

**Report to Congress on
Medical Nutrition
Therapy**

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I. Introduction

This report conducts a further review of medical literature on the efficacy and effectiveness of medical nutrition therapy for certain diseases. Medical nutrition therapy (MNT) is comprised of the assessment of nutritional status and the provision of nutritional counseling by a licensed dietitian or nutritional professional. The first review of medical literature regarding MNT was conducted by the Institute of Medicine (IOM). In 2000, they published the report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly" that outlined the medical literature they found concerning the use of MNT for undernutrition, cardiovascular disease, diabetes mellitus, renal disease, and osteoporosis. IOM recommended that MNT should be covered by the Medicare program for the five conditions identified in its report; it should be provided by a dietitian or qualified nutrition professional; and that enteral and parenteral nutrition-related services continue to be a covered benefit.

When Congress made MNT provided by a qualified dietitian or nutrition professional a Medicare benefit, they selected two of the diseases reviewed in the IOM report for coverage: diabetes and renal disease, and required that DHHS make recommendations for extending coverage for nutritional assessment and counseling to other diseases. Our literature search for any articles regarding nutrition assessment and counseling was done on PubMed, a comprehensive listing of all available medical literature. In evaluating that literature, we ranked the literature from the highest, those that described randomized controlled trials to the lowest, editorials or articles based on anecdotal information. The ranking of the medical literature is based on the quality of the study using standards accepted in the scientific community and how well the findings will apply to the Medicare population.

In our current review, we found the same literature that was identified in the IOM report. Therefore, our review follows the same pattern as the IOM report. Enteral and parenteral nutrition or the types of nutrition professionals are not covered in this report, however, because the statute only directed us to make recommendations regarding MNT or nutritional assessment and counseling. We also reviewed the use of nutritional assessment and counseling in dialysis centers in response to a subsequent Congressional request.

II. Summary of Findings

We conducted an exhaustive medical literature search to determine the availability of literature about nutrition therapy for different diseases and found literature concerning the same diseases outlined in the IOM report. Cardiovascular disease is divided into hypertension, hyperlipidemia, and heart failure as it is in the IOM report. The literature for undernutrition focused almost exclusively on enteral and parenteral nutrition and was therefore, excluded from this review because the purpose of this report is to review the evidence regarding MNT. However, in response to interest from the American Dietetic Association, we did review the provision of MNT for cancer patients with undernutrition. At the request of Congress, we have included a review of nutritional assessment and counseling in dialysis centers. Our analysis and findings are based solely on the quality and amount of supportive evidence found in our medical literature search.

Our review suggests that there may be a benefit resulting from dietary modification using medical nutrition therapy for patients with hyperlipidemia and hypertension. Supportive studies were not found for patients with heart failure. We evaluated the nature of the interventions (counseling sessions) and outcomes (dietary modification and the effect on the symptoms of disease) in each of the studies. A large number of randomly controlled trials using dietitians or nutritionists demonstrated that dietary modification was effective in treating hyperlipidemia and hypertension. However, the studies were not designed to show if dietitian/nutritionist interventions were more effective than interventions provided by physicians during office visits. Two articles did state that there was evidence that dietary modification may be more successful when patients are counseled by dietitians/nutritionists (medical nutrition therapy) in addition to receiving dietary counseling routinely provided in physician office visits. We did not find supportive evidence for dietary modification in the treatment of osteoporosis or undernutrition for cancer patients in the medical literature.

Our research into the adequacy of MNT provided in renal dialysis centers found that the MNT provided in that setting was comparable to the MNT provided under the fee-for-service benefit.

The American Dietetic Association did provide comments to DHHS. They recommended that the MNT benefit be expanded (to cardiovascular disease, malnutrition, pharmacotherapy), and that DHHS be given the authority to further expand the benefit under the national coverage determination process. They also made a recommendation regarding reimbursement for MNT which is not covered in this report.

II. Background

Section 4108 of the Balanced Budget Act of 1997 included a provision that required the Secretary of the Department of Health and Human Services (DHHS) to contract with National Academy of Sciences to examine the benefits and costs associated with

extending Medicare coverage for some preventive services including MNT. As a result of that study, the Institute of Medicine (IOM) report, “The Role of Nutrition in Maintaining Health in the Nation’s Elderly” was published in 2000. The report examined the use of MNT for managing disease in beneficiaries with undernutrition, cardiovascular disease, diabetes mellitus, renal disease, and osteoporosis. It recommended that MNT should be a reimbursable benefit for Medicare beneficiaries.

Effective January 1, 2002, Congress created a Medicare benefit for MNT for beneficiaries with diabetes or a renal disease (except for those receiving dialysis) in section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA). MNT services are defined in statute as “nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician...” The benefit is further defined in CMS's final rule dated November 1, 2001 (CMS-1169-FC), as face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols. (The protocols currently recognized by CMS as nationally accepted are the protocols developed by the American Dietetic Association and the National Kidney Foundation.)

Enrollment of dietitians/nutritionists as a new provider group started in December of 2001 and Medicare contractors started paying Medicare claims for MNT for diabetes and renal disease for services provided on or after January 1, 2002, the statutory effective date.

BIPA also required the Secretary of the DHHS to recommend expansions of the MNT benefit to other Medicare beneficiary populations by July 1, 2003. This report fulfills that mandate. We also have included the results of our study of the adequacy of MNT provided to dialysis patients.

III. Diseases Reviewed

A. Undernutrition

The Institute of Medicine (IOM) report, “The Role of Nutrition in Maintaining Health in the Nation’s Elderly”¹ discusses undernutrition in terms of markers and syndromes. The markers they note are:

- Weight loss and morphometric measures of undernutrition,
- Poor nutritional intake, and
- Biochemical markers of malnutrition (albumin, transferrin, retinol binding protein).²

¹ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation’s Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.

² Ibid.

The syndromes noted are:

- Body composition changes with aging or sarcopenia,
- Cachexia,
- Wasting,
- Protein-energy undernutrition, and
- Failure to thrive.³

All of these conditions except for poor nutritional intake are not specific for undernutrition. They are symptoms of disease states such as cancer. In this report, we will focus on undernutrition for patients with cancer.

Malnutrition may be defined as a condition caused by inadequate intake or inadequate digestion of nutrients. It is a general term that indicates a lack of some or all nutritional elements, and may occur with various conditions, especially digestive conditions, malignancies and chronic infections. Malnutrition may range from mild with no symptoms to severe with considerable detriment to health.

In cancer, diet and nutrition play important roles in prevention and the subsequent treatments. Since dietary recommendations for cancer prevention are similar to general dietary recommendations, we will focus on malnutrition and nutrition services for patients diagnosed with cancer. Since weight loss and malnutrition are fairly common in patients with cancer due to the nature of the disease and treatments, weight loss may be considered a surrogate marker for malnutrition in some instances. It has been reported that “40% of cancer patients are already malnourished, before the onset of any medical or surgical treatment.”⁴

As noted earlier, the 2000 Institute of Medicine (IOM) Report, “The Role of Nutrition in Maintaining Health in the Nation’s Elderly” written by the Institute of Medicine is used as a baseline for this report.

We define undernutrition as inadequate nutrition from any cause. Undernutrition markers include weight loss, poor nutritional intake, and biochemical markers of malnutrition (albumin, transferrin, and the reinton binding protein). The weight loss for undernutrition has varying definitions that include the amount and duration of the weight loss.⁵ The IOM report uses a definition for outpatient settings of 10 pounds in 6 months, 4 to 5 percent of body weight in 1 year, or 7.5 percent of total weight in 6 months. For nursing home residents the Omnibus Budget Reconciliation Act of 1987 mandates the use of Minimum Data Set (MDS) and Resident Assessment Protocols (RAPs) to ensure prompt identification and response to problems in nursing home residents. The MDS defines undernutrition as weight loss that is greater than or equal to 5 percent of body weight in

³ Ibid.

⁴ Cohen and Lefor, 2001.

⁵ Ibid.

the past month or greater than or equal to 10 percent in the last 6 months.⁶ Involuntary weight loss is associated with an increased risk of mortality.⁷ The report also notes however, that no randomized clinical trial data had evaluated any relationships between nutrition therapy and better health outcomes.

Poor nutritional intake is defined as average or usual intake of servings of food groups, nutrients, or energy below recommended amounts. The IOM report states that poor nutritional intake is between 66 and 75 percent of the Recommended Dietary Allowance.⁸ Poor nutrient intake for patients translates into higher rates of in-hospital and 90-day mortality.⁹

As individuals age, nutritional assessment methods may be affected. Notable changes take place in body composition that also affect the nutrient requirements of older individuals. Not all changes have been shown to have a relationship with undernutrition.¹⁰

However, wasting is a direct result of poor dietary intake that results in weight loss.¹¹ Wasting is a clinically observed in patients with marasmus, cancer, advanced AIDS with opportunistic infection, critical illness without nutrition support, and chronic organ failure syndromes such as renal failure.¹² Treatment of wasting has focused on supplementing nutrient intake and drug therapy to stimulate appetite. However, the wasting and inability to accumulate lean body mass appears to be a result of the underlying disease process, not from poor dietary intake.¹³ Protein-energy undernutrition or PEU is defined by conditions like wasting and by biochemical markers such as albumin. Prealbumin has been shown to be of value in predicting mortality of patients in nursing homes. Treatment of PEU has focused on improving nutritional intake but there is no evidence to support this practice.

The IOM report notes that undernutrition is very common among hospitalized and nursing home residents. However, there is no evidence that the undernutrition resulting from aging and disease processes can be effectively treated with nutrition therapy or that increased normal nutrient intake (not enteral or parenteral nutrition) would be effective

⁶ Ibid.

⁷ Wallace JI, Schwarts RS, LaCroix AZ, Uhlmann RF, Pearlman RA, "Involuntary weight loss in older outpatients: Incidence and clinical significance." *J Am Geriatr Soc* 1995;43:329-337.

⁸ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.

⁹ Sullivan, et al., "Protein-energy undernutrition among elderly hospitalized patients: A prospective study." *J Am Med Assoc* 1999;47:710-715.

¹⁰ Baumgartner, et al., "Epidemiology of sarcopenia among the elderly in New Mexico." *Am J Epidemiol* 1998;147:755-763.

¹¹ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.

¹² Roubenoff, et al., "Standardization of nomenclature of body composition in weight loss." *Am J Clin Nutr* 1997;66:192-1966.

¹³ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.

treating the condition. We would also note, that the discussion of hospitalized patients is not pertinent to recommendations for outpatient care.

To review the literature on nutrition services for patients with cancer, we conducted a literature search using Medline (1996 to present) and the keywords malnutrition and cancer, and nutrition services and cancer. Numerous citations were found; however, there were no clinical trials that directly addressed nutrition services or tested nutritional interventions in patients with cancer. A large proportion of articles addressed enteral and parental nutrition, which are usually covered under the hospital inpatient DRG system. These articles were not considered for support of new services for patients with cancer.

Since there were no specific clinical trials on nutritional interventions in cancer patients and outcomes, review articles were also included in our study. Two reviews have stated that nutrition assessments and interventions would be prudent. In 1996 Mercadante reported that nutritional evaluation, counselling and adequate follow-up according to the progression of the disease are necessary before any nutritional intervention is planned.”¹⁴ In 2000, Nitenberg and Raynard reported that “a simple nutritional assessment and early counseling by a dietitian are essential to guide nutritional support and to alert the physician to the need for enteral (EN) or parental nutrition (PN).”¹⁵

In summary, there were no clinical trials that directly addressed nutrition counseling or services for patients with cancer. However, since malnutrition is common in cancer patients, early nutrition assessments and interventions may be prudent.

B. Cardiovascular Disease

The IOM Report, “The Role of Nutrition in Maintaining Health in the Nation’s Elderly” (2000) reported that Medical Nutrition Therapy (MNT) was recommended as part of the standard of care for Hyperlipidemia (described as Dyslipidemia in the IOM Report), Hypertension, and Heart Failure. In this section, we will focus our review on these three indications within the general category of Cardiovascular Disease and make recommendations regarding only these indications.

The literature search for the 2000 IOM Report is also used as a baseline for the literature search for this section of the report. In addition, we conducted a search of PubMed for medical literature published after the publication of the IOM report searching for meta-analyses and randomized controlled trials for hyperlipidemia and hypertension searching under the search terms nutrition and cardiovascular, nutrition and dyslipidemia, nutrition and lipids, nutrition and heart disease, and nutrition and hypertension. We also searched for clinical trials for the indication, heart failure. The results were limited using aged: 65+ years, human, English, and published after January 1, 1999. Studies evaluating the use of specific supplements and studies not related to evaluating the effects of nutrition

¹⁴ Mercadante, 1996.

¹⁵ Nitenberg and Raynard, 2000.

therapy on reducing the risks of heart disease or reduction in morbidity and mortality were not used. In addition, we reviewed articles supplied by the American Dietetic Association as part of their comments on this topic.

In our review, we were interested in studies where nutrition provided by a nutrition professional or a multidisciplinary intervention approach (usually including exercise, etc.) reduced blood pressure, lipids, evaluated compliance with medical instructions, or reduced mortality and morbidity due to heart disease.

Hyperlipidemia

The IOM report defines dyslipidemia (hyperlipidemia) as a high total cholesterol level as well as other abnormalities in blood lipid levels. Hyperlipidemia increases the risk of atherosclerotic cardiovascular disease. The relationship between high lipid levels and subsequent coronary heart disease has been documented in several major observational studies (Kahn et al, 1984; Martin et al, 1986; MRFIT, 1996; Shekelle et al, 1981). It has been generally noted that risk of coronary heart disease increases with high lipid levels. The IOM report also notes there is also an increasing body of evidence linking lipids to the occurrence of stroke.

Evidence related to the positive effects of drug therapy is stronger than the evidence showing that dietary intervention is effective in affecting hyperlipidemia. However, it has been suggested that many patients could reduce their lipid levels through nutrition therapy with a nutrition professional to the point that they no longer require medication. The IOM report noted that the National Cholesterol Education Adult Treatment Panels suggests that it might be possible to reduce the number of patients needing drug therapy in half (Carleton et al., 1991).

The report notes that there is substantial evidence from observational studies and from randomized clinical trials to support the use of nutritional therapy to improve lipid profiles and thereby prevent or delay cardiovascular disease in the elderly (Martin et al., 1986; Shekelle et al., 1981; Dayton et al., 1969; Downs et al., 1998; Lipid Research Clinic Program, 1984; Sacks et al., 1996; and Shepherd et al., 1995). The report also noted that nutrition therapy was advocated by guidelines prepared by the American Heart Association (Krauss et al., 1996); the National Heart, Lung and Blood Institute (LaRosa et al., 1990,1994).

As noted earlier, we conducted a search of articles and studies published after the publication of the IOM report. We found one meta-analysis and seven randomized controlled trials related to hyperlipidemia that were published after the IOM report analysis was completed.

In the meta-analysis (Ketola, et al., 2000), the main outcomes of interventions by nutrition professionals were reductions in cardiovascular morbidity and mortality. Reductions in risk factors for cardiovascular disease were also reviewed. Ketola found that studies reported on intermediate outcomes more than on the effects on morbidity and

mortality. However, they did find that both single and multifactorial life-style interventions (diet, exercise, smoking cessation, etc.) could reduce cardiovascular disease morbidity and mortality.

Ketola found that the quality of studies varied substantially. The number of participants varied a great deal by study. Dropouts were reported for most studies and excluded from the analyses. Of particular interest was the reporting that high-quality controlled studies with long follow-up times were rare and the widely varying outcome measurements made it hard to combine results. The combination of different interventions also made it difficult to separate the effects of nutrition therapy from other interventions. However, the MRFIT trial did reach statistical significance in morbidity and mortality after several years of follow-up.

Ketola also found that prevention programs targeted at pre-Medicare patients with undiagnosed cardiovascular disease had little effect on cardiovascular morbidity and none on mortality. The meta-analysis findings support use of preventive actions aimed at patients already diagnosed with coronary heart disease or others at high risk and had a beneficial effect on overall cardiovascular mortality.

None of the randomized control trials contradicted the findings of the IOM report. Some studies found that nutrition therapy had a short-term effect for weight loss but the reduction in fat intake could also be long term.¹⁶ Weight loss was an important intermediate outcome to determine reductions in cardiovascular risk factors for those under age 65.¹⁷ This supports the protocols provided to DHHS by the American Dietetic Association that recommend additional nutrition therapy in the years following the initial dietary intervention. Long-term interventions were found successful in inducing weight loss and improved cardiovascular risk factors.¹⁸ Of note were two studies that showed that dietary interventions by both physicians and dietitians for the same patients were even more effective.^{19 20}

¹⁶ Van der Veen, et al., "Stage-matched nutrition guidance for patients at elevated risk for cardiovascular disease: a randomized intervention study in family practice." *J FAM Pract.* 2002 Sep;51(9):751-8.

¹⁷ Flynn MM, et al., "Lipoprotein response to a National Cholesterol Education Program step II diet with and without energy restriction." *Metabolism.* 1999 Jul;48(7):822-6.

¹⁸ Metz JA, et al. "A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction." *Arch Intern Med.* 2000 Jul 24;160(14):2150-8.

¹⁹ Delahanty LM, et al., "Clinical and cost outcomes of medical nutrition therapy for hypercholesterolemia: a controlled trial." *J Am Diet Assoc.* 2001 Sep;101(9):1012-23.

²⁰ Hebert JR, et al., "A dietitian-delivered group nutrition program leads to reductions in dietary fat, serum cholesterol, and body weight: the Worcester Area Trial for Counseling in Hyperlipidemia (WATCH)." *J Am Diet Assoc.* 1999 May;99(5):544-52.

Hypertension

The IOM report defines hypertension as elevated blood pressure and notes that it is the most common and important risk factor for atherosclerotic cardiovascular disease in the general population and among Medicare beneficiaries.²¹ Approximately 50 percent of individuals age 65 or older have hypertension. Treatment of hypertension is very important for minority populations such as black women where nearly 80 percent over age 60 have hypertension.²² The report also notes that the evidence that elevated blood pressure is causally related to coronary heart disease, stroke, and kidney disease is strong and consistent.²³ McMahon (1990) summarized these studies and showed the relationship between blood pressure, stroke, and coronary heart disease is direct and graded as blood pressure increases.

The literature related to the positive effects of drug therapy is stronger than the literature showing that dietary intervention is effective in treating hypertension. This is true primarily because of the difficulty in not using drug therapy when it is available for such a serious condition. The normal approach to treating hypertension is to include lifestyle modifications such as changes in diet in addition to pharmacologic approaches. Non-pharmacologic approaches such as changes in diet are used as the initial therapy for Stage 1 hypertension²⁴ and as an adjunct to drug therapy.

The report notes that there is substantial evidence from observational studies and from controlled clinical trials to support the use of nutritional therapy to lower blood pressure. The intermediate outcomes of adoption of an overall healthy diet such as the Dietary Approaches to Stop Hypertension Trial (DASH) diet includes reduced salt intake, reduced alcohol intake, and increased potassium, magnesium, and calcium intake.

There is a preponderance of evidence as noted in the IOM report, that a high intake of salt adversely affects blood pressure. Three meta-analyses are noted that support this assumption: Cutler et al., 1997; Graudal et al., 1998; and Midgley et al., 1996. Intersalt Cooperative Research Group, 1988; and Khaw and Barrett-Connor, 1990 are observational studies that also support this assumption. Older individuals and African-Americans appear to be particularly sensitive to the effects of salt on blood pressure. The findings were shown to be applicable to the elderly in Whelton et al., 1998. The IOM report also noted that nutrition therapy for hypertension is recommended as part of the standard of care by the Working Group Report on Hypertension in the Elderly (National High Blood Pressure Education Program Working Group, 1994).²⁵

²¹Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, p. 100.

²² Ibid.

²³ Ibid, p. 101.

²⁴ Stage 1 hypertension refers to either a systolic blood pressure of 140 to 159 mm Hg or a diastolic blood pressure of 90 to 99 mm Hg (IOM report, p. 101).

²⁵ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, p. 106.

As noted earlier, we conducted a search of articles and studies published after the publication of the IOM report. We found six randomized controlled trials related to hypertension that were published after the IOM report analysis was completed.

None of the randomized control trials contradicted the findings of the IOM report. The primary outcome measured was a reduction in blood pressure. Secondary findings included reductions in risk for coronary heart disease, kidney disease, and stroke. Mortality was not addressed in the studies. Several studies found that a comprehensive lifestyle change can substantially lower blood pressure in patients also receiving drug therapy.^{26 27} While the measured effects were short term, other studies show that blood pressure reduction persists as long as participants adhere to therapy.^{28 29} Lifestyle modifications are also important in view of survey data that shows hypertension control rates of less than 27 percent nationwide.³⁰

Weight loss/dietary modification was an important intermediate outcome to determine reductions in cardiovascular risk factors for those under age 65.³¹ This supports the protocols provided to DHHS by the American Dietetic Association that recommend additional nutrition therapy in the years following the initial dietary intervention by dietary professionals. Long-term interventions were found successful in inducing weight loss and improved cardiovascular risk factors.³²

Some of the studies did not have participants over the age of 65 and a small number of participants that limited the value of the study.³³ The sample sizes for the other studies ranged from 45 to 459. Some of the studies did include individuals up to 70 years of age and are therefore considered applicable to the Medicare population. The interventions included more than nutritional counseling by dietary professionals. Therefore, the outcomes of the studies cannot be completely attributed to nutrition therapy, especially those including prepared meal plans.^{34 35}

²⁶ Miller ER, et al., "Results of the Diet, Exercise, and Weight Loss Intervention Trial (DEW-IT)." *Hypertension* 2002;40:p.616.

²⁷ Metz JA, et al. "A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction." *Arch Intern Med.* 2000 Jul 24;160(14):2157.

²⁸ Whelton PK, et al., "Sodium reduction and weight loss in the treatment of hypertension of older persons: a randomized controlled trial of nonpharmacological interventions in the elderly (TONE)" *JAMA* 1998;279:839-846.

²⁹ Steven VJ, et al., "Long-term weight loss and changes in blood pressure: results of the Trials of Hypertension Prevention, Phase II." *Ann Intern Med* 2000;134:1-11.

³⁰ Burt VL, et al., "Trends in the prevalence, awareness, treatment, and control of hypertension in the adult US population." *Hypertension* 1995;26:60-69.

³¹ Flynn MM, et al., "Lipoprotein response to a National Cholesterol Education Program step II diet with and without energy restriction." *Metabolism.* 1999 Jul;48(7):822-6.

³² Metz JA, et al. "A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction." *Arch Intern Med.* 2000 Jul 24;160(14):2150-8.

³³ *Ibid.*

³⁴ Hayes RB, et al., "Nutritionally complete prepared meal plan to reduce cardiovascular risk factors: A randomized clinical trial." *J of the Am Diet Assoc* Sept 1999;99(9):1077.

Heart Failure

The IOM report defines heart failure as a clinical syndrome resulting from damage to the heart that results in the heart pumping blood ineffectively. The condition is the most frequent cause of hospitalization among Medicare beneficiaries and is considered the most costly cardiovascular illness in the United States.³⁶ The vast majority of heart failure patients are the elderly.³⁷

Heart failure is typically treated with drug therapy and nonpharmacologic therapy to control symptoms, improve the quality of life, prolong survival, and prevent acute episodes requiring hospitalization.³⁸ The primary non-pharmacologic therapy is sodium restriction, as noted in the guidelines from the American College of Cardiology and the American Heart Association.³⁹ However, the IOM report notes that no trial has specifically tested the effects of nutrition therapy alone for heart failure patients.

The most common factor leading to acute episodes requiring hospitalization for urban African-Americans was nonadherence to medical regimen (diet and/or drugs) for 64 percent of patients admitted with heart failure.⁴⁰ Therefore, if nutrition therapy could change behavior for these patients, it would be very valuable in reducing hospitalizations.

The IOM report found that several small randomized clinical trials and a few observational studies supported the use of multidisciplinary programs (including nutrition therapy) to treat heart failure (Chapman and Torpy, 1997; Ghali et al., 1988; Rosenberg, 1971; Kortis et al., 1994; Rich et al., 1995; Stewart et al., 1999). They also noted that nutrition therapy is recommended as part of the standard of care in guidelines prepared by the American College of Cardiology and the American Heart Association.^{41 42}

As noted earlier, we conducted a search of articles and studies published after the publication of the IOM report. We found one randomized controlled trial (and no clinical trials) that related directly to our questions about nutrition and heart failure. We excluded

³⁵ Metz JA, et al. "A randomized trial of improved weight loss with a prepared meal plan in overweight and obese patients: impact on cardiovascular risk reduction." *Arch Intern Med*. 2000 Jul 24;160(14):2150.

³⁶ Rich MW, Nease RF, "Cost-effectiveness analysis in clinical practice. The case of heart failure." *Arch Intern Med* 1999;159:1690-1700.

³⁷ Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, p. 107.

³⁸ Ibid.

³⁹ Packer M, Cohn JN, eds., "Consensus recommendations for the management of chronic heart failure." *Am J Cardiol* 1999;83:1A-38A.

⁴⁰ Ghali JK, et al., "Precipitating factors leading to decompensation of heart failure. Traits among urban blacks." *Arch Intern Med* 1988;148:2013-2016.

⁴¹ Packer M, Cohn JN, eds., "Consensus recommendations for the management of chronic heart failure." *Am J Cardiol* 1999;83:1A-38A.

⁴² AHA (American Heart Association), *1999 Heart and Stroke Statistical Update*, Dallas, Tex:American Heart Association.

studies about renal dialysis, treatment of pressure ulcers, and the use of nutritional supplements.

The randomized controlled trial was a follow-up to the Lyon Diet Heart Study that evaluated relationships of dietary patterns and traditional risk factors for recurrence after a first myocardial infarction. The Lyon Diet Heart Study is a randomized, single-blind secondary prevention trial to test the Mediterranean type diet.⁴³ The randomized controlled trial found that the protective effect of the Mediterranean dietary pattern was maintained up to four years after the first infarction. However, the study failed to show a reduction in myocardial infarctions and did not prove that nutritional interventions could reduce the incidence of heart failure.

C. Osteoporosis

Osteoporosis is a bone disease that causes a patient's bones to become thin and fragile so that they can break during normal daily activities. Osteoporosis is also characterized by the structural deterioration of bone tissue. These broken bones, also known as fractures, occur typically in the hip, spine, and wrist.

Osteoporosis is a major public health threat for an estimated 44 million Americans. In the U.S. today, 10 million individuals are estimated to already have the disease and almost 34 million more are estimated to have low bone mass, placing them at increased risk for osteoporosis. Of the 10 million Americans estimated to have osteoporosis, eight million are women and 2 million are men. 34 million Americans, or 55% of the people 50 years of age and older, have low bone mass, which puts them at increased risk of developing osteoporosis and related fractures.⁴⁴

Among women, osteoporosis appears to have different rates of incidence in different ethnic groups. Five percent of non-Hispanic black women over age 50 are estimated to have osteoporosis; an estimated additional 35 percent have low bone mass that puts them at risk of developing osteoporosis. Twenty percent of non-Hispanic white and Asian women age 50 and older are estimated to have osteoporosis, and 52 percent are estimated to have low bone mass.⁴⁵

Osteoporosis generally affects fewer men than women and varies among different ethnic groups. Seven percent of non-Hispanic white and Asian men age 50 and older are estimated to have osteoporosis, and 35 percent are estimated to have low bone mass.

⁴³ DeLorgeril M, Salen P, Martin JL, Monjaud I, Delaye J, Mamelle N, "Mediterranean Diet, Traditional Risk Factors, and the Rate of Cardiovascular Complications After Myocardial Infarction." *Circulation* 1999;99:779-785.

⁴⁴<http://www.osteoporosis.org/newfile.asp?doc=fast&doctitle=Fast+Facts+on+Osteoporosis&doctype=HTML+Fact+Sheet>

⁴⁵<http://www.osteoporosis.org/newfile.asp?doc=fast&doctitle=Fast+Facts+on+Osteoporosis&doctype=HTML+Fact+Sheet>

Four percent of non-Hispanic black men age 50 and older are estimated to have osteoporosis, and 19 percent are estimated to have low bone mass. Three percent of Hispanic men age 50 and older are estimated to have osteoporosis, and 23 percent are estimated to have low bone mass.⁴⁶

Osteoporosis is responsible for more than 1.5 million fractures annually, including:

- 300,000 hip fractures;
- 700,000 vertebral fractures;
- 250,000 wrist fractures; and
- 300,000 fractures at other sites.

Although there are no symptoms of the disease the National Institutes of Health (NIH) has determined that there are risk factors that the public should take into consideration. Some of these risk factors include:

- Personal history of fracture after age 50
- Current low bone mass
- History of fracture in a 1st degree relative
- Being female
- Being thin and/or having a small frame
- Advanced age
- A family history of osteoporosis
- Estrogen deficiency as a result of menopause, especially early or surgically induced

The economic impact of this disease in the United States is costly. The estimated national direct expenditures (hospitals and nursing homes) for osteoporotic and associated fractures were \$17 billion in 2001 (\$47 million each day) - and the cost is rising.⁴⁷

Today there is no known cure for osteoporosis, therefore the osteoporotic suffer is limited to the use of various drugs that are prescribed, often to women, at the onset of menopause. There are medications that are also prescribed to men.

Due to the lack of a cure many experts suggest that prevention, by way of nutrition, would help alleviate the high incidence of osteoporosis. Vitamin D and calcium intake are the primary focus of the medical nutritionists to alleviate the burden of this disease. The area of medical nutrition therapy has increased the need to educate patients about what they can do to prevent the onset of the disease.

The IOM Report was one of the primary articles utilized to determine the need to review osteoporosis and medical nutrition therapy for the Medicare population. This report utilized articles from 1993 through 1999. This report utilized one consensus statement from the World Health Organization of 1994 and the National Osteoporosis

⁴⁶ Ibid

⁴⁷ Ibid

Foundation (1999) both of which were strongly supportive of incorporating nutritional interventions for osteoporosis. Of the 32 articles reviewed, 12 articles were used in the evidence summary that represented a strong opinion to support implementation of medical nutrition for osteoporosis. The remaining sources were review articles.

Klurfield (2001) evaluated the synergy between medical and nutrient therapies. He states in this review article that nutrients such as calcium, vitamin D, and others play an important role in this disease. He notes that weight management is an important factor that is often overlooked in the management of this disease. The author cautions the readers not to ignore the strong placebo effect associated with many alternative nutritional therapies.

The journal of Public Health Nutrition (2001), a British journal, recommends that a safe and effective way to reduce osteoporotic fractures is by increasing sunlight exposure⁴⁸ and providing the daily intake of 400-800 IU of vitamin D and a daily intake of 700-800mg of calcium. These recommended daily intakes are for those elderly living in Europe.

Bonjour and colleagues (2001) discuss the necessity of protein intake and bone growth. They state that there is a link to the bone mass in adolescence and the fracture rate in the elderly. The rate of bone growth is described as hereditary and genetic, and linked to bone mass in adolescents and to osteoporotic fracture in the elderly. They state that protein under-nutrition plays a key role in the rising incidence of hip fractures in the elderly. The importance of weight-bearing exercise along with increased protein intake is also stressed as an important combination to strengthen bones in adolescents.

The articles that were reviewed did not provide a clear treatment or preventive measure. The subjects that participated in each of reviews varied in age from adolescence to the elderly. It also seems that researchers have not fully agreed on what nutritional supplement, protein intake, calcium increase, or vitamin D contributes to bone creation and strengthening. Some proponents of strengthening bones state that this can only be done via weight-bearing physical exercise, which will strengthen the muscles surrounding the bone and make the bone less likely to fracture.

A literature search was performed using the criteria of medical nutrition and osteoporosis, osteoporosis and nutrition. The date range was from 2000 through 2003 to utilize the most current literature. The search was isolated to human subjects and English articles. The yield of usable articles was six articles that were specific to the relationship between osteoporosis and nutrition. None of the articles were based on randomized clinical trials (RCTs). None of the articles were based on clinical trials. One article, Blalock et al, was based on behavioral intervention and was comprised of a two by two factorial design, which insured that all levels of the intervention occurred with all other levels. The Institute of Medicine (IOM) Report was also utilized.

⁴⁸ Excessive exposure to sunlight may increase the incidence of skin cancer.

Not all proponents of medical nutrition therapy have agreed that the use of increased vitamin and mineral intake is the method by which to reduce the onset or prevalence of osteoporosis. The use of the increases in vitamin D, calcium, and protein are not universal specific amounts. In other words there is no agreement as to the doses to be given to alleviate the risk of this disease. In Europe as well as in America, the lack of sunlight may cause the fractures and having more time in the sun as well as having more vitamin D may decrease elderly patients' risk of osteoporosis. The use of calcium has long been the main focal point of regenerating bone mass, due to the calcium found in bones; however, the dosage needed to cause this regeneration of bone tissue is unclear. The FDA will not allow products to be labeled with the suggestion that the product will prevent osteoporosis due to its level of calcium.

Based on the literature reviewed by CMS, it is suggested that no single factor will influence the amount of osteoporotic fractures for the elderly. Although it is important to eat a diet that contains calcium, get enough sunshine and ingest the proper amount of vitamin D, the importance of heredity, ethnicity, gender, and predisposing factors during adolescence cannot be forgotten.

Currently there are large campaigns in effect to broaden the public's knowledge of the need for more calcium to strengthen their bones. The milk manufacturers in America sponsor many of these advertisements. Physiologically, bone development continues until the third decade of life, at which time bone formation begins to decline. In order for the literature to be sufficient to demonstrate the efficacy of calcium in the treatment of osteoporosis, it would be necessary for the literature to show that bone formation declines may be reversed by the intake of calcium or vitamin D, or even protein.

D. End Stage Renal Disease - Dialysis

The number of individuals with End Stage Renal Disease (ESRD) continues to grow in the United States. In 1999, 424,179 people were diagnosed with renal disease that resulted from diseases such as diabetes, hypertension, and glomerulonephritis.⁴⁹ The Government Accounting Office recently projected that the dialysis population will continue to grow at a 7 percent annual rate.⁵⁰ Nutrition therapy has always been a part of the treatment of individuals receiving maintenance dialysis.

When BIPA provided medical nutrition therapy coverage for patients with renal disease, it excluded renal patients who were receiving dialysis for which payment is made under section 1881 of the Social Security Act.⁵¹ Congress did not cover MNT for dialysis patients because dietary services are already provided to dialysis patients under the minimal service requirements at 42 CFR 405.2163. This regulation requires the attending physician and a qualified dietitian⁵² to evaluate the nutritional needs of dialysis patients. The dietitians are responsible for assessing the nutritional and dietetic needs of each patient, recommending therapeutic diets, counseling patients and their families on prescribed diets, and monitoring adherence and response to diets. However, no data was available concerning the quality of MNT services provided under the dialysis benefit. Congressional staff requested that DHHS conduct research to determine the adequacy of MNT provided as part of the renal dialysis benefit and include our findings in this report.

DHHS contracted with the University Renal Research and Education Association (URREA) at the University of Michigan to evaluate certain aspects of nutrition therapy provided to dialysis patients. While a long term study of outcomes associated with nutrition therapy would have been ideal, within the time available, we measured certain factors and compared them to how services are provided under the fee-for-service MNT benefit. A study called the Modification of Diet in Renal Disease Study (MDRD) found that the ratio of dietitians to participants and the frequency of contact had important implications for adherence to the dietary requirements which are believed to slow the progression of renal disease.⁵³ Therefore, we evaluated these and other factors to determine the amount of nutrition therapy provided (measured in time) to all dialysis patients. This amount was compared to the amount of medical nutrition therapy we currently cover for other renal patients (3 hours plus additional hours based on medical necessity). The study was not designed to compare nutrition counseling services provided to different types of renal patients.

⁴⁹ www.niddk.nih.gov/health/kidney/pubs/kustats/kustats.htm.

⁵⁰ GAO-04-63, October 2003.

⁵¹ Compilation of the Social Security Laws, Volume I, U.S. Government Printing Office, Washington:2001, section 1861(s)(2)(V)(ii), p. 1084.

⁵² 42 CFR 405.2102 defines a dietitian for the purposes of being considered a qualified dietitian in an ESRD facility as a person who is eligible to be a registered dietitian by the American Dietetic Association or has baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

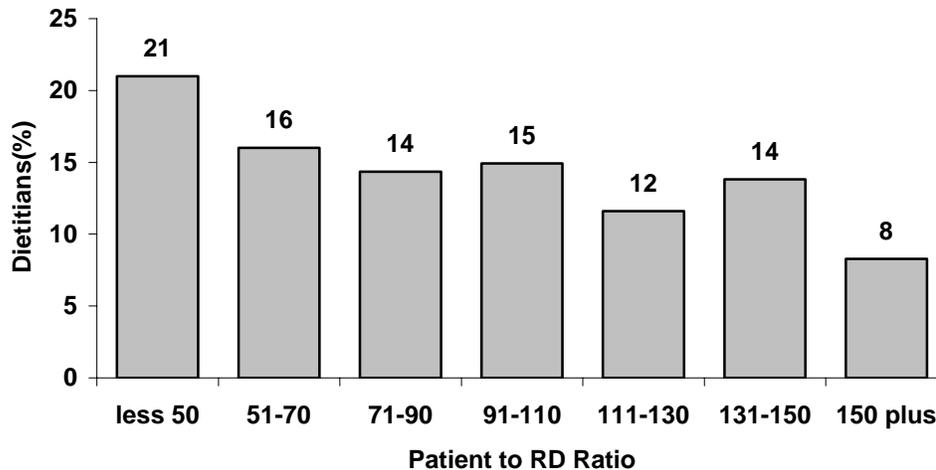
⁵³ Ibid.

The findings from URREA's report are included below.

Patient to Dietitian Ratio

As noted earlier, we used the patient to dietitian ratio as one of the most important measures in determining the adequacy of nutrition therapy in dialysis centers. Figure 1 shows the distribution of dietitian responses regarding the patient-to-Registered Dietitian (RD) ratio. Almost half of the dietitians (49%) reported ratios of 90 or more patients per RD. This included hemodialysis and peritoneal dialysis patients combined. The mean ratio was 94 patients per RD and the median was 90, with a range of 20-280 patients per RD. However, it should be noted that our patient to dietitian ratios include part time dietitian work. In the industry, those figures are typically based on only full-time employees.

Figure 1: Patient to dietitian ratio for hemodialysis and peritoneal dialysis patients combined⁵⁴



Total Dietitian Time at a Dialysis Facility

When considering the appropriateness of nutrition therapy in dialysis centers, we determined that we should measure the amount of dietitian resources by measuring the total hours per week registered dietitians spend providing dietetic services dialysis facilities (Figure 2A). More than half of the facilities (54%) had at least a half-time dietitian (≥ 20 hours per week), and 5% of the dietitians reported spending more than 40 hours per week at a dialysis facility. The mean was 25.3 hours per week, and the median

⁵⁴ University Renal Research and Education Association (URREA) CMS contract 500-00-0028, Task Order No. 0001, "MNT Survey of Renal Dialysis Centers", Ann Arbor, MI, March 2003, p. 6.

was 24 hours. The responses ranged from 4-60 hours per week. There was a linear relationship between the patient-to-dietitian ratio and the total hours per week a dietitian spent at a dialysis facility (Figure 2B and Table 3). Dietitians in the highest tertile (>110 patients per dietitian) spent twice as much time, on average, at a dialysis facility than dietitians in the lowest tertile (<65 patients per dietitian).

Figure 2A: Total hours per week of dietetic services provided at a dialysis unit⁵⁵

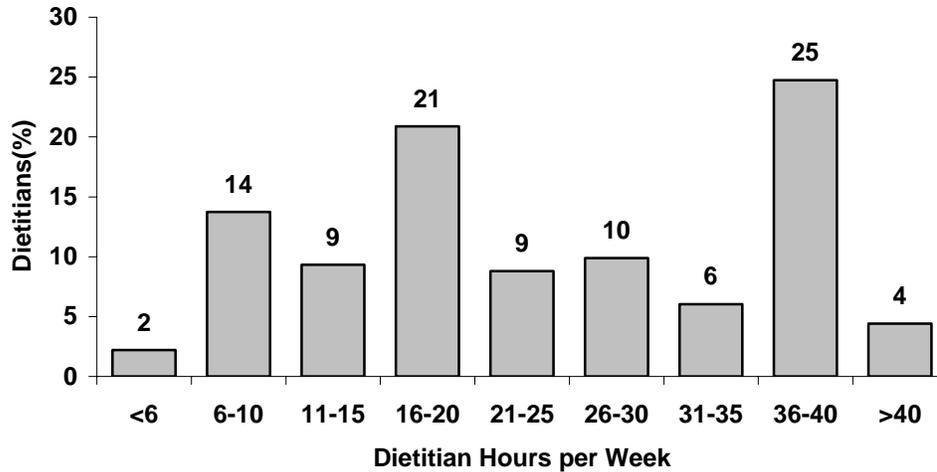
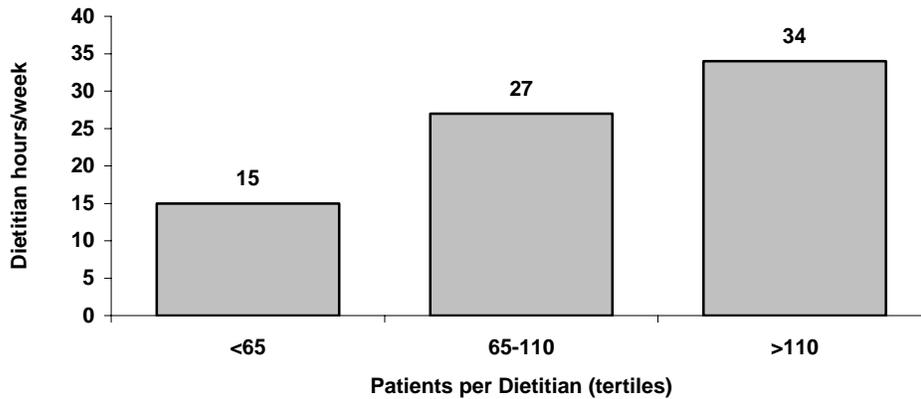


Figure 2B: Dietitian hours per week by tertiles of patient-to-dietitian ratio⁵⁶



⁵⁵ Ibid., p. 7.

⁵⁶ Ibid.

Face-to-Face Patient Contact Time

As a quality issue, we were concerned with the amount of time that dietitians spend in face-to-face interactions with patients. Several data elements characterizing patient interactions were measured. Figure 3 illustrates the distribution of dietitian visits per year for the average chronic in-center hemodialysis (CHD) patient and chronic peritoneal dialysis (CPD) patient. Approximately 68% of the dietitians reported that their CHD patients received 30 visits or less per year (i.e., ≤ 2.5 visits per month). The mean number of visits per year for CHD patients was 28 and the median was 24, with a large range of 4-78 visits per year. In contrast to CHD patients, 95% of the dietitians reported that their CPD patients receive 20 visits or less per year. Both the mean and the median for CPD patients was 12 visits per year, with a range of 1-52.

Figure 3: Number of visits the average dialysis patient receives per year⁵⁷

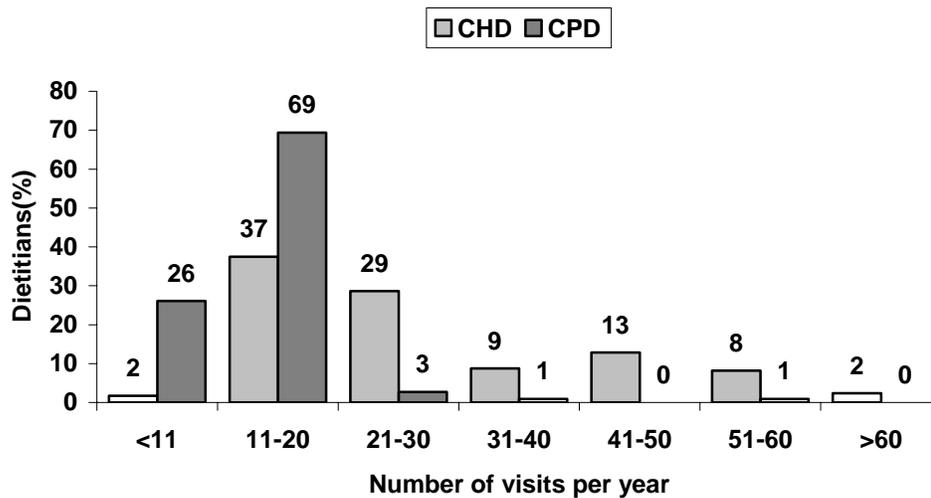
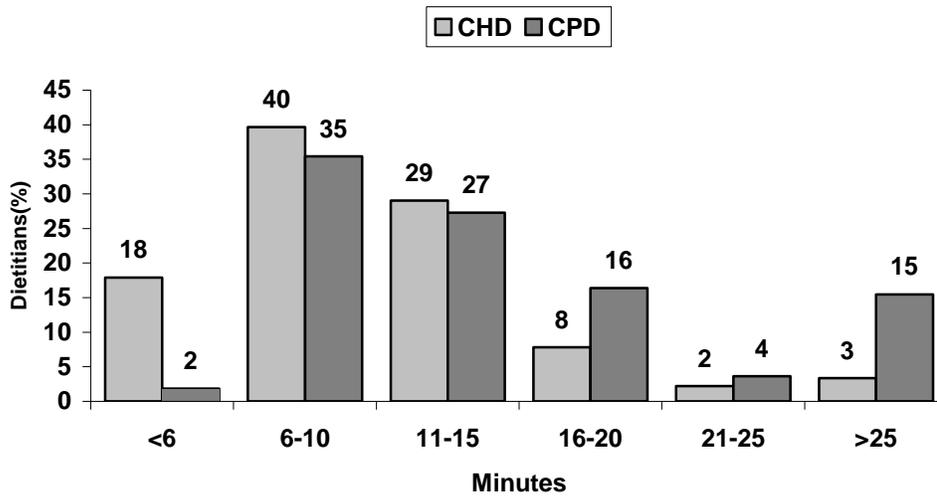


Figure 4 shows the average time spent by dietitians in face-to-face interactions with dialysis patients during a typical visit (excluding initial comprehensive assessments). Not surprisingly, it appears that CPD patients receive longer, but fewer, dietitian visits per year compared with CHD patients. This is not unexpected because the CPD patients who receive dialysis at home come into the facility less frequently than those receiving dialysis in the Center. The median face-to-face contact time was 15 minutes for CPD patients and 10 minutes for CHD patients per typical dietitian visit.

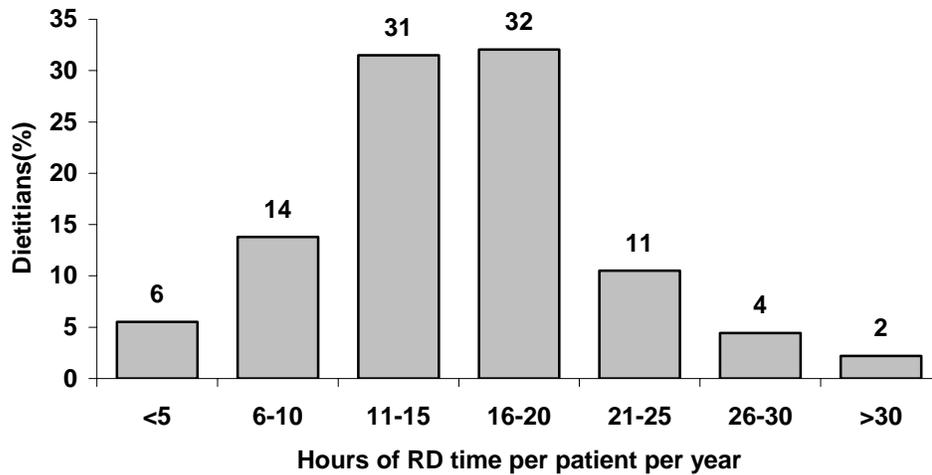
⁵⁷ Ibid., p. 8.

Figure 4: Average face-to-face contact time between dietitian and patient per typical visit (excluding initial comprehensive assessments)⁵⁸



We estimated the total hours of dietitian time per patient per year using both the total hours of dietitian time per week at a dialysis facility and the patient-to-dietitian ratio (Figure 5). The mean and median time was 15 hours per patient per year, with a range of 2-38 hours.

Figure 5: Total hours of dietitian time per patient per year⁵⁹



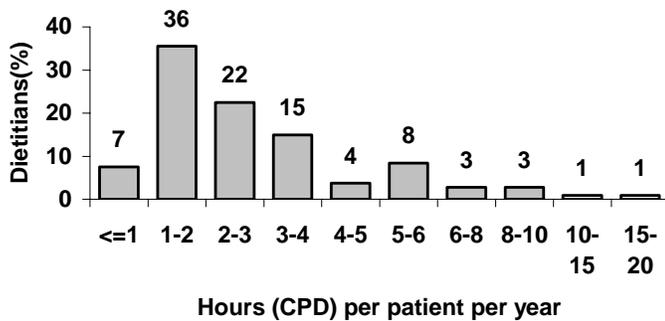
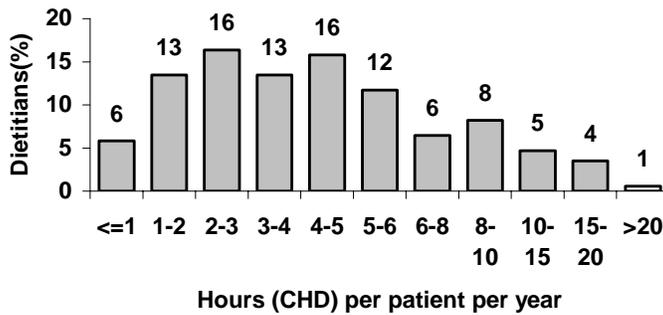
⁵⁸ Ibid., p. 9.

⁵⁹ Ibid., p. 10.

This total dietitian time per patient per year includes face-to-face contact time, as well as other activities that indirectly relate to patient care. More than half of the dietitians reported that they spent 50%-55% of their time in face-to-face activities and the remainder of their time on activities such as care planning, chart documentation, CQI initiatives, meetings, and other administrative duties. Furthermore, 85% of the dietitians reported that chart documentation was done on a monthly basis for CHD patients.

Perhaps of greater importance is the total face-to-face contact time per patient per year. In order to calculate this information, we used the number of visits per year per patient (Figure 3) and the reported face-to-face contact time per visit (Figure 4). Figure 6 shows that the total face-to-face contact time per patient per year was typically less for CPD patients compared with CHD patients. The mean was 5.3 hours and the median was 4.2 hours, with a range of 0.6-24 hours per CHD patient per year. In comparison, the mean was 3.3 hours and the median was 3.0 hours, with a range of 0.25-17.5 hours per CPD patient per year.

Figure 6: Hours of dietitian face-to-face contact time per patient per year (excluding initial comprehensive assessments)⁶⁰

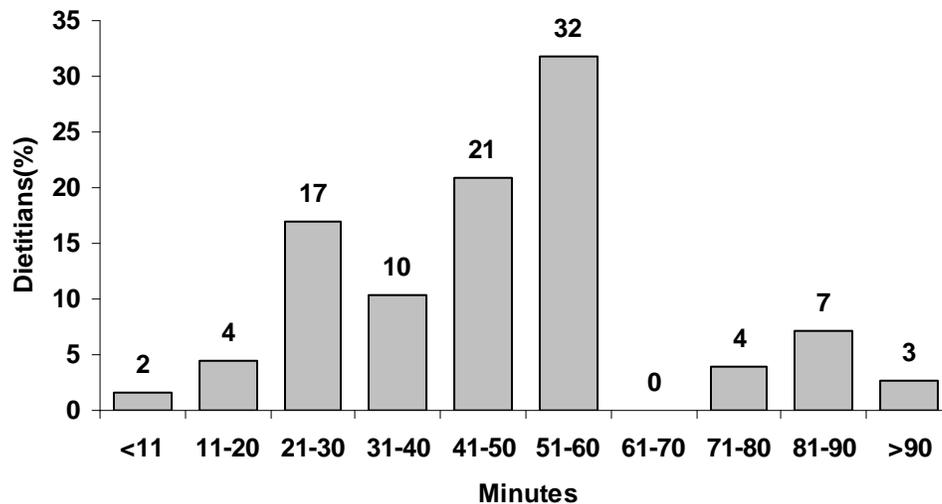


⁶⁰ Ibid., p. 11.

Comprehensive Initial Evaluations

The statistics reported thus far have been for the typical routine follow-up visits between dietitians and dialysis patients. For the longer comprehensive assessments that are initially performed for new patients, a separate series of questions was asked. The dietitians reported a mean of 45 and a median of 38 comprehensive initial assessments performed in the last year. Figure 7 shows the average time spent with a patient during an initial assessment. The mean number of minutes per comprehensive assessment was 51 minutes, with a median of 45 minutes and a range of 10-120 minutes.

Figure 7: Average time spent with a patient during a typical comprehensive assessment⁶¹



Nutrition Assessment Tools

Table 2 shows the type of measures most commonly used by dietitians to assess nutritional status. The most commonly used indicators were the clinical measures most readily available at dialysis facilities.

⁶¹ Ibid.

Table 2: Tests for nutritional assessments⁶²

Nutritional Assessment	% Yes
Body weight	100.0
Serum potassium	100.0
Serum phosphorus and calcium	100.0
Serum albumin	99.3
Dietary interviews and food diaries	98.0
Blood Urea Nitrogen (BUN)	97.3
Intact parathyroid hormone (iPTH)	95.3
Serum cholesterol	86.4
Serum creatinine	83.8
Percent of standard (NHANES II) body weight	70.1
Predialysis or stabilized serum albumin	59.5
Protein Equivalent of Total Nitrogen Appearance or Protein Catabolic Rate	49.3
Anthropometric measurements	48.7
Subjective global assessment	45.3
Serum pre-albumin	16.9
Creatinine index	5.6
Dual energy x-ray absorptionometry (DEXA)	1.4

*Nearly identical results were seen when restricted to one respondent per facility.

Laboratory Measures

Laboratory measures are an important aspect of nutritional assessment, especially for dialysis patients where these values must be carefully monitored. Figures 8-10 show the distribution of patients within certain ranges of serum albumin, phosphorus, and potassium. For serum albumin, 70% of the dietitians reported that their facility used the Bromocresol green (BCG) test and 11% used the Bromocresol purple (BCP) test. The remaining dietitians (19%) reported that they did not know which test was used at their facility.

⁶² Ibid., p. 12.

Figure 8: Mean percent of patients within indicated serum albumin ranges, by laboratory method⁶³

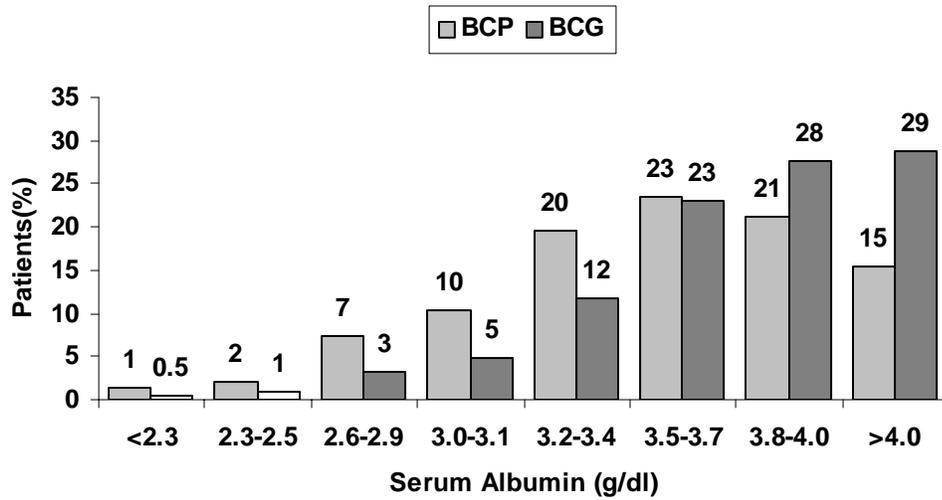
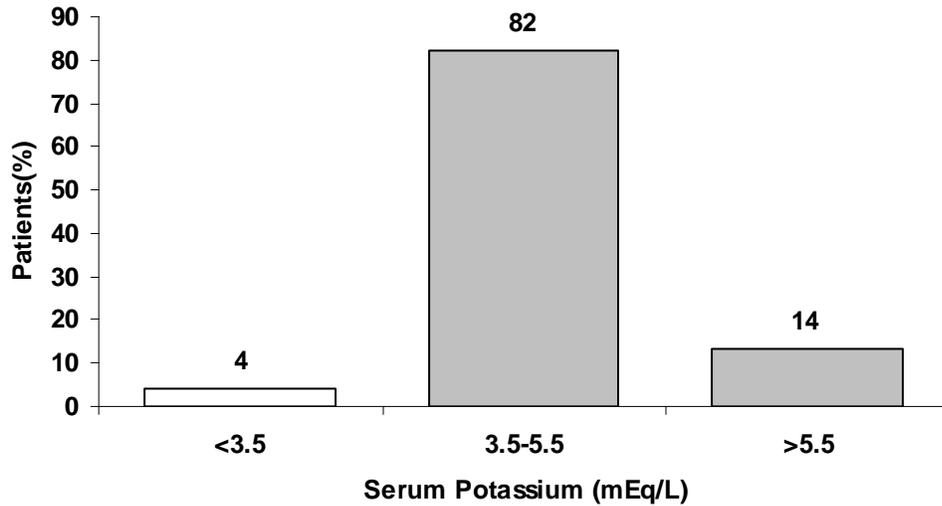


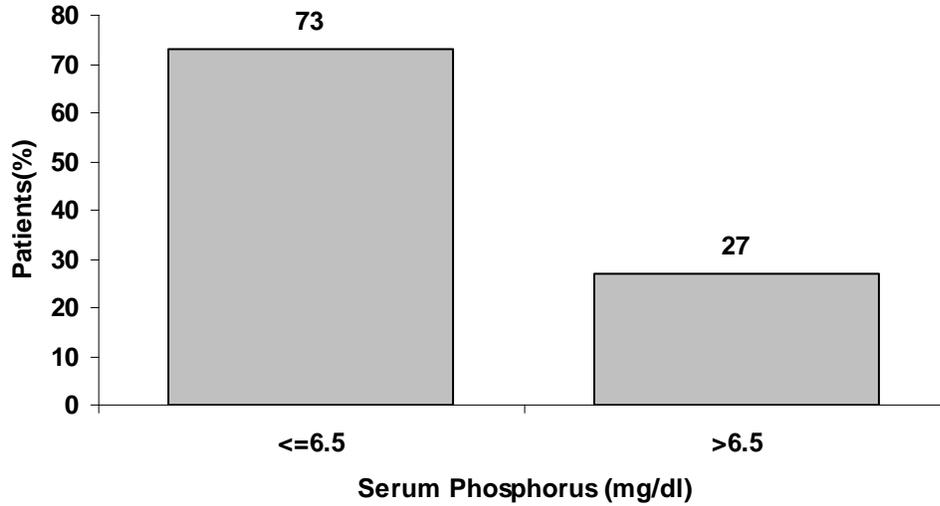
Figure 9: Mean percent of patients within indicated serum potassium ranges⁶⁴



⁶³ Ibid., p. 13.

⁶⁴ Ibid., p. 13.

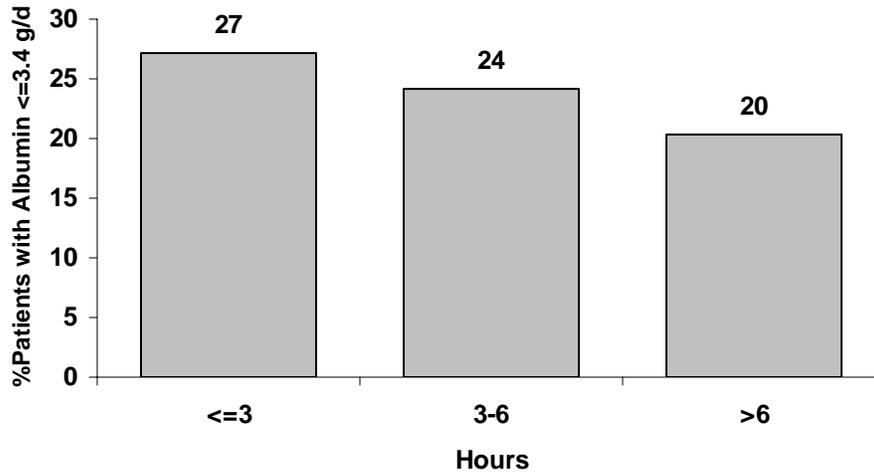
Figure 10: Mean percent of patients within indicated serum phosphorus ranges⁶⁵



We analyzed the association between several of the MNT parameters described above (e.g., number of visits, duration of visits, face-to-face contact time) and the mean laboratory values reported in Figures 8-10. A statistically significant association was observed between total face-to-face contact time and serum albumin values. Figure 11 shows that, in a categorical model, greater face-to-face contact time (i.e., >6 hours compared with ≤ 3 hours) is associated with fewer patients having a low albumin value of ≤ 3.4 g/dl ($P < 0.04$).

⁶⁵ Ibid.

Figure 11. Association of dietitian face-to-face contact time per CHD patient per year and percent of CHD patients with albumin value ≤ 3.4 g/dl.⁶⁶



In the continuous face-to-face contact time model, each hour increase in contact time was associated with a -0.50 change in the percentage of patients with albumin ≤ 3.4 g/dl ($p=0.10$).

Summary Descriptive Statistics of Dietitian Survey

Clearly, the size of the facility and the ratio of patients to dietitians affect many of the values reported on dietitian availability. Table 3 shows the summary of the statistics previously reported by tertile of patient-to-dietitian ratio (<65 , $65-110$, and >110 patients). The total hours per week a dietitian spends at a dialysis facility providing dietetic services increases as the patient ratio increases. More importantly, the total dietitian time per patient per year and the total face-to-face contact time per patient per year does not decrease significantly as the patient load per dietitian increases.

⁶⁶ Ibid., p. 14.

Table 3: Descriptive statistics of dietitian survey by tertiles of patient-to-dietitian ratio⁶⁷

Tertiles of Patient:RD Ratio	Variable	Mean	Med	SD	Min	Max
First (<65)	Total hours per week providing dietetic services	15.1	15.0	7.3	4.0	40.0
	%Time spent on assessments (face-to-face)	21.3	20.0	12.1	5.0	60.0
	%Time spent on intervention/education (face-to-face)	35.1	30.0	15.7	5.0	70.0
	%Time spent on care planning (not face-to-face)	23.7	20.0	15.9	5.0	75.0
	%Time spent on other activities (not face-to-face)	21.4	20.0	14.2	5.0	80.0
	Average time (minutes) of face-to-face contact between dietitian and CHD patient per visit	12.1	10.0	6.5	0.0	30.0
	# of visits the average CHD patient receives in one year	27.3	24.0	16.6	4.0	75.0
	Total # of comprehensive assessments performed in past year	30.5	22.0	25.6	2.0	150.0
	Avg time (min) per patient during comprehensive assessment	52.7	45.0	21.2	20.0	120.0
	Hours of RD time per patient per year	17.3	15.6	7.3	4.5	37.8
	Hours of RD face-to-face contact time/CHD patient/year	5.5	4.0	4.5	0.9	24.0
	Hours of comprehensive evaluations per year	25.0	18.8	19.3	2.5	93.8
Second (65-110)	Total hours per week providing dietetic services	26.7	25.5	10.2	8.0	45.0
	%Time spent on assessments (face-to-face)	20.6	20.0	10.8	5.0	50.0
	%Time spent on intervention/education (face-to-face)	36.9	35.0	14.6	8.0	75.0
	%Time spent on care planning (not face-to-face)	16.8	15.0	10.9	1.0	50.0
	%Time spent on other activities (not face-to-face)	27.4	25.0	18.6	2.0	83.0
	Average time (minutes) of face-to-face contact between dietitian and CHD patient per visit	11.3	10.0	4.8	2.0	25.0
	# of visits the average CHD patient receives in one year	30.4	24.0	16.4	12.0	78.0
	Total # of comprehensive assessments performed in past yr	41.0	30.0	30.0	2.0	150.0
	Avg time (min) per patient during comprehensive assessment	52.8	60.0	23.7	10.0	120.0
	Hours of RD time per patient per year	15.7	15.7	5.6	4.2	29.7
	Hours of RD face-to-face contact time/CHD patient/year	5.3	4.2	3.9	1.0	20.0
	Hours of comprehensive evaluations per year	37.4	25.5	32.9	0.3	162.5

⁶⁷ Ibid., p. 15.

Third (>110)	Total hours per week providing dietetic services	33.8	40.0	11.0	8.0	60.0
	% Time spent on assessments (face-to-face)	25.3	25.0	14.7	3.0	70.0
	% Time spent on intervention/education (face-to-face)	32.7	30.0	13.6	10.0	75.0
	% Time spent on care planning (not face-to-face)	15.7	10.0	11.0	3.0	60.0
	% Time spent on other activities (not face-to-face)	27.1	25.0	18.1	2.0	65.0
	Average time (minutes) of face-to-face contact between dietitian and CHD patient per visit	11.9	10.0	6.7	2.0	30.0
	# of visits the average CHD patient receives in one year	25.9	24.0	13.9	6.0	52.0
	Total # of comprehensive assessments performed in past year	62.9	51.0	47.7	1.0	240.0
	Avg time (min) per patient during comprehensive assessment	48.2	45.0	18.9	10.0	105.0
	Hours of RD time per patient per year	12.5	13.9	4.8	2.4	26.2
	Hours of RD face-to-face contact time/CHD patient/year	5.0	4.4	3.6	0.6	20.0
	Hours of comprehensive evaluations per year	51.9	38.8	45.7	0.2	217.5

Results are for both CHD and CPD patients, unless specified.

Discussion

Patient-to-Dietitian Ratio and Dietitian Time

The mean ratio observed in this study (94 patients per RD; range 20-280 patients) was lower than the currently recommended ratio of 100-150 patients per dietitian⁶⁸. However, 8% of the dietitians reported ratios of 150 patients or more per dietitian. Table 3 shows that as the patient-to-dietitian ratio increases, the total dietitian time per patient per year and the total face-to-face contact time per patient per year decreases. This may be an indicator that patients receive less interaction and individualized care in facilities that are less well staffed and where resources are more likely to be limited.

That this is a potential problem is supported by Figure 11, which shows that greater face-to-face contact time with dietitians may be associated with better serum albumin measures. Of course, there are many non-nutritional factors that may affect serum albumin measures, especially in the dialysis population, such as infection or inflammation, fluid overload, and anabolic or catabolic processes.⁶⁹ Therefore, this relationship may not be a causal relationship. Part of the relationship may be due to more frequent monitoring of laboratory data at facilities where there is greater patient interaction with dietitians.

⁶⁸ National Kidney Foundation, "K/DOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure." *AM J Kidney Dis*, 2000;35(6) Suppl2:S9-S10, and S17-S104.

⁶⁹ Pifer TB, et al., "Mortality risk in hemodialysis patients and changes in nutritional indicators:DOPPS." *Kidney Int*, 2002;62(6):2238-2245.

The results of this survey showed a wide variation for face-to-face contact between dietitians and dialysis patients. Mean face-to-face contact time for all dialysis patients was 4.4 hours per patient per year (median of 3.2 hours). This value was less for peritoneal dialysis patients (mean=3.3; median=3.0) and higher for chronic in-center hemodialysis patients (mean=5.3 hours, median=4.2). The recommended amount of face-to-face contact time for patients with diabetes and chronic renal insufficiency (i.e., excluding dialysis patients) per patient per year under the current MNT benefit is 3 hours (base) for the first year and 2 hours for all subsequent years. Additional hours are covered if deemed medically necessary by the treating physicians [4]. Given the greater severity of renal failure and complications of ESRD and dialysis, it is not surprising that the total hours of face-to-face contact time per dialysis patient per year is higher than the currently recommended levels for MNT benefit coverage for less severe stages of renal disease.

Nutrition Assessment

The most commonly used nutritional indicators listed in Table 2 were the tools most readily available at dialysis facilities (body weight and laboratory measures). Furthermore, these laboratory measures may have critical implications for dialysis patients if not carefully monitored (e.g., phosphorus, calcium, albumin, and PTH). It is clear from Table 2 that dietitians use a number of different nutritional indicators for assessment rather than one single indicator. This is in line with Guidelines 1 and 2 of the NKF-K/DOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure⁷⁰, which states the importance of utilizing a panel of nutritional markers to assess nutritional status. Many of the commonly used nutritional indicators have been shown to be highly predictive of ESRD patient outcomes.^{71 72} However, it is surprising that only 45% of the dietitians reported using subjective global assessment (SGA) as a measure of nutritional status. SGA, an evaluation that correlates subjective and objective aspects of a patient's medical history and physical examination, is an inexpensive and simple method to use and has been shown to be highly predictive of patient mortality and morbidity.^{73 74}

⁷⁰ National Kidney Foundation, "K/DOQI Clinical Practice Guidelines for Nutrition in Chronic Renal Failure." *AM J Kidney Dis*, 2000;35(6) Suppl2:S9-S10, and S17-S104.

⁷¹ Pifer TB, et al., "Mortality risk in hemodialysis patients and changes in nutritional indicators:DOPPS." *Kidney Int*, 2002;62(6):2238-2245.

⁷² Leavey SF, et al., "Simple nutritional indicators as independent predictors of mortality in hemodialysis patients." *Am J Kidney Dis*, 1998;31:997-1006.

⁷³ Pifer TB, et al., "Mortality risk in hemodialysis patients and changes in nutritional indicators:DOPPS." *Kidney Int*, 2002;62(6):2238-2245.

⁷⁴ McCann L, "Subjective global assessment as it pertains to the nutritional status of dialysis patients." *Dial Transplant*, 1996, 25:199-202.

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