Crohn's disease: enteral nutrition practices of registered dietitians in New Mexico

Nicole Sara Horvath

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CROHN’S DISEASE

ENTERAL NUTRITION PRACTICES OF REGISTERED DIETITIANS IN NEW MEXICO

BY

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THESIS

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DEDICATION

I dedicate this paper to Robert Ackerman, a close friend of mine.

Robert has lived with Crohn’s disease for most of his life. Over the years, Robert has exposed me to the impact that Crohn’s disease can have on one’s life. He continues to struggle with Crohn’s disease not knowing what each new day will bring. As an individual with Crohn’s disease, he faces an uncertain future until advancements in Crohn’s disease research are made that can help improve the available medical treatments in healthcare or a cure is discovered for Crohn’s disease. Robert Ackerman, thank you for demonstrating that “life isn’t about waiting for the storm to pass; it’s about learning to dance in the rain” (Unknown).
ACKNOWLEDGEMENTS

I sincerely acknowledge Deborah Cohen, my advisor and thesis chair, for her continued support, motivation, openness, availability and encouragement through my matriculation at the University of New Mexico. She has provided me with a substantial foundation of knowledge in the field of Nutrition and Dietetics. Her guidance, professionalism, kindness and devotion to helping others will remain with me as I continue my career in dietetics.

I appreciate the efforts of my committee members in their endeavor to help me succeed academically and professionally. I would like to thank my committee members, Elizabeth Yakes and Jean Cerami, for their continued support, specialized knowledge, and valuable recommendations pertaining to this study and assistance in my professional development.

Lastly, I would like to thank my friends and family for their patience, optimism and encouragement!
CROHN’S DISEASE: ENTERAL NUTRITION PRACTICES OF
REGISTERED DIETITIANS IN NEW MEXICO

by

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ABSTRACT

Objective: To identify which enteral nutrition (EN) formulations are currently recommended in the acute care setting by registered dietitians (RDs) in New Mexico for patients with active Crohn’s Disease (CD) and to compare these recommended formulations to the ASPEN and ESPEN guidelines.

Methods: The link to an electronic survey was e-mailed to 109 potentially eligible RDs employed at acute care facilities in New Mexico during the spring of 2011. E-mail addresses were obtained from the Commission on Dietetic Registration. Descriptive statistics, Fisher’s exact, Pearson’s $\chi^2$ and Cramer’s $V$ tests (SPSS; version 21) were used to analyze relationships between variables.

Results: Twenty-three participants fit the inclusion criteria and completed the survey (42.6% response rate). All eligible participants were 26 to 64 years of age, 82.6% were females, 91.3% were Caucasian, 56.5% worked at an urban location, 69.6% had been practicing dietetics for more than 15 years and 56.5% worked solely with adult patients. Seventy-four percent of RDs reported using semi-elemental and elemental EN formulations. ASPEN (26%), ESPEN (22%) and AND NCM (22%) guidelines were the most commonly reported guidelines used by RDs. RDs employed at a rural location (26.1%) were more likely to report access challenges ($p = .025$). Practicing dietetics for less than 15 years (34.8%) was statistically associated with the use of ESPEN guidelines ($p = .016$). RDs that reported using ASPEN and ESPEN guidelines (40%) did not necessarily recommend polymeric EN formulations for patients with active CD ($p =$
.382). RDs that reported using ASPEN guidelines (67%) were more likely to report using polymeric EN formulations (p = .025).

Conclusion: RDs employed at acute care facilities in New Mexico generally recommend semi-elemental and elemental EN formulations for patients with active CD, even though the ASPEN and ESPEN guidelines recommend the use of polymeric EN formulations. This study demonstrated that access issues, limited available research and physician resistance to the use of EN may be factors associated with decreased use of EN in patients with active CD. Further research on the use of EN in patients with active CD should be conducted, so that evidence-based guidelines can be developed.
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CHAPTER 1: INTRODUCTION

Crohn’s disease (CD), also known as regional enteritis, is a disease that was first described by Dr. Burrill B. Crohn and his colleagues in a paper published in 1932 (1). CD is a type of inflammatory bowel disease (IBD) that can affect any part of the gastrointestinal (GI) tract. The two major types of IBD are ulcerative colitis and CD. CD can affect the entire thickness of the small intestinal wall and typically occurs in the ileum and the proximal large intestine (2). Unlike CD, ulcerative colitis only involves the colon and does not affect all layers of the intestinal wall. CD can skip portions of the intestines leaving healthy, unaffected portions in between patches of diseased intestine (3). CD typically consists of two phases: active and remission (3). CD is considered active when symptoms are present or a patient has a score of greater than 150 using the Crohn’s Disease Activity Index (CDAI) on a scale of 0 to 600 (4). CD symptoms in adults can differ from those in the pediatric population. CD symptoms in adults may include diarrhea, cramping, fever, abdominal pain, nausea, decreased appetite, weight loss, fatigue and rectal bleeding (5, 6). In the pediatric population, delayed onset of puberty and poor linear growth, weight gain and bone mineralization may be the primary symptoms of CD (2, 7). CD is an idiopathic and incurable chronic condition, but it can be managed with medications, surgery, nutrition support or a combination of these therapies.

There are five types of CD that are classified according to the location in the GI tract where the disease occurs (5). Granulomatous colitis only affects the large intestine, while gastroduodenal CD affects both the stomach and duodenum and Crohn’s ileitis affects the ileum. The most common type of CD is ileocolitis and it affects the large intestine and ileum. Lastly, jejunoileitis produces patches of inflammation in the jejunum. CD can cause severe complications, with voluminous diarrhea and corrosion caused by excessive secretion of digestive enzymes leading to fluid and electrolyte imbalances and nutrient deficiencies and promotion of the development of fistulas and intestinal obstructions (5, 8, 9, 10).
The prevalence and incidence of CD have been increasing in Western countries since the 1970’s (11). The prevalence of CD in the United States (US) is approximately 320 out of 100,000 people (11). CD is most frequently diagnosed between the ages of 15 and 30 years, but it may be diagnosed at any age (2). There is a slight predominance of the female gender being diagnosed with CD. Caucasians, especially those of Eastern European Jewish descent appear to develop CD more often than other ethnicities (6).

The etiology of CD is complex. A combination of environmental, genetic and autoimmune factors is thought to contribute to the development of CD (12). Cigarette smoking has been found to be a risk factor in the development of CD and may promote an exacerbation of CD (11). On the other hand, being breastfed in infancy may reduce the risk of developing CD in adulthood (7). It is theorized that a Westernized diet high in saturated fat and processed foods may have an influence in the development of CD due to the presence of pro-inflammatory substances in a Westernized diet (9, 13, 14).

Nutritional therapy in addition to surgical, medical or pharmacological therapies is important in the treatment of active CD (3). Nutritional therapies (Table 1) may include parenteral nutrition (PN), enteral nutrition (EN), medical nutrition therapy (MNT) or a combination of these therapies (15, 16, 17). EN has been found to stimulate remission in approximately 53 to 84% of individuals with active CD when used exclusively or as an adjunct to corticosteroids (8, 18). However, EN appears to be more effective in inducing and maintaining remission in pediatric patients than in adults with CD and is more commonly used in the pediatric population (19).

### Table 1: Types of Nutritional Therapies

<table>
<thead>
<tr>
<th>Nutritional Therapy</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenteral Nutrition (PN)</td>
<td>• Nutrition is provided through an intravenous tube called a catheter that is directly inserted into the veins (17).</td>
</tr>
<tr>
<td>Enteral Nutrition (EN)</td>
<td>• Nutrition is provided through a feeding tube into the GI tract (17).</td>
</tr>
<tr>
<td>Medical Nutrition Therapy (MNT)</td>
<td>• Nutrition assessment, intervention, monitoring and evaluation provided by a registered dietitian (RD) to manage a specific disease state (e.g. IBD) through diet (20).</td>
</tr>
</tbody>
</table>

Approximately 75% of hospitalized patients with active CD have unintentional weight loss (15, 17). Unintentional weight loss, specifically more than 10% of total body weight
in a period less than 6 months in an underweight individual, may deplete nutritional reserves and put the individual at risk for malnutrition. An individual with unintentional weight loss may greatly benefit from nutrition therapy, such as oral nutrition supplements or EN (15, 21). Malnutrition may impair the functions of the GI, cardiac, pulmonary, renal and immune systems; hence hindering healing, increasing the risk of health complications and predisposing an individual to a decreased quality of life (QOL) and loss of independence (21). EN support either as an adjunct to oral nutrition or as sole nutrition is the therapy of choice in malnourished patients with active CD (15). If a patient requires exclusive EN and does not tolerate EN support for five days, it is recommended that PN be initiated (12). However, bowel rest may not be necessary in most patients with CD because it does not seem to affect remission in CD (17).

The mechanism by which EN induces a remission in some patients is unclear, but may be due to: 1) exclusion of pro-inflammatory dietary components present in oral diets, 2) changes in bacterial flora, 3) reduction of total fat, or 4) the addition of glutamine in EN formulas that may decrease wound healing time (3, 12). EN is recommended for patients with active CD if they are intolerant to corticosteroids, refuse corticosteroids, are undernourished, as an adjunct to corticosteroids and in patients that have inflammatory stenosis of the intestine (15).

There are three types of EN formulations: elemental, semi-elemental and polymeric formulations (Table 2). Elemental EN formulations are believed to be less allergenic and the easiest to absorb with nutrients provided in forms that require minimal digestion prior to absorption: nitrogen in the form of amino acids, carbohydrate as monosaccharides and fats primarily from medium-chain triglycerides (MCT) (8, 17). The limitation of elemental EN formulations is their decreased palatability and increased cost. Semi-elemental formulations contain nitrogen as partially hydrolyzed protein blends (peptides), glucose polymers (sucrose or maltodextrin) and fat mostly as MCTs. Research is lacking in the effectiveness of semi-elemental formulations in inducing remission in patients with CD. On the other hand, polymeric formulations are generally more palatable and less expensive. Polymeric formulations contain nitrogen in the form of whole proteins,
carbohydrates as hydrolysates of starch and fat from oils mostly in the form of long-chain triglycerides (LCT) and may be more difficult to digest and absorb in a person with a damaged intestinal mucosa.

Table 2: Breakdown of Macronutrient Content of the Types of EN Formulations

<table>
<thead>
<tr>
<th>Types of EN</th>
<th>Polymeric Formulation</th>
<th>Semi-Elemental Formulation</th>
<th>Elemental Formulation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protein Content</strong></td>
<td>• Intact proteins or peptides</td>
<td>• Peptides or a combination of peptides and amino acids</td>
<td>• Amino acids</td>
</tr>
<tr>
<td></td>
<td>• Usually from cow’s milk or soybeans</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Fat Content</strong></td>
<td>• Polysaturated fatty acids from corn, safflower, sunflower or soybean oil or from animal fat</td>
<td>• A proportion of medium-chain triglycerides is usually provided to improve fat absorption</td>
<td>• Medium-chain triglycerides</td>
</tr>
<tr>
<td><strong>Carbohydrate Content</strong></td>
<td>• Maltodextrin and hydrolyzed cornstarch, glucose-derived saccharides or corn syrup</td>
<td>• Carbohydrate complexity varies and is generally lactose-free (sucrose or maltodextrin)</td>
<td>• Monosaccharides</td>
</tr>
<tr>
<td><strong>Advantages</strong></td>
<td>• Increased palatability</td>
<td>• Easier to digest</td>
<td>• Easier to digest</td>
</tr>
<tr>
<td></td>
<td>• Decreased cost</td>
<td>• Easier to absorb</td>
<td>• Easier to absorb</td>
</tr>
<tr>
<td><strong>Disadvantages</strong></td>
<td>• Nutrients must be broken down prior to absorption</td>
<td>• Increased cost</td>
<td>• Decreased palatability</td>
</tr>
<tr>
<td></td>
<td>• May not be tolerated by the patient</td>
<td>• Decreased palatability</td>
<td>• High osmotic load of simple sugars and amino acids</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Increased cost</td>
</tr>
</tbody>
</table>

Researchers have investigated the effectiveness of the different EN formulations in inducing remission in patients with active CD (22, 23). Evidence suggests that patients receiving an exclusive diet of a polymeric EN formulation may have similar remission rates to those who receive their sole nutrition from an elemental EN formulation (22). Polymeric formulations are generally more palatable and less expensive than elemental formulations, so they are generally recommended for use as an oral supplement in patients with active CD (15, 22).

Benefits of using EN as a therapy for CD include improved weight, improved QOL, promotion of intestinal mucosal healing, promotion of beneficial bacterial flora in the intestine, reduction of the exposure of the mucosa to antigens, improved absorption of nutrients and resolution of protein loss (3, 9). Additionally, the use of EN is correlated with reduction in levels of pro-inflammatory cytokines (9). Elemental EN formulations may be beneficial for patients with CD because it has been observed that there are reduced total bacteria per gram in patient’s feces receiving an elemental EN formulation compared to a polymeric formulation (14, 17). Animal studies have demonstrated that animals raised in a germ-free environment do not develop intestinal disease, thus
suggesting that use of exclusive EN may prevent a CD exacerbation due to decreased antigen exposure (24). Additionally, exclusive consumption of an elemental EN formulation may allow for bowel rest and some studies have found remission rates to be as high as 84% in patients consuming an exclusive diet of elemental EN (25).

The European Society for Parenteral and Enteral Nutrition (ESPEN) published guidelines in 2006, which recommend EN for patients who are undernourished and in the active stage of CD (15). Polymeric formulations are recommended as the first nutritional therapy of choice and if symptoms of intolerance (diarrhea, constipation, abdominal distention, abdominal pain, nausea or vomiting) develop, then elemental EN formulations should be utilized (15, 26). The American Society for Parenteral and Enteral Nutrition (ASPEN) published guidelines that are similar to ESPEN guidelines with respect to the recommendations regarding the promotion of EN in patients who cannot consume adequate nutrition orally (15, 16). Additionally, both ASPEN and ESPEN guidelines recommend polymeric EN formulations as the primary nutrition therapy of choice, as there appears to be no significant difference between the types of EN formulations in inducing remission (16).

Hospitalization is not uncommon in individuals suffering with CD, especially those with severe exacerbations of their disease. Utilizing MNT during active CD may improve clinical outcomes (27). The risk of developing malnutrition during acute exacerbations increases due to frequent medical procedures, need for bowel rest, severe diarrhea, nutrient malabsorption and hospital acquired infections. Malnutrition is associated with negative outcomes, such as decreased lean body mass, weight loss, poor wound healing and decreased immune function, which can increase hospital length of stay (13, 28). Improving the nutritional status of patients with CD is a major goal. Consultation with a registered dietitian (RD) is associated with improved medical efficiency, decreased nutrition-related hospitalizations and improvement in nutritional management (29). In general, it has been found that specialized nutrition support is cost-effective and may prevent infectious complications as well as decrease the patient’s duration of
hospitalization by 51% (27). However, there is no published data on the role of the RD in the treatment of patients with active CD.

RD intervention may play an important role in the MNT for a patient with active CD. The RD can use MNT for the prevention of malnutrition, improvement of nutritional status, and promotion of remission and gut healing in patients with active CD (30).

To date, there are no published studies regarding whether RDs utilize current clinical nutrition recommendations (ASPEN or ESPEN) for the use of EN in patients with active CD or what, if any, guidelines they currently use in the acute care setting. The purpose of this study was to compare the EN formulations that are currently recommended in the acute care setting by RDs in New Mexico who provide MNT for patients with active CD to the current ESPEN and ASPEN guidelines. For this study, an acute care facility was considered to be an accredited health care facility in New Mexico that admits patients for overnight stays for medical treatment. The hypothesis of this study was that RDs that work in acute care facilities in New Mexico follow the current clinical nutrition guidelines (ASPEN and ESPEN) and recommendations for EN support in patients with active CD.
CHAPTER 2: REVIEW OF THE RELATED LITERATURE

The purpose of this literature review is to summarize the most recent published literature on the use of EN support both as an adjunct to an oral diet and as the sole nutritional therapy in the treatment of patients with active CD. In addition, current EN guidelines for CD will be reviewed, as well as the role the RD plays in the MNT for patients with active CD. There are multiple therapies available for CD with the goal of reducing inflammation and the symptoms associated with the disease as well as prolonging the periods of remission between active CD exacerbations (3). Limited published research has focused on the use of EN support for either sole therapy or as an adjunct to surgical and pharmacological therapies. This literature review will focus on the use of EN as a therapy in adult patients with active CD. Pediatric studies will be discussed as well, due to the limited published research conducted on adult patients with CD.

Benefits of EN Therapy in the Treatment of Active CD

CD incidence in the US has increased in the twentieth century, which may be related to the increased intake of potentially pro-inflammatory substances (saturated fat, sugar and sodium) found in processed and fast food, which are commonly consumed in Western diets (9, 13, 14). Western diets also contain large amounts of dust and food additives, which may promote an immune response when consumed (14). EN as a sole source of nutrition allows for the avoidance of substances in the Western diet that may be pro-inflammatory, which could potentially cause an exacerbation of CD in those with an already damaged intestinal mucosa (3, 13). Evidence suggests that EN therapy may promote remission in adults with active CD and that it should be utilized more frequently to prevent active CD and maintain remission in these individuals (30).

Another theory behind the pathogenesis of CD is that some bacteria in our environment are transmitted to the gut (i.e. via food consumption) and may promote the inflammatory process that is observed in CD (19). In CD, there is an increase in intestinal permeability due to abnormalities in the tight junctions found between enterocytes in the intestines (17). This may allow for antigen-uptake and promotion of bacterial growth, which
encourages the inflammation observed in CD. In patients with IBD, there are a larger number of bacteria in contact with the intestinal mucosa (12). Interestingly, IBD lesions occur in segments with the highest concentrations of bacteria, which is in the ileo-cecal valve and the colon. Surgery involving removal of this part of the GI tract for CD patients decreases the rate of relapse of CD (12). One group of investigators found that a diet consisting of an exclusive elemental EN formulation may be beneficial for patients with CD because it was observed that there were reduced total bacteria per gram in patient’s feces who received an exclusive diet of an elemental EN formulation, hence EN may promote remission and decrease the inflammatory process observed in CD (3, 31).

**Evaluation of the use of EN Therapy as a Treatment for Patients with Active CD**

The effectiveness of utilizing diets consisting of polymeric, semi-elemental and elemental EN formulations to achieve and maintain remission in patients with active CD has been evaluated (22). These formulations have many important differences including the macronutrient composition and cost. Elemental and semi-elemental formulations can cost up to 400% more than standard polymeric formulations (8). The premise behind the use of elemental EN formulations is that patients with CD, who have a damaged intestinal mucosa, have a reduced ability to secrete digestive enzymes for adequate absorption of nutrients and villous atrophy, which may reduce absorptive capacity.

Semi-elemental and elemental EN formulations are more easily absorbed, less allergenic and better tolerated in malabsorptive states than polymeric formulations because they require minimal digestion prior to absorption (8, 14, 23). Polymeric formulations provide nitrogen as a whole protein and are considered standard formulations. Polymeric formulations are less expensive, more palatable and are generally recommended as the primary EN formulation of choice (15).

**The Role of EN in Inducing Remission During Active CD**

The use of EN in the pediatric population is the preferred therapy for active CD because corticosteroids may impair children’s linear growth (13). An estimated 20 to 30% of
children under the age of 16 years taking corticosteroids for CD have an abnormally short stature later in life (13, 19).

Day et al. (19) demonstrated the benefits of EN in inducing remission and improving nutritional status in pediatric patients with active CD. This study consisted of 27 male children between the ages of three and 16 years with active CD who consumed an exclusive diet consisting of a standard polymeric EN formulation (varying amounts of Osmolite or Modulen IBD depending on weight gain) for 6 – 8 weeks. Eighty-nine percent of the children completed the study by consuming an exclusive EN diet for 6 – 8 weeks (n = 12 with longstanding CD and n = 12 with newly diagnosed CD). Nineteen children consumed the EN orally (80%) without the need for insertion of a naso-gastric (NG) feeding tube. Seventy-nine percent of the children who completed the study entered remission, which was based on the Pediatric CDAI (on a scale of 0 to 80), with a score of less than 15 indicative of remission. Gradually, a normal diet was reintroduced during the 15.2-month follow-up. Eleven patients elected to continue supplementary EN (300 – 2750 ml/day without other medical therapies in four participants and in addition to other medical therapies in seven children) in addition to their oral diet. This study reported improved standard inflammatory markers (e.g. erythrocyte sedimentation rate [27.83 vs. 17.62 mm/h, < .04], C-reactive protein [29.19 vs. 5.38 mg/L, p < .002], albumin [31.14 vs. 35.43 g/L, p < .02] and platelets [407 vs. 331.5 x10^9/L, p < 0.049]) in all patients that entered remission. None of the children lost weight during this study; however, by eight weeks, the children with long-standing CD that achieved remission (n = 7, 58%) gained an average of 4.86 kg compared to 2.29 kg in the children who did not (n = 5, p < 0.05). Also, the children with newly diagnosed CD who achieved remission (n = 12, 100%) gained an average of 4.7 kg compared to 0.75 kg in children that did not complete their course of exclusive EN (n = 3, p < .05). Linear growth of up to 3 cm was documented in this study; however, there was no change in height Z scores over the 6 – 8 week period. A limitation of this study was that the range of 300 to 2750 ml daily of EN is a large range and would have resulted in a huge variance in the amount of calories and nutrients consumed from the EN formulations. The results of this study show that a diet consisting exclusively of a polymeric EN formulation can induce remission during an
exacerbation of CD, improve nutrition status, prevent weight loss and result in an improvement of inflammatory markers in patients with active CD.

Borelli et al. (23) evaluated the efficacy of exclusive EN therapy (no other treatment) to that of corticosteroid therapy as treatments for pediatric patients with active CD. This prospective trial consisted of 37 children (ages four to 17 years of age) who were randomly assigned to consume an exclusive polymeric EN diet (n = 19) or were provided oral corticosteroids with an unrestricted diet (n = 18) over a ten-week period. The investigators found that there was significant improvements of mucosal healing, which was measured via the Crohn’s Disease Endoscopy Index of Severity and a histological scoring system, in the children consuming polymeric EN compared to the children that received an unrestricted diet with corticosteroids (74% vs. 33% of patients that were on corticosteroids exclusively, p < 0.05). Intestinal healing was assessed by an endoscopy and histology at baseline and at the end of the study. Limitations of this study include the small sample size that may have led to a lack of generalizability, the study was not blinded and the subjects were provided different dosages of EN and corticosteroids depending on the requirement of each patient. Borelli’s data support the use of a polymeric formulation in children with active CD because use of polymeric EN formulations lead to increased mucosal healing. Lastly, the investigators of this study emphasized the need for dietary measures that can prolong remission and decrease the need for pharmacotherapy and surgical interventions in CD.

In a randomized controlled trial (RCT) conducted by Mansfield et al. (32), subjects were randomly assigned to receive an exclusive diet of semi-elemental or elemental EN formulations via NG feeding tubes for 28 days. The purpose of this study was to assess the effectiveness of elemental and semi-elemental formulations as sole nutritional therapies for adults with active CD. This study included 44 participants (63% males and 37% females). Twenty-two participants were randomized to the elemental diet group and the other 22 participants were given the semi-elemental formulation. All medical treatments, including corticosteroids that patients were receiving prior to the study, were gradually withdrawn during the first 12 days of the study. All participants received the
EN via an NG feeding tube with no other oral intake. The EN consisted of an exclusive semi-elemental (oligopeptide, as the protein source; Pepti-2000 LF liquid) or elemental (nitrogen in the form of amino acids; Elemental 028) EN diet. Sixteen (36.4%) participants (semi-elemental group n = 8, elemental group n = 8) achieved remission, which was determined by a reduction of the patient’s CDAI score by 100 points or 40% of the baseline value, control of symptoms and withdrawal of all treatments the participant was receiving prior to the study. EN feedings were discontinued in six (13.6%) subjects due to intolerance to the NG tube and 22 (50%) participants did not attain clinical remission (11 from each group). The results of this study support the use of semi-elemental and elemental formulations to promote improvements in CD symptoms and reduction in intestinal inflammation. A major limitation of this study is that the ages of the participants were not published. This is a limitation because the human body functions differently depending on one’s age. An additional limitation is that prior medical treatments were withdrawn during the study period (there was no washout period), which may have affected the study’s results; especially since this study was only conducted over a 28 day period. However, the investigators concluded that elemental EN formulations are not necessarily more beneficial than semi-elemental formulations in the treatment of adult patients with active CD.

EN support can be used to induce and maintain remission (17, 22). EN promotes intestinal healing and improves the nutritional status of CD patients; therefore polymeric EN formulations as an adjunct to other therapies for active CD should be utilized due to their cost-effectiveness and increased palatability to encourage increased dietary compliance.

**Clinical Nutrition Guidelines for EN Support in Patients with Active CD**

**ESPEN Clinical Nutrition Guidelines for CD**
The European Society for Enteral and Parenteral Nutrition (ESPEN) is a multidisciplinary society that is dedicated to the study of metabolic problems associated with diseases and their nutritional implications (15). ESPEN aims to encourage the rapid
diffusion of knowledge in the field of clinical nutrition and metabolism. The ESPEN guidelines published in 2006 state that corticosteroids are a more effective treatment therapy in adult patients with active CD and that EN as a sole therapy is “indicated mainly when treatment with corticosteroids is not feasible”, e.g. due to intolerance or refusal...“combined therapy (EN and drugs) is indicated in undernourished patients as well as in those with inflammatory stenosis of the intestine” (15). Also, ESPEN encourages the use of polymeric EN formulations as the primary formula of choice in addition to oral intake (15).

According to ESPEN, indications for EN in patients with active CD include the “prevention and treatment of undernutrition, improvement of growth and development in children and adolescents, improvements in quality of life, acute phase therapy, perioperative nutrition [which refers to the three phases of surgery: preoperative, intraoperative, and postoperative nutrition] and maintenance of remission in chronic active disease” (15). Maintenance of remission in the case of persistent intestinal inflammation can be achieved by using oral nutritional supplements (EN and vitamin/mineral supplements). EN and oral nutritional supplements are recommended in addition to normal food, to improve the nutritional status of the patient and to eliminate consequences of malnutrition and growth retardation (15).

According to ESPEN, there are no significant differences between the effects “of free amino acid, peptide-based and whole protein formulae for tube feeding” in patients with active CD (15). Therefore, free amino acid (elemental) or peptide-based (semi-elemental) formulations are not recommended, unless the patient cannot tolerate the polymeric formulation (15).

**ASPEN Clinical Nutrition Guidelines for CD**
The American Society for Parenteral and Enteral Nutrition (ASPEN) is an interdisciplinary organization devoted to improving patient care by advancing the science and practice of clinical nutrition and metabolism (20). In 2008, ASPEN published clinical practice guidelines for IBD (16). The ASPEN guidelines emphasize that EN
should be used in adult CD patients that require specialized nutrition support, but specialized nutrition support and bowel rest should never be the primary therapies for CD. This emphasizes the need to encourage intake by mouth prior to initiation of enteral intake (tube feedings) and to provide EN as an adjunct to other therapies (medical, surgical and pharmacological). Similar to ESPEN guidelines, ASPEN guidelines support the use of polymeric EN formulations because EN “effectively reverses malnutrition” (20). Additionally, both ASPEN and ESPEN guidelines state that PN should be a last resort for patients with IBD, unless they have fistula-associated CD. However, ASPEN does not provide recommendations on how EN should be provided to individuals with active CD.

**AND Nutrition Care Manual Guidelines for CD**

The Academy of Nutrition and Dietetics (AND) publishes an online diet and professional practice manual, the Nutrition Care Manual (NCM), that provides evidence-based nutrition care information for various medical conditions (33). The NCM describes MNT for patients with active CD due to the digestive issues associated with CD. The NCM states that EN or PN “is used as a supportive mechanism when oral diet or vitamin supplementation cannot meet nutritional needs” (33). Additionally, the guidelines state that “formula choice will depend on [the] functional status of the [GI] tract”; however, it does not provide detailed information on the use of EN to help promote remission and nutritional stability in patients with active CD (33).

**Current Practices of the RD in the Treatment of Patients with Active CD**

The RD is important in the care of patients with disorders of the GI tract (21, 31, 34). RDs are qualified to identify inadequate nutrient intakes in patients with IBD and to provide individualized nutrition advice, which “improves nutritional knowledge, nutritional intake and nutritional status in patients with intestinal failure” (35). In 2006, the United Kingdom (UK) conducted their first national audit in the area of gastroenterology and found that there was an unacceptably low number of RDs working in gastroenterology, with only 37% of CD patients who have ever seen a RD (34). It is important to utilize the RD to promote optimal nutritional status in patients with IBD, to
prevent malnutrition and improve QOL (36). The RD is important in the treatment of patients with active CD; however RDs are underutilized in gastroenterology in general (34, 35). Utilizing RDs is essential in providing optimal care for patients with active CD to improve their medical outcomes and nutritional status.

Prince et al. (28) aimed to identify and explore nutritional issues of concern to patients with IBD and their opinions of the health services that they receive for these nutritional issues. Seventy-two adults diagnosed with either CD (n = 47) or ulcerative colitis (n = 25) participated in this survey. Fifty-six percent were females, 56% were white and all were older than 18 years (mean age of 39 years). The participants completed a questionnaire that was administered via a face-to-face interview at adult outpatient gastroenterology clinics at Guy’s and St. Thomas’ NHS Foundation Trust in the United Kingdom. Forty-five percent of all respondents rated food and nutrition as ‘important’ or ‘extremely important’ with respect to their disease. Eighty-three percent of individuals with CD reported experiencing problems with food and nutrition with 94% reporting problems with body weight, specifically unintentional weight loss. Lethargy was reported by 85% of all respondents as an issue and was often associated with iron deficiency or poor overall nutritional intake. Half of all respondents reported that they had consulted with an RD as part of their treatment. A limitation of this study is that the authors did not report whether those who were referred to an RD found it to be beneficial or had improved health outcomes. Results of this study suggest that individuals with IBD have nutritional concerns and may avoid foods that they perceive to exacerbate their condition, which may put them at nutritional risk for malnutrition or other nutritional deficiencies. The investigators suggested that there is a need for RDs to provide individualized nutritional assessment and counseling to individuals with IBD to treat those with malnutrition or at risk for developing malnutrition as a result of their disease.

The Role of the RD in Medical Nutrition Therapy

There is limited research on the role of the RD on patient care or outcomes in the acute care setting. The following discussion reviews studies on the skills and standards of care provided by nutrition experts (e.g. nutritionists, RDs), prescriptive practices of RDs, and
the positive impact that RD involvement in healthcare can have on patient and clinical outcomes.

Due to the limited research available on practices of RDs for their patients with active CD, a study on the practices of RDs, nutritionists and physicians in the care of PKU patients will be discussed. In 2008, a group of investigators conducted a survey at a meeting of the European Nutritionist Expert Panel on phenylketonuria (PKU) with attendees from ten European centres with the aim of highlighting the key differences in dietary management among the centres and exploring possible reasons for the differences (37). Each centre was represented by a single RD, nutritionist or physician who completed the survey in person at the PKU meeting. The questionnaire consisted of a set of questions that collected information regarding the number of patients who visited each centre, management guidelines, training background of the nutrition expert, their roles and responsibilities, the individuals responsible for monitoring the patient’s diet, reimbursement for monetary cost of special diets or food products, challenges associated with disease management and policies on specific diets. The results of this study indicate that all the European centres have different recommendations and practices regarding nutritional therapy for PKU. A limitation of this study includes the various training and education levels of the respondents because RDs, nutritionist and physicians have unequal training, status and responsibilities throughout Europe. Degree courses in dietetics are not standard and RDs and nutritionists may have different skill sets and competencies depending on their training. It was reported that in some centres, the physician, not the RD, prescribes the diet and the RD may only be involved in the discussion and provision of dietary information. As a result of this study, the investigators concluded that it would be beneficial to standardize the nutritional therapy for PKU patients in order to provide optimal medical care. This study suggests that practices vary among RDs and nutritionists in Europe in the nutritional therapy of PKU. As in this study, due to the limited published literature on RD practices on patients with active CD, it is possible that practices of RDs vary for their patients with active CD.
Weil et al. (38) surveyed 1,500 clinical nutrition managers (CNMs), using an online survey website. The CNMs were employed at an acute care hospital with more than 150 beds that were registered with the American Hospital Association in 2005. The purpose of the survey was to evaluate the barriers to nutritional practices and prescriptive authority in the hospital settings in America. Three hundred fifty-one CNMs responded to the survey with a response rate of 23%. Fifty-four percent of respondents reported that they had no prescriptive authority. Thirty-six percent of respondents reported dependent prescriptive authority meaning that the RD had the authority to order diets, nutritional supplements, nutrition-related laboratory tests or procedures, as per the facilities protocol, but the RD could also discuss the nutritional care provided with the physician and document the order in the medical record. Ten-percent of respondents reported independent prescriptive authority (the RD was able to place an order without the physician). Barriers to independent prescriptive authority included opposition from physicians and liability issues. The investigators concluded that the majority of respondents did not have independent prescriptive authority, but valued the ability to have prescriptive authority. Limitations of this study included the low response rate, bias secondary to access to technology and inability to distinguish between responders and non-responders to the survey. In addition, respondents may have completed the survey more than one time. This study contributed more information regarding RD prescriptive practices and the roles of RDs in acute care settings. The results of this study indicate that physician opposition is a main barrier to independent prescriptive authority even though there are many benefits to increased prescriptive authority, which include: timely implementation of nutrition-related orders, increased quality of care and recognition of RD expertise. The researchers of this study suggested that a higher level of prescriptive authority may require the RD to meet additional educational competencies during their training and that future research should focus on identifying these additional competencies necessary for higher prescriptive authority, so that a curriculum of continuing education models could be provided to support RDs with the increased responsibilities associated with prescriptive authority. This study highlights the importance, benefits and barriers of the RD in achieving higher prescriptive authority. Depending on the prescriptive authority of RDs in New Mexico, they may only be
involved in the recommendations for EN support in their patients with active CD and may not be involved in the initiation and management of EN in their patients with active CD.

Soguel et al. (39) conducted a prospective interventional study to investigate the clinical impact of a two-step interdisciplinary quality nutrition program. The study participants included 572 patients that required greater than 72 hours in the Intensive Care Unit (ICU). Subjects were predominately male (68%) with the mean age of 59 years. The study intervention involved three periods: 1) baseline, 2) a bottom-up implementation of the protocol on feeding guidelines to increase the early delivery and amount of nutrition (calories) provided to ICU patients, and 3) the continued implementation of the feeding guidelines protocol with the additional presence of an RD in the ICU. The daily energy balance difference between baseline and period 3 (protocol with RD presence) was significant (based on improved energy deficit from -5870 kcal/week to -3950 kcal/week, p < 0.001) with the cumulative energy balances of patients improving over all three periods. The amount of days with nutrition therapy increased significantly (59% at baseline, 69% at implementation of bottom-up approach and 71% with the protocol in the presence of an RD, p <.0001) with less ICU days of patients receiving nothing by mouth or oral feeds (which were associated with decreased energy intake). The researchers concluded that having an RD significantly improved the amount of energy provided in order to meet the ICU patients’ energy needs due to early detection of energy deficits, earlier introduction of nutrition therapy and the RD’s suggestion to use combined feedings to increase the energy provided to patients. A limitation of this study was that patients in the first period of the study (baseline) were less sick and had a lower mortality rate, per the study investigators. Therefore, the patients in period 1 had a better chance of receiving adequate caloric needs. The results of this study support the need for an ICU feeding protocol and RD to manage and oversee the overall nutrition provided to ICU patients. The implementation of the ICU feeding protocol with the involvement of the RD improved the amount of calories provided to ICU patients. This study implies that having an RD can significantly improve nutritional status and prevent malnutrition in the acute care setting. It is especially important for patients with active CD to be seen by an
RD due to their increased risk for malnutrition and weight loss and to optimize their energy and nutrient intake.

Culkin et al. (36) evaluated the effectiveness of an intervention, which consisted of providing nutrition education materials and dietary counseling by an RD, on improvement in patient knowledge, oral intake, nutritional status and QOL in individuals with chronic intestinal failure (CIF). Forty-eight patients participated in the study. Thirty-three received home PN and an oral CIF diet, five consumed an exclusive oral CIF diet, four received oral nutritional supplements in addition to a CIF diet, four received home intravenous fluids and a CIF diet and two received subcutaneous fluids in addition to a CIF diet. The average age of the participants was 56 years, with females in the majority (65%). Patients completed baseline and post-intervention questionnaires (to evaluate QOL and nutrition knowledge), as well as kept 3-day diet and GI-output diaries. The RD was present when the patients completed the questionnaires to ensure that participants were answering questions based on knowledge and not by referring to the educational booklet on CIF. Also, the RD provided and explained the educational booklet about CIF, nutrition and medications to the patients. The researchers found that energy intake improved (2129 kcal/day at baseline vs. 2341 post-intervention, p < .04), fat intake improved (93 g at baseline vs. 110 g post-intervention, p < .003) and that patients demonstrated increased knowledge (via scores obtained from the knowledge questionnaire on a scale of -100% to +100%) after the intervention with the RD (64.3% at baseline vs. 80.7% post-intervention, p < 0.001). This study demonstrated that nutritional counseling by an RD when paired with nutrition education via written materials may significantly improve patient knowledge about nutrition and resulted in improved fat and energy intakes in patients with CIF. However, it remains unknown if the written material or the RD alone could produce similar results and if improved patient nutritional knowledge led to any behavior changes or improvement in fat and energy intakes. The researchers listed a number of factors that may affect patient knowledge, which included the RD’s empathy, knowledge, encouragement, realism, confidentiality, importance, explanation, listening skills, negotiation skills, time usage, non-verbal cues, appearance and prejudice. It would be interesting if future studies could determine which factors
affect patient knowledge more than others, so that RDs could focus on improving their skills and effectiveness. This study demonstrates the usefulness of the RD and written material to improve energy and fat intake and nutrition knowledge in individuals with GI conditions. As in CIF, it is crucial that the RD be involved in the nutrition care of patients with active CD, not only to provide the patient with information on the benefits of using EN to prevent malnutrition and achieve remission, but to help the patient achieve an optimal nutrition status.

These studies demonstrate that there is a need for standards of practice that are evidence-based in the field of dietetics and emphasize that the RD is essential for providing appropriate MNT recommendations for their patients.

**Conclusion**

This literature review suggests that there is no difference in effectiveness of elemental and semi-elemental EN formulations in the treatment of patients with active CD. Additionally, polymeric EN formulations are recommended as the primary EN therapy in the treatment of adults with active CD to help improve nutrition status by promoting remission and aiding the prevention of weight loss and malnutrition (15, 17). This emphasizes the importance of nutritional support in adult patients suffering from active CD. However, there is limited published information regarding whether current guidelines for the care of patients with CD are being utilized by RDs who provide MNT to patients with active CD. The articles discussed in this literature review emphasize the importance of the RD in providing MNT and nutrition education materials to improve nutrition knowledge, as well as medical and nutritional outcomes. Additionally, it was discussed that RDs are underutilized in the care of patients with GI conditions, but that patients with GI conditions may value consultation with an RD. With the limited research available on the appropriate nutritional therapy for patients with CD, it is difficult for the RD to provide evidence-based MNT. The purpose of this research study is to compare the EN formulations that are currently recommended in the acute care setting by RDs in New Mexico for their patients with active CD to the current ESPEN and ASPEN clinical nutrition guidelines.
CHAPTER 3: METHODOLOGY

Human Research Protections

The study protocol was submitted to the University of New Mexico (UNM) Human Research Protections Office (HRPO) and Institutional Review Board (IRB) approval was obtained before the study commenced (Appendix A).

Survey Design

This study used a cross-sectional research design. During the spring of 2011, a pilot survey was developed based on the ASPEN and ESPEN clinical nutrition guidelines and EN formula company online websites (Abbott Nutrition and Nestlé Nutrition) (40, 41).

Pilot Study

Six individuals participated in the pilot survey, they included: one dietetic intern, two UNM Nutrition Faculty Members and three RDs who were currently working at an acute care facility in Albuquerque, New Mexico. The pilot study participants completed the eight-question multiple-choice answer questionnaire and demographic questions via an online survey and provided feedback via an evaluation form (Appendix B & C). The pilot participants were given two weeks to complete the pilot questionnaire and evaluation form. They received an initial, reminder and final e-mail with the HRPO approved cover letter attached to each e-mail. Each e-mail described the purpose of the study, the amount of time that the survey was expected to take and explained that by completing the survey they indicated consent to participate in the study (Appendix D, E, F). Based on the feedback collected from the pilot study, three questions were modified (questions 2, 5 & 6) and an additional question was added to include a comments section. The survey was modified to include eight multiple-choice questions about: 1) which EN formulations are recommended for patients with active CD, 2) reasons for choosing a particular type of EN formulation, 3) number of patients with active CD assessed annually, 4) number of patients with active CD treated with EN support annually, 5) clinical nutrition guidelines that RDs follow, 6) how EN is provided (sole diet, adjunct to oral diet or adjunct to PN), 7) the situations in which EN is provided and 8) challenges associated with providing EN to patients with active CD. The survey also included six
questions about demographics and one question that allowed respondents to share additional comments (Appendix G). The final online questionnaire (Appendix G) was developed using the online Survey Monkey website (Palo Alto, CA).

Study Recruitment
The target population for this study was RDs who treat patients with active CD in an acute care facility in New Mexico. A list of possible participants was obtained via request from the Commission on Dietetic Registration (CDR). CDR provided a list that included 390 RDs in New Mexico. The CDR list was screened for potential study participants, who were selected based on specific eligibility criteria: they must be current licensed RDs who have treated or were currently treating adult patients with active CD (students, retirees and non-RDs were excluded), have an e-mail address that was on record with CDR and be actively practicing in an acute care facility in New Mexico during the spring of 2011. After screening for potential participants, 109 RDs between the ages of 18 and 64 years were recruited to participate in this study.

One-hundred nine potential participants received a recruitment e-mail that described the purpose of the study, the amount of time that the survey was expected to take and that by completing the survey they consented to participate in the study (Appendix C). The recruitment e-mail contained the link to the online survey and the HRPO approved consent cover letter as an attachment, which indicated that by completing the questionnaire they were consenting to participate in the study (Appendix H). Both the survey and initial recruitment e-mail indicated that only RDs that worked with adult patients with active CD in acute care facilities in New Mexico should participate in the study. The RDs who were deemed eligible to participate received three e-mails in April and May 2011 including: one initial recruitment e-mail and two reminder e-mails within a period of three weeks explaining the purpose of the study, the importance of their feedback, that their participation in the study was crucial to the success of the study, reminders for them to complete the survey and that completion of the study questionnaire was voluntary and indicated informed consent to participate in the study (Appendix D, E, F).
Data Collection

After modification of the questionnaire, the link to the online survey was e-mailed to the 109 RDs in the state of New Mexico who met the study CDR screening eligibility criteria. Eligible RDs received an e-mail asking them to complete a survey on the Survey Monkey website. The HRPO approved cover letter and link to the electronic questionnaire were e-mailed to the RD sample in April and May of 2011. Both the e-mail and questionnaire were used as recruitment and screening tools for the study to ensure that participants fit the eligibility criteria. Forty-five RDs responded to the initial and reminder e-mails indicating that they were not going to complete the survey because they did not fit the inclusion criteria. Those RDs were deleted from the e-mail list and not included in the study sample. Thirty-three completed surveys were screened for eligibility by the primary investigator (NH). Ten respondents were excluded from data analysis because they were ineligible for the study: they reported in the comments section of the survey that they were not actively practicing dietetics, did not work in an acute care facility, reported that they could not appropriately answer the survey questionnaire or answered “I have not treated patients with active CD” to the first survey question. After exclusion, survey results were entered into a Microsoft Excel spreadsheet in preparation for statistical analysis. The final data analysis was conducted on a total of 23 respondents. Excluding potential participants who were deemed ineligible (n = 55), the response rate to the survey was 42.6% (23 out of 54 potential respondents).

Statistical Analysis

The statistical software SPSS 21.0 (IBM Corporation, Armonk, New York) was used for all data analysis. Statistical analyses were conducted using descriptive statistics, Fisher’s exact, Pearson’s $\chi^2$ and Cramer’s V tests as appropriate to examine the relationship between variables. $P < .05$ was considered to be statistically significant. Associations between the reported guidelines used by RDs, the EN formulations recommended for their patients with active CD and the RD’s age, gender, length of time practicing dietetics, location of employment, the patient population they work with, situations in which they recommend EN and the challenges associated with providing EN to patients with active CD were analyzed for statistically significant associations.
To analyze data obtained from the survey, responses were categorized into different groups for questions 1, 7 and 8 (Table 3). Participants were allowed to choose multiple responses for questions 1, 2, 5, 7, and 8; therefore percentages of responses may be greater than 100%.
Table 3: Categorization of Data for Statistical Analysis

<table>
<thead>
<tr>
<th>*Question 1: EN Formulations Recommended to Patients with Active CD</th>
<th>Formulas Recommended:</th>
<th>Number of Responses</th>
<th>Percentage of Responses</th>
</tr>
</thead>
</table>
| Semi-Elemental/Elemental Formulations | • Crucial 1.5 Cal  
• Optimental  
• Pivot 1.5 Cal  
• Peptamen 1.5 Cal  
• Peptamen AF  
• Peptamen OS 1.5 Cal  
• Perative  
• Vital HN  
• Vivonex RTF  
• Vivonex Plus  
• Vivonex TEN | 12 | 52.2% |
| Polymeric Formulations | • Diabetisource AC  
• Fibersource  
• Glucerna 1.2 Cal  
• Glucerna 1.5 Cal  
• Hi-Cal  
• Isosource 1.5 Cal  
• Jevity 1.2 Cal  
• Osmolite 1 Cal  
• Oxepa  
• Promote  
• Promote with Fiber  
• TwoCal HN | 2 | 8.7% |
| Polymeric & Elemental/Semi-Elemental Formulations | Both Polymeric and Semi-Elemental Formulas | 5 | 21.7% |
| No EN Formulation provided | Typically do not recommend EN for CD | 4 | 17.4% |

*Question 7: Situations in Which EN is Recommended in Active CD

<table>
<thead>
<tr>
<th>All Situations</th>
<th>Number of Responses</th>
<th>Percentage of Responses</th>
</tr>
</thead>
</table>
| Medical/Surgical Situations | • Abcess/Fistula  
• Patient’s Level of Alertness  
• Patient with Inflammatory Stenosis of the Intestine  
• Patient is Intubated  
• Post-op  
• Pre-Surgical | 11 | 47.8% |
| Nutritional Issues | • Acute Inflammatory Stage with poor intake  
• Not tolerating an oral diet  
• Poor nutrient intake with weight loss of greater than 5%  
• Undernourished Patient | 18 | 78.3% |
| Related to Steroids | • Patient refuses steroids  
• As an adjunct to steroids | 2 | 8.9% |
| Not Mentioned By RD | n/a | 2 | 8.9% |

*Question 8: Challenges Associated with Managing EN for Patients with Active CD

<table>
<thead>
<tr>
<th>All Reported Perceived Challenges</th>
<th>Number of Responses</th>
<th>Percentages of Responses</th>
</tr>
</thead>
</table>
| Tolerance Issues | • Patient tolerance to EN  
• Re-establishing Oral PO  
• Limited Time  
• Fistulas | 15 | 65.2% |
| Knowledge Issues | • Limited Available Research  
• MD/Physician Resistance | 7 | 30.4% |
| Access Issues | • Formula Cost  
• Limited Formulary | 7 | 30.4% |
| Patient Attitude | • Patient Compliance  
• Patient Acceptance of EN or PN | 8 | 34.8% |
| None | • RD did not know  
• Not mentioned by RD | 2 | 8.7% |

*Participants were able to choose more than one answer for this question. Percentages may total greater than 100%.
CHAPTER 4: RESULTS

Participant Demographics
Of the 54 RDs in the state of New Mexico that were potentially eligible for this study, a total of 23 participants (42.6% response rate) fit the inclusion criteria and completed the survey. The respondent demographics (Table 4) included: 82.6% (n = 19) of respondents were females, 91.3% (n = 21) were Caucasian and 9% (n = 2) were Hispanic/Latino, 73.9% (n = 17) were working at an urban/suburban acute care facility at the time of the study compared to 26.1% (n= 6) at a rural location, 69.6% (n = 16) had been practicing RDs for more than 15 years, 56.5% (n = 13) worked solely with the adult population and 43.5% (n = 10) with both the pediatric and adult population. All respondents were between the ages of 26 and 64 years.

Table 4: Participant Demographics

<table>
<thead>
<tr>
<th>Participant</th>
<th>Gender</th>
<th>Age (in years)</th>
<th>Ethnicity</th>
<th>Years Practicing Dietetics</th>
<th>Acute Care Facility Location</th>
<th>Patient Population</th>
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</thead>
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<td>Adult</td>
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<tr>
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<td>Rural</td>
<td>Pediatric and Adult</td>
</tr>
<tr>
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<td>Adult</td>
</tr>
<tr>
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</tr>
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<td>Adult</td>
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<tr>
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<tr>
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<td>Pediatric and Adult</td>
</tr>
</tbody>
</table>

Participant Completion of Questionnaire
Of the 23 participants included in this study, 65% (n = 15) completed the survey within the first week after the initial e-mail had been sent, 22% (n = 5) of participants completed
the survey during the second week after receiving the reminder e-mail and 13% (n = 3) of participants completed the survey during the third week after receiving the final e-mail reminder. This suggests that most participants respond and participate in survey research within the first week of recruitment.

**RD Practices in New Mexico**

Eighty-three percent of respondents reported that they assess between one and ten patients with active CD annually (n = 19), with only one participant (4.3%) reporting assessing eleven or more patients with active CD annually and three respondents (13%) reporting that they typically do not assess any CD patients annually. Sixty-five percent (n = 15) of respondents reported that they treat one to five patients with active CD with EN support annually and 34.8% (n = 8) of participants reported that they typically do not treat any CD patients with EN support annually. Of the 23 RDs included in this study, four (17.4%) respondents reported that they do not typically recommend EN for their patients with active CD. Of the RDs that recommend EN formulations (n = 19) for their patients with CD, 89.5% (n = 17) reported using elemental and semi-elemental formulations and 36.8% (n = 7) reported using polymeric EN formulations for their patients with active CD.

The ESPEN, ASPEN and AND NCM clinical nutrition guidelines were the most commonly reported guidelines used by RDs for the nutritional assessment and MNT of patients with CD. Approximately 26% (n = 6) of respondents reported using ASPEN clinical nutrition guidelines, 22% (n = 5) reported using ESPEN clinical nutrition guidelines, and 22% (n = 5) reported using AND NCM clinical nutrition guidelines. Other guidelines reported to be used for the nutritional assessment and MNT of CD patients consisted of: guidelines provided by the RD’s acute care facility (8.7%, n = 2) and Critical Care guidelines (4.4%, n = 1). Based on this study’s results, the guidelines reported to be most commonly used are the ESPEN, ASPEN and AND NCM guidelines; however, most RDs reported that they typically use semi-elemental and elemental formulations (52%, n = 12) for their patients with active CD.
Most RDs reported following guidelines for the MNT of patients with active CD, with only 34.7% (n = 8) of participants reporting that they did not follow any clinical nutrition guidelines or did not know the guidelines that they were currently following. Forty-four percent (n = 10) of respondents reported that they use ESPEN and ASPEN guidelines; however use of these guidelines did not necessarily mean that participants used the recommended standard (polymeric) formulations for their patients with CD ($\chi^2[1] = .765$, $p = .382$). However, those that reported using ASPEN guidelines were more likely to report using polymeric EN formulations ($\chi^2[1] = 5.033$, $p = .025$, effect size = .468).

RDs that reported using ASPEN guidelines were more likely to be working at an urban location ($\chi^2[2] = 6.244$, $p = .044$, effect size = .521). Interestingly, no individuals that work with both the adult and pediatric population reported using ASPEN guidelines ($\chi^2[1] = 6.244$, $p = .012$, effect size = .521). RDs that reported using ESPEN and ASPEN clinical nutrition guidelines were more likely to provide EN support annually to their patients with active CD ($\chi^2[1] = 9.436$, $p = .002$, effect size = .641).

There was a statistically significant association between the number of years that the RD has been practicing dietetics (1 – 15 years vs. 16 - 30 years or more) and the use of ESPEN guidelines ($\chi^2[1] = 5.759$, $p = .016$, effect size = .50), with RDs who reported that they have been practicing dietetics for 15 years or less (34.8%, n = 8) being more likely to report using ESPEN guidelines compared to RDs that have been practicing for greater than 15 years (65.2%, n = 15).

In general, RDs reported that when they provide EN support, it is most commonly provided as an adjunct to oral intake (56.5%, n = 13). Twenty-six percent (n = 6) of RDs reported that they provide EN as the patient’s sole intake and 17.4% (n = 4) as an adjunct to PN. Following ESPEN guidelines was not found to be statistically significant in providing EN in a specific way (sole nutrition, adjunct to oral or adjunct to PN, $\chi^2[2] = 2.277$, $p = .32$).
Forty-four percent of respondents (n = 10) reported that the “most important” reason for helping them to determine which particular EN formulations to use was that the particular formulation is on their hospital formulary. Thirteen percent (n = 3) of respondents reported that the “most important” reason for helping them to determine which particular EN formulations to use was that the formulation contained a specific ingredient (Figure 1).

Figure 1: “Most Important” Reasons for Choosing a Particular EN Formulation

Ranked as the top “important” reason for 30.4% (n = 7) of respondents was that it was an elemental EN formulation. Tied for third place, respondents reported that both the macronutrient content (22%, n = 5) and price of a particular EN formulation (22%, n = 5) were their most “neutral” reasons for deciding upon an EN formulation (Table 5).

Table 5: Ranking of the Reasons Why RDs Choose a Particular EN Formulation

<table>
<thead>
<tr>
<th>Reasons for Choosing a Particular EN Formulation</th>
<th>&quot;Most Important&quot;</th>
<th>&quot;Important&quot;</th>
<th>&quot;Neutral&quot;</th>
<th>&quot;Not Important&quot;</th>
<th>&quot;Least Important&quot;</th>
<th>Not Ranked</th>
</tr>
</thead>
<tbody>
<tr>
<td>Price</td>
<td>3 (11%)</td>
<td>0 (0%)</td>
<td>5 (24%)</td>
<td>1 (10%)</td>
<td>5 (26.3%)</td>
<td>9 (22%)</td>
</tr>
<tr>
<td>Contains a Specific Ingredient</td>
<td>5 (19%)</td>
<td>3 (15%)</td>
<td>4 (19%)</td>
<td>3 (30%)</td>
<td>1 (5.5%)</td>
<td>7 (17%)</td>
</tr>
<tr>
<td>Macronutrient Content</td>
<td>3 (11%)</td>
<td>3 (15%)</td>
<td>5 (24%)</td>
<td>2 (20%)</td>
<td>2 (10.5%)</td>
<td>8 (20%)</td>
</tr>
<tr>
<td>Elemental Formulation</td>
<td>4 (15%)</td>
<td>7 (35%)</td>
<td>2 (9.5%)</td>
<td>1 (10%)</td>
<td>5 (26.3%)</td>
<td>4 (10%)</td>
</tr>
<tr>
<td>Polymeric Formulation</td>
<td>2 (7%)</td>
<td>3 (15%)</td>
<td>4 (19%)</td>
<td>2 (20%)</td>
<td>2 (10.5%)</td>
<td>10 (24%)</td>
</tr>
<tr>
<td>On Hospital Formulary</td>
<td>10 (37%)</td>
<td>4 (20%)</td>
<td>1 (4.5%)</td>
<td>1 (10%)</td>
<td>4 (21%)</td>
<td>3 (7%)</td>
</tr>
<tr>
<td>Total Responses For Each Ranking</td>
<td>27</td>
<td>20</td>
<td>21</td>
<td>10</td>
<td>19</td>
<td>41</td>
</tr>
</tbody>
</table>

*Participants were not required to rank each reason listed. Bolded responses indicate the top ranking for each reason. Percentages were calculated based on the total number of responses for each ranking.
RDs reported medical, surgical, corticosteroid, and nutritional reasons for using EN for their patients with active CD (Figure 2). Nutritional issues were the most commonly reported situations in which RDs reported recommending EN for their patients with active CD (78.3%, n = 18), specifically when the patients are undernourished (69.5%, n = 16) or have a poor nutrient intake with 5% or greater weight loss (56.5%, n = 13).

Figure 2: Situations in Which EN is Recommended for Patients with Active CD

RDs reported their perceived challenges with the management of patients with active CD. The reported challenges consisted of access, knowledge, tolerance and patient attitude issues (Figure 3), with the greatest perceived challenges being: patient tolerance to EN (56.5%, n = 13), followed by patient compliance (34.8%, n = 8), the cost of the EN formulation (26.1%, n = 6) and limited research on the area of CD and EN (21.7%, n = 5). Access issues were reported by 30.4% (n = 7) of respondents; these included formula cost (26.1%, n = 6) and limited formulary (4.3%, n = 1) at their acute care facility. Knowledge issues were reported by 30.4% (n = 7) of respondents, which included limited research in the area of CD (21.7%, n = 5) and physician resistance (13%, n = 3). Tolerance issues were reported by 65.2% (n = 15) of respondents and included intolerance to EN (60.9%, n = 14), re-establishing intake by mouth (4.3%, n = 1) and limited time (to assess and follow-up with the patient, 4.3%, n = 1). Patient attitudes were also reported to be an issue by 34.8% (n = 8) of participants, which included the
patient’s compliance with EN recommendations (34.8%, n = 8) and their acceptance of EN or PN support (4.3%, n = 1).

**Figure 3: Challenges Associated with EN Management in Active CD**

![Pie chart showing challenges associated with EN management in Active CD](image)

The $\chi^2$ test revealed that there was a statistically significant association between where the RD was employed and report of access challenges ($\chi^2 [1] = 5.033$, $p = .025$, effect size = .468). Specifically, individuals who worked in a rural location reported more access issues (cost of EN and limited EN formulary) than individuals who were employed at an urban/suburban location. Practicing dietetics for less than 15 years had a statistically significant association with being less likely to be currently practicing at an urban location ($\chi^2 [2] = 9.662$, $p = .008$, effect size = .648).

Lastly, eight RDs provided additional comments on the use of EN in patients with active CD (Appendix I). These comments discussed the need for simple, bullet-point guidelines for use of EN in patients with active CD; as well as guidelines for the assessment, diagnosis and MNT for these patients.
CHAPTER 5: DISCUSSION

The purpose of this research study is to compare the current practices of RDs in New Mexico in caring for their patients with active CD to the current ESPEN and ASPEN clinical nutrition guidelines. Based on the results of this study, we find that the majority of responding RDs employed at acute care facilities in New Mexico fail to follow the current ESPEN and ASPEN clinical nutrition guidelines and recommendations for EN support in patients with active CD.

Respondents reported that the most commonly used clinical nutrition guidelines used in the acute care setting for the nutritional assessment and MNT for their patients with active CD were the ASPEN, ESPEN and AND NCM clinical nutrition guidelines. RDs that reported using ASPEN and ESPEN guidelines were more likely to report treating one to five patients with active CD with EN support annually. Those RDs that did not report using ESPEN or ASPEN guidelines were more likely to report that they do not use EN support for their patients with active CD. This suggests that RDs that don’t use the ASPEN and ESPEN clinical nutrition guidelines aren’t aware that EN support should be used in patients with active CD.

This study revealed that RDs that have been practicing dietetics for less than 15 years were more likely to report using ESPEN clinical nutrition guidelines. Recent dietetic graduates may be more up-to-date with the current research in dietetics than the RDs who have been practicing for a longer period of time. RDs who are further away from their initial training may need continuing education in this area of EN support for CD patients. This may also be explained by the fact that recent RDs are relying more on the available clinical nutrition guidelines because of their lack of experience.

None of the RDs who reported following ESPEN guidelines reported using polymeric EN formulations. ESPEN guidelines are substantially more detailed than ASPEN guidelines in their description of providing EN support to patients with active CD. It is concerning that those RDs that reported using ESPEN guidelines are not utilizing the polymeric EN formulation recommendations, especially since the ESPEN guidelines are readily
available on PubMed’s online journal database. It would be beneficial for future research to examine why known guidelines are not being followed. For example, the guidelines may be difficult to understand, individuals may not be aware that the guidelines exist or other factors (access, knowledge, patient issues, etc.) may be preventing RDs from recommending polymeric EN formulations to their patients. The results of this study suggest that those RDs who reported using ESPEN guidelines, were also more likely to report practicing dietetics for less than 15 years, therefore were more likely to report access issues because they were less likely to be employed at an urban location; hence access issues may be factors decreasing RD compliance with ESPEN guidelines.

The data collected from this study suggests that most RDs recommend semi-elemental and elemental EN formulations when they recommend EN for their patients with active CD. It is important that future research be conducted to evaluate the reasons why RDs are recommending elemental and semi-elemental EN formulations more frequently than polymeric EN formulations, because current nutrition guidelines (ESPEN and ASPEN) recommend the use of polymeric EN formulations. Additionally, RDs reported that the top “important” reason for choosing a particular EN formula was that it was an elemental EN formulation. It is possible that even though polymeric formulations are the primary EN therapy of choice, RDs may consider elemental and semi-elemental EN formulations superior to polymeric EN formulations. One reason may be that many RDs believe that elemental EN formulations may be better tolerated due to better absorption because of advertising by formula companies who promote the use of their formulas for the use of active CD due to possible malabsorptive and malnutrition issues. Also, an NG-tube may be easily placed in the acute care setting, so palatability of the EN formulation may not be an issue. Additionally, polymeric formulas may not be provided because research on elemental diets has been positive, with published research demonstrating that individuals who receive elemental diets may have decreased total bacteria per gram of feces, which may reduce intestinal inflammation. This data suggests that even though current nutrition guidelines recommend use of polymeric EN formulations; it appears, at least in New Mexico, that these guidelines are not being utilized.
On the other hand, RDs that reported using ASPEN guidelines were more likely to report recommending polymeric EN formulations for their patients with active CD. Also, RDs that reported using ASPEN guidelines reported that they only assessed and treated adult patients and were more likely to be working at an urban location. It appears that those RDs that reported using ASPEN guidelines are implementing the recommendations in the guidelines more often than those who reported using ESPEN guidelines. This may be because ASPEN is a membership organization and it may be doing a better job of providing support and explanations of its guidelines or possibly those RDs employed at urban locations have more access to the ASPEN clinical nutrition guidelines and larger, better stocked formularies. ASPEN charges fees and requires membership in order to use their clinical nutrition support tools. Either way, it is interesting that none of the RDs that work with both the adult and pediatric population reported using ASPEN guidelines. It is possible that these RDs are not aware that ASPEN provides guidelines for use in the pediatric population. It would be beneficial for further research to be conducted to determine why RDs that work with both pediatric and adult patient population are not using ASPEN guidelines. It is a concern, since RDs that work with both the pediatric and adult population made up a large percentage of the RDs that responded to the survey and only half reported using any clinical nutrition guidelines at all.

The “most important” reason that RDs reported for choosing a particular EN formula, is that the formula is available on their hospital formulary list. It is easier to use formulas that are readily available on the acute care facility’s formulary. At some facilities, the CNM decides which formulations are available on the formulary; it would be beneficial for these individuals to be educated on ASPEN and ESPEN clinical nutrition guidelines. Typically, formulas not listed on the acute care facility’s formulary are still available for the RD to use. However, time and cost become issues, as the specific formula must be ordered and shipped to the facility, which takes additional time to receive and dispense and can increase the cost the facility spends on EN.

Most RDs reported that they provide EN as an adjunct to oral intake, rather than sole intake or as an adjunct to PN. This suggests that EN is being provided to patients with
active CD to improve their nutritional intake. RDs reported that situations, in which they recommend EN to their patients with active CD include: medical, surgical, nutritional and corticosteroid issues. The most commonly reported situation in which RDs will provide EN support is a nutritional issue, such as an undernourished individual or an individual with poor nutrient intake and greater than 5% weight loss. Most RDs are concerned about the nutritional status of their patients, as it is the RD’s role to promote adequate nutrient intake and prevent future complications through nutrition support and MNT.

RDs reported multiple challenges associated with the management of EN for their patients with active CD. These challenges included: tolerance issues, patient’s attitude towards EN, access issues and knowledge issues (physician resistance to use of EN and limited available research on the use of EN in patients with active CD). The major perceived challenge was tolerance issues: intolerance to EN and limited time to assess and monitor patients. These issues are common at any hospital, as it is the RD’s job to manage EN intolerances and inform the physician of current research on MNT for specific conditions. Limited time is an issue everywhere because people are multitasking more and have less time to complete their tasks (42). Lastly, access challenges (limited formulary and cost of EN formulation) were more likely to be reported by RDs that were employed in rural locations. New Mexico has a dispersed rural population. It would be beneficial to know what is causing the specific access challenges (maybe EN formulations are only delivered once a month, cost may be increased for EN formulations at a rural location and other issues may be involved) in acute care facilities located in rural locations because patient care should not be compromised due to the large distances involved.

Some RDs who responded to the survey provided comments on EN use in their patients with active CD. Based on their comments it appears that simple, bullet-point guidelines could be beneficial in promoting the use of EN for patients with active CD because RDs could use them for a reference, not only for themselves, but could provide them to the physicians that they work with to promote the physician’s use of EN formulation recommendations for patients with active CD.
The results of this study suggest that RDs do not follow ESPEN and ASPEN clinical nutrition guidelines in the care of their patients with active CD. Based on the published literature on EN and active CD, it appears that EN is effective in preventing malnutrition and inducing remission in patients with active CD when used in conjunction with other therapies in the adult population. It would be beneficial for simple guidelines to be provided to RDs through state licensure organizations, continuing educational credits or dietetic practice groups as this would provide a way to create a more uniform standard of practice for patients with active CD. RDs could continue to search out additional guidelines for their patients with active CD, but they would at least be aware of what is recommended by the state in which they are licensed.

Study Strengths

This study provides much needed information, in an area of research where there have been few, if any published articles that have evaluated whether RDs use clinical nutrition guidelines for their patients with active CD in the acute care setting. The major strength of this study is that it fills a gap in the literature regarding how RDs in New Mexico practice in the acute care setting in regards to EN recommendations for their patients with active CD.

Study Limitations

This study has several limitations. The data collected relied on self-report via an online survey questionnaire; therefore it is impossible to know if what RDs reported is truly how RDs practice at their acute care facility. Additionally, multiple exclusion criteria (such as: requiring participants to be current RDs [not students, retirees or RD eligible], actively practicing dietetics, currently residing and working in New Mexico at an acute care facility, registered with CDR with a working e-mail and have worked with adult patients with active CD) were used in selecting the study participants, thereby possibly limiting the generalizability of the study results. Generalizability is limited because of the small sample size and limited geographic area covered, as these data only represent
those RDs who actively provide MNT to patients with active CD in acute care facilities in New Mexico and cannot be generalized to all RDs who treat patients with active CD.

Another limitation is that this study consisted of a very small sample size which impacts the statistical power of a research study. Low power decreases the possibility of detecting significant relationships between variables. In addition, a small sample size limits the ability to conduct multivariate analysis and to control for potential confounders.

A limitation of this study is the low response rate to the survey (42.6%). A low response rate could be attributed to: e-mail addresses that did not work; individuals who moved out of state, retired, changed employment or passed away; and individuals who had limited time to complete the survey, lack of interest in the study, limited access to the internet or reservations about participating in the study. This may hinder the generalizability and reliability of the results. We cannot assume that the results of this survey are representative of all RDs caring for patients with CD in acute care facilities in New Mexico.

Based on the way the questionnaire was worded, the exact number of patients assessed and treated with EN support annually is not known, only an estimated range of the patients assessed and treated annually. The questionnaire provided pre-determined ranges for the responses to the questions: “On average, how many patients with active CD do you assess on a yearly basis?” and “On average, how many patients with active CD do you treat with EN support on a yearly basis?”; hence, it is not known if one patient or ten patients with active CD were assessed annually and if one or five patients with active CD were treated with EN support annually. Allowing the RDs to respond with the exact amount of patients with active CD assessed and treated annually, as well as the number of patients that they generally assess and treat with EN, would have increased our ability to use this variable in statistical analysis.
Additional Research

More research should be conducted on a larger scale, for example on a national level, to determine how RD’s in an acute care setting provide MNT for patients with active CD. Future research should evaluate the reasons RDs have for not using clinical nutrition guidelines and what MNT or EN recommendations that these RDs usually make for their patients with active CD. Not utilizing clinical nutrition guidelines has huge implications to the field of dietetics. RDs are taught to follow current evidence-based MNT, so why are they not following the current clinical nutrition guidelines? Additionally, it would be interesting to test RD awareness of clinical nutrition guidelines because it will help in making MNT in the acute care setting more uniform. It is possible that RDs do not understand the current clinical nutrition guidelines, there is a lack of availability of guidelines (due to cost of obtaining guidelines or membership requirements), that RDs are hesitant to follow guidelines, or that outside factors (access, knowledge, patient issues, etc.) are preventing the RD from following the guidelines.

It is also possible that advertising by formula companies affects the RD’s decision when choosing a formulary for the acute care facility for which they are employed and when recommending EN for a patient with active CD. It would be both interesting and beneficial for research to be conducted on the affect of advertising by formula companies on the RD’s decision of which EN formulation to use.

Lastly, RDs employed in rural locations reported increased access issues (limited formulary and increased cost of EN). More research could examine what is contributing to these problems and determine ways to prevent these access issues from occurring in the future.

Conclusion

The purpose of this study was to identify which EN formulations are currently recommended in the acute care setting by RDs in New Mexico for their patients with active CD and to compare these recommended formulations to the current ASPEN and ESPEN clinical nutrition guidelines. Overall, most RDs who participated in this study
did not follow the ESPEN and ASPEN clinical nutrition guidelines for EN support in patients with active CD. We reject the hypothesis that RDs that work in acute care facilities in New Mexico follow the current clinical nutrition guidelines (ASPEN and ESPEN) and recommendations for EN support in patients with active CD.

Most RDs reported following clinical nutrition guidelines. Even though ESPEN and ASPEN guidelines were the most commonly used guidelines reported by RDs, use of these guidelines did not necessarily mean that RDs used the recommended standard (polymeric) formulations for their patients with active CD. The most commonly recommended EN formulations by RDs were semi-elemental and elemental formulations for patients with active CD. This suggests that the awareness of the guidelines and their recommendations are not being translated into practice. Future research should examine understanding of guidelines used, why semi-elemental and elemental formulations are being recommended over polymeric formulations, ways to improve standards of practice for EN use in patients with active CD and the health outcomes of patients with active CD depending on the nutritional therapy that they receive during their treatment at an acute care facility.

Addendum

ASPEN and ESPEN clinical nutrition guidelines have recently been updated. ASPEN guidelines were updated in 2012, but the guidelines have not changed (20). ESPEN guidelines were updated in 2011 (43). Because this study’s questionnaire was administered prior to the update of the ASPEN and ESPEN clinical nutrition guidelines, the guidelines that were in use during the time of this study were used as a reference for the statistical analysis of this study (15, 26).
APPENDICES

APPENDIX A: IRB EXEMPT APPROVAL FORM

THE UNIVERSITY of NEW MEXICO
Main Campus Institutional Review Board
Human Research Protections Office
MSC08 4560
1 University of New Mexico-Albuquerque, NM 87131-0001
http://hrc.unm.edu/com/research/HRRC/

07-Apr-2011

Responsible Faculty: Deborah Cohen
Investigator: Nicole S. Harvath
Dept/College: Individual Family Comm Educ IFCE

SUBJECT: IRB Determination of Exempt Status
Protocol #: 11-191
Project Title: Practices of Registered Dieticians in New Mexico Regarding Enteral Nutrition in Patients with Crohn’s Disease
Approval Date: 06-Apr-2011

The Main Campus Institutional Review Board has reviewed the above-mentioned research protocol and determined that the research is exempt from the requirements of Department of Health and Human Services (DHHS) regulations for the protection of human subjects as defined in 45CFR46.101(b) under category 2, based on the following:

1. Exemption Determination Form, received 032411 and complete 050511
2. Survey Instrument, received 032411
3. Evaluation of Survey Instrument, received 032411
4. Consent Letter, v032411

Because it has been granted exemption, this research project is not subject to continuing review.

Changes to the Research: It is the responsibility of the Principal Investigator to inform the IRB of any changes to this research. A change in the research may disqualify this project from exempt status. Reference the protocol number and title in all documents related to this protocol.

Sincerely,

J. Scott Tonigan, PhD
Chair
Main Campus IRB
Dear Respondent,
This study is being conducted by Nicole Horvath, a graduate student and Dietetic Intern, and Deborah Cohen, an Assistant Professor and Advisor, at the University of New Mexico. We are conducting this study in order to better understand the practices of Clinical Registered Dietitians who are employed in New Mexico acute care facilities. Specifically, we are interested in the Clinical Registered Dietitian prescriptive practices of enteral nutrition formulas for patients with active Crohn's disease in New Mexico. This research will help Clinical Dietitians to better understand how to treat Crohn's disease in New Mexico. The results of this study will be provided to survey respondents by the winter of 2011.

Since the validity of the results depend on obtaining a high response rate, your participation is crucial to the success of this study. The questionnaire will take approximately 5-10 minutes to complete.

Your completion of this questionnaire indicates your consent to participate in this study. Please be assured that your responses will be held in the strictest confidence. If the results of this study were to be written for publication, no identifying information will be used.

We will send the compiled results in an email to you as soon as the study is completed and compiled. Our hope is that this study may increase your understanding of what enteral formula to prescribe to your patients with Crohn's disease.

Thank you for your participation.
Sincerely,
Nicole Horvath
1. When recommending an enteral nutrition product for your patients who are admitted to the hospital with active Crohn’s disease, which of the following formula(s) do you most often recommend? (check all that apply)

<table>
<thead>
<tr>
<th>Formula</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
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<tbody>
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</tr>
<tr>
<td>Vivonex TEN</td>
<td></td>
<td></td>
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<tr>
<td>Other</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

(List Specific Formula)

2. What are the reasons you choose a particular enteral formula? [Rank the following reasons from 1 (most important) to 5 (least important)]

- Price
- Contains a specific ingredient
- Macronutrient Content
- Elemental Formula
- Polymeric Formula
- On Hospital Formulary

3. On average, how many patients with active Crohn’s disease do you assess yearly?

(select from ranges)

<table>
<thead>
<tr>
<th>Range</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-10</td>
<td></td>
</tr>
<tr>
<td>11-20</td>
<td></td>
</tr>
<tr>
<td>21-30</td>
<td></td>
</tr>
<tr>
<td>&gt;30</td>
<td></td>
</tr>
</tbody>
</table>
4. On average, how many patients with active Crohn’s disease do you treat with enteral nutrition support yearly? (select from ranges)
   - 0-5 ______
   - 6-10 ______
   - 11-20 ______
   - 21-30 ______
   - >30 ______

5. Do you use clinical nutrition guidelines for the nutritional assessment and medical nutrition therapy of Crohn’s disease patients at your facility?
   - Yes ___
   - No ___
   - Don’t know ___
   * If Yes, Which clinical guidelines to you use?
     - European Society for Parenteral and Enteral Nutrition (ESPEN) nutritional guidelines ___
     - Guidelines provided by your acute care facility ___
     - Other ___ (list specific guidelines) _______________________________

6. When providing enteral nutrition support, would you say that enteral nutrition is used primarily as means of providing the sole support of nutrition or as an adjunct to oral intake:
   - Adjunct to oral intake ___
   - Sole source of nutrition ___

7. Enteral Nutrition is recommended during which of the following situations? (check all that apply):
   - Steroid induced hormone imbalance ___
   - Patient refuses steroids ___
   - Undernourished patient ___
   - As an adjunct with steroids ___
   - Patient with inflammatory stenosis of the small intestine ___
   - Pre-surgical ___
Post-operative ___
Obstruction ___
Abscess ___
Poor nutrient intake with a weight loss >5% ___
Other: Please list __________________________________________________

8. What are your perceived challenges associated with the management of patients with active Crohn’s disease that receive Enteral Nutrition? (choose from the following list)
   Limited Nutrition Research/Guidelines regarding enteral nutrition support and Crohn’s disease ___
   Cost of the enteral formula ___
   Patient tolerance to Enteral Nutrition ___
   Patient compliance ___
   Other ______________

   Demographic Questions

9. What is your gender?   Male____   Female____

10. What is your ethnicity? (select from list)
    American Indian ___   Caucasian___
    Hispanic or Latino___   African American___
    Asian ___   Pacific Islander ___
    Other: ______________

11. What is your age? 18-25___  26-40___  41-64___  65+___

12. What is the geographical location in which you work? (select from list)
    Rural (pertaining to less-populated, non-urban areas) ___
    Suburban (relating to the outlying part of a city or town) ___
    Urban (relating to the city) ___

13. How long have you been a practicing Registered Dietitian?
    1-5 years ___  6 –15 years ___  16 – 30 years ___  30 years ___

*Thank you for completing the survey. Please click on SUBMIT to send answers to be compiled with other survey results.
APPENDIX C: EVALUATION OF PILOT QUESTIONNAIRE

Evaluation of Survey: Registered Dietitian Clinical Nutrition Practices

Directions:
• Please complete this evaluation form as you do the survey. Your feedback is very valuable; please feel free to add additional comments and suggestions directly on the survey.
• Return survey and evaluation form in the enclosed stamped envelope no later than April 15, 2011 to Nicole Horvath. Thank you very much for your time and input.

1. How long did it take you to complete the survey?
   ____ 5-10 minutes
   ____ 10-15 minutes
   ____ 15-20 minutes
   ____ longer than 20 minutes

2. Did you have any trouble understanding any of the questions?
   ____ yes
   ____ no

   If yes, which questions were difficult: ____________________________

3. Would you recommend changing any of the questions?
   ____ yes
   ____ no

   If yes, which questions would you change? __________________________

4. Are there any questions you would eliminate?
   ____ yes
   ____ no

   If yes, which question(s) would you eliminate? ______________________

5. Are there any questions you would add?
   ____ yes
   ____ no

   If yes, what question(s) would you add? ____________________________

6. Are there any other comments you would like to make regarding this survey?

   __________________________________________________________________
   __________________________________________________________________
   __________________________________________________________________
   __________________________________________________________________

Thank you very much for your feedback!
APPENDIX D: INITIAL RECRUITMENT E-MAIL

Hello,

I am a graduate student and Dietetic Intern currently conducting a study via an online survey with the help of Deborah Cohen, DCN, RD, Assistant Professor in the Nutrition Program at the University of New Mexico. The purpose of this study is to identify the current practices of Clinical Registered Dietitians who work with adult Crohn’s disease patients in acute care facilities in New Mexico. This survey consists of 10 questions and should take approximately 5-10 minutes to complete. Please complete the survey before May 13, 2011, the last day of my Dietetic Internship.

Please click on the following link to access the survey: http://www.surveymonkey.com/s/3JSZH75. The survey is titled: “Practices of Registered Dietitians in New Mexico Regarding Enteral Nutrition in Patients with Crohn’s disease”. This study has been approved by the University of New Mexico Institutional Review Board. By completing this survey you are indicating your consent to participate in this study.

Thank you for your participation,

Nicole Horvath
Graduate Student & Dietetic Intern
University of New Mexico
(505)610-4623
nhorvath@unm.edu
APPENDIX E: REMINDER E-MAIL

Hello,

If you have not already taken the opportunity to complete the survey “Practices of Registered Dietitians in New Mexico Regarding Enteral Nutrition in Patients with Crohn’s Disease”, please take the time now. The purpose of this study is to identify the current practices of Clinical Registered Dietitians who work with adult Crohn’s disease patients in acute care facilities in New Mexico. This survey consists of 10 questions and should take approximately 5-10 minutes to complete. Please complete the survey before May 13, 2011, the last day of my Dietetic Internship.

Click on the following link to access the survey: http://www.surveymonkey.com/s/3JSZH75. The survey is titled: “Practices of Registered Dietitians in New Mexico Regarding Enteral Nutrition in Patients with Crohn’s disease”. This study has been approved by the University of New Mexico Institutional Review Board. By completing this survey you are indicating your consent to participate in this study.

In order to have a representative sample of Clinical Registered Dietitians in New Mexico, your participation is crucial to the success of this study.

Thank you for your participation,

Nicole Horvath  
Graduate Student & Dietetic Intern  
University of New Mexico  
(505)610-4623  
nhorvath@unm.edu
APPENDIX F: FINAL REMINDER E-MAIL

Hello,

Over the past two weeks, I have been collecting data via a survey for a study about the current practices of Clinical Registered Dietitians who work with adult Crohn’s disease patients in acute care facilities in New Mexico.

If you haven’t yet filled out the survey, would you please take a few minutes now to do so? This is the last week to complete the survey. I would appreciate receiving your response by May 13, 2011, the last day of my Dietetic Internship. You have been selected as a member of a small survey sample and your individual response is crucial for the success of this study. The survey should take approximately 5 to 10 minutes to complete and consists of 10 questions. This study has been approved by the University of New Mexico Institutional Review Board. By completing this survey you are indicating your consent to participate in this study.

Please click on the following link to access the survey: http://www.surveymonkey.com/s/3JSZH75. The survey is titled: “Practices of Registered Dietitians in New Mexico Regarding Enteral Nutrition in Patients with Crohn’s disease”.

If you have completed this survey, thank you very much for your assistance.

Thank you for your participation and support,

Nicole Horvath
Graduate Student & Dietetic Intern
University of New Mexico
(505)610-4623
nhorvath@unm.edu
APPENDIX G: STUDY QUESTIONNAIRE

Practices of RDs in NM Regarding EN in Patients with Crohn's Disease

1. Registered Dietitian Clinical Nutrition Practices

Dear Respondent,

This study is being conducted by Nicole Horvath, a graduate student and Dietetic Intern, and Deborah Cohen, DCN, RD, Assistant Professor, of the Nutrition Program at the University of New Mexico. We are conducting this study in order to identify the practices of Clinical Registered Dietitians who care for adult patients with active Crohn’s disease and who are employed at an acute care facility in New Mexico. This study was approved by the Institutional Review Board (IRB) of the University of New Mexico in April 2011.

Since the validity of the results depend on obtaining a high response rate, your participation is crucial to the success of this study. This questionnaire should take approximately 5-10 minutes to complete.

Your completion of the questionnaire below indicates your consent to participate in this study. Please be assured that your responses will be held in the strictest confidence. If the results of this study were to be written for publication, no identifying information will be used.

We will send the compiled results in an email to you as soon as the study is completed and compiled.

Thank you for your participation.

Sincerely,

Nicole Horvath
Dietetic Intern and Graduate Student
University of New Mexico

*1. When recommending an enteral nutrition product for your patients who are admitted to the hospital with active Crohn’s disease, which of the following formula(s) do you most often recommend? (Check all that apply)

- Peptamen OS 1.5 Cal
- Peptamen with Prebio
- Perea
- Pivot 1.5 Cal
- Promote
- Promote with Fiber
- TwoCal HN
- Vital HN
- Vivonex Plus
- Vivonex RTF
- Vivonex TEN
- Peptamen AF
- I typically do not recommend enteral nutrition for my patients with Crohn’s disease
- Peptamen 1.5 Cal
- I have not treated patients with active Crohn’s disease

Other (please specify)

*2. What are the reasons you choose a particular enteral formula?

[Rank each of the following reasons of importance to you, from 1 (most important) to 5 (least important).]

<table>
<thead>
<tr>
<th>Reason</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contains a specific ingredient</td>
<td></td>
<td></td>
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<tr>
<td>Elemental Formula</td>
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</tr>
<tr>
<td>Macronutrient Content</td>
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<tr>
<td>On Hospital Formulary</td>
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<tr>
<td>Polymeric Formula</td>
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</tr>
</tbody>
</table>
3. On average, how many patients with active Crohn's disease do you assess on a yearly basis? (select from ranges)
   - 0
   - 1-10
   - 11-20
   - 21-30
   - >30

4. On average, how many patients with active Crohn's disease do you treat with enteral nutrition support on a yearly basis? (select from ranges)
   - 0
   - 1-5
   - 6-10
   - 11-20
   - 21-30
   - >30

5. What clinical nutrition guidelines do you use for the nutritional assessment and medical nutrition therapy of Crohn's disease patients at your facility? (choose one from the following list. If more than one guideline is used, write the multiple guidelines in the "Other" box)
   - European Society for Parenteral and Enteral Nutrition (ESPEN) nutritional guidelines
   - Guidelines provided by my acute care facility
   - I do not use clinical guidelines
   - I do not know
   - Other (please list specific guidelines)

6. When providing enteral nutrition support, would you say that enteral nutrition is used primarily as a means of providing the sole source of nutrition, as an adjunct to oral intake or as an adjunct to parenteral nutrition?
   - Sole source of nutrition
   - Adjunct to oral intake
   - Adjunct to parenteral nutrition

7. In which of the following situations do you recommend enteral nutrition for your patients with Crohn's disease? (Check all that apply. If you have never treated a patient with Crohn's disease, please indicate this in the "Other" box.)
   - Steroid induced hormone imbalance
   - Patient refuses steroids
   - Undemoralized patient
   - As an adjunct with steroids
   - Patient with inflammatory stenosis of the small intestine
   - Pre-surgical
   - Post-operative
   - Abscess
   - Poor nutrient intake with a weight loss >5%
   - Other (please specify)
*8. What are your perceived challenges associated with the management of patients with active Crohn's disease that receive Enteral Nutrition? (choose all that apply)
   - Cost of the enteral formula
   - Limited Nutrition Research/Guidelines regarding enteral nutrition support and Crohn's disease
   - Patient compliance
   - Patient tolerance to Enteral Nutrition
   - Other (please specify)

*9. Demographic Questions

What is your gender? [ ] Male [ ] Female
What is your ethnicity? [ ] Hispanic [ ] Non-Hispanic
What is your age?
What is the geographical location in which you work?
How long have you been a practicing Registered Dietitian?
What patient population do you work with?

10. Do you have any comments about using nutrition support in your patients with Crohn's disease?
Dear Respondent,

This study is being conducted by Nicole Horvath, a graduate student, and Deborah Cohen, an Assistant Professor and Advisor, at the University of New Mexico. We are conducting this study in order to better understand the practices of Clinical Registered Dietitians who are employed in New Mexico acute care facilities. Specifically, we are interested in the Clinical Registered Dietitian prescriptive practices of enteral nutrition formulas for patients with active Crohn’s disease in New Mexico. This research will help Clinical Dietitians to better understand how to treat Crohn’s disease. The results of this study will be provided to survey respondents by the winter of 2011.

Please complete the questionnaire by clicking on the link to SurveyMonkey.com. Since the validity of the results depend on obtaining a high response rate, your participation is crucial to the success of this study. The questionnaire will take approximately 5-10 minutes to complete.

Your completion of this questionnaire indicates your consent to participate in this study. Please be assured that your responses will be held in the strictest confidence. If the results of this study were to be written for publication, no identifying information will be used.

We will send the compiled results in an e-mail to you as soon as the study is completed and compiled. Our hope is that this study may increase your understanding of what enteral formula to prescribe to your patients with Crohn’s disease.

This study will also provide information to the Crohn’s and Colitis Foundation of America to help them in their search for maintenance therapy for Crohn’s disease.

If you have any questions about this study, you can contact the person(s) below:

Nicole Horvath
Nutrition/Dietetics
COE at the University of New Mexico
1 University of New Mexico
Albuquerque, NM 87131-0001
(505)610-4623
nhorvath@umn.edu

Deborah Cohen, MMSc, DCN, RD
Nutrition/Dietetics
COE at the University of New Mexico
1 University of New Mexico
Albuquerque, NM 87120
(505)277-6430
dcohen02@umn.edu

This study has been reviewed and approved by The University of New Mexico’s Institutional Review Board (IRB). The IRB has determined that this study meets the ethical obligations required by federal law and University policies. If you have questions or concerns regarding this study please contact the Investigator or Advisor. If you have any questions regarding your rights as a research subject, please call the Human Research Protection office at (505)272-1129.

Thank you for your participation.

Sincerely,

Nicole Horvath

HRPO #: 11-191
Page 1 of 1
Version: 3/24/11

APPROVED: 4/8/11

OFFICIAL USE ONLY

The University of New Mexico Institutional Review Board (HRRC/MCIRB)
### APPENDIX I: REGISTERED DIETITIANS’ ADDITIONAL COMMENTS

<table>
<thead>
<tr>
<th>Additional Comments Reported by RDs that Work with Patients with Active CD:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “I have had only 2 patients with active Crohn’s Disease, both of which initially required TPN r/t small bowel resections. The only reason these patients were transitioned to EN as opposed to oral feedings was because both were too weak to pass a swallow evaluation. And both tolerated the EN without problems. Both had good outcomes.” [This RD reported that she used semi-elemental formulations for these patients].</td>
</tr>
<tr>
<td>• “I agree with the use of EN designed for malabsorptive conditions in severe Crohn’s [disease]. We do not see a lot of patients, but do have them on occasion.”</td>
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<tr>
<td>• “I will prescribe a low residue diet if they [patients] are somewhat symptomatic.”</td>
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<tr>
<td>• “Diet may not be as important as we once thought.”</td>
</tr>
<tr>
<td>• “RD clinicians need simple, bullet-pointed guidelines on best practices on use of enteral [nutrition] to give to physicians. Need to keep them educated with quick info.”</td>
</tr>
<tr>
<td>• “Will use it [EN] only if not tolerating oral intake.”</td>
</tr>
<tr>
<td>• “I work at a level 3 trauma center for last 11 years and though we seen plenty of Crohn’s disease [patients] we don’t see them for that only and most of the time they do not need nutrition support. I have had one [who received nutrition support] in the last 11 years. I have an interest in Crohn’s as my good friend was diagnosed when we were 26. I have learned a lot from her journey and this is why I remember this odd fact. Thanks for the study.”</td>
</tr>
<tr>
<td>• “I would love to know more...I’ve only had one patient so far. I’d love some nutrition assessment &amp; diagnosis guidelines, support guidelines, and MNT guidelines.” [This respondent reported in a previous question that she was using TPN for her one patient with CD].</td>
</tr>
</tbody>
</table>
REFERENCES


