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In This Issue

Nutrition Management of Gastric Bypass In Patients with Chronic Kidney Disease

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Growing numbers of patients with chronic kidney disease (CKD) with a BMI of 40 or greater are pursuing kidney transplantation but may be denied candidacy due to poorer patient and graft survival rates. Weight loss procedures in this population provide the prospect of kidney transplantation as well as improvement in or resolution of hypertension, diabetes mellitus, GERD, and other co-morbid conditions (Alexander et al., 2004).

Unfortunately, there is report of acute kidney injury (AKI) occurring post-gastric bypass (GBP), especially in patients with a prior history of CKD. Medical history of certain co-morbid conditions and use of certain pre-operative medications independently increase the risk of postoperative AKI, which a retrospective review determined to be "not-infrequent" following GBP surgery (Thakar, Kharat, Blanck, & Leonard, 2007). Additionally, patients with renal disease prior to GBP may be at higher risk of oxalate nephropathy. Conversely, a retrospective review by Sharma et al. (2006) concluded that "primary acute renal failure after laparoscopic GBP is an uncommon complication" (p. 389).

Despite these reports of negative outcomes, patients and healthcare providers continue to consider bariatric surgery as a means to improve kidney transplantation candidacy, since several other studies describe the benefits of GBP in patients with CKD. A retrospective review by Takata et al. (2008) concluded that laparoscopic Roux-en-Y (RYGBP) improved the candidacy for transplantation of patients. Alexander et al. (2004) and Alexander and Goodman (2007) performed RYGBP on patients with Stages 3-4 CKD, patients on hemodialysis (HD), and patients who were post-kidney transplant, and concluded that GBP may safely be recommended for patients in any stage of CKD or post-transplant.

Since there is little literature on the nutritional management of patients with CKD who undergo GBP, this article compiles both current, general guidelines with limited, available CKD-specific information. Common GBP procedures, methods of weight loss, and the nutritional implications are reviewed.

– Continued on page 3.

RPG

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From the Editor's Desk

Sara Erickson, RD, CSR, LDN, CNSC
Editor

Hello RPG Members!

In this issue we are highlighting article reprints that address hot topics in our field of renal nutrition. In particular, we hope the articles on developing research design and interpreting study designs will inspire you to either complete a study or perhaps a case study and literature review. Further, we hope you would consider submitting your work for publication in the Renal Nutrition Forum as we are always in need of subject matter.

The Featured Article, written by our RPG Chair Rachael Majorowicz, RD, LD, entitled "Nutrition Management in Gastric Bypass in Patients with Chronic Kidney Disease" is a terrific resource for renal dietitians working with obese patients, particularly those awaiting kidney transplants.

With the increasing awareness of phosphate additives patients may be turning more toward non-animal protein sources in their diet. Through collaboration with the Vegetarian DPG we are able to share their RD Resource for professionals, "Vegetarian Diets in Chronic Kidney Disease". The pdf version of this handout will also be available on the RPG website, www.renalnutrition.org.

Thanks to Managing Editor, Megan Sliwa, RD, LDN, MBA and our new Assistant Editors, Amy Braglia Tarpey, MS, RD, CSR, CNSC, and Jackie Termont, RD for all your hard work and support. We are so excited to have you both on the team Amy and Jackie! Thanks also to our test writer, Amy Hess-Fishl, MS, RD, LDN, BS-ADM, CDE for your guidance and expertise in CPEU development.

Happy Spring!

Sara Erickson

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Procedures

The common GBP procedures performed on patients with CKD tend to be adjustable gastric band (AGB), sleeve gastrectomy, and standard RYGBP. The AGB and sleeve gastrectomy are restrictive weight loss procedures, in which food intake is limited by creating a smaller stomach pouch. The laparoscopic AGB (see Figure 1) generally restricts stomach capacity initially to about 15 mL, but the adjustability allows for fine-tuning as necessary. Sleeve gastrectomy is essentially the restrictive component of the duodenal switch (DS), as seen in Figure 2 (A), with the benefit of maintaining the pylorus but without any alteration of the small intestine. RYGBP (see Figure 3) restricts stomach capacity to 10 to 30 mL, bypassing the pylorus and only a short length of small intestine, but creating minimal malabsorption (McMahon et al., 2006). Multivitamin/multimineral supplements post-surgery should include 100% daily values and 1500 mg calcium daily (Aills, Blankenship, Buffington, Furtado, & Parrott, 2008).

Malabsorptive procedures are generally reserved for the severely obese. Longer limb RYGBP (see Figure 4) bypasses most of the stomach, the pylorus, the entire duodenum, and a greater length of the jejunum. This reroutes bile and pancreatic enzymes, limiting interaction with food to the last 100 cm of small intestine ("common channel"). The longer the limb, the greater the malabsorption, risk of bone disease, diarrhea, and oxalate nephropathy (McMahon et al., 2006). Deficiencies of iron, B12, folate, and calcium are common, and multivitamin/multimineral supplements post-surgery should include 200% of daily values (Aills et al., 2008).

Duodenal switch creates a sleeve gastrectomy, with the pylorus and a small portion of the duodenum left intact, reducing dumping syndrome. As seen in Figure 2, (A) depicts the sleeve gastrectomy, the section of small intestine to be bypassed (XY), the remaining 250 cm of small intestine to be connected to the stomach, including the 100 cm common channel (where Y is reconnected) preceding the ileocecal valve; (B) depicts the finalized procedure, where a majority of the stomach is removed (Kendrick & Dakin, 2006). Protein and fat-soluble vitamin deficiencies are common, as well as anemia and abnormal calcium levels (Hirschfeld & Stoernell, 2004). Multivitamin/multimineral supplements post-surgery should include 200% of daily values (Aills et al., 2008).

Nutritional Complications

Preoperative

Aills et al. (2008) summarized common nutrient deficiencies prior to weight loss surgery. Pre-operative deficiency was reported in 13% to 64% of patients for B-vitamins or folate, up to 16% iron deficiency in women, and 28% for zinc. Proper identification and treatment of existing deficiencies are crucial to improved surgical outcomes and preventing post-surgical deficiencies or complications.

Initial

In the first post-surgical year, dumping syndrome and vomiting can be common following malabsorptive procedures. Dumping syndrome occurs in RYGBP due to bypass of the pylorus, resulting in the inability to regulate gastric emptying of simple carbohydrates into the intestine. Symptoms include: lightheadedness, sweating, nausea, weakness, and sometimes diarrhea (McMahon et al., 2006). Vomiting and dehydration are common with smaller pouch sizes. Reinforce with the patient to avoid high fat or sugar foods, limit portions to appropriate pouch size, chew well, and eat slowly. Generally, 6 to 8 cups of fluid per day are recommended for patients with adequate kidney function. There are no guidelines available for patients with CKD, so close monitoring for signs of dehydration is necessary, as is frequently adjusting the estimated dry weight for patients on dialysis. Patients can drink water, skim/low-fat milk, or unsweetened fruit juices as tolerated and as laboratory results allow.

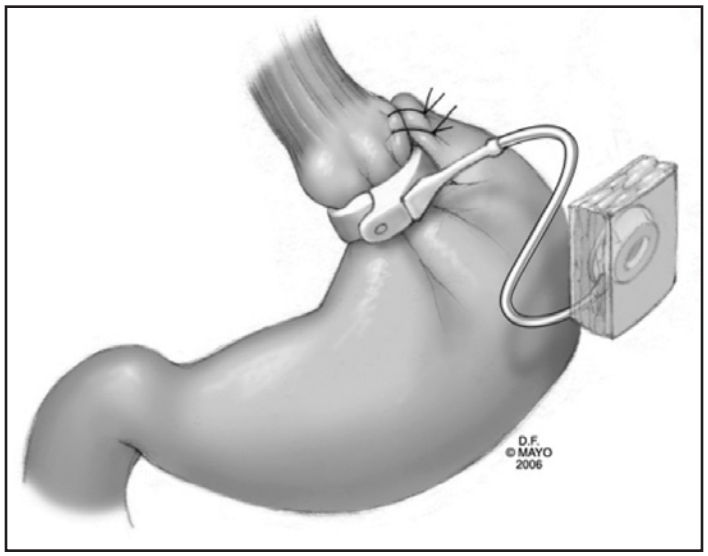
Long-Term

Numerous long-term complications can arise following malabsorptive procedures, especially those with longer limb lengths. See Table 1 for common nutrient deficiencies and suggestions for management. There are no guidelines regarding the frequency of monitoring laboratory values of patients with CKD post-GBP, but some general recommendations are included in Table 1. Due to the limited literature on patients with CKD who have GBP, especially patients on dialysis, it is advisable to monitor electrolytes frequently or until initial complications subside, laboratory results stabilize, and the rate of weight loss declines. In addition, patients should be observed for changes in subjective global assessment, dry weight should be adjusted frequently in patients on hemodialysis, calorie or protein supplement doses should be adjusted regularly, and diet recommendations should be modified as needed. If possible, the nephrology team should work closely with the bariatric care team to best manage the needs of the patient.

Summary

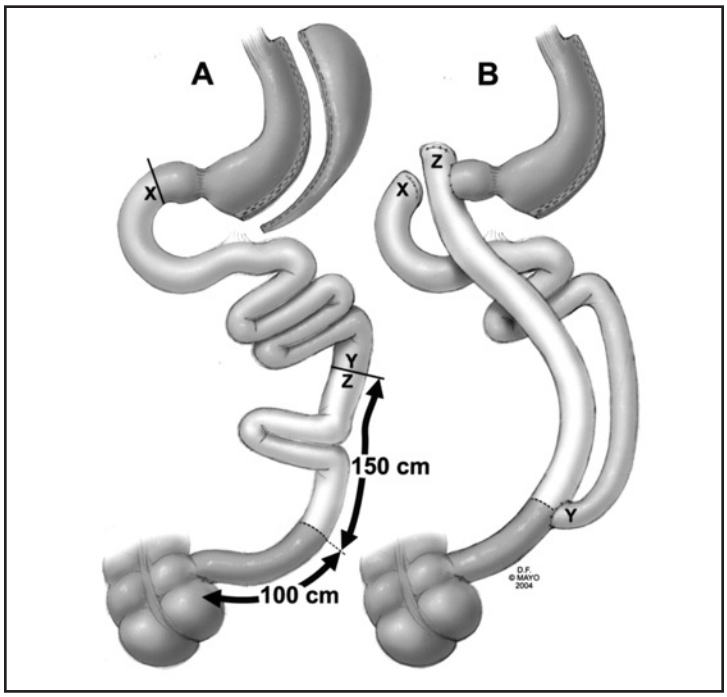
Frequent monitoring by a dietitian can ensure desirable progression of the post-surgery diet, adequate nutritional composition, management of food intolerances, and ongoing education/reinforcement of the post-surgical nutritional needs. Additionally, it is critical for dietitians to assess the type of GBP because increased nutritional risks result with longer limb lengths and will require closer monitoring. With close follow up and adherence to recommendations, patients with CKD who undergo GBP can reduce the risk of post-surgical nutrition complications.

Figure 1: Adjustable Gastric Banding



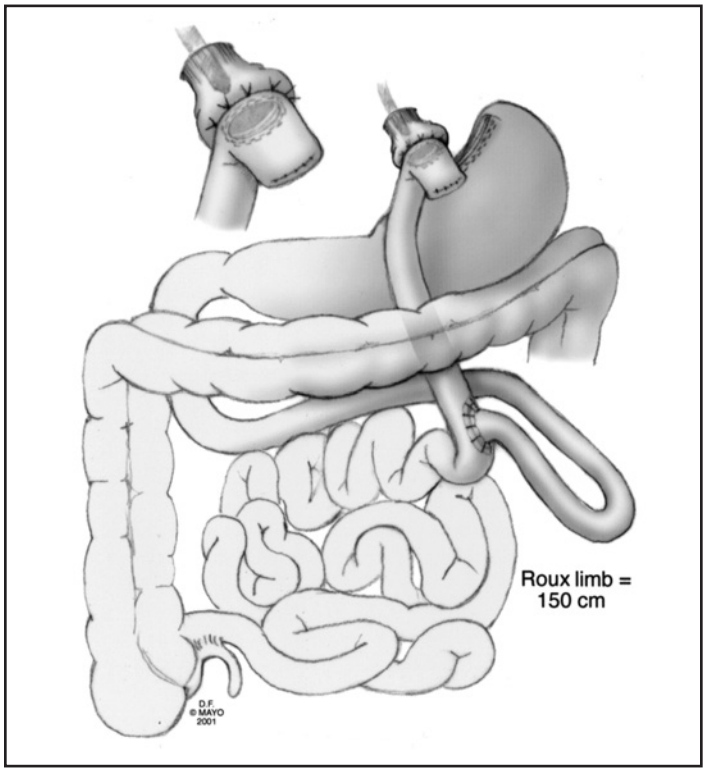
Source: Kendrick & Dakin, 2006.

Figure 2: Sleeve Gastrectomy and Duodenal Switch



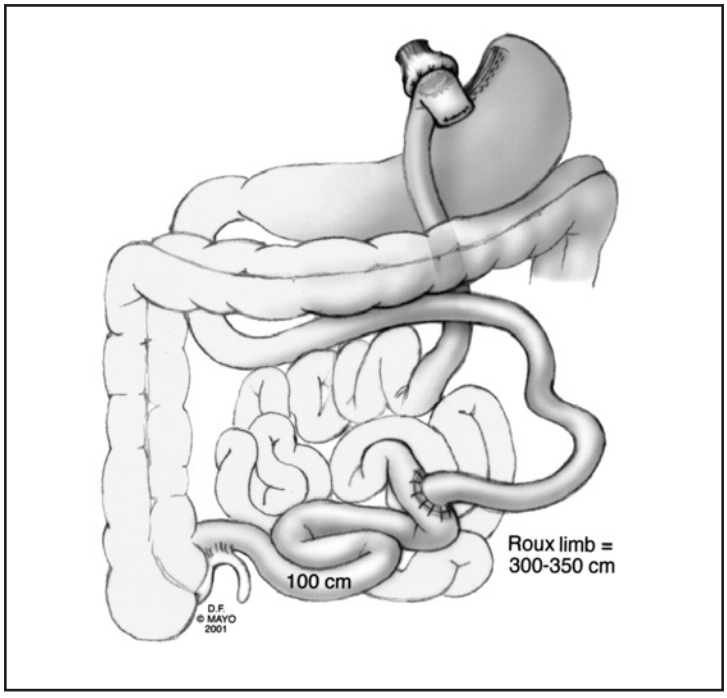
Source: Kendrick & Dakin, 2006.

Figure 3: Roux-en-Y GBP



Source: Kendrick & Dakin, 2006.

Figure 4: Very, Very Long Limb RYGBP



Source: Kendrick & Dakin, 2006.

Table 1: Potential Nutrient Deficiencies (Not Specific for the Renal Population Unless Stated as Such)

Nutrient	Absorption	Deficiency Post-Op	Treatment*	Laboratory Values
Thiamin (B_1)	Proximal jejunum	Post-op is rare, but occurs in all patients with GBP early if persistent vomiting Beriberi or peripheral neuropathy	Preventable with daily multivitamin 50 to 100 mg/day IV for advanced neuropathy or persistent vomiting Renal-specific multivitamin twice daily (Alexander et al., 2004)	Serum thiamin
Pyridoxine (B_6)		Rare; consider deficiency with unresolved anemia	Renal-specific multivitamin twice daily (Alexander et al., 2004)	PLP
Cobalamin (B_{12})	Decreased HCl, pepsin, and IF reduce absorption in the terminal ileum	35% occurrence Pernicious anemia	350 to 500 mcg/day oral tablet or 1,000 mcg monthly IM injection (may not be needed in patients on HD) (Alexander et al., 2004)	Serum B_{12} at least annually If symptomatic with low-normal B_{12}, watch for elevated MMA and total homocysteine
Folate	Proximal small intestine, can occur along entire small bowel with post-op adaptation	41% to 47% one-year post-op Mostly asymptomatic or subclinical; may have macrocytic anemia, neurological changes or headaches (McCann & Kelly, 2006); forgetful, irritable, or paranoid	800 to 1000 mcg/day for prevention 1000 mg/day in deficiency (not more or can mask B_{12} deficiency) Renal-specific multivitamin twice daily in patients on HD (Alexander et al., 2004)	RBC folate Normal serum and urinary MMA Homocysteine
Iron (Fe)	Most efficient in duodenum and proximal jejunum, but also reduced due to less gastric acid	20% to 49% post-op Higher risk – menstruating women and obese men, and patients less than 25 years old Microcytic anemia, fatigue, pica, pale nail beds, or spooning fingernails (McCann & Kelly, 2006)	325 mg Fe sulfate with Vitamin C for increased absorption (ADA, 2009); separate from Ca supplements by 2 hours Anemia protocols should correct for any Fe deficiency in patients on dialysis	Measure serum Fe, TIBC, ferritin, Hct, and Hgb 6 months post-op and annually.
Protein		With a DS pouch of less than 200 mL, supplementation likely needed (American Dietetic Association [ADA], 2009) In time, the colon adapts and increases absorption	For patients on HD: 1 g/kg actual weight (Alexander et al., 2004) or 1.5 g/kg ideal weight (ADA, 2009) Patients may be intolerant to meat and/or dairy products; utilize complete protein, low-sugar and low-fat, supplements as needed	Serum albumin and nPCR (in patients on HD)
Calcium (Ca)	Duodenum and proximal jejunum (facilitated by vitamin D)	Hyperparathyroidism	1,500 to 2,000 mg/day liquid or chewable Ca citrate or carbonate (ADA, 2009); divided doses In patients on HD, Ca citrate is not advised due to promoting Al^+ absorption, but Alexander et al. (2004) used 1 to 2 Ca citrate daily	Serum Ca In patients on HD: Ca x P less than 55

Table 1 (continued): Potential Nutrient Deficiencies (Not Specific for the Renal Population Unless Stated as Such)

Nutrient	Absorption	Deficiency Post-Op	Treatment*	Laboratory Values
Vitamin A**	Upper small intestine	52% in patients with RYGBP and BPD; 25% in patients with AGB Decreased vision or night blindness	10,000 IU to prevent deficiency 50,000 IU q 2 weeks to correct deficiency (retinol sources) Initiate 2 to 4 weeks post-op	Plasma retinol or Vitamin A in 6 months (McMahon et al., 2006) and annually thereafter
Vitamin D**	Jejunum and ileum	68%, with higher risk in patients who are obese Hyperparathyroidism and metabolic bone disease in the long term	2000 IU D3 (via multivitamin and Ca supplements) In deficiency, 50,000 IU ergocalciferol (NKF, 2003); in patients on HD, follow vitamin D protocol Weight-bearing exercise	Frequent phosphorus, alk phos, and Ca 25(OH)D and PTH at least in 6 months (McMahon et al., 2006)
Vitamin E**	Upper small intestine	Not prevalent	100% daily value for prevention	Plasma alpha tocopherol annually
Vitamin K**	Upper small intestine	14% one year and 68% four years post-op, especially in patients with BPD/DS	300 mcg daily; caution with coagulation therapy	Prothrombin time frequently and serum Vitamin K in 6 months (McMahon et al., 2006) and annually thereafter
Zinc	Dependent on fat absorption	Post-op: 36% to 51%, with chronic diarrhea Altered taste, impaired healing, or scaly/red skin lesions on nasolabial folds and hands (McCann & Kelly, 2006)	A zinc-containing renal-specific vitamin may be advisable for the patient on dialysis	Plasma zinc and RBC zinc (interpret according to albumin level due to being albumin-bound)

Source: Aills et al. (2008) (except where otherwise indicated).
Notes: IV = intravenous; IM = intramuscular; IF = intrinsic factor; RBC = red blood cell; TIBC = total iron binding capacity; Hgb = hemoglobin; Hct = hematocrit; alk phos = alkaline phosphatase; Al+ = aluminum; Ca = calcium; PLP = pyridoxal-5'-phosphate; MMA = methylmalonic acid; PTH = parathyroid hormone.
**Multivitamin and individual supplements should initially be provided in liquid or chewable forms, progressing to whole tablets/capsules as tolerated.*
***Can be provided in water-soluble form. Encourage a very low-fat diet to decrease loose stools (Hirschfeld & Stoernell, 2004).*

Additional Readings

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The **Issues in Renal Nutrition** in Nephrology Nursing department is designed to focus on nutritional issues for nephrology patients. Address correspondence to: Ann Cotton, Contributing Editor, Nephrology Nursing Journal; East Holly Avenue/Box 56; Pitman NJ 08071-0056; (856) 256-2320. The opinions and assertions contained herein are the private views of the contributors and do not necessarily reflect the views of the American Nephrology Nurses' Association.

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for providing our test questions

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Developing the Research Question and Study Design

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Carrie P. Earthman, PhD, RD

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Abstract

Research entails investigation of a problem that results in new information or conclusions. The research process is complex and requires detailed thought, planning, and creativity. The first step in the process is to develop the research question, which describes a gap in knowledge and can be answered through systematic investigation. Several characteristics need to be considered when conceptualizing the research question, including importance, specificity, measurability, and feasibility of the question. The question also should be empirically derived, based on prior knowledge, and be of significant interest to the researcher. Key areas for consideration in formulating the study design include whether the study will be experimental or observational, if the data will be qualitative or quantitative, how frequently data will be collected, and what instrument(s) will be used for data collection. This article outlines the steps involved in developing a research question and designing a study that effectively answers the question.

Introduction

Research, as defined by the Merriam-Webster Dictionary, is an "…investigation or experimentation aimed at the discovery and interpretation of facts, revision of accepted theories or laws in the light of new facts, or practical application of such new or revised theories or laws" (1). Despite this rather straightforward definition, the research process, especially in science, is complex and entails detailed thought, planning, and creativity.

Identifying the Research Question

The research process begins with formulation of a question based on previous research (2,3), a literature review (2–8), and/or observations (2). The research question is a tool to describe a gap in knowledge (5), and it can be answered through systematic analysis or assessment, ultimately yielding new information (3). Conceptualizing the research question encourages the researcher to consider the study's overall purpose (9). Among the important characteristics to consider when formulating a research question are the importance, specificity, measurability, and feasibility of the question (Table 1) (3). The question should be empirically derived, based on prior knowledge, and be of significant interest to the researcher (3).

Developing and Refining the Research Question

Once a research question has been identified, it must undergo further refinement to help the researcher develop a framework to direct the entire research project (5). According to Bordage (13), absence of a well-defined research question is a common reason for reviewers to reject manuscripts for publication. Therefore, it is paramount for the researcher to spend time crafting a well-written question. Refining the research question can be guided by using one of three similar mnemonic devices:

- PICO (Patient, population, or problem; Intervention or independent variable; Comparison; and Outcome) (14,15)
- PICOM (Patient/Problem, Intervention, Comparison, Outcome, and Methodology) (3)
- PICOT (Population, Intervention, Comparison, Outcome, and Time) (16,17)

Use of PICO/PICOM/PICOT is widely suggested for developing the research question (17) and can aid the researcher in defining a focused question that embodies the previously cited characteristics. Table 2 provides a list of considerations for each component of the mnemonic device and an example of how to apply this process to the nutrition-related problem introduced in Table 1.

Although important and integral to the study, the initial research question rarely is reported in the literature. Instead, researchers develop hypotheses or formal statements based on the research question (18). Hypotheses state a relationship between two or more variables (19) and should be composed so they can be answered as either "true" or "false" based on the results of the experiment (18). Using the nutrition related problem introduced in Table 1, a hypothesis based on this research question might be "LOS will be significantly lower in pediatric burn patients who are provided with an immune-enhancing enteral formula compared to those provided with a standard enteral formula." Not only does a hypothesis define the population of interest (18), but it states the expected results of the study and helps frame the study design (8).

Developing the Study Design

Once the research question and subsequent hypothesis have been developed, the next step is to formulate the study design. Although the study design inherently is considered when developing the research question/hypothesis, specific details are needed. For example, the researcher needs to ask several questions, including:

- Will the study be experimental or observational?
- Will data collected be qualitative or quantitative?
- How often will data be collected?
- What instruments will be used to collect data?

Table 1: Characteristics of a Research Question

Nutrition-related research question: Do pediatric burn patients who are provided with an immune-enhancing enteral formula (e.g., glutamine-enriched) have decreased hospital length of stay (LOS) compared to those provided with a standard pediatric enteral formula?

Characteristic	Definition	How Research Question Fulfills Characteristic
Importance	Relevant to the current problems and issues within the field.	Evidence exists that enteral glutamine should be considered in adult burn patients, although evidence is limited in the pediatric population (10).
Specificity	Identifies the variables and population of interest (3).	Variable: Hospital LOS Population: Pediatric burn patients
Measurability	Concepts in the research question must have a method by which they can be evaluated or assessed (3).	Assess hospital LOS in pediatric burn patients who were provided with either a glutamine-containing enteral formula or a standard enteral formula.
Feasibility	Question must be able to be answered in a realistic time frame, using ethically appropriate methods, and at a reasonable cost (3).	The study design proposed for this study is retrospective: chart reviews will be conducted on pediatric burn patients who were provided with either a glutamine-containing enteral formula or a standard enteral formula. Therefore, the study is realistic from time, ethical, and cost perspectives.
Empirically derived	Concepts in a research question should be based on previous research, a literature review, and/or observations.	A review of the literature yields studies that report an association between enteral glutamine supplementation and decreased LOS in adult burn patients (11,12).
Interest to the researcher	Research requires much time and self-interest. Therefore, the researcher should be passionate about the topic to promote dedication (3).	Not applicable.

Table 2: Application of PICO/PICOM/PICOT Components of a Research Question

P	I	C	O	M	T
Patient, Population, or Problem	Intervention or Independent Variable	Comparison	Outcome	Methodology	Time
What patient, population, or problem will be studied? **Pediatric burn patients**	What intervention or exposure of interest will be studied? **Immune-enhancing enteral formulas (e.g. , glutamine-enriched)**	What will be the comparison? **Standard pediatric enteral formulas**	What will be the variable of interest? **Hospital length of stay**	How will the data be collected? **Retrospective medical chart review**	When will the outcome be assessed? **Medical charts of both pediatric burn patients provided with immune-enhancing enteral formulas and those provided with standard enteral formulas will be reviewed once, after discharge**

Final research question: Do pediatric burn patients who are provided with an immune-enhancing enteral formula (e.g., glutamine-enriched) have decreased hospital length of stay compared to those provided with a standard pediatric enteral formula?

Adapted from Heddle (16).

Experimental Versus Observational

Study designs can be divided into two primary categories: experimental and observational (Figure 1) (4,20). Experimental studies are characterized by alteration of the independent variable and evaluation of the effect of this change on the dependent variable(s) (4). The randomized, controlled trial (RCT) is an example of an experimental study design that is considered the gold standard in research methodology (20). The typical overall goal of an RCT is to investigate the efficacy of a certain intervention or treatment by comparing treated study participants with those who were untreated (i.e., control group) (21,22). RCTs are characterized by random assignment of the intervention or treatment (22), and according to Hanson, they are the strongest study design to test for cause and effect (20).

Randomization eliminates the effect of confounding variables, such as demographics. However, when an RCT does not assign participants randomly to study groups, instead using other methods such as date of birth or order of participant recruitment, the study is considered a quasi-RCT (20). Caution is warranted with interpreting results of quasi-RCTs because the observed difference between groups cannot be attributed with certainty to the treatment or intervention (21). Instead, confounding variables that were not controlled for with randomization might be involved.

Unlike experimental study designs, observational study designs seek to determine relationships between variables that have not been altered (4). Examples of observational studies include cohort and case-control. Cohort studies are considered the gold standard of observational studies (20). In a cohort study, a group of individuals is followed forward in time to observe participant experiences, with disease being the most commonly studied outcome (22). At the beginning of the study, study participants are assumed to be free of disease and are recruited based on treatment status or presence/absence of a certain factor or exposure (22). The individuals then are followed prospectively to identify the outcome of interest (20,22). Cohort studies can be considered as tools to identify the potential cause of a disease (21). Although well-suited to establish an association between exposure and outcome, cohort studies are unable to establish causality among variables (21).

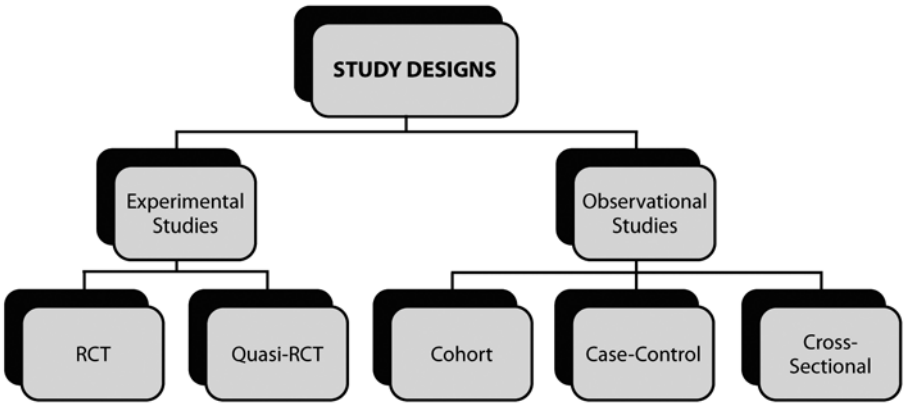
Case-control studies are another type of observational study that identify possible contributing factors to a disease or condition, but unlike cohort studies, the observations are made retrospectively (21,22). Briefly, exposure status is compared between "cases" that develop the outcome of interest and "controls" that do not have the outcome (20–22). Case-control studies are ideal for outcomes that are rare (20–22) and are less expensive and time-intensive than cohort studies (22). However, similar to a cohort study, a limitation with the case-control study design is that causation cannot be established; only associations can be made between the factor and the outcome of interest (21).

Qualitative Versus Quantitative

Scientific research can be either qualitative or quantitative, and both approaches commonly are used in the same study (4). Data collected using qualitative research approaches are characterized by words; numbers are indicative of quantitative data (4). Qualitative data collection is suited best for studies that strive to evaluate social occurrences, such as behaviors and attitudes, in a natural setting (2,6). For example, understanding how Native Americans who have diabetes perceive the American health system and manage their disease would be evaluated best using qualitative approaches, such as a focus group (23). In this example, researchers asked for opinions and experiences of Native Americans who had diabetes in a small group discussion. Although this type of data is considered subjective and may not be applicable to other populations, it is more comprehensive than data elicited from a survey.

In contrast, quantitative data collection is most appropriate for experimental studies, such as an RCT. Quantitative studies generally require more standardized methods than do qualitative studies and rely heavily on statistical analyses (2,6). An example of quantitative data collection is the assessment of fluid and body composition changes after gastric bypass surgery (24). The data collected in this example were objective and included urine, serum, and body weight, which were analyzed using statistical procedures and yielded data that described the participants in the study in terms of their changes after gastric bypass surgery. Overall, quantitative data yield information that is succinct and relatively free of bias (provided the samples are analyzed according to

Figure 1: Study designs



RCT: randomized, controlled trial
Adapted from Hanson (20).

protocol), but such data cannot describe how the changes occurred. That interpretation is up to the researchers. In summary, neither research method is superior to the other, with studies often employing both. The choice of which to use depends on the specific research question and hypothesis.

Frequency of Data Collection

The frequency and timing of data collection are important logistical considerations. Both time and finances dictate how often data are collected and the study duration. In the cross-sectional study, which is the shortest study design, data are collected at one time point only. Because individuals are not followed long term, such an observational design is considered "a snapshot in time" and is not sufficient to establish causal relationships. However, one advantage of a cross-sectional study design is its simplicity and relatively low expenses because no follow-up is needed. In addition, determination of associations between exposure and disease is possible (25), which can lead to more in-depth follow-up studies, such as an RCT. In contrast, the longitudinal study is characterized by data collection at more than one time point. Study participants are followed for days to years, depending on the needs of the study, and a longitudinal design allows the establishment of causal relationships, if the study is an RCT. However, because study participants are followed long-term, studies can be time-intensive and, therefore, costly. In sum, the frequency of data collection is an important consideration when planning the study design, and time constraints, budget, and the research question/hypothesis determine the necessary timetable.

Instrumentation

The choice of tool(s) for data collection might be one of the most important features of the study design. The research question primarily determines the type of instrument(s) needed. Examples of study instruments include surveys, assay kits, and clinical assessment tools. First, the researcher must decide if he or she will develop a new instrument or use an existing one (8). Perusing the literature can help identify if a tool has been developed that fits the scope of the study. However, researchers should not select an existing tool based solely on convenience (8), because such a choice could jeopardize study results if the instrument is not appropriate. It is beneficial to use existing instruments for which the reliability and validity have been established to make possible comparisons between studies (8). However, if existing instruments are not appropriate for the study, the researcher must modify an existing instrument, create a new instrument, or use an existing instrument in a manner that has not been done previously. For any of these options, the researcher must describe clearly what was done so that the validity can be assessed (8) and future researchers who wish to replicate the study have a specific path to follow. Overall, study results are only as reliable as the chosen instrumentation. Therefore, prudent research and selection from all available options is recommended.

Outcomes Research

Outcomes research emerged in the early 1980s as a tool to evaluate the effectiveness of health care services and has changed how the health care system evaluates end results of procedures, treatments, interventions, and programs (26). Unlike the RCT, which determines efficacy through controlled conditions, outcomes research measures the effectiveness of services in "real life" settings (27,28). Typically, assessed outcome categories include: clinical, patient, and cost (27). Clinical outcomes are concerned with health status and examples include mortality, symptoms, and clinical events (26,27). Patient outcomes are characterized by a response to an intervention and examples include survival, symptom relief, LOS, and nutrition status (27). Cost outcomes, as would be expected, are concerned with the financial aspects and include what it costs to initiate the intervention or procedure and the cost ramifications of the resulting outcome (27).

Results of outcomes research are applicable to both health care providers and patients. For example, clinicians and patients can glean information (e.g., benefits, risks) to help guide an informed decision about treatment options (26,28,29). Data from outcomes research also can aid health care providers in the development and/or improvement of protocols, programs, and clinical guidelines for the most effective care. More specifically, dietitians can incorporate outcomes research into their daily work routine, thereby playing an active role in improving health care outcomes and patient experiences. Including outcomes research in current practice should not be perceived as a laborious task. It does not require large populations or expensive equipment; rather, it requires information from daily activities (30). For example, using medical records, a clinical dietitian could assess if those who receive a nutrition consultation have decreased nutritional complications or LOS. Other parameters that a dietitian could assess include:

- Patient satisfaction with hospital meals
- Clinical outcomes in patients who receive immune-enhancing enteral formulas
- Weight status in postgastric bypass surgery patients who attend support group sessions
- Glycosylated hemoglobin values in patients with diabetes who attend outpatient diabetes education sessions

Outcomes research assesses the effectiveness of health care interventions and programs, and in an ever-changing health care environment, this methodology is integral for the determination of what works and what does not. Data that support the use of interventions and programs represent a powerful tool to ensure that the services provided by the dietitian are sustainable.

Conclusion

Developing a scientific research study is not a static process; rather, it evolves continuously with completion of each step. The process begins with the identification and refinement of the

research question. Detailed attention to this step is essential because it forms the framework for the overall study, and a well-written question can increase the chance for publication success. Once the research question has been developed, the researcher should pay attention to the details of the study design. The overall research question helps to guide the process, along with consideration of whether the study will be experimental or observational, the data will be primarily qualitative or quantitative, how often data will be collected, and what instrument(s) will be used to collect data. Good researchers spend a significant amount of time thinking about and developing these initial steps because they form the basis for the entire research project and if well done, can result in useful and novel data.

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June 26-30, 2012
www.renalnutrition.com

July 2012
24th International Congress of the Transplantation Society
Berlin, Germany
July 15-19, 2012
http://transplantation2012.org

August 2012
NATCO 37th Annual Meeting
Grand Hyatt Washington DC, Washington DC
August 12-15, 2012
http://www.natco1.org

October 2012
Academy Food & Nutrition Conference & Expo
Philadelphia, PA
October 6-8, 2012
www.eatright.org/fnce/

ASN Kidney Week 2012
San Diego Convention Center; San Diego CA
October 30-November 4, 2012
www.asn-online.org

February 2013
CRRT 2013 Conference (Continuous Renal Replacement Therapies)
February 12-15, 2013
http://www.crrtonline.com

March 2013
33rd Annual Dialysis Conference
Seattle, WA
March 10-12, 2013
http://som.missouri.edu/Dialysis/

2013 Canadian Society of Transplantation Annual Scientific Conference
Lake Louise, AB
March 14-16, 2013
http://www.cst-transplant.ca/AnnualConference.cfm

April 2013
National Kidney Foundation 2013 Spring Clinical Meetings
Walt Disney World Swan and Dolphin Resort, Orlando, FL
April 2-6, 2013
www.kidney.org/news/meetings/clinical/index.cfm

May 2013
2013 American Society of Pediatric Nephrology Annual Meeting
Washington, DC
May 4-7, 2013
http://www.aspneph.com

American Transplant Congress 2013
Seattle, WA
May 18-21, 2013
www.atcmeeting.org

ISN World Congress of Nephrology 2013
May 31 – June 4, 2013
Hong Kong
www.wcn2013.org

Critical Appraisal of Nutrition Support Research

Joseph Krenitsky, MS, RD

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Abstract

The process of carefully evaluating the methods and results of research publications, also known as critical appraisal, is an essential component of evidence-based practice. Mastery of critical appraisal can be a powerful asset for the nutrition support professional. Providing recommendations for the individual patient that are supported by the best available data can enhance credibility with other members of the health care team. An understanding of basic research methodology and an eye for detail are the essential tools for critical appraisal. This article provides an overview of various types of studies, practical research methods, and key components of a published study that must be considered in the critical appraisal of results and conclusions. Suggestions and tips are offered to promote efficient, accurate, and successful application of nutrition support into clinical practice.

Introduction

Evidence-based clinical practice requires an understanding of the most current research (1). The number of randomized studies has exploded in the past 25 years, and information technology and the internet have accelerated the task of searching topics and finding research. Nonetheless, research still must be read and critiqued before it can be incorporated properly into clinical practice. There is a world of difference between reading and critically appraising research. Critical appraisal is the process of carefully examining research to determine if the methods, results, and conclusions are valid and trustworthy and if the study results are relevant to individual patients. A clinician's ability to implement or reject new research appropriately depends on critical appraisal of the study. Furthermore, a clinician's credibility can be enhanced or compromised based on his or her level of understanding of current research. In an environment in which physicians have received training in evidence analysis since medical school, an inability to defend recommendations with appropriate evidence can compromise credibility or create a communication gap between dietitians and physicians. Our experience has been that once physicians learned how thoughtfully and thoroughly dietitians evaluated new literature, we attained a new level of respect and acceptance of our recommendations.

Unfortunately, many clinicians find the process of critical appraisal intimidating, which discourages them from critiquing research adequately. Some of the comments that dietitians have shared include: "I only have a bachelor's degree", "I hate math; I don't understand the statistics", "I am not a researcher", "Can't I just trust the conclusions in the abstract if it is a reputable journal?" and "I have a life; I can't spend hours and days reading an article". This article is designed to allay some of the concerns, remove much of the mystery, and provide common sense guidelines related to the critical appraisal of nutrition support research.

Is This Trip Really Necessary?

Considering that reputable journals subject every research report to peer review and editorial revision, it is reasonable to ask why critical appraisal of published research is necessary. In reality, all research is subject to a certain amount of bias, which occurs when some aspect of the study influences the results and conclusions. An important aspect of critical appraisal is to evaluate sources of bias and determine if the bias is sufficient to compromise the validity of results.

A second reason for critical evaluation is to determine if the results of the study represent a clinically significant patient outcome. One of the core concepts of evidence-based medicine is evidence that is based on meaningful patient outcomes. The preference for clinically meaningful outcomes also has been described as Patient-Oriented Evidence that Matters (POEM) (2,3). POEM deals with outcomes of importance to patients, such as changes in morbidity, mortality, or quality of life, rather than disease-oriented evidence that deals with surrogate end points, such as changes in laboratory values or other measures of response. A study of enteral nutrition (EN) products provided in the intensive care unit may report statistically increased prealbumin values or weight status in one group, but if there is no improvement in patient outcome such as survival, duration of mechanical ventilation, or length of time in the intensive care unit or hospital, the statistically significant change in laboratory values or weight has no clinically meaningful importance.

The third major aspect of critical appraisal is to determine if the results of the study apply to the patients for whom you care. In many ways, the methods section of a study that details patient selection and inclusion/exclusion criteria is most important to the practicing clinician. If researchers investigating the incidence of aspiration pneumonia with gastric versus jejunal feeding exclude all patients who have a history of vomiting, gastroparesis, or other gastrointestinal motility disorder, results of that study may not apply to the intensive care unit patient who has severe diabetic gastroparesis.

Systematic reviews, guidelines from professional health care societies, and the American Dietetic Association Evidence Analysis Library are invaluable tools for evidence-based practice (4).

However, a substantial amount of published research may not be addressed in a systematic review or does not fit the practice question in the Evidence Analysis Library. Further, new studies are published more frequently than guidelines can be updated. Knowing how to evaluate new studies is essential to understanding whether the latest findings justify a change in practice. Finally, the details of every study and each patient population in reviews and guidelines are not sufficient to determine if the results apply to individual patients or circumstances.

An additional benefit from the critical appraisal process is providing insights into the strengths and weakness of other studies mentioned in the discussion section of an article. The appraisal process helps the clinician to assimilate information from the study. Although it is not possible for most people to remember the details of every study, developing some "take-home messages" after compiling the critique is helpful for remembering the most pertinent parts of the study for your practice.

Do I Have the Tools for This Job?

One of the most frequent concerns of dietitians attempting to critique the literature is their lack of an advanced degree or proper training in this area. Fortunately, the process of critical appraisal does not require an advanced degree, experience in conducting research studies, or an advanced understanding of statistics. The very attributes that make a good nutrition support professional, such as examination of all available information, attention to detail, and ability to use common sense, are exactly the skills needed to appraise research critically. In fact, our experience in teaching evidence-based process and skills is that once the basics are understood and practiced, dietitians often have exceptional skills at critical appraisal.

Types of Studies/Levels of Evidence

Randomized, Controlled Trial (RCT)

Space constraints do not permit a discussion of every type of study, so this article outlines the studies most frequently encountered in the nutrition support literature. The strongest study design for establishing whether a treatment works or to compare two different treatments is an RCT. RCT participants are placed into groups in a truly random fashion, in which all patients have the same chance of being placed into any of the groups. The goal of random allocation is to produce two groups with similar characteristics, in which the differences between subjects (e.g., age, sex, degree of illness, number of comorbidities) eventually can "even out" between the groups, allowing the researchers to see the effect of the intervention alone. Of note, many randomized studies do not result in two perfectly homogenous groups, especially in studies involving small numbers of participants. This is one factor that must be evaluated when critiquing a study. In true randomization, the investigator cannot know into which group an individual will be placed. Awareness of this information can influence the decision of the patient(s) to enter the study, thereby subverting the randomization and producing unequal groups.

Ideally, neither researchers, participants, nor caregivers are aware of the type of treatment the patient is receiving during the study. Such "blinding" of allocation into groups throughout the study prevents anyone's expectations from influencing the results. In addition, blinding helps to ensure equal treatment of groups. A single-blind study is one in which the patient is unaware of treatment allocation, but the researcher/caregiver is aware. In a double-blind study, neither the patient nor the researcher/caregiver is aware of group allocation during the study. Studies that are randomized and double-blind generally are considered to provide the best level of evidence, as long as adequate numbers of patients are enrolled. Certain types of investigations are difficult or impossible to conduct as double-blind studies, such as directly comparing parenteral nutrition (PN) with EN support.

Prospective Studies

Prospective studies, which collect data in real-time as the study evolves, are not always performed with randomization of patients into groups. Investigators may collect outcome data for a time period before and then after a new protocol or product is implemented for general use. Investigators compare the outcomes (e.g., pneumonia or length of stay) between the two groups (cohorts) of patients. An example of this type of cohort study is collecting data on diarrhea and Clostridium difficile infection for six months in an intensive care unit while using open-system EN sets, followed by collection of the same information for six months after the hospital changes to closed-system feeding sets. The advantage of this type of study is fast enrollment of large numbers of patients. The disadvantage of this type of cohort study is that the groups could have differences in care unrelated to the study intervention that can affect the outcomes being measured. Especially when groups are separated by time, factors such as changes in the antibiotics available, hand hygiene products used, new resistant strains of pathogens, and myriad other unrecorded factors could influence patients and the outcomes of the study. Data from cohort studies generally are not considered as strong as that from randomized studies. However, a number of large cohort studies that all demonstrate the same result often are considered a higher level of evidence than one small or poor-quality randomized study.

Observational Studies

Observational studies collect data without providing an intervention or influencing the care of those being studied. Observational studies can be retrospective, which go back in time to recorded data, or prospective, collecting data as they accrue. Observational studies can record associations, but such associations should not be used to imply cause and effect. Often, the known factors that influence outcome can be controlled for, but there is no way to control statistically for all factors that influence a patient's outcome. Interpreting results from an

observational study citing that patients who received EN or PN had longer and more complicated hospitalizations compared with patients who did not receive specialized nutrition support to imply that the nutrition support caused the complications would be premature. Even if the association remained after known risk factors were controlled for, intrinsic differences between the two groups of patients that influenced both the need for nutrition support and the length of stay and complications are likely. Observational studies should be used to form theories that are tested in randomized studies. Observational studies are extremely valuable for that purpose, but their data generally do not provide strong enough evidence to suggest changes in clinical practice.

Review Articles

All studies have some degree of bias, but the best level of evidence generally is considered to be a review of randomized studies. Intuitively, this makes great sense because a number of RCTs that all have the same result provide stronger evidence than a single study. However, because inevitably some studies produce conflicting results, it is possible to create a biased review of randomized studies by including only certain investigations and excluding or minimizing those containing dissenting data. Evaluations of the quality of medical review articles have found substantial room for improvement (5).

A systematic review is designed to address the concern of bias in review articles by having a "transparent" approach to the selection of the articles included and rejected by the investigators. A systematic review focuses on specific questions and tries to identify, appraise, and judge the quality of the research addressing each question. The objective is for investigators to assign predetermined levels of evidence to the "answer" for each question based on the best (highest quality) available research. A systematic review should disclose the criteria for study selection and reveal how articles were found. In addition, a systematic review itemizes the articles that were found but rejected, often detailing the reasons for article rejection.

Systematic reviews have become an essential part of evidence-based medicine, but they do have certain limitations. Understandably, a quality systematic review is time-consuming, and due to new research, some systematic reviews are out of date within 1 or 2 years. In fact, in some fields, such as cardiology, reviews can be dated by the time they are published (6). Further, the quality of reviews can vary, and the outcome of the review can differ, depending on the preselected criteria for article selection. Finally, there are no universal criteria for judging the quality of individual articles. As evidence of the limitations of systematic reviews, some systematic reviews of the same topic by different authors have produced different and even opposite conclusions (7,8).

Meta-analysis

Meta-analysis is a method of pooling the results of several similar studies and analyzing them, with the goal of having adequate numbers of subjects to achieve statistically meaningful results (9). A meta-analysis can be based on a systematic review, but this is not always so. One limitation of meta-analysis is that there is no perfect or universally agreed-upon method of deciding which studies are sufficiently similar to be pooled. From a practical standpoint, systematic reviews and meta-analyses are tremendously useful, but clinicians still must be able to evaluate the individual studies to determine if results are applicable to their own patients and be aware of the limitations of each study. The methods and limitations of each individual study in a review or meta-analysis generally cannot be detailed, but such information can influence how the results translate into practice at an individual facility.

Evaluating an Article

The Abstract

The abstract of an article is like an ad: it should pique readers' interest and make them want to know more, but readers must realize that there is "fine print" that needs to be read. It is possible to become misinformed about the current level of evidence on topics by reading only review articles and abstracts from Medline/PubMed searches. A review of six large medical journals found that as many as 68% of articles had data in the abstract that were either inconsistent with or absent from the main body of the article (10,11). After scanning the abstract, readers should identify the location where the research was conducted and the investigators who conducted the study. Coworkers or physicians with whom you discuss the article will want to know who is responsible. Also, it is never too early (or late) in your career to develop a sense of who/where is originating good research, perhaps for future employment or just for a potential keynote speaker at the next state conference. It is worthwhile to note the funding source for the study and be wary of possible commercial influence in the tone of an article, although funding source alone never should make or break the evaluation of an article. The reality is that federal funding for nutrition support research is extremely limited, and there are a finite number of grants from nutrition and dietetics societies. Good research costs money, and no hospital has extraneous funds these days, so funding from industry is indispensible. Ultimately, the quality or limitations of the study should speak for themselves, regardless of the funding source.

Materials and Methods

A review of the article's introduction should provide a sense about past research and the rationale for the current study. However, the most important part of the paper is the materials and methods section (Table 1). The first consideration is the type of study. Is it an observational study or are the investigators manipulating some factor (experimental research)? If the investigators are manipulating a factor or testing interventions, have the patients been allocated randomly into groups? If it is a randomized study, the methods section should state this and indicate what tool (e.g., a random number table or computer-

Table 1. Methods Overview
- Interventional or observational
- Randomized or quasi-experimental
- Blinded: single- or double-blind
- Appropriate control group(s)
- Outcomes appropriate to answer question
- Adequate number of patients
- Protocols and definitions

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generated randomization) was used to randomize the patients. If a nonrandomized method for allocating patients into groups was used (e.g., every other patient into the intervention group), the investigators would be aware of patient group assignment and consciously or unconsciously may have unbalanced the groups, ultimately influencing the results. The term quasi-randomized often is used for those studies that allocate subjects into groups with a method that may appear to be random (such as every other patient or based on day of the week) but actually provides investigators with foreknowledge of a potential subject's group allocation. The next step is to determine whether the study was unblinded, single-blind, or double-blind. If the methods section does not specify by term (single-blind, double-blind) or description that the study was conducted so that neither the researchers nor patients were aware of treatment allocation, most likely the study was not blinded.

How were patients selected or recruited for the study and what were the inclusion and exclusion criteria? As discussed previously, this information is crucial to understand to whom the study results apply. Studies normally exclude patients who have medical histories that may make it dangerous for them to participate in the study. A study that excludes patients who have a wide variety of comorbidities may be more likely to have similar groups with fewer factors that could confound the results, but it is not always clear if the results translate well to all patients. A quality study lists how many patients were evaluated, how many met criteria for inclusion, and how many were randomized into each group to demonstrate that no bias was introduced by manipulating who was allowed to be in the study.

Another important factor to consider is the primary endpoint or outcome being investigated and its appropriateness to answer the research question. Are the outcomes being measured clinically relevant to the population being studied? Some studies use a surrogate endpoint, which is a laboratory value or other physical sign that attempts to substitute for or predict a clinically meaningful outcome (13). Surrogate endpoints generally are not appropriate substitutes for monitoring the actual outcome of a patient unless the surrogate has been thoroughly validated as an absolute arbiter of the outcome in question.

The number of patients enrolled in a study is an important concern. The number necessary for a "good study" is highly dependent on the factor being studied and the population being examined. Investigators usually mention how many participants need to be enrolled to allow adequate "power" for detecting a statistical difference in the primary endpoint. A sample size (power) analysis is based on how often the primary endpoint occurs, what type of difference in this endpoint the investigators expect or consider to be clinically significant, the statistical significance level, and what is the acceptable probability of not having enough patients to detect a real difference. Many studies use a power of 0.80, which means that the researchers accept that the study has a 20% chance of not having enough patients.

A number of secondary outcomes often also are measured. If many secondary outcomes are measured, one of them may reach statistical significance by chance alone. Some researchers also analyze the results of a selected subgroup(s) of patients because the intervention or outcome may be significant only for certain types of patient, such as the sickest or those in the intensive care unit for longer than 1 week. However, selection of subgroups should be decided before the study begins. Analysis of the results of numerous subgroups after study completion may yield a significant result that is unrelated to the intervention being studied.

Readers should examine carefully the operational definitions and the protocols for conducting the study. If operational definitions are defined too loosely (e.g., diarrhea = 2 or more bowel movements per day) or too strictly (e.g., diarrhea = more than 6 liquid bowel movements per day), the study can be biased in a certain direction. Are the primary measurements based on objective data (e.g., cultures of bronchoalveolar lavage) or subjective evaluation (e.g., purulent-appearing sputum)? The use of objective outcome measures is particularly important in studies where a double-blind protocol is not feasible. Readers also should note if the protocols for care used in the study are similar to those employed in their facilities.

The statistical methods used for the study is described in the methods section, but most of the primary limitations encountered in studies are apparent without delving into the statistical methods. A recent two-part review is a helpful reference (14,15).

Results

After reviewing the materials and methods of an interventional study, it is important to examine the baseline characteristics of the groups of patients (Table 2). Commonly, these data are presented in a table, which can be scanned to determine if characteristics such as age, sex, and severity of injury are similar between the groups. Differences in a number of baseline patient characteristics between the two groups or a significant difference in a baseline characteristic that would have a strong influence on the primary outcome should raise concern about the reliability of study results.

Results should be presented clearly and objectively so that it is apparent which outcomes were significantly different between the groups and which were not significantly different. Ideally, those

Table 2. Results Considerations

- Scan baseline characteristics: are the groups alike?
- Number of subjects analyzed
  - Did patients "disappear"?
  - Intention to treat?
  - Size of the subgroups?
  - Size of the final group?
- Is the math correct in the tables?
- Did the patients receive the amount of nutrition that was ordered?

Used with permission from the *University of Virginia Health System Nutrition Support Traineeship Syllabus* (12).

outcomes that were numerically but not statistically different, along with the implications of any trends in the data, are reviewed in the discussion section, but this is not always the case.

Some results can be statistically significant but have no real clinical significance. For example, a statistically significant difference in weight of 3 lbs or time on the ventilator of only several hours (not days) can have no real clinical significance in given populations. It is also helpful to notice the values used to report the final results, and if they are not familiar, to translate them to common values. One study our group reviewed that reported "similar" protein provision between two groups of patients receiving EN presented protein intake data as grams of nitrogen. Translated to grams of protein per day or to grams of protein per kilogram of patient weight revealed a significant difference between the groups.

The number of patients in each group used in the final analysis is very important. Ideally, the number of patients in the final analysis should be the same as the number randomized. Dropping data from patients who died or were unable to remain compliant with a protocol from the analysis can create a false impression of treatment effectiveness. Analyzing data based on the original group allocation (intention to treat) preserves the randomization so that the known/unknown factors that influence the outcome remain equally distributed between groups.

The details of any patients who dropped out of the study should be provided, including the number of patients from each group and the reason for early termination from the protocol. A marked difference in the number of dropouts between the two groups raises concerns about bias, especially in an unblinded or single-blind study. Readers also should look at the number of patients used in the overall analysis and in the analysis of any subgroups. Comparing the final number of patients analyzed with the number of patients deemed necessary to detect significant differences based on the power calculation (in the method section) can be revealing. Occasionally, there are so many dropouts or subgroups end up being so small that it is not appropriate to make strong statements about the outcome of the final population or subgroup.

One of the factors unique to EN therapy studies is the need to determine the presence of documentation regarding the amount of nutrition that actually was provided to the patients. Many patients receiving EN do not consistently receive the full volume of formula that is ordered, and the amount of nutrition received can vary by degree of illness and population (16). Ideally, data on the amounts of EN formula actually received by patients and documentation of how these data were collected should be a standard requirement for EN therapy studies. Unfortunately, details on the amount of formula actually administered to patients are not provided routinely in all EN therapy studies. It is a conundrum that although intention-to-treat analysis does preserve the randomization process, it is unclear how useful data are from studies involving limited numbers of patients who actually received significant amounts of the formula being studied.

Discussion

Investigators review the findings of the study and discuss the significance or implications of their results in the discussion section. Readers must consider carefully if the authors have stated the implications of their results objectively or if they make unsubstantiated conclusions. Be watchful for language or discussion that suggests differences between groups when the differences were numerical, but not statistical. Such trends can be real and important, but the discussion should recognize the need for larger follow-up studies rather then suggest changes in practice based on such results.

One of the most valuable aspects of the discussion section is the recognition of study limitations. Investigators also frequently compare and contrast the results and methods of their study to other similar research, which is helpful to understand the limitations of other studies. The critique as well as the comparison to other studies found within the discussion section are two of the reasons why reading the entire paper is so valuable to critical appraisal.

Conclusion/Take Home Message

The author's conclusions should be objective and consider the limitations of the study. The conclusions the reader reaches after careful evaluation of the entire article may be at odds with the conclusions in the abstract and at the end of the article. Such differences may be related to how the results and protocols translate to individual facilities, protocols, and patients. However, it is not uncommon that enthusiasm for research that requires an enormous effort to plan, conduct, and report leads to some degree of overstatement in the conclusions.

A frequently asked and debated question is: "When is the data strong enough to change practice?". The answer is easy when studies are small, nonrandomized, and have uneven groups or are observational studies. The answer is similarly easy when large, multicenter, randomized trials are published with results that

confirm the results of observational and cohort studies. However, when studies are of modest size and have minor limitations, the decision process is more complicated, especially if not all of the studies are in full agreement. This topic evokes debate and considerable passion in editorials, letters to the editor, and review articles. Our practice has evolved with time to be more conservative and await confirmatory studies before implementing the findings from studies of modest size, especially in the critical care realm. The history of medicine and nutrition support over the past 30 years offers numerous instances of unintended consequences and collateral damage from practices, protocols, and feedings uncovered in large, randomized studies that initially appeared to fit into the "might help, won't hurt" category based on the results of initial smaller studies.

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Vegetarian Diets in Chronic Kidney Disease

People with chronic kidney disease (CKD) require varying degrees of nutrition intervention based on numerous factors, including stage of kidney disease and treatment modality.

Additionally, there is a wide diversity among vegetarians regarding what foods are acceptable. Diets should be planned according to individual needs and preferences.

Dietary Goals

Dietary goals for people with CKD include the following[1]:

- to slow the rate of progression of kidney failure
- to maintain good nutritional status
- to minimize uremic toxicity and the metabolic disorders of kidney failure
- to decrease proteinuria
- to decrease the risk of secondary complications associated with kidney disease such as heart disease, bone disease and altered blood pressure control

Stages of Kidney Disease

Chronic kidney disease is classified according to the level of kidney function, based on the glomerular filtration rate (GFR), widely accepted as the best overall measure of kidney function in health and disease[2]. Nutrition needs vary depending on the stage of kidney function and other co-morbid conditions, such as hypertension, diabetes and cardiovascular disease.

Quantity and Quality of Protein

High protein intakes have long been known to have potential adverse effects in those with pre-existing kidney disease. The relatively lower protein intake typical of vegetarians may help reduce the risk of progression of kidney disease without compromising nutritional status. Emerging epidemiological evidence indicates that higher protein intake (> 20% versus 10% of total daily calories) is associated with loss of kidney function in women with mild kidney insufficiency and with the development of microalbuminuria in people with diabetes and hypertension[3]. Based on two meta-analyses, low protein diets reduced risks related to loss of kidney function, based on GFR and/or increased albuminuria, with greater benefits seen in those with diabetes[4-5]. In people with type 1 diabetes and CKD stage 2, even a modest limitation of dietary protein intake to 0.9 g/kg/day provided benefits beyond established medical therapies[3]. In the DASH and DASH-Sodium diets, a higher protein intake (1.4 g/kg/day) is recommended. However, sources of protein in the DASH diets emphasize vegetables, low-fat or nonfat dairy products, whole grains, nuts, legumes, fish and poultry. Data suggest that nonmeat protein may have a beneficial effect on blood pressure[6]. Plant sources of protein have been shown to decrease proteinuria, reduce glomerular filtration rate and renal blood flow, and result in milder renal tissue damage when compared to animal proteins. Several small studies in diabetes and CKD indicate that vegetable or soy protein sources also may be kidney sparing compared to red-meat sources, and in the Nurses Health Study, the risk of losing kidney function in women with mild kidney insufficiency was related primarily to animal meat intake. Higher dairy or vegetable protein intake did not increase this risk[3,7].

Therefore, a DASH-type diet that emphasizes sources of protein other than red meat may be a reasonable alternative to a lower protein intake in people with hypertension and CKD stages 1 to 2. A modified version of the DASH diet is recommended for people with diabetes and in CKD stages 3 and 4[8]. Reductions in albuminuria and stabilization of kidney function have been reported with dietary protein intakes at the RDA level of 0.8 g/kg body weight/day or ~10% of daily caloric intake[3]. Regardless of the level of protein intake, 50% to 75% of the protein should be of high biological value, derived predominantly from dairy, soy, and vegetable-based proteins. By CKD stage 5 on renal replacement therapies, higher protein intakes of 1.2 to 1.5 g/kg/day are recommended[1].

Quantity and Quality of Carbohydrates and Fat

When dietary protein intake is limited, increases in carbohydrates and fats will be required to meet caloric needs, and the qualitative aspects of these macronutrients should be considered. Dietary guidelines recommend that carbohydrates come primarily from whole grains, fruits, vegetables, and nonfat or low-fat dairy products[9]. Dietary fiber is encouraged and may produce metabolic benefits on glycemia and lipids. Available evidence suggests that increased intake of omega-3 and monounsaturated fatty acids may have potentially favorable effects on progression of CKD[3,10]. Cardiovascular disease is the leading cause of death among people with kidney disease, regardless of treatment modality[10]. Vegetarians typically have lower blood cholesterol levels and lower rates of hypertension[9]. Consumption of soy products provides a modest reduction in LDL-cholesterol and triglycerides[11].

Phosphorus, Potassium, and Sodium

Phosphorus binders will be needed by CKD stages 3 to 5 if emphasis on whole grains and dairy products is maintained. Dietary phosphorus should be restricted to 1.0 g/day and potassium to 2.4 g/day. Dietary sodium is restricted to 2.3 g/day, consistent with the DASH diet. The sodium content of some processed vegetarian foods can be quite high[1,12].

Minimizing the metabolic disorders of kidney failure can be a challenge since, other than egg whites, animal flesh proteins offer the lowest quantity of phosphorus relative to the quantity and quality of protein. About 50 to 70% of phosphorus is absorbed from a typical mixed diet. In general, phosphorus bioavailability is

Chronic Kidney Disease: A Clinical Action Plan[2]

Stage	GFR (ml/min)	Description	Diet Needs
1	90	Kidney damage, protein in the urine, normal filtration	DASH*-Sodium diet (and treatment of any co-morbid conditions; CVD risk reduction)
2	60-89	Kidney damage with a mild decrease in filtration	DASH*-Sodium diet (and treatment of any co-morbid conditions; CVD risk reduction)
3	30-59	Moderate decrease in filtration; evaluate and treat complications	Low Sodium, low phosphorus and low protein
4	15-29	Severe decline in filtration; begin preparing for kidney replacement therapy	Low sodium, low phosphorus, low protein and low potassium
5	< 15	Kidney failure and dialysis or transplant will be needed soon.	Low sodium low phosphorus, low potassium, high protein, fluid restriction

*Adapted from: National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification. Am J Kidney Dis 2002; 39(suppl 1):S1-S266. * DASH = Dietary Approaches to Stop Hypertension diet*

greater in animal products (>70%) than from plant-based foods (50%). Much of the phosphorus in grains and legumes can be in the form of phytic acid (inositol phosphate), which reduces the absorption of phosphorus to approximately 50%[12]. The widespread use of phosphorus-containing additives in many processed foods creates additional challenges.

Fruits, vegetables, dairy and legumes may need to be limited in people who must restrict their intake of potassium. With careful planning these foods can be worked into a vegetarian diet, however, amounts will need to be modified and potassium levels monitored carefully[1].

Vitamins D and B12, Calcium, Iron and Zinc

Even in the general chronic kidney disease population, these nutrients are all supplemented to some degree depending on the metabolic status of the patient. All vegans must regularly consume reliable sources of vitamin B12, such as fortified foods (nutritional yeast, ready-to-eat cereals, meat analogs, and soymilk). If these foods are not eaten regularly (2-3 servings per day) a daily vitamin B12 supplement of 5 to 10 µg or a weekly B12 supplement of 2,000 µg may be used[9]. Serum levels of vitamin D, calcium, iron, and zinc should be evaluated before supplements are prescribed[1].

Minimizing Uremic Toxicity

The last goal of diet therapy in kidney failure may be more difficult to manage on a vegetarian diet. Essential amino acid needs can be provided by both vegetable and animal protein sources. However, with the exception of soy, vegetable proteins will contribute a greater amount of nonessential amino acids when compared to animal proteins. The metabolic outcome is an increased amount of urea generated. When a mixture of plant protein foods is consumed, some complementation of amino acids will occur to decrease the urea load. However, minimizing uremic toxicity symptoms in vegetarians may be more difficult to achieve in a patient approaching end-stage renal disease. Vegetarian patients undergoing dialytic treatments should achieve sufficient urea reduction, assuming an adequate dialysis prescription is being delivered[12].

Summary Points

- Substitution of vegetable protein for animal protein may protect against the development of proteinuria in patients with diabetes.
- High protein intake, from either animal or vegetable sources, likely accelerates CKD.
- Vegetable protein diets can meet protein requirements and provide adequate nutrition in people with CKD.
- Meal plans need to be individualized to include vegetarian eating preferences as much as is possible within the constraints of the diet for kidney disease.
- Increased phosphate binders may be needed at meals and snacks for CKD stages 3-5.
- The dialysis prescription should be adjusted as needed for adequate urea clearances and possible lower potassium dialysates.

Resources

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RPG WEBSITE & ELECTRONIC MEDIA HIGHLIGHTS

Some exciting new additions & updates!

ONLINE STORE:
Please check out the RPG Online Store for new products-the most recent addition is the 2012 Recorded Webinars, "Directing Patient Conversations Toward Meaningful Behavior Change: Plain Language, Self-Management, & Motivational Interviewing Strategies" & "Directing Patient Conversations toward Behavior Change, Part 2"; both presented by: Kristin S. Vickers Douglas, Ph.D.

Now you have the option to purchase both the English & Spanish update versions of this popular and useful patient education tool. ***http://www.renalnutrition.org/store/item_view.asp?estore_itemid=1000007***

RNF reprints for articles after 2003 are available for purchase from the online store for members & nonmembers.

2 NEW AWESOME MEMBER BENEFITS NOW AVAILABLE:

The Professional Resource Center (formerly the Lending Library) is now available online. Resource requests and refundable deposits can all be made via the RPG Online Store now!

The RNF Archives have received a much needed facelift and are now an archived searchable database of full issues and individual articles that can be found under the author, subject or title. Please give it a try!

ONLINE WEBSITE POLL-Membership Feedback:
Please take a few minutes to complete the brief online member survey about how YOU view your RPG membership. WE WANT TO HEAR FROM YOU-your feedback is important!

MEMBER TIPS:
Many member inquiries regarding whether the CPE quizzes and credits recorded online are forwarded to CDR. Please note that RPG has provided the member benefit for online recording as a tool for members to have access to a compiled summary of the credits completed online over time. Thus it is the responsibility of each member to transfer the CPE credit information into their respective CDR Portfolio for credits.

"Be a yardstick of quality. Some people aren't used to an environment where excellence is expected."
– STEVE JOBS

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Researching a topic for a presentation? Check out the New Renal Research ToolKit
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Can't find a resource or have a suggestion for a great link?

WE WANT TO HEAR FROM YOU!
Cathy M. Goeddeke-Merickel, MS, RD, LD
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Visit RPG's web site: www.renalnutrition.org for CPEU offerings and valuable professional and patient resources

Renal Dietitians Chair Message

Rachael Majorowicz, RD, LD
RPG Chair
majorowicz.rachael@mayo.edu

New. Fresh. Growth. These are a few of the many words used to describe the spring season. Similarly, the RPG Executive Committee (EC) has been busily working to bring forth new and fresh ideas, as well as growth of opportunities on the EC. You could say that we are ripe for spring!

In recent months, the RPG Executive Committee approved an expansion with 8 new positions. These new positions highlight the EC's continued focus on maximizing member benefits and services, as well as patient resources. The new positions include: Mentor Chair, Social Media Chair, Webinar Chair, Projects Chair, Handouts Subcommittee Chair, Website Updates Subcommittee Chair, iPad Subcommittee Chair, and the Kidney Friendly Foods Initiative Chair. Stay tuned for more details!

In previous chair messages, I shared some of the many projects RPG has undertaken in the past year. I hope you are enjoying the recent webinars and have contributed to surveys on dialysis 'disparities in care' and the Kidney Friendly Food Shelf project. As much as everyone else, I also anticipate the updated *A Clinical Guide to Nutrition Care in Kidney Diseases* this year!

At the Food & Nutrition Conference & Expo (FNCE), October 6-9th in Philadelphia, RPG chair-elect Sarah Kruger is planning the following exciting events:

- An RPG and Dietetics in Health Care Communities (DHCC) joint-hosted members' reception cruise on the Spirit of Philadelphia. This is a first for RPG... be sure not to miss it! More information on registration for this event will be announced at a later date.
- RPG-planned, phenomenal spotlight session, "Is Phosphorus the New Trans Fat? Implications of Food Additives," presented by Janeen Leon, MS, RD, LD and Geoffrey Block, MD on October 7 from 8:00-9:30am.

Register for FNCE today and plan to meet us there!
www.eatright.org/fnce

Although spring generally conveys new beginnings, in this case, it signals my last chair message. In my final message to this esteemed group, I would like to thank you for the opportunity to serve as your chair. It has been an honor and a tremendous learning opportunity.

I would also like to welcome the newly elected EC members:

- Aimee Zajc, Chair-elect
- JoAnn Randazzo, Secretary
- Valarie Hannahs, Nominating Committee

Additionally, I would like to thank the current members of the Executive Committee for all their time and efforts the past year, including the outgoing board members: Kathy Madigan (past chair), Jane Louis (secretary), & Kathy Harvey (nominating chair). In June, Sarah Kruger will assume the chair position, under whose leadership RPG will truly shine! But she will need your help to do it. In order for RPG to continue providing valuable services and resources, we need member input regarding where to focus our efforts. So please complete eblast surveys, participate in online polls, or simply send us your feedback or ideas. Or if you're more hands-on, consider writing articles for the Forum, joining an EC position, or contributing to projects!

This is a time of great creativity and energy within RPG. I look forward to the great things we can accomplish together!

SAVE THE DATE!

SUNDAY, OCTOBER 7, 2012

RPG Members' Reception Cruise at FNCE 2012

Join fellow RPG members aboard the Spirit of Philadelphia!

www.spiritofphiladelphia.com

More information on registration for this evening event will be coming soon.

WE HOPE TO SEE YOU THERE!

CRN Chairperson Message

Lisa Gutenkunst, MSEd, RD, CSR, CDN
NKF-CRN Chair

Collaboration and Research

Happy Spring to everyone! In Buffalo, it has come EARLY and we have been enjoying the great outdoors for a few weeks now!

I want to update everyone on the collaboration efforts between the Council on Renal Nutrition (CRN) and the Renal Dietitians Practice Group (RPG). First and foremost, I must congratulate Rachael Majorowicz, Sarah Kruger, Susan DuPraw, Cathy Goeddeke-Merickel, Lindsey Zirker, and Kimberly Kirchher on the work they are doing on two major projects. Additionally, I would like to thank everyone who has contributed to and worked on the 4th Edition of the Renal Nutrition Practice Guide. I know we are all busy with work and home, so the additional time you have taken to get these projects rolling and completed is gratefully acknowledged.

In addition to updating *A Clinical Guide to Nutrition Care in Kidney Diseases*, which will be published and released this year, the CRN and RPG are working on two additional projects. The first is a survey looking at disparities in healthcare. This survey focused on how bundling has affected renal dietitians' practices. As more focus is placed on economics and outcomes, we, as a group, are looking at how this has affected your job and job responsibilities. Our hope is to utilize the information gathered to appeal to the Centers for Medicare & Medicaid Services (CMS) to assure adequate nutrition coverage. Our second joint project came from the desire for a Kidney Friendly Shelf in supermarkets. Instead of focusing on bringing the shelf to the public, the subcommittee found that there is a large need to educate corporate dietitians on the special nutritional needs and restrictions faced by our population. We hope to develop education materials for those dietitians who work not only at the corporate supermarket level, but also to those who work with food companies developing new convenience products. This is the first step in establishing the long desired Kidney Friendly Shelf.

Finally, this spring the joint CRN/RPG group will submit a proposal for a position paper regarding phosphorus. There has been a lot of research that now suggests that phosphorus not only affects the renal population but also the general population. The National Kidney Foundation met this winter to discuss phosphorus in the Chronic Kidney Disease (CKD) population. During these talks, those who attended reviewed the long and arduous process to bring phosphorus content back to the nutrition label. Additionally, the International Society of Renal Metabolism and Nutrition is holding a phosphorus consortium this summer at its biennial meeting to look at the global impact of phosphorus, specifically in the form of phosphate additives, on the renal and general populations. We are all hoping to make inroads to reducing phosphate and phosphate additive exposure not only to improve the lives of CKD patients, but our own.

On a personal note, I hope that many of you will read my CRN Chair message in the July issue of the Journal of Renal Nutrition. It was a very personal experience and I wrote it with tears in my eye and great happiness in my heart. For those of you who are unable to read it, please contact me and I will send you a copy (lisa.gutekunst@davita.com).

Wishing you all a great spring with lots of flowers!

The Renal Dietitians Practice Group (RPG) is expanding our Executive Committee to improve our member benefits!

Congratulations and Welcome to the Newly Appointed Executive Committee Members!!

Public Policy Chair
(formerly Legislative Chair)
Sarah Mott, MS, RD, LDN

Member Outreach Services Chair
(expanded role)
Nilima Desai, MPH, RD, LD

Mentor Chair
(new position)
Mary Kay Hensley, MS, RD, CSR

Kidney Friendly Foods Initiative Chair
(new position)
Lindsey Zirker, RD

Social Media Chair
(new position)
Sarah Coffin, MS, RD

Webinar Chair
(new position)
Annamarie Rodriguez, RD, LD

Website Updates Subcommittee Chair
(new position)
Erin Nelson, MPH, RD, LD

Handouts Subcommittee Chair
(new position)
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Vision: RPG members are a valued source of expertise in nephrology nutrition.

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RNF Guidelines for Authors

Article length:
Article length is determined by the Editor for each specific issue. The feature article (including abstract) is approximately 3000 words (not including tables/graphs). Other articles are usually 1000-1500 words; member highlights and reports are approximately 400-500 words.

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

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

References:
References should be cited in the text in consecutive order parenthetically. At the end of the text, each reference should be listed in order of citation. The format should be the same as the Journal of the Academy of Nutrition and Dietetics.

Reference citation examples:
Article in periodical:
Knower WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Eng J Med.* 2002;346:393–403.

Book:
Institute of Medicine. *Dietary Reference Intakes: Applications for Dietary Assessment*. Washington, D.C.: National Academy Press; 2001.

Chapter in a book:
Walsh J. Which insulin to use and how to start. In: Using Insulin. San Diego, Calif.: Torry Pines Press; 2003.

Web site:
Medscape drug info. Available at www.medscape.com/druginfo. Accessed August 15, 2011.

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

All submissions for publication should be submitted to the editor as an email attachment (MS Word file). The feature articles from the Renal Nutrition Forum will be posted on the Members Only Section of the RPG website (password protected). Thus, please include a brief abstract and 2-3 key words along with feature article submissions.

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