetic practice group is leading the future of dietetics by promoting and supporting ADA members working in nephrology practice.
Vision: RPG members are a valued source of expertise in nephrology nutrition.

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■ RNF Guidelines For Authors

Article Length: Article length is determined by the Editor for each specific issue. The lead article is approximately 3000 words (not including tables/graphs). Other feature articles are usually 1000-1500 words; member spotlights, etc. are 500 words.

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

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

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

Reference citation examples:

Article in periodical:

Knowler 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 book:

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

Web Site:

Medscape drug info. Available at www.medscape.com/druginfo. Accessed Feb. 3, 2004.

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

Submissions: All submissions for publication should be submitted to the editor as an email attachment (either an MS word file or text file). A new feature on the RPG Website will be to post the lead articles from the Renal Nutrition Forum on the Members Only Section of the RPG website (password protected). Thus, please include a brief abstract (for the website) along with your article submission.

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**Complete Nutrition For
People on Dialysis**

Catherine M. Goeddeke-Merickel, MS, RD, LD
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