I, Megan E Coleman, hereby submit this original work as part of the requirements for the degree of Master of Science in Nutrition.

It is entitled:
Oral supplements and serum albumin levels in dialysis patients as a function of food insecurity

Student’s name: Megan E Coleman

This work and its defense approved by:

Committee chair: Debra Ann Krummel, Ph.D.
Committee member: Heather Duncan, Ph.D.
Abstract

Oral supplements and serum albumin levels in dialysis patients as a function of food insecurity

Background: Food insecurity, defined as access by all people at all times to have enough food for an active life, is associated with many chronic diseases that affect Americans annually. These include heart disease, cancer, stroke as well as chronic kidney disease and end stage renal failure. A food security survey can be used in the dialysis centers to determine patient’s access to food and help health care professionals understand the importance of nutrition within this population. Providing or arranging access to oral nutrition supplements can improve overall nutrition status and help decrease food insecurity. In addition, oral nutrition supplements can decrease the food gap that is prevalent in patients on dialysis.

Purpose: The purpose of this study was to explore the relationship between access to food and oral nutrition supplements and blood albumin levels in patients receiving outpatient dialysis.

Study Design: Survey and Chart Review

Subjects: Participants were eligible if they were over the age of 18 years, English speaking, and had their blood albumin measured within 30 days of the study.

Location: The study took place in Cincinnati, OH at two DCI (Dialysis Center Incorporated) locations, McMillan and Western Hills.

Methods: The validated USDA survey was used to assess food security. Also, three additional questions were added pertaining to oral supplements.

Results: Associations were observed between measured variables and food security scores and albumin levels. Race, gender, access and location showed no relationship to food security scores. Age was inversely correlated to food security score. An increase in household members corresponded to an increase in food security scores. In regards to albumin, there was no relationship between albumin levels, food security score, and consumption of oral supplements. Albumin was significantly related to the number of oral supplements consumed, gender, access and age. A greater proportion of patients consuming supplements had inadequate albumin levels. Patients using Medicaid to receive their oral supplements had lower average albumin levels than those who were self-pay or received supplements through donations. Additionally, patients who were >60 years of age were also more likely to have lower average albumin levels. In regards to gender, men had higher mean albumin levels than females. None of the aforementioned variables were significant predictors of albumin levels.

Conclusions: 85 participants, Mean age, 58 +/- 11, 48.2% Male, 51.8% Female, 90.6 % African American, 9.4% Caucasian. Mean food security score- 1.8. 44.7% consumed some form of nutrition supplement, with the majority consuming 1 per day (55.3%). Mean albumin- 3.79mg/dL. 39% had albumin levels (4.0mg/dL or greater) and 61% had albumin levels (3.9mg/dL or less).
Acknowledgements

First and foremost, I would like to thank my parents, Brian and Michele Coleman, for their continued support since I began my educational journey. They are both inspiring role models that I look up to and strive to become every day. I would also like to thank my employer, Lincare, for the financial support and opportunity to complete my master’s degree, while working full time. They have been my backbone to this program and without their flexibility; I would not have been able to pursue this degree. To friends and faculty from The University of Cincinnati, thank you for the continued support and education to challenge me to complete my master’s degree. To Dr. Duncan, thank you for serving on my committee and allowing me to complete my research with the DCI location’s and the guidance in the preparation of this thesis. And finally to my committee chair and advisor throughout my graduate work at UC, Dr. Krummel, thank you for always challenging me; this thesis would not exist if it were not for your dedication, guidance, and participation.
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Introduction

The presence of hunger in American households due to insufficient resources to obtain food has been a long-standing challenge to U.S. health, nutrition, and social policy.\(^1\) Food security can be defined in many different ways, however, it is best defined as, “Access by all people at all times to have enough food for an active, life”.\(^1\) On the other hand, food insecurity can be defined as a limited or uncertain availability of nutritionally adequate and safe foods or limited or uncertain ability to acquire acceptable foods in socially acceptable ways.\(^1\) The United States Department of Agriculture (USDA) has divided food insecurity into two separate categories. These two categories include low food security, “reduced quality, variety, or desirability of diet but little or no indication of reduced food intake” and very low food security, “multiple indications or no indication of reduced food intake”.\(^2\) In the last decade, policies have been implemented to ensure that every American has enough to eat.\(^1\) Food insecurity is associated with many chronic diseases and has become increasingly common in the dialysis population. Renal health care professionals should assess patients for possible food insecurity so that appropriate interventions can be implemented.\(^3\)
Review of the Literature

Household Food Security in the US

Evidence of rising amounts of food insecurity in the United States in the early 1980s motivated the president, Ronald Reagan to form an advisory committee to assess the scope of the problem and make recommendations for improving food assistance programs.\(^4\) This was the first time food security was reviewed at a national level and since then many different organizations have implemented plans and goals to improve overall food security. According to recent national estimates, 85.4\% of US households were food secure throughout the year 2008. However, 14.6\% of households representing 49.1 million people experienced food insecurity sometime during the year of 2008, due to resource constraints.\(^4\) Of all US households 8.9\% of them (10.4 million households) experienced low food security and another 5.7\%, representing 17.3 million people experienced very low food security.\(^4\)

In most households, children, especially younger children, were protected from hunger by older members of the households, especially the mother. Overall, 1.1 million or approximately 1.5\% of US children lived in house-holds classified as very low food security. Over the years, the estimates for households at risk for food insecurity include households with incomes below the in-come-to-poverty ratio, households with children headed by a single woman or man, households headed by a black non-Hispanic (25.7\% of households) or Hispanic (26.9\% of households); and households located in principal cities (17.7\% of households).\(^5\) Low food security is more common than very low food security, but individuals may avoid falling in the very low food security category if they (1) eat less varied diets; (2) participate in federal food and nutrition assistance
programs; and or (3) obtain emergency food from community food pantries, emergency kitchens, and shelters.⁴

**Household Food Security in Ohio**

According to an article discussing the state of Ohio’s food security status, 15.5 percent of the state’s population was food insecure in the year 2012. This 15.5 percent equates to approximately over two million people. One should also note- that 6.4 percent of the food insecure Ohioan’s are very low food secure. Currently, Ohio ranks 11th amongst the US states for low food security and eighth for very low food security.⁶ In regards to the locations of food insecurity in Ohio, the following five counties make up the top food insecure: Pike, Athens, Lucas, Cuyahoga and Scioto. To date, Ohio averages a 1.5% increase per year of individuals becoming food insecure. Even though that percentage seems small, the overall nation’s food security percentage has not change or increased in recent years, but Ohio data shows annual increases.⁶ In addition, previous data shows that one in ten households experienced low food security sometime between the years of 1996-1998. Since then, low food security in Ohio has increased by almost 60% and very low food security has increased over 88%.⁶

**Defining Food Security**

Food security metrics may focus on food availability, access, utilization, the stability of food security over time, or some combination of these domains.⁴ Food security status of each household is characterized into four different categories developed by the USDA. The four categories include: high food security, marginal food security, low food security and very low food security. The table below describes the definitions of each category according to the USDA.¹
### Table 1 Definition of Food Security

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High food security</td>
<td>Households had no problems, or anxiety about, consistently accessing adequate food</td>
</tr>
<tr>
<td>Marginal food security</td>
<td>Households had problems at times, or anxiety about, accessing adequate food, but the quality, variety, and quantity of their food intake were not substantially reduced.</td>
</tr>
<tr>
<td>Low food security</td>
<td>Households reduced the quality, variety, and desirability of their diets, but the quantity of food intake and normal eating patterns were not substantially disrupted.</td>
</tr>
<tr>
<td>Very low food security</td>
<td>At times during the year, eating patterns of one or more household members were disrupted and food intake reduced because the household lacked money and other resources for food</td>
</tr>
</tbody>
</table>

For most reporting purposes, USDA describes households with high or marginal food security as food secure and those with low or very low food security as food insecure. In order to determine the criteria of food security, a series of questions about behaviors and experiences associated with difficulty in meeting food needs are asked in a survey. The questions on most surveys cover a wide range of severity of food
insecurity. In order to determine food insecurity, households that answer at least three or more conditions of food insecurity are classified as food insecure, meaning that, they were at times unable to acquire adequate food for one or more household members. Reasons that one may be classified as insecure could be because they either had insufficient money to purchase food or the possibility that their food supply did not last. Households in the United States are surveyed by the Current Population Survey (CPS) which is presented in USDA's food security statistics¹. CPS not only surveys the US for food insecurity, but it also provides statistics for the US monthly unemployment rates, annual income, and poverty statistics¹. On average, 45,000 households respond to the food security questions and to questions about food spending. CPS also states that they interview many different households in order to be representative of all civilian households at state and national levels.¹ The USDA also has a food security questionnaire that is used for assessing food insecurity in households with children.

American Dietetic Association Position On Food Security

According to the American Dietetic Association, in order to eliminate food insecurity, interventions are needed. These interventions include adequate funding, utilization of food and nutrition assistance programs, inclusion of food and nutrition education in such programs and innovative programs to promote and support individual and household economic self-sufficiency.⁷ Food insecurity in children, adolescents, and adults has negative nutrition and non–nutrition-related outcomes. Some of these negative outcomes include substandard academic achievement, inadequate intake of key nutrients, poor health, increased risk for and development of chronic disease, poor disease management, and poor psychological and cognitive functioning.⁷ The American
Dietetic Association supports health professionals such as registered dietitians and dietetic technicians to play key roles in ending food insecurity and also recommends these health professionals to improve nutrition education, aid in research and help individuals access a safe, secure, and sustainable food supply.\textsuperscript{7}

**Food Security and Health Status**

Collectively, the literature demonstrates that food insecurity has negative nutrition and non-nutrition outcomes and underscores the potential negative implications of food insecurity on the health of citizens and residents of the United States and US healthcare costs.\textsuperscript{1} Health status, chronic disease incidence and risk, diabetes, overweight, obesity, school performance, and mental health are all related to food insecurity.\textsuperscript{1} Food insecurity is a preventable health threat.\textsuperscript{1} Therefore, it is imperative to document outcomes of food insecurity through collaborative research projects across the life course.\textsuperscript{1} In the study, “Household Food Insecurity is Associated with Adult Health Status” researchers evaluated the relationship between food insecurity and self-reported health status in adults. The U.S. Food Security Survey Module and the Short Form 12-item health survey were used to determine food security and health status. The study found that adults who were food insecure were more likely to report their health status as poor or fair.\textsuperscript{8} In addition, the food insecure participants scored significantly lower on physical and mental health than secure individuals.\textsuperscript{8}

**Food Security and Chronic Diseases**

Rates of chronic disease including heart disease, cancer and stroke, which account for more than 50% of all deaths each year, are higher in food insecure populations.\textsuperscript{9} Evidence shows that several chronic diseases tend to be more prevalent...
in food insecure individuals. A recent study that was released, reviewed this hypothesis. Individuals who were food insecure were more likely to report hypertension (45.1% compared to 29.5%), diabetes (15% compared to 9.3%), heart disease (13.5% compared to 6.8%) and metabolic syndrome (10.1% compared 4.4%). In addition, this study controlled for the demographic variables and high cholesterol, heart disease, and metabolic syndrome were all associated with individuals who were food insecure. These findings demonstrate a relationship between food insecurity and chronic diseases and postulate that food insecurity may play a role in developing one of these diseases.

**Food Security and Dialysis Patients**

To date, Wilson et al. published the only paper that assessed the prevalence of malnutrition and food security in hemodialysis patients. Ninety-eight participants from multiple Louisiana dialysis centers completed the 16-item food security questionnaire. Most of the participants (83.7%) were categorized as food secure, 7.1% were food insecure without hunger, and 9.2% were food insecure with moderate hunger. Thus, 16.3% of subjects were found to be food insecure. The Subjective Global Assessment (SGA) screening tool was used to assess nutritional status. The SGA includes assessment of physical parameters such as loss of subcutaneous fat in the shoulders, muscle wasting, edema, and ascites. From the SGA, patients are categorized as well-nourished, mild to moderate malnutrition, or severe malnutrition.

The results indicated that 64% of the subjects were mildly to moderately malnourished and another 13% were severely malnourished. Thus, the both food insecurity and malnutrition were observed in the hemodialysis population.
Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines

According to the KDOQI 2000 guidelines, individuals undergoing maintenance dialysis, who are unable to meet their protein and energy needs through food for a long period of time, should be supplemented with nutritional support.\textsuperscript{11} Research has shown that maintenance dialysis patients consume, on average eighty percent or less of their recommended energy intake, even when they are being followed by a registered dietitian.\textsuperscript{11,13,14} Inadequate energy intake may have a variety of causes which can include anorexia, inability to access or prepare food, psychiatric illnesses, mechanical impairments, such as lack of dentures, and cultural food preferences.\textsuperscript{11,13,14,15} It is recommended that nutritional counseling to increase protein and energy intake, oral nutritional supplements, and tube feeding, should be considered as the first line of defense to help improve overall nutritional intake in maintenance dialysis patients.\textsuperscript{11,13,14} Also, hemodialysis patients can be solely supplemented with oral nutrition products to improve intake and nutritional status.\textsuperscript{16}

One primary criteria used to determine nutritional status is the serum albumin level. In renal patients, the goal is to achieve a serum albumin greater than or equal to 4.0mg/dL.\textsuperscript{11} Serum albumin is a highly water-soluble protein, located mainly in the extracellular fluid. Levels below 2.5 g/dL have been associated with a 20 times higher risk of death compared to the reference level of 4.0 to 4.5 g/dL in patients undergoing hemodialysis: albumin levels of 3.5-4.0mg/dL (considered to be within normal ranges) were associated with doubling the risk of death.\textsuperscript{12} In addition, low levels of albumin may also indicate poor protein intake and impaired digestion and absorption.\textsuperscript{11} Today, registered dietitians use albumin as an indicator to assess protein status and typically
review this lab on a monthly basis, due to the half-life of albumin being approximately 20 days.

**Enteral supplement consumption and outcomes in dialysis patients**

Malnutrition increases morbidity and mortality risks in dialysis patients. The negative consequences of malnutrition can include chronic inflammation, a low quality of life, and complications that could lead to cardiovascular disease. Chronic inflammation in dialysis patients intensifies malnutrition. In regards to malnutrition and patients on dialysis, research shows that these patients do not have a sufficient energy-intake, have a depressed appetite, and poor mental status which can include depression and social issues. Oral nutrition supplements have been introduced into the dialysis setting in order to help improve depressed appetite, weight loss, albumin levels and overall nutrition status. Oral nutrition supplementation (ONS) is recommended if nutritional counseling does not achieve an increase in nutrient intake. ONS may also be recommended when a patient's protein or caloric intake does not meet his or her nutritional requirements. ONS vary in the content of protein, calories, carbohydrate, fat, potassium and phosphorus, meaning it is important to evaluate these parameters when choosing an appropriate ONS for a dialysis patient.

A recent study evaluated the relationship between oral supplement consumption and overall nutrition status. The study included 30 hemodialysis patients with protein calorie malnutrition and they were compared to 25 well-nourished hemodialysis patients. The malnourished dialysis patients were given an oral supplement and asked to take the supplement at a dose of 125 ml twice a day for 90 days, which is equivalent to one oral nutrition supplement per day. Nutritional status was compared between the two groups using the Subjective Global Assessment score, and biochemical data,
albumin and pre-albumin were assessed. The two group’s baselines were comparable at the beginning of the study. After the three months, the malnourished group receiving the oral nutrition supplement had an improvement in their overall nutrition status, pre-albumin and albumin levels. The controlled groups SGA scores were 7 points lower at the end of the study compared to the intervention group. Albumin was significantly different amongst the two groups in that the albumin levels in the intervention group were 3.9 +/-4.7 compared to 3.6 +/-2.4 at a P-value of <.05. This study showed that oral supplementation improves overall nutrition status and has an impact on the blood protein, albumin.

Healthy People 2020

In healthy people 2020, one goal for the next 10 year plan is to reduce household food insecurity and in doing so reduce hunger. Currently, statistics show that 14.6 percent of households were food insecure in the year 2008 and the new goal is to reduce food insecurity to 6 percent. Another initiative of Healthy People 2020 is to eliminate the category of very low food security among children. In 2008, data revealed that the current baseline for the US is 1.3 percent of households with children have very low food security. The new goal is to reduce this value to 0.2 percent. The method for reducing this statistic is through the consistency of national programs, regulation, policies and law. Many health professionals will be needed to address this goal, however, registered dietitians play a key role in approving and achieving this goal and helping eliminate food insecurity in the US.
**Null Hypotheses H₀:**

H₀₁- In dialysis patients, there is no relationship between food security score and location.

H₀₂ – In dialysis patients, there is no relationship between food security score and age.

H₀₃- In dialysis patients, there is no relationship between food security score and gender.

H₀₄- In dialysis patients, there is no relationship between food security score and race.

H₀₅- In dialysis patients, there is no relationship between food security score and household number

H₀₆ – In dialysis patients, there is no relationship between food security score and oral supplements.

H₀₇- In dialysis patients, there is no relationship between food security score and albumin.

H₀₈- In dialysis patients, there is no relationship between albumin and oral supplements

H₀₉- In dialysis patients, there is no relationship between albumin and (frequency) the number of supplements consumed

H₁₀- In dialysis patients, there is no relationship between albumin and access to oral supplements.

H₁₁- In dialysis patients, there is no relationship between albumin and age.

H₁₂- In dialysis patients, there is no relationship between food security score and insurance.

H₁₃- In dialysis patients, there is no relationship between Albumin and gender.

H₁₄. The proportion of patients who said that they consumed supplements is not related to the number of supplements reported.
Methods

Purpose

The purpose of this thesis was to study whether access to food and oral supplements affects blood albumin levels in patients receiving outpatient hemodialysis treatment. The study protocol was approved by the University of Cincinnati Institutional Review Board and the Dialysis Center Incorporated Administrative Review Office.

Participants

The study inclusion criteria included the following: being over the age of 18 years, ability to speak English, being a patient at one of the selected dialysis centers, and having a measured albumin level within the last 30 days. Participants were excluded from the study if they resided in a nursing home, or had active liver disease based on Alanine Aminotransferase (ALT) laboratory measurements. If the ALT concentration was three times the normal limit (108 U/L or greater), the participants were excluded. These levels were screened prior to the recruitment.

Screening

Patients in the dialysis centers used for the study were notified of the study via the monthly clinic newsletter. In many instances, they were also notified in person to determine their willingness to be consented and complete the survey. This “pre-screening” allowed the researchers to focus on patients willing to participate.

Data Collection

Patients who were interested were identified on a list for the researchers to approach for consenting. To prevent disruption in the dialysis unit, subjects were not interviewed during the changeover times in the unit.
The surveys were distributed at two Dialysis Center Incorporated (DCI) locations in Cincinnati, Ohio, DCI McMillan and DCI Western Hills. Due to prescreening of participants, data was able to be collected over 5 days in October 2013. Patients receiving hemodialysis during any shift, 6am to 5om Monday through Friday were screened for participation.

Prior to survey distribution, subjects completed informed consent and Health Insurance Portability and Accountability Act forms. Then all three researchers, (Megan Coleman, Dr. Debra Krummel and Dr. Heather Duncan), read (most cases) or handed out the surveys to the participants. During the week of the study there were approximately 160 patients receiving dialysis at the two locations and 86 patients completed the survey. From the 86 surveys completed, 85 were entered into the study. One patient was excluded due to elevated liver enzymes. Once the surveys were completed they were stored in a locked drawer in Dr. Krummel's lab, University of Cincinnati, French East room 201.

Survey

The survey used in this study was developed in 1995 by the United States Department of Agriculture. Questions were adapted from the U.S. Household Food Security Survey Module, refined through focus groups and cognitive interviews, and tested in a pilot survey. Questions pertaining to food security were scored using a validated chart designed by The National Center for Health Statistics. The original survey consisted of 7 questions. Demographic information such as age, gender, race, and dialysis location was added to the survey. Other questions that were added were related to household number, food purchasing, and consumption and access to oral
supplements. For access, participants were asked if they received supplements from Medicaid, self-pay or donations. Medicaid of Ohio covers oral supplements at one hundred percent.

The food security score was computed as described below. Responses of “often true” or “sometimes true” on questions 3 and 4, and “yes” were coded as affirmative, (yes). Responses of “almost every month” and “some months but not every month” were coded as affirmative, yes. DK (“don’t know”) and “Refused” are blind responses, meaning, they are not presented as response options but marked if volunteered. The sum of affirmative responses to the questions pertaining to food security was the household’s raw score on the scale. The raw score was categorized as show in Table 2 with the lowest scores indicating high food security and the highest scores indicating food insecurity.

**Table 2 Computation of the Food Security Score (USDA, Survey Tools)**

<table>
<thead>
<tr>
<th>Raw Score</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-1</td>
<td>High or marginal food security</td>
</tr>
<tr>
<td>2-4</td>
<td>Low food security</td>
</tr>
<tr>
<td>5-6</td>
<td>Very low food security</td>
</tr>
</tbody>
</table>

**Albumin**

Serum albumin levels were taken from the patients charts. A level of 4.0mg/dL was chosen as the prime level as research has shown that dialysis patients with albumin’s <4.0mg/dL have a greater risk of death.¹²
Data Analysis

IBM SPSS statistics (version 22, Chicago, IL) was used for all analyses. Descriptive analyses were completed. Pearson correlations were run to determine bivariate linear relationships between variables that were continuous variables. T-tests or one-way ANOVA with post hoc tests were used for comparisons of continuous variables between groups. A Kruskal-Wallis test was used to determine if samples originated from the same distribution. The proportions were analyzed using chi-square tests. Logistic regression was used to determine predictors of food security/insecurity. The significance level was set at P<0.05.
Results

Most of the sample were African-American and from the dialysis center located on McMillan Ave (See Table 3). There was no significant difference in any variables by dialysis center location.

Table 3 Demographic Information on Subjects

<table>
<thead>
<tr>
<th>Variable</th>
<th>DCI McMillan</th>
<th>DCI Western Hills</th>
<th>Sum of all Dialysis Centers</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N=62</td>
<td>N=23</td>
<td>N=85</td>
<td></td>
</tr>
<tr>
<td>Participants</td>
<td>72.9%</td>
<td>27.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>.629</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean age</td>
<td>59 +/- 12</td>
<td>58 +/- 11</td>
<td>58.6 +/- 1.27</td>
<td></td>
</tr>
<tr>
<td>&lt;50 years</td>
<td>16 (26%*)</td>
<td>5 (21%)</td>
<td>21 (24.7%)</td>
<td></td>
</tr>
<tr>
<td>&gt;51 years</td>
<td>46 (74%)</td>
<td>18 (79%)</td>
<td>64 (75.3%)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>.593</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>31 (50%)</td>
<td>10 (43%)</td>
<td>41 (48.2%)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>31 (50%)</td>
<td>13 (56%)</td>
<td>44 (51.8%)</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>59 (95%)</td>
<td>18 (78%)</td>
<td>77 (90.6%)</td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>3 (5%)</td>
<td>5 (12%)</td>
<td>8 (9.4%)</td>
<td></td>
</tr>
</tbody>
</table>

*N, (% of sample), all such values

Most participants purchased their own food and had high food security (See Table 4). There was no significant difference between blood albumin concentrations in subjects at the two dialysis center locations.
<table>
<thead>
<tr>
<th>Variable</th>
<th>DCI McMillan</th>
<th>DCI Western Hills</th>
<th>Sum of all Dialysis Centers</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household Number</td>
<td></td>
<td></td>
<td></td>
<td>.221</td>
</tr>
<tr>
<td>Mean household number</td>
<td>1.94 +/- 1.4</td>
<td>1.65 +/- .94</td>
<td>1.86</td>
<td></td>
</tr>
<tr>
<td>Food Purchaser</td>
<td></td>
<td></td>
<td></td>
<td>.208</td>
</tr>
<tr>
<td>Self</td>
<td>44 (70%)*</td>
<td>13 (57%)</td>
<td>57 (66%)</td>
<td></td>
</tr>
<tr>
<td>Significant other</td>
<td>5 (8%)</td>
<td>2 (9%)</td>
<td>7 (9%)</td>
<td></td>
</tr>
<tr>
<td>Relative</td>
<td>3 (5%)</td>
<td>0</td>
<td>3 (4%)</td>
<td></td>
</tr>
<tr>
<td>Combination</td>
<td>10 (17%)</td>
<td>8 (34%)</td>
<td>18 (21%)</td>
<td></td>
</tr>
<tr>
<td>Food Security Score</td>
<td></td>
<td></td>
<td></td>
<td>.968</td>
</tr>
<tr>
<td>Food Security Score</td>
<td>1.8 +/- 2.03</td>
<td>2.2 +/- 2.02</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>High Food Security</td>
<td>35 (56%)</td>
<td>10 (43%)</td>
<td>45 (53%)</td>
<td></td>
</tr>
<tr>
<td>Low Food Security</td>
<td>19 (30%)</td>
<td>9 (39%)</td>
<td>28 (33%)</td>
<td></td>
</tr>
<tr>
<td>Very Low Food Security</td>
<td>8 (14%)</td>
<td>4 (18%)</td>
<td>12 (14%)</td>
<td></td>
</tr>
<tr>
<td>Oral Nutrition Supplement</td>
<td></td>
<td></td>
<td></td>
<td>.273</td>
</tr>
<tr>
<td>Yes: Consuming</td>
<td>28 (45%)</td>
<td>10 (11.7%)</td>
<td>38 (44.7%)</td>
<td></td>
</tr>
<tr>
<td>No : Consuming</td>
<td>34 (55%)</td>
<td>13 (56.5%)</td>
<td>47 (55.3%)</td>
<td></td>
</tr>
<tr>
<td>Oral Nutrition Supplements</td>
<td></td>
<td></td>
<td></td>
<td>.995</td>
</tr>
<tr>
<td>Frequency</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 per day</td>
<td>12 (44%)</td>
<td>8 (80%)</td>
<td>20 (54%)</td>
<td></td>
</tr>
<tr>
<td>2 per day</td>
<td>8 (30%)</td>
<td>2 (20%)</td>
<td>10 (27%)</td>
<td></td>
</tr>
</tbody>
</table>
Age was significantly, inversely correlated to food security score (Table 5). Older adults had lower food security scores, meaning they were more food secure.

### Table 5 Pearson Correlations between Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Albumin</th>
<th>1 or 2 ONS/Day</th>
<th>Age</th>
<th>Household Number</th>
<th>FSS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Pearson Correlation</td>
<td>1 ( (N=85) )</td>
<td>-.350 ( (N=30) )</td>
<td>-.320** ( (N=85) )</td>
<td>-.092 ( (N=85) )</td>
</tr>
<tr>
<td>1 or 2 ONS/Day</td>
<td>Pearson Correlation</td>
<td>-.352 ( (N=30) )</td>
<td>1 ( (N=30) )</td>
<td>.186 ( (N=30) )</td>
<td>.073 ( (N=30) )</td>
</tr>
<tr>
<td>Age</td>
<td>Pearson Correlation</td>
<td>-.320** ( (N=85) )</td>
<td>.186 ( (N=85) )</td>
<td>1 ( (N=85) )</td>
<td>-.251* ( (N=85) )</td>
</tr>
<tr>
<td>Household Number</td>
<td>Pearson Correlation</td>
<td>-.092 ( (N=85) )</td>
<td>.073 ( (N=85) )</td>
<td>.251* ( (N=85) )</td>
<td>1 ( (N=85) )</td>
</tr>
</tbody>
</table>
There was a moderate negative correlation between age and albumin levels, with advanced age being associated with decreased albumin status. There was a weak positive association between age of participant and participant's household number, indicating older age was associated with less people living in the household. There was a weak negative correlation between food security score and age. This implies that younger participants were more likely to be food insecure as compared to older adults.

** Table 6 Food Security Score and Age **

<table>
<thead>
<tr>
<th>Variable</th>
<th>&lt;50 years</th>
<th>51-60 years</th>
<th>&gt;61 years</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSS Mean</td>
<td>2.48 (N=21)</td>
<td>2.31 (N=26)</td>
<td>1.26 (N=38)</td>
<td>.025</td>
</tr>
<tr>
<td>SD</td>
<td>2.56</td>
<td>1.83</td>
<td>1.67</td>
<td></td>
</tr>
</tbody>
</table>
An independent samples t-test was conducted to compare the food security scores for males and females. There was no significant difference in scores for males (M=1.59, SD=2.012) and females (M=2.16, SD=2.022). t (83) =-1.130, p=.995. We were unable to test for association between food security score and race as 91% of our sample was African American.

An independent-samples t-test was conducted to compare the mean food security scores by food security status. As expected, the mean food security score was significantly lower in the food secure group (t=-14.037, P <.0005). This provides a measure of internal validity.

Table 7 Food Security Score and Household Size

<table>
<thead>
<tr>
<th>Variable</th>
<th>Secure</th>
<th>Insecure</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Household Size</td>
<td>Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2.16</td>
<td>1.53</td>
<td>0.022</td>
</tr>
<tr>
<td></td>
<td>(N=45)</td>
<td>(N=40)</td>
<td></td>
</tr>
<tr>
<td>SD</td>
<td>1.58</td>
<td>.82</td>
<td></td>
</tr>
</tbody>
</table>

Level of Albumin Varying by Food Security Score

A one-way between groups ANOVA was conducted to explore whether food security score varied by adequacy of albumin level in blood. There was no significant difference in patients grouped by adequacy of albumin level and food security score.

A chi-square test for independence indicated a significant association between frequency of oral supplements and the adequacy of albumin in the blood. A greater proportion of patients with inadequate albumins were more likely to be receiving oral supplements.
A one-way between groups ANOVA was conducted to explore whether mean albumin levels varied by the way in which supplements were obtained. Participants were divided into three groups according to their access to oral supplements (by insurance, purchased with own money; donation’s or received from some other way). There was a significant difference in albumin for the three categories of obtaining the oral supplements $P = .005$. Subjects who received their supplements through donations had higher albumin levels than persons who self-paid or received supplements through Medicaid insurance (See Table 9).

**Table 8 Albumin and frequency of oral supplements**

<table>
<thead>
<tr>
<th>Variable</th>
<th>1,2,3 or any in a week</th>
<th>No Supplement</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Mean</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.64</td>
<td>3.90</td>
<td>0.002</td>
</tr>
<tr>
<td></td>
<td>(N=37)</td>
<td>(N=48)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.45</td>
<td>0.31</td>
<td></td>
</tr>
</tbody>
</table>

**Table 9 Blood Albumin Concentrations by Access to Oral Supplements**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Insurance</th>
<th>Self Pay</th>
<th>Donations</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Mean</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3.6</td>
<td>3.69</td>
<td>3.9</td>
<td>0.005</td>
</tr>
<tr>
<td></td>
<td>(N=25)</td>
<td>(N=9)</td>
<td>(N=51)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.51</td>
<td>0.34</td>
<td>0.31</td>
<td></td>
</tr>
</tbody>
</table>

A chi-square test for independence indicated a significant association between
albumin and age. A greater proportion of patients, who were older than 60 years, had inadequate albumin levels. From our sample, 61% of the individuals had an albumin that was inadequate, or ≤3.9 mg/dL and 39% of the individuals had an albumin that was adequate, or ≥4.0 mg/dL.

**Figure 1 Adequacy of Albumin Level by Age**

Food security score and access to oral supplements

A one-way between groups ANOVA was conducted to explore the impact of food security score and access to oral supplements. The groups were divided into three different groups based on the way in which they received their supplements. There was no significant difference amongst the groups. An independent-samples t-test was
conducted to compare the albumin levels for males and females. Men had higher albumin concentrations than women (See table 10).

**Table 10 Blood Albumin Concentration levels by Gender**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Males</th>
<th>Females</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Albumin</td>
<td>Mean</td>
<td>3.9</td>
<td>3.7</td>
</tr>
<tr>
<td></td>
<td>(N=41)</td>
<td></td>
<td>(N=44)</td>
</tr>
<tr>
<td></td>
<td>SD</td>
<td>0.33</td>
<td>0.44</td>
</tr>
</tbody>
</table>

A chi-square test for independence indicated a significant association between reporting consumption of supplements and the frequency of consumption of supplements reported. All of the individuals who stated that they receive and consume supplements corresponded to the amount of supplements reported (see Table 10). This is a source of internal validity.

**Table 11 Proportion of patients consuming and number of supplements reported**

<table>
<thead>
<tr>
<th>Variable</th>
<th>1,2,3, or any in a week</th>
<th>No Supplement</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency</td>
<td>100</td>
<td>0</td>
<td>0.000</td>
</tr>
<tr>
<td>(N=38)(N=47)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Neither food security score, age nor frequency of consumption of oral supplements predicted adequacy of albumin levels (P>.05).

**Discussion**
Many studies have shown the benefits of oral nutrition supplements in dialysis patients, but there are no studies to date that looked at a biomarker of nutrition status, blood albumin levels as a function of oral nutrition supplements and, food security status. Therefore, we examined this relationship in persons receiving hemodialysis treatment in urban Cincinnati dialysis centers. Among measured demographic characteristics, age and household size were significantly related to food security status.

To date there is one study that looked at the relationship of food security status in patients receiving hemodialysis. That study had 98 participants. The mean age of subjects was 59.1 +/- 14.2 years. The sample was 44% white and 56% black; 49% male and 51% female and the USDA short item survey was used. The study found that 16% of their sample was food insecure. Our study was comparable in regards to the type of survey used, patients receiving hemodialysis, and age and gender. We found that 47% of our sample was food insecure. Research has also shown that food insecurity is more prevalent in populations with chronic diseases and our study was only completed in patients who had chronic kidney disease and who were on hemodialysis.

The literature has suggested that an oral supplement of 250ml/day or one supplement per day increases blood albumin concentration in patients receiving hemodialysis. Our study showed that the participants who were consuming supplements (1,2,3 or any in a week) had lower blood albumin levels than the participants who did not receive supplements. However, a limitation to this study was that the length of supplement consumption was not assessed and the baseline albumin level before the participant started consuming the supplement was not assessed. This
information would be pertinent to see if there was an association between blood albumin levels in patients receiving oral supplements based on duration.

Other studies have shown that patients receiving hemodialysis tend to have blood albumin levels lower than the recommended value of 4.0mg/dL. Our study also supports the literature in that 61% of our sample had inadequate albumin levels (≤3.9mg/dL) and 39% had adequate albumin levels (≥4.0mg/dL). Although this albumin level is difficult for a dialysis patient to maintain due to poor appetite, possible inflammation and other chronic diseases, the KDOQI guidelines recommend patients to reach an albumin of 4.0mg/dL or greater while on dialysis.

For household number, it is possible that having more individuals in the household could result in a higher household income thereby increasing the food security status. A limitation of the study is that we did not ask who lived in the household. It would be pertinent to know this information as a family of two could consist of a child and mother, or husband and wife etc. Similarly, another limitation to this study was that we did not ask about children in the household.

Age was significantly related to FSS. Adults over the age of 61 years of age were the most food secure, followed by adults under the age of 50 then adults between the ages of 51-60 years. This could be because as individuals reach the age of 65 years, some qualify for Social Security and the additional funds received could help improve food access, whereas all individuals under the age of 65 would not qualify for this benefit. Another explanation is that older individuals were recently diagnosed with chronic kidney disease after retirement compared to the younger participants who may have had to leave work at an earlier age, and also have younger children to support.
When asked who purchased the food for the household, 67.1% answered “self”. This reveals that many of the participants are responsible in purchasing their own food and making their own food choices.

Although our sample was limited in the number of people on oral nutrition supplements, our availability to detect a direct association between food insecurity and consumption of oral supplements, the fact that frequency and access of supplements was significant and 47% of the participants had some form of food insecurity, this study shows important implications for renal health care professionals. Looking forward, renal health care professionals should look at insurance status (Medicare and Medicaid), family dynamic, household income, and those who participate in state and federal programs to help improve food security status in the renal population. In addition, oral nutrition supplements should be available to patients who would benefit from them and who does not need a fluid restriction, to potentially increase albumin levels.

References


Appendices

Appendix 1: Research Protocol

Appendix 2: Consent Form

Appendix 3: Survey
Appendix 1: Research Protocol

UNIVERSITY OF CINCINNATI
INSTITUTIONAL REVIEW BOARD – SOCIAL AND BEHAVIORAL SCIENCES (IRB-S)
PROTOCOL

TITLE:

Oral supplements and serum albumin levels in dialysis patients as a function of food insecurity

Principal Investigator: Megan Coleman, RD, LD

1. PURPOSE of the research project AND GENERAL INFORMATION:

27. PURPOSE

The purpose of this research study is to study how access to food and oral supplements affect blood albumin levels in patients on dialysis.

28. BACKGROUND

1) Prior research

A descriptive correlation study conducted in Louisiana dialysis centers determined that a relationship exists between nutrition status and food security of patients on hemodialysis. Ninety-eight hemodialysis patients were given the 16-item US FSSM questionnaire to determine food security status. Nutrition status was evaluated using a subjective tool, based on medical history and physical examinations. Sixty-Four percent of the patients were mildly to moderately malnourished and 13% were severely malnourished. Eighty-four percent were classified as food secure and 7.1% as food insecure without hunger and 9.2% as food insecure with moderate hunger. A total of 16.3% of subjects were found to be food insecure. (2)

This study showed the prevalence of food insecurity in dialysis patients but lacked the clinical component to determine the relationship between food insecurity and disease outcome.

2) Significance

Food security is defined as when "the availability of nutritionally adequate and safe foods or the ability to acquire acceptable foods in socially acceptable ways is limited or uncertain". (1)

There is a high incidence of poor nutrition status in the dialysis population, as indicated by albumin levels. Food insecurity may be a predictor of poor nutrition status. We plan to examine the relationship between these factors by correlating survey information the ability to obtain foods (food security) with nutritional lab
29. FUNDING
   1) No funding for this research study.

30. FACILITIES

   Research will be completed at the DCI (Dialysis Clinic Incorporate) dialysis locations in Cincinnati, Ohio (DCI McMillan, DCI Western Hills, DCI West Chester and DCI Forest Park), where patients dialyze 3 days a week, on one over several shifts. See the tentative chart below. An application for the study will be approved by the dialysis centers before research begins.

<table>
<thead>
<tr>
<th>Week 1</th>
<th>DCI McMillan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 2</td>
<td>DCI Western Hills</td>
</tr>
<tr>
<td>Week 3</td>
<td>DCI West Chester</td>
</tr>
<tr>
<td>Week 4</td>
<td>DCI Forest Park</td>
</tr>
</tbody>
</table>

31. DURATION OF STUDY

   The study will take place during the fall of 2013. All data will be collected within 3 months, including the albumin levels which will be taken from the patient charts.

f. RESEARCH TEAM
   1) Research team and time commitment

<table>
<thead>
<tr>
<th>Job Title / Responsibility</th>
<th>Time Commitment</th>
</tr>
</thead>
<tbody>
<tr>
<td>PI/conduct the research (Megan Coleman, RD, LD)</td>
<td>100 hours</td>
</tr>
<tr>
<td>Faculty Advisor/oversee study (Heather Duncan, PhD)</td>
<td>50 hours</td>
</tr>
</tbody>
</table>
2) Training team members in research ethics

All research members are CITI trained and HIPAA trained.

3) Training team members in research activities

(a) Training

Team members will attend a trial run of the study one month prior to the first visit at the dialysis centers. The training will review how to properly conduct the survey and store the information. The researchers will also be trained on the consent process and how to collect the survey information.

2. PARTICIPANTS:
   a. RECRUITMENT

During dialysis treatment, patients will be notified of the research study. Patients will be given a brief overview of the research study and their role as the participant. They will also be notified that they will need to complete a survey to participate in the research. All participants will receive a copy of the consent form, and only participants that sign and agree to the study will participate. Participants may drop out of the study at any time. The average time for a patient to complete a dialysis treatment is four hours. Given this time, it will allow the researchers to identify, interview and consent patients that decide to participate in the study. There will also be an announcement of the study in the DCI clinic newsletter. This short announcement will allow the participants to read over the study’s objectives and their role as a participant. The announcement is provided and attached.

1) Number of participants
   (a) Minimum and maximum number of participants

There are over 300 patients treated at the DCI locations across the greater Cincinnati area. The goal of the study is to collect data and surveys on approximately 80 patients of the DCI population. Participants will only be included if there is a recent albumin level and the survey is completed.

(b) Rationale

The estimated number of 80 participants was chosen due to the fact that there are many patients that could be excluded from the study, not interested, withdrawal or do not complete the study.

2) Inclusion and exclusion criteria
Inclusion Criteria- Adults (both male and female) over the age of 18 who receive dialysis treatment at one of the four Dialysis Center Incorporate clinics.

Exclusion Criteria- Any patient receiving parenteral nutrition (receiving intravenous nutrition through a large vein) and also patients that do not speak English. (This will be screened in patients chart and the participant will be excluded). Patient with active liver disease will be excluded (based on chart review of liver enzymes).

3) Vulnerable participants
   (a) Vulnerability

   Subject of low income may be approached for participation; however no incentive is provided so they are not expected to feel coerced. Study is chart review for lab results and survey only, no intervention.

   (b) Rationale
   n/a

   (c) Confirmation
   n/a

4) Risks and discomforts from participating
   (a) Type and level of risk or discomfort

   Since this study involves completion of a short survey and the questions are not of a sensitive nature, there are no known risks or discomforts. Patients will take part in the study during their dialysis treatment and the survey will not cause any risks or discomforts.

   (b) Safety monitoring plan – not applicable.

   (c) Reporting
      (1) Notification of PI

      Participants will be given all phone numbers of the researchers to call to report any risks or discomforts they may have. These phone numbers will be provided to the participants in the consent form.

      (2) Notification of IRB

      Participants will be given the phone number to the IRB. Also, researchers will be able to contact the IRB for any participant that experiences a risk of discomfort from this research.
(3) Other notification

(4) Available resources

All phone numbers will be provided to the patients in their consent form.

5) Direct benefits to the participant

There are no known direct benefits for the participants.

6) Recruitment activities

(a) Recruitment materials

An announcement in the dialysis newsletter.

(b) Personnel

Research activities will be conducted by Megan Coleman and Heather Duncan.

(c) Recruitment activities

Newsletters will be passed out to the participants at the dialysis centers. Megan Coleman, RD, LD will also be able to answer questions related to the study but not any detailed information (i.e. Questions pertaining to the survey).

(d) Participant response

Participants will notify the researchers if they are interested. They will then receive the consent form. Participants are allowed to back out of the study at any time.

b. CONSENT PROCESS

1) Presenting information to potential participants

The participants will receive the consent form to read over and sign if interested in participating in the study. The participants will be given the consent form individually, while they are at dialysis, and will have up to one week to review and decide on participation.

2) Answering questions from potential participants
Candidates will have an opportunity to ask question prior to signing the consent form, and will be given phone numbers for the research staff as well.

3) Indicating consent

The participants signature located on the consent form indicates their willingness to take part in the research study. Also, the researchers (Heather Duncan, PhD and Megan Coleman, RD, LD) will sign when the participate consents and they will receive a copy.

4) Legally authorized representative (LAR) for minors or cognitively impaired participants

No patients with LARs will be approached for this study.

5) Verification of LAR for cognitively impaired participants

n/a

6) Avoiding coercion

This study does not involve any vulnerable participants. The study is completely voluntary, and the participants can back out at any time.

7) Recruitment incentives

There are no recruitment incentives for this study.

c. **CONSENT DOCUMENTS (ICDs)**

   See attached

3. **RESEARCH-RELATED ACTIVITY:**

   a. Data set/ Data collection

   1) Person or entity that holds the dataset

   Once complete, the data set will be stored and locked at the University of Cincinnati, College of Allied Health Sciences, lab room 201, in a locked drawer. Only the researchers (Megan Coleman, RD, LD and Heather Duncan, PhD will have access to the raw data).

   2) General description of the data, including when and how the data were obtained.

   The survey will serve as the main data for the study. See attached survey. Data will also be collected from a chart review.
3) List of the fields (or description of the kinds of information) that will be used from the dataset, with specific mention of any individually identifying data

The following will be collected from the chart: (Medical record number, name, age, gender, race, albumin, AST and ALT labs. AST and ALT are two types of liver labs that when elevated, indicate that there may be something wrong with the liver. AST and ALT labs will be viewed to exclude any patients with active liver disease; however the AST and ALT liver labs will not be included in the data analysis. The data will be collected once all of the surveys are completed.

4) Explanation why individually identifying data are needed for your study, how confidentiality of individually identifiable data will be assured, and how soon identifiers will be purged from the dataset

The participant name will be needed to obtain the most current albumin levels, liver labs (AST and ALT) and demographic information. The participant name will be located on the survey but only an identification code for the survey will be entered into SPSS. The participant names will not be used in the data analysis or results.

5) Explanation of how the dataset (or portion of the dataset) will be obtained from the current holder

The information needed for the dataset will be obtained from the chart audit.

c. RESEARCH ACTIVITIES

1) Privacy of participation

The surveys will be completed while the participants are seated for dialysis. They will be collected in a large room, however participants will not share surveys with each other. They each have their own individual chair, and will be asked to complete the survey while seated. This will allow privacy to the participants and for others to not see their answers to the survey. If requested, subjects can complete their survey in an exam room in the clinic before or after their dialysis treatment.

2) Confidentiality of data

All research data (consents, surveys, demographics and albumin levels will be maintained in research-staff only storage.

3) Research-related activities

(a) Participant cohorts
Participants will be identified based on their dialysis location (four locations: McMillan, Forest Park, Western Hills, and West Chester).

(b) Activities and duration

Participants will only be asked to fill out the survey for this research. They will only be included if the survey is completed, and there is an available albumin level. They will be allowed to leave the study at any time. If there are surveys that are not completed, they will not be entered into the data analysis and they will be discarded. The estimated time for each participant is 10 min.

(c) Data collection tools

List:
Survey

(d) Payments to participants:

No payment will be provided to the participants.

4. DATA ANALYSIS:

Descriptive statistics will be used and all data will be entered into SPSS.

5. REFERENCES:


6. ADDITIONAL DOCUMENTATION:

See attached survey
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Oral supplements and serum albumin levels in dialysis patients as a function of food insecurity

UC IRB Study #: 2013-3956

Investigator Information:
Megan Coleman, RD, LD 440-212-4696

Principal Investigator Telephone Number 24 hr Emergency Contact

Subject Name ______________________________ Date of Birth _____ / _____ / _____

INTRODUCTION

Before you agree to participate in this research study, it is important that you be told the purpose, procedures, benefits, risks, discomforts, and precautions for this study. You should also be told what alternative procedures are available to you if you do not participate in this research study.

Your participation in this research study is entirely voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from the study at any time without penalty. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without unfairness to you or any effect on your medical care. We do not promise that you will receive any benefits from this study.

This informed consent document is a brief written summary of what your study recruiter is telling you. Be sure to ask questions while you read this if there is anything that you do not understand.

WHY IS THIS RESEARCH BEING DONE?

Some dialysis patients, especially those who are underweight, are at higher risk for malnutrition as shown by a low level of a protein in blood known as albumin. Patients on
dialysis and who have low albumin levels tend to be nutritionally compromised. We are interested in studying how access to food and oral supplements affect blood albumin levels in patients on dialysis. In a previous study conducted in patients on hemodialysis, many were found to be mild or moderately malnourished with some being severely malnourished. The study also showed that many of these patients have difficulty obtaining food. This study will help us to learn if oral nutrition supplements will help to maintain albumin levels in the recommended levels for dialysis patients.

WHY HAVE YOU BEEN ASKED TO TAKE PART IN THIS RESEARCH STUDY?
You are being asked to take part in this research study because you are a dialysis patient above the age of 18 years old. Researchers at the University of Cincinnati want to learn more about how oral nutrition supplements and access to food affects your blood albumin levels. Any patients on dialysis can participate unless you are currently

32. Pregnant
33. Drugs/alcohol abuse
34. Liver disease,
35. Active infection
36. Receive IDPN (Intradialytic Parenteral Nutrition) treatments

HOW LONG WILL YOU BE IN THE RESEARCH STUDY?
You will participate in the study during one of your dialysis treatments; therefore, the time in the study will be for one day. After your participation, the next available albumin measurement will be collected from your medical chart. The medical record containing information regarding your medical history will be looked at to collect this information. This consent, unless you choose to withdraw it, shall remain in effect until the end of the research study.

You may withdraw from the study at any time. If you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor before withdrawing first. The researchers may decide to remove you from this research study at any time.

You may be contacted in the future by representatives of the University of Cincinnati who are interested in asking you survey questions about your participation in this research study. If you choose to participate in the survey, your responses will be used for quality assurance purposes only.

WHO IS CONDUCTING THE RESEARCH STUDY?
This study is being conducted by Megan Coleman, RD, LD and Heather Duncan, PhD, Field Service Associate Professor, both of the University of Cincinnati.
HOW MANY PATIENTS WILL TAKE PART IN THE RESEARCH STUDY?

Approximately 80 dialysis patients will take part in this study.

WHAT IS INVOLVED IN THE RESEARCH STUDY?

This study involves completing a short questionnaire (11 questions) about your access to food and use of oral nutrition supplements.

WHAT ARE THE RISKS AND DISCOMFORTS OF THE RESEARCH STUDY?

Since this study involves completion of a short questionnaire and the questions are not of a sensitive nature, there are no known risks of discomforts.

ARE THERE BENEFITS TO TAKING PART IN THE RESEARCH STUDY?

If you agree to take part in this research study, there is no known direct benefit for you. Prior studies of oral nutrition supplementation, using similar questionnaires as will be used in this study, suggest a possible positive effect on albumin levels in dialysis patients. The investigators believe that the information learned from this research study will benefit other patients and future research in dialysis patients.

WHAT OTHER CHOICES FOR CARE ARE THERE?

Instead of being in this research study, you have the option not to join. Deciding not to join will not have any effect on your medical care. Participation in the study will not alter your medical care in any way.

HOW WILL INFORMATION ABOUT YOU BE KEPT PRIVATE AND CONFIDENTIAL?

Every effort will be made to maintain the confidentiality of your study records. Data is stored in a locked file in a locked room. Agents of the University of Cincinnati will be allowed to inspect sections of your medical and research records related to this study. The data from the study may be published; however, you will not be identified by name. Your identity will remain confidential unless disclosure is required by law.

AVAILABILITY OF INFORMATION

You will receive a copy of this signed consent form. The full protocol (description of this research study) will be made available to you upon request. You will be told about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHAT ARE YOUR COSTS TO BE IN THIS STUDY?
There is no cost to you for participating in this study.

**WILL YOU BE PAID TO PARTICIPATE IN THIS RESEARCH STUDY?**

You will receive not be paid to take part in this research study.

**WHAT ARE YOUR RIGHTS AS A PARTICIPANT?**

You may choose either to take part or not to take part in this research study. If you decide to take part, you may decide to leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to you. The investigators will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

If you have questions about the study, you will have a chance to talk to one of the study staff or your regular doctor. Do not sign this form unless you have had the chance to ask questions and have received satisfactory answers.

Nothing in this consent form waives any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

**WHO DO YOU CALL IF YOU HAVE QUESTIONS OR PROBLEMS?**

If you have questions, concerns or complaints about this research study or to report a research-related injury, please contact Heather Duncan, PhD. At 513-559-3362). Please call the University of Cincinnati Medical Institutional Review Board at 513-558-5259 (Monday – Friday 8 am to 5 pm) if you:

- g. Think the research has hurt you;
- h. Have general questions about giving consent or your rights as a research participant in this research study;
- i. Have questions, concerns, or complaints about the research; or
- j. Cannot reach the research team or you want to talk to someone else.

To report complaints or concerns to an independent agency in an anonymous and confidential manner, please call the Research Compliance Hotline at 1-800-889-1547.
SIGNATURES

I have read or someone has read to me, this Informed Consent Document which describes the purpose and nature of this research. I have had time to review this information and have been encouraged to ask questions. I have received answers to my questions. If I do not participate or if I discontinue my participation, I will not lose any benefits. I will not lose any legal rights if I discontinue. My participation in this research is completely voluntary. I give my consent for myself to participate in this study. I have received (or will receive) a copy of this form for my records and future reference. I have also been given sufficient time to consider if I should participate in this study.

<table>
<thead>
<tr>
<th>Participant</th>
<th>Date</th>
<th>Time</th>
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</table>

PERSON OBTAINING CONSENT
I have read this form to the participant and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject’s satisfaction. In my judgment, the subject has demonstrated comprehension of the information.

<table>
<thead>
<tr>
<th>Signature and Title of Person Obtaining</th>
<th>Date</th>
<th>Time</th>
</tr>
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<tbody>
<tr>
<td>Consent and Identification of Role in the Study</td>
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Appendix 3: Survey

Subject Name/MRN number___________ Code___________

Dialysis Location___________________________

Albumin Level/Date Age ______ Male or Female? Race________

1. How many people live in your household?___________

2. Who purchases the food you eat?___________

Now I’m going to read you several statements that people have made about their food situation. After you read the statement, please tell me whether the statement was often true, sometimes true, or never true for you in the last 3 months.

3. “The food that was bought just didn’t last, and didn’t have money to get more.” Was that often, sometimes, or never true for the household in the last 3 months?

[ ] Often true
[ ] Sometimes true
[ ] Never true
[ ] Don't Know or Refused

4. “(I/we) couldn’t afford to eat balanced meals.” Was that often, sometimes, or never true for (you/your household) in the last 3 months?

[ ] Often true
[ ] Sometimes true
[ ] Never true
[ ] Don't Know or Refused

5. In the last 3 months, since last May, did the household ever cut the size of the meals or skip meals because there wasn't enough money for food?

[ ] Yes
[ ] No (Skip 5a)
[ ] Don't Know (Skip 5a)

5a. How often did this happen—almost every month, some months but not every month, or in only 1 or 2 months?

[ ] Almost every month
[ ] Some months but not every month
6. In the last 3 months, did you ever eat less than you felt you should because there wasn't enough money for food?

[ ] Yes  
[ ] No  
[ ] Don't Know

7. In the past three months, were you ever hungry but didn't eat because there wasn't enough money for food?

[ ] Yes  
[ ] No  
[ ] Don't Know

8. In the past three months have you consumed any form of a liquid nutrition supplement? (Ensure, Boost, Nepro)

[ ] Yes  
[ ] No (skip 8a and 8b)  
[ ] Don't Know

8a. How often do you consume the liquid nutrition supplement?

[ ] one per day  
[ ] two per day  
[ ] three or more per day  
[ ] Don't Know

8b. How do you get your liquid nutrition supplement?

[ ] Through my insurance (Ohio Medicaid, Molina, Caresource, Buckeye, Amerigroup)  
[ ] I buy it with my own money  
[ ] I receive it through donations  
[ ] Don't Know