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Impact Of Nutritional Supplements On Albumin Levels Of Dialysis Patients: Nutrition Supplement Grant Program National Kidney Foundation Of South Carolina

By Roxanne G. Poole, RD, Abdullah Hamad, MD, Lynn Thomas, DrPH, RD, CNSD, Peggy Strawhorn. Roxanne has been a renal dietitian for 16 years and is employed with DaVita. Roxanne can be reached by phone # 800-533-1550, fax # 803-531-2060 or by email at Roxanne.Poole@davita.com.

Introduction

Based on the 2003 Annual Data Report (1), there are over 325,000 patients with end stage renal disease (ESRD) on dialysis in the United States (1). Mortality in ESRD patients remains high despite advancements in all aspects of medicine. Cardiovascular diseases cause the bulk of morbidity and mortality in dialysis patients (2,3). There is an increase in mortality and morbidity for ESRD patients who have an albumin below 4 mg/dl (4). Kalantar-Zadeh et al studied longitudinally a 2-year cohort of 58,058 maintenance hemodialysis (HD) patients and found that hypoalbuminemia predicts all-cause and cardiovascular death (5). He also found that increased serum albumin is associated with better survival over time, independent of baseline serum albumin or other strong predictors of cardiovascular surrogates (5). Other studies have confirmed the relationship between malnutrition and mortality in dialysis patients (6-8).

Many dialysis patients have co-morbid conditions that can impact their albumin through different mechanisms (9-14). Hakim and Levin divide the factors that affect nutritional status into different categories:

- Dialysis factors
- Biochemical factors
- Gastrointestinal factors
- Miscellaneous factors:
 - depression
 - multiple medications
 - recurrent hospitalizations
 - underlying illness
 - low socioeconomic status (10).

Peritoneal dialysis (PD) may cause anorexia through different mechanisms as part of the effects of this modality. The presence of the dialysate fluid in the abdominal cavity can cause abdominal discomfort which may interfere with gastric emptying and intestinal motility. The absorption of the glucose can inhibit feelings of hunger. Peritonitis as a result of the infection and inflammation can cause anorexia (11).

Bossola et al showed that advancing age was significantly associated with lower energy and protein intakes in HD patients. They also noted that there is a well established decline in food intake with increasing age in populations of healthy persons (9).

The addition of nutritional supplements to patients' current intake could help improve their nutritional status. Previous studies have been conducted to determine the effectiveness of oral supplementation in the treatment of malnutrition (5, 15-21). In a meta-analysis of 18 trials evalu-

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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:
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Please forward information to:
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I would like to begin with a quote from Mark Twain that helps remind me to stick by my goals and aspirations no matter what challenges I face every day. "Keep away from people who try to belittle your ambitions. Small people always do that, but the really great make you feel that you too can become great." I am grateful for those great dietitians that I have considered my mentors and made a difference in my life.

As the incoming Editor, I would like to welcome Lesley Wujastyk the new assistant editor. We are excited to have her join the Editorial Board and RPG! Stay tuned because she is a fresh face and adds a new perspective to our organization. Thank you to Sharon Griff, the outgoing Editor who now transitions into the Managing Editor position. She has initiated an exciting vision that we have to introduce new authors to our publication. She has taken the time to reach out to our members and solicit valuable feedback for suggestions and ideas to improve our publication. She has helped identify and groom new authors for the Forum as well as providing clinically relevant information to our members during her tenure.

Someone who is often overlooked but very much a part of what makes our publication great is our publisher. Lorna Brown is the general manager of AlphaGraphics Printshop in Cincinnati, Ohio. We are grateful

for her expertise, commitment to our publication and most of all for her great ideas and suggestions that help keep us on the cutting edge! Thank you Lorna and staff for helping to making our publication look great and provide a valuable resource to our members.

The focus of this issue is research. The feature article by Roxanne Poole is an example of dietitian-directed research. Alison Steiber provides an interesting look at research and dietitian involvement. Research is the cornerstone to our every day practice and it can be conducted on a small scale to a large one. In September, the RPG initiated a member eblast to communicate important information and opportunities to our members. One of those opportunities was an invitation from Anna Parker, a Nutrition Master's student at the University of Medicine and Dentistry New Jersey. As part of her research she invited members to participate in an online survey and complete 5 web-based education modules. I hope that all of you had the opportunity to take advantage of the free CPE credits offered and participate. Whether you choose to be a participant in a survey study, initiate or coordinate a survey study or write a proposal for clinical research, don't miss the opportunity to make a difference for yourself, our profession and elevate the recognition of the skills and expertise of the nephrology dietitian.

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Thank you to the following peer reviewers for this issue:

Sarah Carter Sharon Griff
Maria Karalis Lynn Munson
Susan Salmi

One of the biggest challenges we face is finding the time to become more involved with research. Stress is one the reasons that we feel so overwhelmed at times and unable to do one more thing in our lives! Janie Walters, a motivational speaker, wrote an excellent book entitled Blow a Bubble: Not a Gasket about how to make our stressful lives more manageable. The book is divided into 5 sections (physical fun, social fun, mental fun, emotional fun, spiritual fun) and packed with fun ideas to that help to remind us that life is worth living, just for the fun of it. So the next time you feel stressed, try a couple of these fun stress releasers so that you can be ready to meet the research challenge when the opportunity comes your way! Here is a brief list of some of the suggested stress relievers from each of the 5 sections: skip-it helps to keep the child inside of us alive, send funny greeting cards-laughter is the best medicine, laugh out loud-research has shown many benefits, illuminate and brighten

your life with candles, gaze at the stars for a few minutes of peace, choose a mascot or logo that through good and bad helps to remind you of your goals and last but not least don't forget to have an ounce of fun and smell the roses every day!

It is through the efforts of those dietitians involved in research that our profession continues to be recognized for the scientific expertise and skill that we all possess. Kudos to all those dietitians who help to make a difference in nutrition related research.

Please feel free to contact me via rnfeditor@yahoo.com with ideas, comments or suggestions.

Catherine M. Goeddeke-Merickel

**Congratulations to the
2006 RPG Outstanding Service
Award Recipient:
**Laura Byham-Gray,
PhD, RD, CNSD****



Laura D. Byham-Gray, PhD, RD is an assistant professor in the Department of Primary Care, School of Health Related Professions at the University of Medicine and Dentistry of New Jersey. At UMDNJ-SHRP, Dr. Byham-Gray teaches graduate level nutrition courses specifically related to vitamin and mineral metabolism, body composition, and nutrition in aging. In addition, Dr. Byham-Gray advises both thesis and doctoral students in their research projects and studies.

Dr. Byham-Gray has 20 years of experience in the field of clinical nutrition, with specialty practice in nutrition support, kidney disease, and home care. Dr. Byham-Gray has been active on the local, state, and national level in nutrition and kidney disease, holding offices on several Executive Boards and Committees, including the American Dietetic

Association (ADA), the National Kidney Foundation (NKF), and American Society of Parenteral and Enteral Nutrition (ASPEN). Dr. Byham-Gray has currently been appointed to ADA Clinical Standards of Practice Committee as a representative of RPG because of her expertise in kidney disease, outcomes research, and evidence-based practice guideline development. She has been a long time member of RPG and has previously served as the Chair and Editor. She also serves on the editorial board for the Journal of Renal Nutrition. Presently, Dr. Byham-Gray is a consultant for the ADA as an evidence analyst for the Evidence Analysis Library recently launched by the Association.

Dr. Byham-Gray has several peer-reviewed articles and over 30 professional presentations related to kidney disease, dietetics practice and clinical decision-making as well as management. She has also authored one self-study publication entitled Medical Nutrition Therapy in Renal Disease, 2nd Edition with Wolf Rinke Associates, and most recently she has co-edited the ADA publication, A Clinical Guide to Nutrition Care for Kidney Disease. For her dedication to the field of renal nutrition, Dr. Byham-Gray has received numerous awards, including the Outstanding Renal Dietitian for Council on Renal Nutrition Network 4 and the 2005 Dean's Research Award for Excellence in Research from the UMDNJ-SHRP for her research contributions.

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ing feeding in dialysis patients, Stratton et al reported that enteral nutritional support increased total protein intake, and serum albumin concentration improved by 0.23 g/dl (21). Steiber et al concluded that intervention with nutritional supplements of the patients' choice decreased the risk of hospitalization (20). Sharma et al showed a significant increase in albumin level in the short term with intervention of nutritional supplements (18).

Many dialysis patients are unable to afford nutritional supplements to help increase their oral intake when various factors and conditions limit their consumption of foods. Samples of supplements have become difficult to obtain and are not sufficient to make an impact on one patient, let alone several patients.

In South Carolina, dialysis clinics are responsible for the distribution of prescribed nutritional supplements for ESRD patients as part of the participation of care in the Medicaid program. Clinics are reimbursed at a set fee for the supplements. The National Kidney Foundation of South Carolina (NKF of SC) Nutrition Supplement Grant Program was designed for patients who did not have Medicaid, but had an income to expense ratio that did not allow for the flexibility to purchase supplements. This nutritional supplement grant program from the NKF of SC was designed to provide a 90 day supply of specific liquid nutritional supplements or a powdered protein supplement at no cost to the patient.

Methods

Program description

The NKF of SC provided funds from the Patient Services budget to purchase supplements and have them delivered to the approved patient's clinic. The patient signed a form giving permission for NKF of SC to access specific medical and financial information to be used for screening purposes and follow-up data collection. In addition, dialysis companies had patients sign release of information forms, giving permission to release information to the NKF of SC.

The application form had two parts. One was completed by the social worker to obtain information about household income, monthly expenses, and number of persons in the household. The second part of the form was to be comple-

ed by the dietitian and requested information as to why the patient needed the supplements, co-morbid conditions, relevant laboratory data supporting the request, body weights for the past 3 months, usual body weight, age, modality of dialysis (either HD or PD), albumin levels for the past 3 months, and recent hospitalizations or infections.

Dietitians were also asked to complete and send in a tracking form to the NKF of SC at the end of Phase B (3 months of supplementation) and Phase C (3 months following cessation of supplementation). This tracking form included information about monthly dry weights, phosphorus levels, albumin levels, and whether the patient had an infection or was hospitalized. Even though phosphorus levels and dry weights were tracked, the data analysis has not been completed for these factors. A sub group analysis is underway to evaluate the impact of supplementation on dry weight.

For clarification, the total observational period of the study was 9 months. Three months of data (Phase A) was requested on the initial application and 6 months of data was obtained and recorded on the tracking forms. The 6 month time frame was divided into two different phases: the 3 month supplementation period (Phase B) and the 3 month observational period (Phase C) following the cessation of supplements.

Due to the large response of patient applications and the limited funds available for this program, patients approved were those who had albumins <3.5 for at least 2 of the 3 months, or who had lost >5% in body weight in one month or >10 % in 6 months. A committee comprising the patient services coordinator and 1-2 dietitians reviewed the supplement requests and determined which requests met the criteria for approval.

Inclusion Criteria

Patients qualified who did not have insurance coverage for nutritional supplements. Their annual incomes were < \$24,000, albumin levels <3.5 mg/dl for two consecutive months and/or experienced significant weight loss (>5% in one month, >7.5% in three months or >10 % in six months). Patients were not excluded for age or any co-morbid medical conditions.

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Study Design

Three months prior to applying for supplements, dietitians observed patient body weights and albumins (stage A). Patients received a 3 month supply of the liquid supplements allowing 2 cans daily or powdered protein equivalent to 6 scoops daily. The 3 month supply was sent directly to the home of each patient participating in the study. Adherence was assessed by dietitians at least monthly. Body weights and albumin levels were tracked during the three month supplementation phase (stage B). For an additional three months, body weights and albumins were tracked after nutritional supplements were discontinued (stage C).

Supplements used

The supplements were chosen based on the product cost and funds available.

Oral Nutrition Supplements:

Boost®, Boost Plus®, Boost HP®, Boost® Diabetic (Novartis Nutrition)

Powdered Protein Supplement:

Procel ® (Global Health Products, Inc.)

Results

One hundred and thirty dialysis patients in South Carolina qualified and received supplements in 36 dialysis clinics. There were 65 males and 65 females. Mean age was 62.3 years. There were 99 HD and 31 PD patients. Eighty seven dialysis patients qualified using criteria of low albumin, 14 patients for criteria of weight loss, and 29 for criteria of low albumin and weight loss.

Etiologies and factors contributing to malnutrition in dialysis patients were studied. Table 1 illustrates the breakdown of the contributing factors to malnutrition in the patients participating in the study. Hypertension (85%) and diabetes mellitus (61%) and diabetic complications were the most common factors associated with malnutrition. Table 2 stratifies patients based on their number of risk factors (RF) for malnutrition, with most patients having two to four risk factors. There was a significant difference in the number of risk factors associated patients over 70 years old (4.3 RF) compared to those patients less than 70 years old with 4.3 RF and 2.8 RF, respectively (p value < 0.001).

Table 1

Risk factors contributing to malnutrition for 130 study participants (expressed as # of pts & % of pts)

Hypertension	110	84.6%
Diabetes	79	60.8%
Gastrointestinal Conditions	43	33.0%
Age ≥ 70	41	31.5%
Infections	31	23.8%
Leg Amputation	15	11.5%
Stroke	14	10.8%
Cancer	13	10.0%
Psychiatric Disorder	6	4.6%
Dementia	6	4.6%
Alcohol and Substance Abuse	5	3.8%
Neurological Disorders	4	3.0%
Severe Lung Diseases	3	2.0%
Sickle Cell Disease	2	1.5%

Table 2

Number of risk factors (RF) for malnutrition

Risk Factors (RF) from Table 1 for the 130 study participants broken down with number of RF per person

# of RF	0	1	2	3	4	≥ 5
# pts	3	17	23	37	33	17
% pts	2.0%	13.0%	17.7%	28.5%	25.4%	13.0%

Table 3

Comparison of albumin levels during the 3 study phases

Observation for Albumin n=130 patients

	Mean Albumin
Stage A <i>Months 1,2,3</i>	2.9 + .4 mg/dl
Stage B <i>Months 4,6,5</i>	3.45 + .42 mg/dl
Stage C <i>Months 7,8,9</i>	3.49 + .4 mg/dl
P value A vs. B or C	<.004

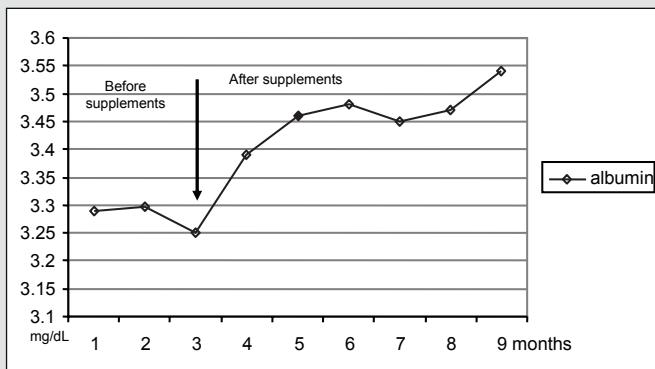
There was a statistically significant increase in albumin level starting in the first month of supplement use that persisted throughout the three months the supplement was given. In-

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Graph 1

Mean Albumin levels for all patients

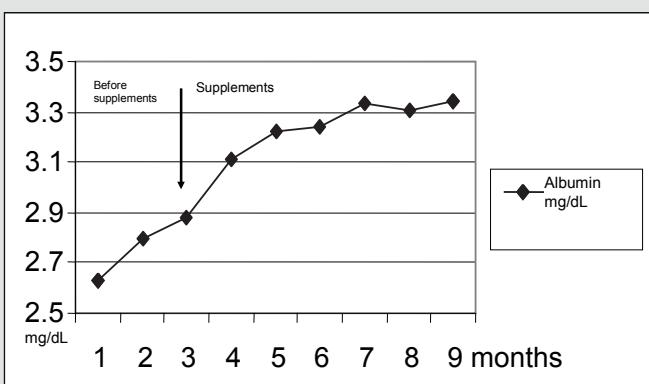
Mean Albumin during study
n=130 patients, p <.004



Graph 2

Mean Albumin levels for patients with initial albumin below 3.0 mg/dl

n=19 patients, p <.0005



terestingly, improvement of albumin levels persisted even after the supplement was stopped during the three month observation period. The improvement continued to be statistically significant. Table 3 summarizes this data and graph (1) illustrates the improvement in albumin levels.

Patients with albumin levels less than 3.0 mg/dl received the most benefit from the supplement with albumin levels improving over 0.5 mg/dl on average (2.67 mg/dl to 3.3 mg/dL).

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mg/dl). Although this sample size was small (n=19), the improvement was statistically significant (*p* value < 0.0005). Graph (2) illustrates the improvement in albumin levels in this group.

Discussion

Malnutrition is a common problem in dialysis patients and has many contributing factors. Malnutrition is correlated with increased morbidity and mortality. Many interventions have been used to treat or improve this condition with varying success (9). Intradialytic parenteral nutrition showed variable results (22-24). Approval for IDPN requires extensive documentation, may take several weeks for approval, and is expensive. Oral supplements are a more affordable option that have shown promising results in many studies (15-17). Our study illustrates a successful intervention in trying to address this common problem.

Dialysis patients are characterized by having multiple medical problems. Factors that contribute to decreased albumin and weight loss in dialysis patients are numerous and include recurrent infections, depressed immune function, loss of protein during dialysis (especially PD), frequent hospitalizations, and gastroparesis. Other factors include inability to consume enough protein and calories, living alone, dental problems, poor appetite, dementia or depression, decreased activities of daily living and poor dietary choices.

Our study differed from many previous studies in that we did not exclude any patient based on their health situation or co-morbidities. We found several studies in the literature that excluded patients with recent surgeries or sepsis, hospitalizations longer than one week, unintentional weight loss greater than 10% over 6 months, HIV, and active malignancy (16). There are valid reasons for these exclusions which are primarily to limit the number of confounding factors.

Supplements were provided without cost to the patients in our study. The improvement in serum albumin levels that resulted from nutritional supplement intervention in other studies was proven to be associated with a decreased morbidity and mortality (25, 26). We feel there may be a significant savings in the management of CKD Stage 5 by providing such a program on a large scale through decreased hospitalizations, decreased medication usage, and ultimately by

improving the incidence of mortality.

Patients with the lowest albumin had the greatest improvement in albumin level. Although there were only 19 patients in this group, the great improvement in albumin was statistically significant, confirming the need to target these patients.

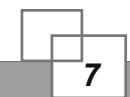
Intensive nutritional counseling impacts general nutritional status and albumin levels. In a study that combined nutritional counseling with supplementation, Wilson et. al. showed that nutritional counseling alone could not sustain the short-term improvement in albumin that was initially obtained (16). Apkele and Bailey suggested that for patients with protein-calorie malnutrition, intensive dietary counseling was of greater benefit than the use of nutritional supplements alone (27). It is difficult to isolate the positive effects of the counseling while providing the supplements. The dietitians in our study kept track of the patient's usage and tolerance of the supplements and as a result may have spent more counseling time with the patients. Additionally, the fact that patients were aware that they were participating in the study may have increased their adherence.

Our study showed that malnutrition in dialysis patients is multifactorial. Two or more contributing factors were found in most patients. Most of these factors are non-modifiable. Programs to provide nutritional and social support to this population should be encouraged.

Although our study did not look at morbidity and mortality outcomes, the study demonstrated a clinically and statistically significant improvement in serum albumin levels which is strongly linked and related to improved morbidity and mortality. Based on our study, providing 3 months of nutritional supplementation improved albumin levels. This improvement was sustained for the additional three month observational period.

Monitoring results was important for validating the effectiveness of the program. Initially, \$10,000 was requested from the NKF of SC as a one-time request for the nutrition supplement grant program. Reports were provided quarterly to the board of directors on the positive impact the program was making in the quality of life for the patients as well as

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improved conditions substantiated by data from the tracking forms. The following year, this program became a part of the regular budget under Patient Services with an allotment of \$18,000. The next year, the amount was increased to \$20,000, and the last 2 years, \$30,000 has been budgeted for the program. Monitoring data, ongoing tracking of the patients utilizing the program and regular communication to the board, helped validate the need for this program. It has been recognized as a valuable service for the patients and helped to justify the need for increased funding in subsequent years.

The NKF of SC Nutrition Supplement Grant Program has characteristics that can be easily adapted by others. The overhead costs were low since existing personnel and clinical data were used. The lab data and information on the tracking forms were part of the patient's medical records and no extra lab work was required. The levels of albumin, body weights, and hospitalizations were variables that were easy to measure. Grant programs that provide nutrition supplements to patients who have limited resources to purchase them could have a major impact in improving the overall treatment and outcomes of CKD Stage 5 patients throughout the country.

Acknowledgements

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FNCE 2006 Honolulu Meeting DPG SHOWCASE



RPG Board Members gather in front of the Booth.
(Left to Right) Pat Weber, Marianne Hutton, Connie Cranford, Cathy M. Goeddeke-Merickel
and Leslie Wujastyk



More RPG Board Members
(Left to Right) Pam Kent, Pattie Barba, Cathi Martin

Dietitians in Research: Part 1

By Alison L. Steiber, PhD, RD, LD. Alison is an Assistant Professor in the Department of Nutrition, Case Western Reserve University. Alison can be reached by phone # 216-368-2075, fax # 216-368-6644 or by email at Alison.steiber@case.edu.

Ten years ago, I received a copy of the summer edition of *Renal Nutrition Forum* featuring an article by Linda Moore, RD, who practiced as a renal dietitian with an active caseload, which included conducting clinical research and publishing research papers. This article hit me like a Mack Truck! The purpose of the article was to get clinical renal dietitians to incorporate research into their everyday practice. Moore suggested "renal dietitians should be integrally involved in determining new or better methods for improved care". The message behind the article resonated with me and I began to feel it was my professional responsibility to become involved in research. Her words inspired me, a new renal dietitian at a community hospital, to write a research proposal and grant. The grant that I submitted was designed to evaluate clinical indicators associated with poor oral intake of patients with renal failure. Unfortunately, I did not receive the grant. Nevertheless, I was so motivated by Moore's article that I eventually managed to execute my proposal and publish the findings in the *Journal of Renal Nutrition*. This process was so exciting and rewarding that it inspired me to become involved in renal nutrition research. Currently, I am an assistant professor and direct a coordinated dietetic internship/master's degree program. Part of my personal mission is to continue conducting renal nutrition research and inspire others to follow the same path.

Many dietitians become overwhelmed at the thought of adding research to their list of activities. To me, however, research has a very natural relationship with clinical practice; and it is something many of us are already doing, in continuous quality improvement (CQI) projects. Dietitians are by nature detail-oriented, linear thinkers, with strong backgrounds in science. They have access to patient populations and are, by the very nature of their work, typically in situations where they can evaluate current therapies and create hypotheses on ways to improve nutritional care. They are often strong collaborators in routine data collection and reporting, such as CQI activities.

However if current research findings can be believed, dietitians are not conducting or participating in a significant amount of research. Eck et. al. published data showing that, of the articles published during 1996 in the *Journal of Parenteral and Enteral Nutrition*, the *Journal of the American Dietetic Association*, and *Nutrition in Clinical Practice*, only 8% had a clinical dietitian as the first author and only 3% had clinical dietitians as coauthors (1). In 2002, Gardner et al surveyed 300 dietitians from the Clinical Nutrition Managers practice group of the American Dietetic Association (ADA) and found only 27% of the respondents had conducted outcomes research and of those 27%, only 64% reported their findings outside of their facilities.

Why are dietitians as a group not participating in research? Dietitian-identified barriers to conducting research seem to vary; however, common themes are lack of training in the area of research and a lack of time (2,3). In an as-yet-unpublished study by our laboratory group, renal dietitians were surveyed on their perceived barriers to conducting and participating in research. Time and energy needed to participate in research were barriers, with 55% reporting these as major factors. Ninety-four percent of the dietitians felt that they were not hindered by someone; but 26% felt they did not have adequate support from their facility. It was reported that 35% of dietitians had difficulty reading research papers; 37% had a hard time understanding statistical analyses in particular; and 30% had trouble with basic interpretation. It was disturbing that there appeared to be no significant difference between the practitioners with graduate training and those without for the responses to these questions. Why was there no difference, when logically there should have been? The limits of this database are such that an answer cannot be given. However, these results definitely warrant further investigation in future studies which have large, nationally representative samples.

The greatest challenge that we face is how to train and inspire future and current dietitians to become involved in research? It is imperative for our profession to support and develop opportunities for nutrition students to participate in hands-on training in research. As an educator, I believe these opportunities exist but we need to encourage this trend in more nutrition education programs across the country.

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Dietitians in Research *continued from page 10*

The Commission on Dietetic Accreditation and Education (CADE) has incorporated research into the curriculum of Didactic Programs in Dietetics and in Dietetic Internships (4). The program I am currently involved in offers two semesters of training with a research preceptor. Students are able to experience the entire research process from idea conception to data analysis and interpretation. Recently we have been able to submit the students' work to local and national meetings, allowing them to share the findings of their supervised research in professional forums (5).

Perhaps the most challenging barrier is in training and motivating dietitians who are already in practice. Fostering a work environment that is patient-focused and subsequently outcome research focused, requires financial and professional support and creative thinking. Practitioners may "get their feet wet" by joining already existing research projects. Gardner et al suggests that collaboration with other health care providers or researchers could increase dietitian participation in research (2). Mentoring programs and research projects which allow busy practitioners to participate in a small section of a larger study can provide valuable research experience and foster excitement in the research process. The National Kidney Foundation's Council on Renal Nutrition (NKF-CRN) has been a fore-runner in creating opportunities for renal dietitians to participate in research studies at all levels of practice.

In November of 1995, NKF-CRN held a special workshop at the Fall Scientific Meeting to assist renal dietitians with an interest in research get one-on-one mentoring with experienced researchers. Then, in 1998 the results of NKF-CRN's first National Research Question were published by Beto et al (6). This study was designed to allow maximum participation by renal dietitians. All members of NKF-CRN received a letter requesting participation in the study. Dietitians could participate by collecting clinical data on a few patients for two time periods of 8 months and 3 months, respectively. The data was sent to Beto, the primary researcher, for analysis. This collaborative project resulted in the participation of over 211 dialysis centers and 1527 dialysis patients. Dietitians designed, conducted and published this study.

Recently, another National Research Question was funded by NKF-CRN with a similar design for data collection.

Letters were sent out to all members of NKF-CRN and the Canadian Association of Nephrology Dietitians to request participation in the Subjective Global Assessment (SGA) Validation Project. Again, renal dietitians accepted the challenge and participated which resulted in a successful study. Unfortunately, from the initial 1998 study to the 2006 study the number of dietitians who volunteered and were able to secure support from their facilities dropped dramatically from 211 dietitians to fewer than 52. We must ask ourselves: Why this decrease? Was the communication process not sufficient to encourage support for the study? Are dietitians more burdened at work now than 8 years ago? Was the topic of the study more intimidating or less appealing? Are facilities less likely to support dietitians in this type of endeavor? The cause of decreased dietitian participation may be a combination of all these items.

Regardless of the reason, it is imperative that we as a profession of renal dietitians work together to achieve common goals to foster more dietitian-directed research. Some of these goals include a professional mission to advance the field of renal nutrition and to contribute in a significant way to the growing body of literature that indicates quality of life and mortality rates of patients with Chronic Kidney Disease are strongly linked to nutritional status.

What can be done in the future, and what has already been done to increase the number of renal dietitians participating in research? I would like to suggest that for this movement to be truly successful, two key things must occur. First, administrators and medical directors must value and encourage, dietitian participation in research both with time and financial incentives. It is important for upper management to realize that research brings benefits back to the facility! Secondly, renal dietitians must actively seek out opportunities for training in research-related skills and opportunities to participate in nutrition-related research studies. NKF has offered numerous workshops on research for dietitians, social workers, and nurses; they have created opportunities for dietitians to be involved in National Research Questions such as the Beto et al study, and most recently, a website has been dedicated to mentoring NKF-CRN members in research activities: <http://www.kidney.org/professionals/crn/bb/login.cfm> (accessed Nov '06) This website provides detailed guidelines for initiating research

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projects and offers the assistance of three expert renal dietitians function as personal mentors to anyone interested in initiating a project.

The American Dietetic Association has suggested that dietitians need post-baccalaureate training to increase the respect dietitians receive from other health care providers, and possibly this is true. However, I think there is more to it, beyond years of education. I believe we must continue to provide exceptional nutritional care to our patients, while moving forward as peer members of research teams. These teams need to have strong nutritional input so that the field of nutrition and dietetics can be fostered in an accurate direction. This will allow other team members to appreciate the valuable input dietitians have to offer in the area of outcomes research. Dietitians must advocate on their behalf and solicit support to allow for active participation in all phases of patient care, including research to validate current practice and lead the way to changes in practice patterns. Not being an integral part of the research process may eventually endanger our job security and profession as a whole.

I strongly encourage all dietitians new and experienced to become actively involved in local or national research projects. In order to accomplish this they may have to work beyond or outside their normal time and comfort zones. However, the ultimate result of this effort will be increased job satisfaction, increased respect from health care team members, and ultimately, improved nutrition outcomes for patients.

1. Eck LH, Slawson DL, Williams R, Smith K, Harmon-Clayton K, Oliver D. A model for making outcomes research standard practice in clinical dietetics. *J Am Diet Assoc* 1998;98:451-7.
2. Gardner JK, Rall LC, Peterson CA. Lack of multidisciplinary collaboration is a barrier to outcomes research. *J Am Diet Assoc* 2002;102:65-71.
3. Hays JE, Peterson CA. Use of an outcomes research collaborative training curriculum to enhance entry-level dietitians' and established professionals' self-reported understanding of research. *J Am Diet Assoc* 2003;103:77-84.
4. Commission on Accreditation for Dietetic Education: *Accreditation Handbook*. Chicago: American Dietetic

Association; 2002.

5. Steiber A and Barkoukis H. Individualized research experience in a dietetic internship program. *Topics in Clinical Nutrition*. 2006, July-September.
6. Beto J, Bansal V, Gohlke N, Hano J. Using the hemodialysis prognostic nutrition index and urea reduction ratio to predict morbidity and mortality: A pilot study of the 1995 council on renal nutrition national research question. *JREN*. 1998;8:21-24.

**Congratulations to
the winner of the
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RPG offered a paid FNCE registration via random drawing to any member that returned their membership survey by the deadline.

**Janice Meredith
from Portsmouth, VA
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**Thank you to all members who participated
in the membership survey and drawing.**

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RENAL DIETITIANS CHAIR MESSAGE

Patricia Weber, MS RD CSR CDE

Are Dietitians the “Rodney Dangerfields”* of the Dialysis Clinics?

One of the members of the Renal Practice Group recently brought a question to our Association through the Issues Management avenue that is available at the eatright.org website. The June 2006 issue of *Dialysis and Transplantation* featured an article that was meant to illuminate the United States Department of Labor “Fair Pay Initiative” related to exempt and non-exempt employees (1). The authors are attorneys, and one had worked for a dialysis provider for almost 10 years. With that background, it was surprising to see that the authors indicated that dietitians who work for end-stage renal providers need only have a baccalaureate degree, but no advanced training, and therefore would not meet the standards for professional employee exemption.

Whether or not a dietitian chooses to accept employment as an exempt or non-exempt employee is an individual matter, but one questions the sidebar issue. How did the unique qualifications and federal regulations related to the employment of registered dietitians in dialysis facilities escape the knowledge of someone who spent almost 10 years as an executive of a leading dialysis company? Why don’t some people know that after completion of a *minimum* of a Bachelor’s Degree, the candidate must complete an accredited Dietetic Internship or Coordinated Program, and then pass a registration exam? Why wasn’t it mentioned that the Federal Register states that a registered dietitian who works in an ESRD facility must meet state requirements and have at least one year of experience? How can we fill this knowledge deficit?

While many of us in nephrology do feel that we are treated as valuable members of the medical care team, there are still opportunities to showcase our advanced training and competencies. We have our professional portfolio, in which we maintain all of our continuing education and advanced training certificates. At the 2004 Food and Nutrition Conference and Exhibition in St. Louis, Judy Beto, PhD, RD, inspired many of us to begin keeping a notebook that shows just how much we do each year, for example, the professional and patient projects, the articles or newsletters, the

power-point presentations, and the performance improvement initiatives. The bottom line is that we as an integral part of the medical care team are responsible for educating our administrators and management about our skills and extensive science background. We have to advocate on behalf of our profession and for job security too. The choice of exempt or non-exempt may be your opportunity to negotiate and educate.

1. R Levy and J Peak. Department of labor issues opinion on overtime requirements for social workers. *Dialysis & Transplantation* 2006(6):385-391

*For those of you who do not remember him, Rodney Dangerfield (1921-2004) was a comedian whose signature line was “I get no respect”.

Member Issues:

- We care about the concerns of ADA members.
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Sensipar® is indicated for the treatment of secondary hyperparathyroidism (HPT) in patients with chronic kidney disease on dialysis.

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

The Sooner the Better

Sensipar® simultaneously lowers^{1,4-6}



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

Important Safety Information: Sensipar® lowers serum calcium; therefore, it is important that patients have a serum calcium ≥ 8.4 mg/dL when initiating therapy. Significant reductions in calcium may lower the threshold for seizures. Secondary HPT patients, particularly those with a history of a seizure disorder, should be carefully monitored for the occurrence of low serum calcium or symptoms of hypocalcemia. The most commonly reported side effects were nausea and vomiting.

References: 1. Moe SM, Chertow GM, Coburn JW, et al. Achieving NKF-K/DOQI™ bone metabolism and disease treatment goals with cinacalcet HCl. *Kidney Int*. 2005;67:760-771. 2. National Kidney Foundation. K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. *Am J Kidney Dis*. 2003;42(suppl 3):S1-S201. 3. Data on file. Amgen Inc, Thousand Oaks, Calif. 4. Block GA, Martin KJ, de Francisco ALM, et al. Cinacalcet for secondary hyperparathyroidism in patients receiving hemodialysis. *N Engl J Med*. 2004;350:1516-1525. 5. Sensipar® (cinacalcet HCl) prescribing information, Amgen. 6. Kammerer J, Nolen J, Bradley C, Turner S. Using START (Sensipar®) treatment approach to reach K/DOQI™ targets to optimize Sensipar® use. *Adv Chronic Kidney Dis*. 2005;12:244.

Brief Summary

See package insert for full prescribing information

SENSIPAR® (cinacalcet HCl) Tablets

INDICATIONS AND USAGE

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

CONTRAINDICATIONS

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

WARNINGS

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

PRECAUTIONS

General

Hypocalcemia: Sensipar® lowers serum calcium, and therefore patients should be carefully monitored for the occurrence of hypocalcemia. Potential manifestations of hypocalcemia include paresthesias, myalgias, cramping, tetany, and convulsions. Sensipar® treatment should not be initiated if serum calcium is less than the lower limit of the normal range (8.4 mg/dL). Serum calcium should be measured within 1 week after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium should be measured approximately monthly (see DOSAGE AND ADMINISTRATION). If serum calcium falls below 8.4 mg/dL, but remains above 7.5 mg/dL, or if symptoms of hypocalcemia occur, calcium-containing phosphate binders and/or vitamin D sterols can be used to raise serum calcium. If serum calcium falls below 7.5 mg/dL, or if symptoms of hypocalcemia persist and the dose of vitamin D cannot be increased, withhold administration of Sensipar® until serum calcium levels reach 8.0 mg/dL, and/or symptoms of hypocalcemia have resolved. Treatment should be re-initiated using the next lowest dose of Sensipar® (see DOSAGE AND ADMINISTRATION). In the 26-week studies of patients with CKD on dialysis, 66% of patients receiving Sensipar® compared with 25% of patients receiving placebo developed at least one serum calcium value < 8.4 mg/dL. Less than 1% of patients in each group permanently discontinued study drug due to hypocalcemia. In CKD patients with secondary HPT not on dialysis, the long-term safety and efficacy of Sensipar® have not been established. Exploratory investigation indicates that CKD patients not on dialysis have an increased risk for hypocalcemia compared to CKD patients on dialysis, which may be due to lower baseline calcium levels. In a small, short-term study, in which the median dose of cinacalcet was 30 mg at the completion of the study, 74% of cinacalcet treated patients experienced at least one serum calcium value < 8.4 mg/dL. **Adynamic Bone Disease:**

Adynamic bone disease may develop if iPTH levels are suppressed below 100 pg/mL when assessed using the standard Nichols IRMA. One clinical study evaluated bone histomorphometry in patients treated with Sensipar® for one year. Three patients with mild hyperparathyroid bone disease at the beginning of the study developed adynamic bone disease during treatment with Sensipar®. Two of these patients had iPTH levels below 100 pg/mL at multiple time points during the study. In the three 6-month, phase 3 studies conducted in CKD patients on dialysis, 11% of patients treated with Sensipar® had mean iPTH values below 100 pg/mL during the efficacy-assessment phase. If iPTH levels decrease below the NKF-K/DOQI recommended target range (150-300 pg/mL)* in patients treated with Sensipar®, the dose of Sensipar® and/or vitamin D sterols should be reduced or therapy discontinued. **Hepatic Insufficiency:** Cinacalcet exposure as assessed by AUC(0-inf) in patients with moderate and severe hepatic impairment (as indicated by the Child-Pugh method) were 2.4 and 4.2 times higher, respectively, than that in normals. Patients with moderate and severe hepatic impairment should be monitored throughout treatment with Sensipar® (see CLINICAL PHARMACOLOGY, Pharmacokinetics and DOSAGE AND ADMINISTRATION). **Information for Patients:** It is recommended that Sensipar® be taken with food or shortly after a meal. Tablets should be taken whole and should not be divided.

Laboratory Tests: Patients with CKD on Dialysis with Secondary Hyperparathyroidism:

Serum calcium and serum phosphorus should be measured within 1 week and iPTH should be measured to 4 weeks after initiation or dose adjustment of Sensipar®. Once the maintenance dose has been established, serum calcium and serum phosphorus should be measured approximately monthly, and PTH every 1 to 3 months (see DOSAGE AND ADMINISTRATION). All iPTH measurements during the Sensipar® trials were obtained using the Nichols IRMA. In patients with end-stage renal disease, testosterone levels are often below the normal range. In a placebo-controlled trial in patients with CKD on dialysis, there were reductions in total and free testosterone in male patients following six months of treatment with Sensipar®. Levels of total testosterone decreased by a median of 15.8% in the Sensipar®-treated patients and by 0.6% in the placebo-treated patients. Levels of free testosterone decreased by a median of 31.3% in the Sensipar®-treated patients and by 16.3% in the placebo-treated patients. The clinical significance of these reductions in serum testosterone is unknown. **Drug Interactions and/or Drug/Laboratory Test Interactions:** See CLINICAL PHARMACOLOGY, Pharmacokinetics and Drug Interactions. Effect of Sensipar® on other drugs: Drugs metabolized by cytochrome P450 2D6 (CYP2D6): Sensipar® is a strong *in vitro* inhibitor of CYP2D6. Therefore, dose adjustments of concomitant medications that are predominantly metabolized by CYP2D6 and have a narrow therapeutic index (e.g., flecainide, vinblastine, thioridazine and most tricyclic antidepressants) may be required. Amitriptyline: Concurrent administration of 25 mg or 100 mg cinacalcet with 50 mg amitriptyline increased amitriptyline exposure and nortriptyline (active metabolite) exposure by approximately 20% in CYP2D6 extensive metabolizers. Effect of other drugs on Sensipar®: Sensipar® is metabolized by multiple cytochrome P450 enzymes, primarily CYP3A4, CYP2D6, and CYP1A2. Ketoconazole: Sensipar® is metabolized in part by CYP3A4. Co-administration of ketoconazole, a strong inhibitor of CYP3A4, increased cinacalcet exposure following a single 90 mg dose of Sensipar® by 2.3 fold. Dose adjustment of Sensipar® may be required and PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, erythromycin, itraconazole; see DOSAGE AND ADMINISTRATION). **Carcinogenesis, Mutagenesis, and Impairment of Fertility** **Carcinogenicity:** Standard lifetime dietary carcinogenicity bioassays were conducted in mice and rats. Mice were given dietary doses of 15, 50, 125 mg/kg/day in males and 30, 70, 200 mg/kg/day in females (exposures up to 2 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). Rats were given dietary doses of 5, 15, 35 mg/kg/day in males and 5, 20, 35 mg/kg/day in females (exposures up to 2 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). No increased incidence of tumors was observed following treatment with cinacalcet. **Mutagenicity:** Cinacalcet was not genotoxic in the Ames bacterial mutagenicity assay or in the Chinese Hamster Ovary (CHO) cell HGPRT forward mutation assay and CHO cell chromosomal aberration assay, with and without metabolic activation or in the *in vivo* mouse micronucleus assay. **Impairment of fertility:** Female rats were given oral gavage doses of 5, 25, 75 mg/kg/day beginning 2 weeks before mating and continuing through gestation day 7. Male rats were given oral doses 4 weeks prior to mating, during mating (3 weeks) and 2 weeks post-mating. No effects were observed in male or female fertility at 5 and 25 mg/kg/day (exposures up to 3 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). At 75 mg/kg/day, there were slight adverse effects (slight decreases in body weight and food consumption) in males and females. **Pregnancy Category C:** In pregnant female rats given oral gavage doses of 2, 25, 50 mg/kg/day during gestation no teratogenicity was observed at doses up to 50 mg/kg/day (exposure 4 times those resulting with a human oral dose of 180 mg/day based on AUC comparison). Decreased fetal body weights were observed at all doses (less than 1 to 4 times a human oral dose of 180 mg/day based on AUC comparison) in conjunction with maternal toxicity (decreased food consumption and body weight gain). In pregnant female rabbits given oral

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

ADVERSE EVENTS

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

Table 1. Adverse Event Incidence ($\geq 5\%$) in Patients On Dialysis

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

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

The incidence of serious adverse events (29 % vs. 31%) was similar in the Sensipar® and placebo groups, respectively. **12-Month Experience with Sensipar®:** Two hundred and sixty-six patients from 2 phase 3 studies continued to receive Sensipar® or placebo treatment in a 6-month double-blind extension study (12-month total treatment duration). The incidence and nature of adverse events in this study were similar in the two treatment groups, and comparable to those observed in the phase 3 studies. **Parathyroid Carcinoma:** The most frequent adverse events in this patient group were nausea and vomiting. **Laboratory values:** Serum calcium levels should be closely monitored in patients receiving Sensipar® (see PRECAUTIONS and DOSAGE AND ADMINISTRATION).

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Sensipar® tablets should be taken whole and should not be divided. Sensipar® should be taken with food or shortly after a meal. Dosage must be individualized. **Secondary Hyperparathyroidism in Patients with Chronic Kidney Disease on Dialysis:** The recommended starting oral dose of Sensipar® is 30 mg once daily. Serum calcium and serum phosphorus should be measured within 1 week and iPTH should be measured 1 to 4 weeks after initiation or dose adjustment of Sensipar®. Sensipar® should be titrated no more frequently than every 2 to 4 weeks through sequential doses of 60, 90, 120, and 180 mg once daily to target iPTH consistent with the NKF-K/DOQI recommendation for CKD patients on dialysis (150-300 pg/mL). Sensipar® can be used alone or in combination with vitamin D sterols and/or phosphate binders. During dose titration, serum calcium levels should be monitored frequently and if levels decrease below the normal range, appropriate steps should be taken to increase serum calcium levels, such as by providing supplemental calcium, initiating or increasing the dose of calcium-based phosphate binder, initiating or increasing the dose of vitamin D sterols, or temporarily withholding treatment with Sensipar® (see PRECAUTIONS). **Special Populations: Geriatric patients:** Age does not alter the pharmacokinetics of Sensipar®, no dosage adjustment is required for geriatric patients. Patients with renal impairment: Renal impairment does not alter the pharmacokinetics of Sensipar®, no dosage adjustment is necessary for renal impairment. **Patients with hepatic impairment:** Cinacalcet exposures, as assessed by AUC(0-inf), in patients with moderate and severe hepatic impairment (as indicated by the Child-Pugh method) were 2.4 and 4.2 times higher, respectively, than in normals. In patients with moderate and severe hepatic impairment, PTH and serum calcium concentrations should be closely monitored throughout treatment with Sensipar® (see CLINICAL PHARMACOLOGY, Pharmacokinetics and PRECAUTIONS). **Drug Interactions:** Sensipar® is metabolized in part by the enzyme CYP3A4. Co-administration of ketoconazole, a strong inhibitor of CYP3A4, caused an approximate 2-fold increase in cinacalcet exposure. Dose adjustment of Sensipar® may be required and PTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor (e.g., ketoconazole, erythromycin, itraconazole; see CLINICAL PHARMACOLOGY, Pharmacokinetics and PRECAUTIONS).

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

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

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CRN CHAIRPERSON MESSAGE

Revisiting the Nutrition Guidelines: The Value of Survey Research

Deborah Brommage, MS, RD, CSR, CDN

Surveys are everywhere—we are inundated with surveys in our personal lives from retail stores, restaurants, hotels and numerous other service providers. Questionnaires come to us via regular mail, email and telephone. It is easy to understand that with our busy schedules many of these surveys are ignored. But when it comes to professional surveys, participation should be taken more seriously.

The use of self-administered surveys is considered to be an important tool for researchers. The survey process involves eliciting relevant information from a select sample population, analysis of the results in a quantitative manner and determining correlations based on the responses submitted. The conclusions drawn from the analysis can then be generalized to the population from which the sample was selected. (1)

The three basic objectives of survey research are description, explanation and exploration. Surveys are often performed to make a descriptive discovery about a select population, such as the distribution of certain traits or characteristics. Surveys using multivariate analysis have an added objective of making explanatory assertions about the population, such as why survey participants prefer for one entity over another. Surveys can also function as an exploring or searching mechanism to discover critical elements on a subject that could otherwise be missed. A study may have one or all three of these objectives. (1)

As CRN and RPG members, we are often asked to participate in surveys because we represent a unique group of registered dietitians who specialize in nephrology care. As a professional member of this specialty we have the ability to provide information that can shape the future of our profession and renal nutrition by identifying similarities and differences in our clinical practices. Here are examples of three surveys that are worthy of our attention.

The first is titled “*Job Functions of Renal Dietitians Survey*” administered by Bonnie Thelen, RD, for her Master of Science thesis. The purpose is to assess what functions

renal dietitians are performing, how practices may vary by geographic region and what barriers impact professional roles and activities. This body of work will be used to further evaluate scope of practice in renal nutrition.

The second project is being initiated by the European Dialysis & Transplant Nurses Association/European Renal Care Association (EDTNA/ERCA) nutrition interest group for development of the *European Consensus Statement on Nutrition Support in Adults on Renal Replacement Therapy* (RRT). The survey will be conducted in a minimum of 6 European Countries and the U.S. to assess their nutritional support practice and recommendations for adults on RRT. The objectives are to develop an expert consensus and recommendations on nutrition support methods to ensure clinically effective practice and to establish evidence-based recommendations appraised by an expert panel to form the basis of recommended guidelines for nutritional support in adults on RRT.

Finally, a survey on *The Nutrition Practices in Hemodialysis Centers throughout the United States* by doctoral candidate Joyce M. Vergili, MS, RD will address gaps in our knowledge regarding how renal dietitians deliver nutrition care to adults on maintenance hemodialysis. The purpose of this study is to learn how dietitians working in nephrology care are currently practicing in the absence of formally established guidelines for certain nutrition issues. The results of this survey will contribute to the development of renal nutrition practice guidelines where none currently exist.

Start now and take the opportunity to seize the opportunity to make a scientific contribution the next time a professional survey comes our way. The information and benefits gained will outweigh the time taken to participate.

Reference

1. Babbie, E. *Survey Research Methods*, Wadsworth Publishing Company, Belmont, CA, 1997.

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¹ Nissenson, et. al. AJKD 2003; 42:325-330 (data on file)

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Survey Research: A Research Methodology

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Surveys are forms of descriptive and exploratory research (1). Surveys may be conducted to test knowledge, perceptions, attitudes, and/or opinions on a particular topic or series of topics. Survey research also includes needs assessments. Needs assessment is used when designing new programs. In fact, it is typical to conduct both an internal and external needs assessment (these are both surveys) in program development. The purpose of this article is to provide a brief overview of survey research with an emphasis on mail surveys. Examples of survey research completed by students and faculty of the University of Medicine and Dentistry of New Jersey School of Health Related Professions (UMDNJ SHRP) masters of science in clinical nutrition program are used throughout the paper to serve as informative examples of survey research. Learn more at:
http://shrp.umdnj.edu/nutr/mscn/mscn_alumni_thesis.htm
(accessed Nov '06).

Survey design

The secret to a good survey is in the design. When designing a survey, the questions of who (to survey), what (to survey about), how (to survey), when (to survey) and where (to survey) must be considered. Dillman (1) describes a "tailored-design" method which includes the "development of survey procedures that create respondent trust and perceptions of increased rewards and reduced costs for being a respondent, which take in account features of the survey situation and have as their goal the overall reduction of survey error" (1).

Who (to survey)

The choice of population depends to a large extent on the nature of the research question. For example, a survey of "Dietitians' personal and professional practices regarding soy protein" will require a sample of registered dietitians (RD). However, there are still decisions to be made regarding this population: Do we use a local sample of RDs in the state or a national sample, and a sample of only one age group, gender, practice group or nationality? The decision rests on how "generalizable" one wants the results to be. If the goal is to be able to have "generalizable" results, a representative sample of RDs in the United States needs to be included.

A power calculation is performed to determine the number of subjects, or "n," that must be included to obtain results that will have statistical significance and are generalizable to the whole population.

One must also consider the response rate when making the decision as to how many surveys to distribute. According to Dillman (1) and consistent with our survey history at UMDNJ, typical results within one's own profession for mail surveys are 40% to 50%. When mailing surveys to another discipline the rate drops to 30% to 40%. If an "n" of 200 surveys returned from RDs (a survey within our discipline) is required, we would need to mail to 500 to reach that "n" at a 40% response rate.

Factors such as cultural issues, level of education, age and gender should also be considered. When surveying a culturally diverse population, the survey may need to be translated into other languages. If translation is necessary, have the translation completed by a native or a professional translator. Translations by hand with a dictionary may result in inaccurate statements and poor use of grammar.

If we wanted to survey "herbal medicine practices of the elderly," how would we go about it? Those decisions require consideration of the age of the population and therefore the how and where to survey. Elders are less likely to respond to a mail survey than younger adults (2). Thus, the next

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question becomes how to get a representative sample. We performed a study of this kind at UMDNJ, with the goal of comparing the results of the herbal medicine practices of consumers to the Eagleton Poll 1999 in New Jersey, so we choose a sample of New Jersey elders. In place of a mail survey we used doctors' office waiting rooms to recruit individuals to complete the survey.

How (to survey)

Surveys can be conducted several different ways. Mail surveys are the most common method. However, mail surveys are not appropriate for all populations. If you are surveying an inner-city population with a high rate of turnover, relying on accurate addresses for a mail survey may be difficult.

Mail surveys should include a cover letter of introduction which incorporates the elements of informed consent, purpose of the survey, reason for participant selection, benefits of participation, and contact information for the study's principal investigator (PI) and Institutional Review Board (IRB). The cover letter must include a statement that indicates that completion of the survey denotes their permission to use the information in a confidential manner. The letter should also include a phone and/or e-mail contact to address questions regarding the survey. Typically, we also ask respondents to include a business card if they would like to receive a copy of the results.

The inclusion of stamped, addressed return envelopes, personalized cover letters, and the use of colored ink increase response rates (3). Response rates more than double with the inclusion of a monetary incentive and with the use of prewarning letters (3–4). The prewarning letter is sent prior to the survey to inform participants that they will be receiving a survey (4).

Anonymous surveys must be coded for the purposes of data entry and analysis. The PI must keep a list of the names and addresses of respondents to determine non-responding participants who require a second survey or second call, and for examining response rate. Once a survey project is completed it is typical to destroy the mailing list so that all links to names and responses are destroyed, keeping the data totally anonymous.

Mail surveys usually have three or more mailings. The first mailing includes the cover letter, survey and return envelope. Second, a brightly colored reminder postcard is mailed 10 days later to all respondents. The third mailing, three weeks after the postcard, again includes a cover letter, survey and return envelopes. However, this is mailed only to non-respondents. These constant mailings and reminders help to increase response rate (3).

Other survey methods include telephone surveys, computer-based surveys, e-mail surveys and interviews. A classic example of a survey utilizing telephone interview is the Eagleton Poll. The National Health and Nutrition Examination Survey studies utilize individually administered interviews. Telephone and in-person interview surveys may be more expensive and time consuming than mail surveys. These methods also require extensive training of the researchers so that there is consistency in interview techniques and questioning among interviewers. Alterations in voice, body language and other non-verbal cues can affect responses.

Interviews are not effective in all situations. Examples of good situations in which interviews are effective include diet intake surveys, psychosocial interviews, and conditions that require complete responses not easily obtained with single questions. An excellent example of the last situation is surveys of the elderly. Interview strategies allow you to confirm responses and clarify any questions regarding interpretation and understanding of survey questions.

Telephone interviews are effective in situations where the number of items queried is limited. The questions utilized during telephone interviews should be short and easy to understand. For example, a short questionnaire on uses of herbal supplements which works well with most adult populations by phone, may not work as a phone interview with elders due to hearing issues.

When (to survey)

Responses to mail surveys can vary according to when the survey is received. The season of the year, day of the week, and proximity to major holidays can decrease the response rate. While there is no empiric evidence to support the following statements, time and experience support these

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Survey Resources (websites accessed Nov '06)

- ▶ Creative Research Systems "The Survey System" via www.surveysystem.com/sdesign.htm
- ▶ American Statistical Association survey research methods section via www.amstat.org/sections/srms/whatsurvey.html
- ▶ The Web Questionnaire Challenge to Survey Methodologists
 - <http://www.whatisasurvey.info/>
- ▶ Dillman DA. Mail and Telephone Surveys: The Total Design Method. New York, N.Y.: J. Wiley and Sons; 1978

practices. Avoid mailing surveys during holidays, such as between Thanksgiving and New Year's, over a holiday weekend, or on Mondays, Tuesdays or Wednesdays. Surveys seem to achieve the best response rates if mailed on Fridays. This ensures that they arrive early in the week, on a Monday or Tuesday, which in turn promotes completion. Another example of considering when to survey involves educators. It would not be prudent to send a survey to educators in July as many baccalaureate and graduate level educators change their schedules during the summer. It would be best to survey this group in mid fall or early spring, after the semester is in progress. However, mid-semester and end-semester surveys may also receive low response rates due to exam scheduling.

Where (to survey)

Where to survey depends on the who and the what of the survey. Although in-person surveys work well with the elderly, one needs access to the population. The "where" will influence your population sampling. For example, in a shopping mall, respondents will be limited to those who typically go to the mall and may, while providing some diversity, shape your socio-economic profile of the respondents. It will not include those who don't mall shop because they don't have transportation, cannot afford to mall shop, or do not prefer that particular mall.

"Where" is also influenced by weather, season and the length of the survey. When deciding "where," take into consideration who, what, how and when. Discuss with colleagues and population-specific experts (i.e., geriatrics health professionals if a geriatric survey) the best approaches for your survey.

What (to survey)

The question of what to ask on the survey depends on what data you want to collect. There are many survey tools currently available. Prior to designing your own survey tool, it is worthwhile to review the literature relating to the topic to ascertain if a tool already exists. Using a pre-existing tool may decrease the amount of testing required prior to implementation of the survey. Whether designing your own survey tool or using an existing one, ensure that questions are included to address all variables you are measuring. If you are using an existing tool, review it concurrently with your research questions and variables. The survey instrument may require some adaptation for your project. (i.e., Use it as a base for modifying, adding or deleting some questions to get at your specific problem.)

If you are designing your own tool, consider the form of the questions and format of the survey. Keep it short and simple! Limit the survey to four or fewer pages. Structure the questions so that the survey can be completed by members of the target population in 20 minutes or less.

Asking questions using several different formats (i.e., multiple choice, fill in the blank, Likert scales) can be confusing to the survey recipient. Try to limit the type of question format to one or two to avoid confusion. If using multiple-choice questions, be sure the question and possible responses are clearly stated and the directions indicate if one or multiple responses may be selected. Avoid open-ended questions when possible. Summarizing all possible responses to a single question using open-ended questions is difficult and analysis will require interpretation on the part of the surveyor. This can alter the true response intended by the respondent. Although multiple-choice responses limit options, they are easily quantified.

Survey questions should use simple words and questions and be arranged in a vertical flow. When feasible, group questions by content area and within content by type of question. Organize the questions so that potentially objectionable or controversial questions fall after less objectionable ones.

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Survey validity and reliability

Survey tools should be tested for validity and reliability prior to large-scale implementation. This is commonly accomplished using pilot testing. If you are using a survey that has previously been validated in a similar population, you may be able to avoid pilot testing. However, in most circumstances pilot testing should be repeated despite previous use if the intended audience is demographically different from the previous audience. When designing new surveys, the best strategy is to use two pilots, an expert opinion pilot, and a representative sample pilot. As part of the expert opinion pilot, experts from the area of practice or topic under study compare the research question to the proposed survey and comment. Their "expertise" assists in the determination of validity of the survey. The representative sample pilot should include a small (five to 10 people) group which represents (but does not include) the population under study. Data should be collected on ease of understanding, length of time to complete, and literacy level. Changes should be made based on this data. Once these edits are completed, the survey is ready to mail.

Summary

This brief introduction to survey research addresses key issues to consider when considering a survey. The reader should be cautioned that IRB approval is typically required prior to conducting the research. Prior to embarking on a research survey, readers are encouraged to review research texts and reputable resources on survey research. Review the resources listed in the table on page 10. Research is a journey; be prepared with the right resources and the journey will be a positive venture.

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Nurture Your Career with a Career Portfolio

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Career Development

Continuing education and career development are critical to success in the field of dietetics. The onset of the Professional Development Portfolio (PDP) as required for registration by the Commission on Dietetic Registration (CDR) has only served to further the need for documenting professional development. Simply tracking required achievements isn't nearly enough to be competitive in the workforce; being able to prove skills and abilities makes you marketable to employers.

Career Portfolios

In today's job market, employers are looking for new ways to find the best people. With many highly qualified applicants competing for the same jobs in dietetics, employers want more details on performance to distinguish the excellent candidates from the average candidates. Having required credentials is no longer considered proof of knowledge, skills, and abilities. Employers are now asking to see results; they want physical evidence that shows people possess the abilities they claim. A company may scan hundreds of résumés to determine the few people who they want to consider for a position, and while a résumé can help a person get an interview, it's not as helpful during the interview itself. That's where a career portfolio comes in. A career portfolio is an organized binder filled with work samples proving a person's skills and abilities. With a

portfolio in hand, the individual can walk into an interview and show the interviewer samples of their work, pictures of projects or community involvement, certificates they've earned, and memberships held. The portfolio becomes a tool that sets an individual apart and helps prove his or her qualifications for the position.

The Benefits of Career Portfolios

A career portfolio visually documents skills and abilities and can help an individual stand out during the interviewing process. A portfolio also boosts self-confidence. While putting a portfolio together, dietitians should be examining their goals, writing down their beliefs about work and their career, documenting their strengths, and identifying their weaknesses. By the time they have put together their first career portfolio they should be able to handle those hard interview questions like "Tell me about yourself," "What are your goals for the future?" or "What do you bring to the table for us?" A well-crafted portfolio shows employers that the individual has the skills and abilities for which they are looking. Those with portfolios may obtain higher starting salaries because they could prove their skills to an employer. The career portfolio can also help a person build self-confidence by demonstrating what they can do and by helping them set and achieve goals. Additionally, individuals who create their own career portfolio have a history of interviewing better and can document their value to get a raise or promotion.

It's a Process

Developing a career portfolio is not just about the final product—it's a process of analyzing skills, needs, strengths and skill gaps, and developing a plan to reach goals. It is also a lifelong plan for documenting a person's professional growth and career successes. The career portfolio process can be as simple or as complex as the individual and his or her abilities and talents. When creating a portfolio, the individual goes through the process of identifying current skills, determining strengths, and delineating the gaps where more training or development is needed. The dietitian also identifies personal skills that can be transferred from one

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field or job to another. The process of developing a career portfolio culminates as the individual gathers materials, records, projects, documents, and certificates that can be used to prove those skills.

The Career Portfolio

The career portfolio is a structured document with specific parts, each of which serves a purpose in career self-management. The career portfolio is designed to give a future or current employer proof of skills and abilities. A complete portfolio for an individual in dietetics may include the following types of information:

- ◆ Work philosophy which overviews their current beliefs about their work
- ◆ Career goals
- ◆ Brief biography written about oneself in the third person
- ◆ Résumé
- ◆ Work samples organized by skill area including:
 - Letters of recommendation
 - Examples of skill sets
 - Presentations
 - Works in progress
 - Certifications
 - Diplomas
 - Degrees
 - Awards
 - Community service
 - Professional memberships
- ◆ Academic plan of study
- ◆ Dietetic Internship Plan (if applicable)
- ◆ Publications
- ◆ Faculty and employer biographies
- ◆ References

The ongoing practice of collecting work samples and identifying the skills employers seek will help individuals identify transferable skills. It also helps the person to understand how each skill could be helpful in a new setting.

Identifying Work Samples

Work samples are the core part of a career portfolio that proves people have the skills and abilities they claim. Work

samples can come from a variety of sources including a job, training and education, activities, and community service work. Common types of work samples include:

- ◆ Documents created on the job
- ◆ Certificates, awards, certifications
- ◆ Pictures of events or projects
- ◆ Reports, handouts, presentations created
- ◆ Work or class projects
- ◆ Published articles or writing samples
- ◆ Performance appraisals
- ◆ Team projects
- ◆ Letters listing accomplishments
- ◆ Thank you letters
- ◆ Letters of recommendation
- ◆ Skill sets – a list of specific skills you have that are signed off by a credible third party

But before people can identify appropriate work samples to include in a portfolio, they must explore and audit their skills. The best way to approach work samples is to consistently collect items that demonstrate a skill that is identified as a personal strength and that you claim you have. Such items may include executive summaries of projects, graphics showing process improvement or design flow, or published articles. These items can be sorted out later into a final format specific to the job interview you may be approaching. Some samples may stand on their own merit; others may need some further refinement such as a condensed format or translation into visual design. The type of work samples a person needs is based upon the type of position they are applying for in the workplace. The U.S. Department of Labor Bureau of Labor Statistics *Occupational Outlook Handbook* contains a breakout of common jobs in the dietetic field. It is a great place to start identifying the key skills and performance areas employers are seeking. Additionally, by checking job postings of a potential employer, the dietitian can identify and highlight in a portfolio those specific skills that are stated as requirements of the job. It is important that individuals select strong work samples that reflect their best work and document the skills they want to prove to each particular employer. Work samples can be added and removed from the career portfolio to customize the portfolio to the needs of each prospective employer.

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The Employer's Prospective

So, what are the employers looking for in a career portfolio? Employers choose candidates who can provide:

- ◆ Dietetic-specific samples
- ◆ Demonstrate skills with concrete examples, not just knowledge from degrees
- ◆ Demonstrate soft skills such as persuasion, negotiation, or organization through third party credibility
- ◆ Identify skills that will make or save the company money

Employers acknowledge and recognize transferable skills from other jobs, related academic areas and personal experience. Overall, employers are seeking the tangible proof that the individual can perform the job for which they are applying and bring some value-added benefits to the company.

Using the Portfolio On the Job

Once you have the job, your portfolio doesn't go into a closet until you're looking for another job. Your portfolio is a living document and it changes as you begin to collect and document your work in your current position. Then your portfolio serves as a tool to track job performance and position you for advancement. It also will assist in tracking continuing education and career development needed to fulfill CDR requirements for the Professional Development Portfolio.

Career Portfolios for the Career Minded Individual

Career portfolios are quickly becoming the wave of the future. Be it in hard copy, paper form, or as an electronic review, a career portfolio will help you compete for the job you want and at the salary you desire. More and more academic institutions are requiring portfolios from all of their students, as they know that being able to prove skills, not just claim knowledge, is a part of assuring their students will be hired in the future.

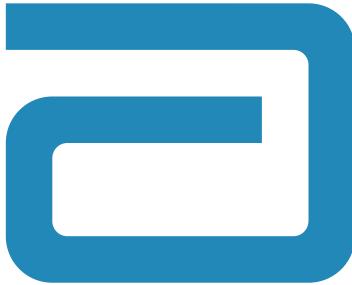
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Article Length: Article length is determined by the Editor for each specific issue. The lead article is approximately 3000 words (not including tables/graphs). Other feature articles are usually 1000-1500 words; member spotlights, etc. are 500 words.

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.: Torry Pines Press; 2003.

Web Site:

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

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

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 of 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 along with your article submission.

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